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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 10-K**

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(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2017

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: **001-37569**

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**STRONGBRIDGE BIOPHARMA plc**  
(Exact name of Registrant as specified in its charter)

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**Ireland**  
(State or other jurisdiction of incorporation or organization)

**98-1275166**  
(I.R.S. Employer Identification No.)

**900 Northbrook Drive  
Suite 200  
Trevose, PA 19053  
+1 610-254-9200**

(Address of principal executive offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
<b>Ordinary shares, par value \$0.01 per share</b>	<b>The NASDAQ Global Select Market</b>

Securities registered or to be registered pursuant to Section 12(g) of the Act:

**None**

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.  Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer

Accelerated Filer

Non-Accelerated Filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).  Yes  No

The aggregate market value of the voting and non-voting stock held by non-affiliates of the Registrant, as of June 30, 2017, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately \$216,524,867. Solely for purposes of this disclosure, shares of common stock held by executive officers and directors of the Registrant as of such date have been excluded because such persons may be deemed to be affiliates. This determination of executive officers and directors as affiliates is not necessarily a conclusive determination for any other purposes.

45,504,848 ordinary shares were issued and outstanding as of March 1, 2018.

**DOCUMENTS INCORPORATED BY REFERENCE: NONE**

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**Strongbridge Biopharma plc**  
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## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS AND MARKET DATA

This Annual Report on Form 10-K (“Annual Report”) contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, size of market or patient population, timing and likelihood of success, plans and objectives of management for future operations, and future results of current and anticipated products, are forward-looking statements. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The words “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “goal,” “intend,” “may,” “might,” “objective,” “plan,” “potential,” “predict,” “project,” “positioned,” “seek,” “should,” “target,” “will,” “would,” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are based on current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management’s beliefs and assumptions, are not guarantees of future results, performance or developments and involve known and unknown risks, uncertainties and other factors that may cause our actual results or developments to differ materially from the expectations contained in the forward-looking statements. Such risks and uncertainties include those described throughout this Annual Report and particularly in “Risk Factors” in Part I, Item 1A of this Annual Report. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. Readers are urged to carefully review and consider the various disclosures made in this Annual Report and in other documents we file from time to time with the Securities and Exchange Commission (the “SEC”) that disclose risks and uncertainties that may affect our business. The forward-looking statements included in this Annual Report do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. In addition, the forward-looking statements in this Annual Report are made as of the date of this filing, and we do not undertake, and expressly disclaims any duty, to update such statements, whether as a result of new information, new developments or otherwise, except to the extent that disclosure may be required by law.

Solely for convenience, the trademarks and trade names in this Annual Report are referred to without the ® and ™ symbols, but absence of such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. The trademarks, trade names and service marks appearing in this Annual Report are the property of their respective owners.

Unless the context requires otherwise, references in this Annual Report to “Strongbridge,” “we,” “us” and “our” refer to Strongbridge Biopharma plc.

## PART I

### ITEM 1. BUSINESS

#### Overview

We are a global commercial-stage biopharmaceutical company focused on the development and commercialization of therapies for rare diseases with significant unmet needs.

Our first commercial product is Keveyis (dichlorphenamide), the first and only treatment approved by the U.S. Food and Drug Administration (the “FDA”) for hyperkalemic, hypokalemic, and related variants of primary periodic paralysis (“PPP”), a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis.

Our second commercial product, Macrilen (macimorelin) is an oral growth hormone secretagogue receptor agonist, and is the first and only oral drug approved by the FDA for the diagnosis of patients with adult growth hormone deficiency (“AGHD”). We expect to launch Macrilen in the United States in mid-2018.

In addition to our two commercial products, we have two clinical-stage product candidates for rare endocrine diseases, Recorlev and veldoreotide. Recorlev (levoketoconazole) is a cortisol synthesis inhibitor currently being studied for the treatment of endogenous Cushing's syndrome. Veldoreotide is a next-generation somatostatin analog being investigated for the treatment of acromegaly and potential additional applications in other conditions amenable to somatostatin receptor activation. Both Recorlev and veldoreotide have received orphan designation from the FDA and the European Medicines Agency (“EMA”).

Given the well-identified and concentrated prescriber base addressing our target markets, we intend to continue to use a small, focused sales force to market Keveyis, Macrilen and any future products, in the United States, the European Union and other key global markets. We believe that our ability to execute on our strategy is enhanced by the significant commercial and clinical development experience of key members of our management team.

Since the introduction of our new management team in August 2014, we have been building a rare disease, franchise-based business model focused on expansion through a disciplined in-licensing and acquisition strategy. In pursuit of our growth strategy, we have raised over \$275 million in equity and debt financings since December 2014. We will continue to identify and evaluate the acquisition of products and product candidates for licensing or acquisition that would be complementary to our existing rare neuromuscular and endocrine franchises or that would form the basis for new rare disease franchises. We believe this approach will enable us to maximize our commercial potential by further leveraging our existing resources and expertise.

#### Our Products and Product Candidates

- *Keveyis (dichlorphenamide), an oral carbonic anhydrase inhibitor and the only therapy approved in the United States to treat hyperkalemic, hypokalemic and related variants of PPP.* PPP is a rare genetic, neuromuscular disorder that can cause extreme muscle weakness and/or paralysis; some forms are also commonly associated with myotonia or muscle stiffness. It often interferes with daily activities and, as patients get older, it can lead to permanent muscle weakness. The two most common forms of this disorder are “hyperkalemic” and “hypokalemic” periodic paralysis. Keveyis was approved by the FDA in August 2015, and has orphan drug exclusivity status in the United States through August 7, 2022. From May 2016 to December 2016, Taro Pharmaceuticals Industries Ltd. and its affiliates (“Taro”), supplied Keveyis on a non-commercial basis to patients through a single specialty pharmacy in the United States. We acquired the U.S. marketing rights to Keveyis in December 2016 and we launched Keveyis in the United States in April 2017.
- *Macrilen (macimorelin), an oral growth hormone secretagogue receptor agonist, is indicated for the diagnosis of AGHD.* Macrilen has been granted orphan-drug designation by the FDA for use in evaluating growth hormone deficiency (“GHD”). On December 20, 2017, the FDA granted marketing approval for

Macrilen, an oral growth hormone secretagogue (GHS) receptor agonist, to be used in the diagnosis of patients with AGHD, which affects approximately 60,000 adults in the United States and Canada. We acquired the U.S. and Canadian marketing rights to Macrilen from Aeterna Zentaris GmbH in January 2018 and we intend to launch Macrilen in the United States in mid-2018.

- *Recorlev (levoketoconazole), a cortisol synthesis inhibitor, is in Phase 3 clinical development for the treatment of endogenous Cushing's syndrome.* Endogenous Cushing's syndrome is a rare endocrine disorder characterized by sustained elevated cortisol levels that most commonly result from a benign tumor of the pituitary gland. We believe that Recorlev, which is the isolated, "left-handed" mirror image, or enantiomer, of ketoconazole, has the potential to become the new standard of care for the drug therapy of endogenous Cushing's syndrome. In July 2017, we completed enrollment of 94 patients in SONICS, a pivotal, multinational Phase 3 clinical trial for Recorlev. We anticipate that top-line data for the primary efficacy analysis will be available in mid-2018. In addition, we have initiated LOGICS, a second pivotal Phase 3 clinical trial of Recorlev for the treatment of endogenous Cushing's syndrome. The LOGICS study will supplement the long-term efficacy and safety data from the ongoing SONICS trial via a randomized, double-blind, placebo-controlled design that will randomize approximately 35 patients, of which up to approximately one-half will have completed the SONICS study. Enrollment in the LOGICS study is anticipated to begin in the first quarter of 2018, and top-line data are expected in the first quarter of 2019.

Upon completion of the clinical development program, we intend to file for marketing authorizations in the United States and elsewhere. Following consultations with the FDA, we have determined that the 505(b)(2) approval pathway, which permits a New Drug Application ("NDA") applicant to rely on data from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference, is the appropriate pathway for a Recorlev NDA. Because NDA approval can rely in part on data already accepted by the FDA or otherwise publicly available, an abbreviated and reduced development program may be possible. We intend to rely on published literature and the FDA's prior findings concerning the safety and/or effectiveness of ketoconazole in our NDA for Recorlev. A similar marketing authorization pathway is available in most of the rest of the world, and we anticipate that the studies supporting U.S. approval will likewise support approvals to market Recorlev elsewhere, including in the European Union.

- *Veldoreotide modified-release, a novel multi-receptor targeted somatostatin analog (SSA) that was previously in Phase 2 development as an immediate release formulation.* Based on the differentiated activation pattern of somatostatin receptor subtypes ("SSTRs") and the preclinical and clinical profile of immediate-release veldoreotide, we believe that modified-release veldoreotide may offer an improved efficacy and safety profile relative to existing drug therapies for acromegaly and other conditions that are modifiable through activation of somatostatin receptors, such as Cushing's disease and neuroendocrine tumors. Veldoreotide has been granted orphan drug designation by the FDA and the EMA for treatment of acromegaly. The lead formulation for veldoreotide modified-release is based upon PLGA microspheres. PLGA is a well-known polymer, which has been widely applied in modified-release formulations due to its biocompatibility, biodegradability, and favorable release kinetics. We expect to initiate a series of pre-clinical studies that seek to determine additional differentiating features of veldoreotide in both endocrine and non-endocrine conditions.

## Product Sales

Product sales for Keveyis in 2017 accounted for 100% of our total revenues as it was our only commercial product sold in 2017. We operate in one operating reporting segment. We sell Keveyis to one specialty pharmacy provider, who is the exclusive distributor of Keveyis in the United States. The specialty pharmacy subsequently resells Keveyis to patients, which are covered by payors that may provide for government-mandated or privately negotiated rebates with respect to the purchase of Keveyis (see Note 3 of our consolidated financial statements).

## Our Strategy

Our goal is to transform the lives of patients by building a leading franchise-based, commercially oriented biopharmaceutical company addressing rare diseases with significant unmet medical needs. We are focused on developing, in-licensing, acquiring and eventually commercializing products and product candidates that target rare diseases across therapeutic areas.

To achieve our goal, we are pursuing the following strategies:

- **Focus on rare diseases.** We are selling or developing treatments for rare diseases, initially PPP, AGHD and endogenous Cushing's syndrome. Rare diseases typically have a high unmet need for innovative treatment options. Drug development for the treatment of rare diseases often requires smaller clinical trials than for common diseases. Product candidates focused on rare diseases also often qualify for orphan drug designation, which in the United States provides for seven years of market exclusivity and in the European Union provides for 10 years of market exclusivity after regulatory approval to market has been granted.
- **Independently commercialize Keveyis, Macrilen and other products in the United States and the European Union.** We have commercialized Keveyis in the United States and intend to market Macrilen in the United States and Canada. Our other rare disease product candidates, if approved, may be marketed in the United States, the European Union, and, selectively, in other key global markets. Given the relatively small prescriber bases for Keveyis, Macrilen and our two product candidates, we believe we can use a relatively small, focused sales force to effectively promote our products. We have established sales, marketing, market access and patient service capabilities in the United States to market Keveyis. We believe that some of the activities involved in our commercialization of Keveyis and Macrilen will provide synergies to our commercialization of Recorlev if successful. We believe that our ability to execute on this strategy is enhanced by the significant prior commercial experience of key members of our management team. Prior to joining our company, members of our management team were involved in the launch or commercialization of over 20 pharmaceutical products.
- **Expand our portfolio through a disciplined in-licensing and acquisition strategy.** We plan to source new product candidates by in-licensing or acquiring them. Our management team seeks to mitigate the potential risks of this strategy by adhering to our disciplined criteria of focusing on in-licensing or acquisition of products that are already commercially available or that have human clinical data that we believe suggest a relatively high probability of success for development and an attractive potential return on investment. As a result of our management team's experience in sourcing, selecting, in-licensing and acquiring products and product candidates, we were successful in acquiring the U.S. rights to Keveyis and the U.S. and Canadian rights to Macrilen, as well as augmenting our rare endocrine franchise by adding veldoreotide to our product pipeline.
- **Utilize a franchise model built on rare disease therapeutic areas.** We intend to build our company by in-licensing and acquiring products and product candidates that target rare diseases in therapeutically aligned franchises with significant commercial opportunity. We believe that complementary products and product candidates will allow us to significantly leverage our expertise as well as our development and commercial infrastructure. For example, Keveyis serves as the basis of our rare neuromuscular franchise, and Macrilen and Recorlev, if approved, will serve as the basis for our rare endocrine franchise.
- **Expand indications of products and product candidates within our franchises.** In addition to identifying products and product candidates that can form the basis of new rare disease franchises, we also intend to leverage opportunities to develop potential products and product candidates for additional indications within their respective therapeutic franchises. We believe that this approach will enable us to maximize our commercial potential by further leveraging our existing resources and expertise.

## Our Product Candidate Pipeline

The following table illustrates our product candidates by stage:

	Indication/ Target Disease	Preclinical	Phase 1	Phase 2	Phase 3	Marketed
<b>KEVEYIS<sup>®</sup></b> (dichlorphenamide)	Primary Periodic Paralysis (FDA-approved; FDA orphan drug designation)					Marketed
<b>MACRILEN<sup>™</sup></b> (macimorelin)	Adult Growth Hormone Deficiency diagnosis (FDA-approved; FDA orphan drug designation)				FDA-Approved	
<b>RECORLEV<sup>™</sup></b> (levoketoconazole)	Endogenous Cushing's syndrome (FDA and EMA orphan drug designation)				Phase 3	
<b>veldoreotide modified-release</b>	Acromegaly (FDA and EMA orphan drug designation) and other conditions that are modifiable through activation of somatostatin receptors, such as Cushing's disease and neuroendocrine tumors	Pre-Clinical				

## Our Rare Neuromuscular Franchise

In December 2016, we initiated our rare neuromuscular franchise by acquiring the U.S. marketing rights to Keveyis (dichlorphenamide) from Taro Pharmaceuticals North America, Inc., a subsidiary of Taro Pharmaceutical Industries Ltd. Keveyis is the first and only therapy approved in the United States to treat hyperkalemic, hypokalemic and related variants of PPP, a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis

### Overview of PPP and Keveyis

PPP is a rare, genetic, neuromuscular disorder related to a defect in muscle ion channels with multiple variants and subtypes. The disease is characterized by episodes of muscle weakness and paralysis. It often interferes with daily activities and, as patients get older, it can lead to permanent muscle weakness. PPP may be localized ("focal") or more widespread ("generalized"), and it often goes underdiagnosed and/or undertreated. Types of periodic paralysis are differentiated by criteria including underlying genetic mutations and changes in blood potassium during an episode. The two most common forms of PPP are hypokalemic, when episodes can be induced by low blood levels of potassium, and hyperkalemic, when episodes are associated with elevated levels of blood potassium. We believe, based on our market research, that there are approximately 4,000 to 5,000 patients in the United States diagnosed with PPP.

Keveyis is an oral carbonic anhydrase inhibitor that was approved by the FDA in the United States in August 2015 to treat hyperkalemic, hypokalemic and related variants of PPP. The exact mechanism(s) through which oral carbonic anhydrase inhibitors, and Keveyis in particular, decrease the frequency and severity of periodic paralysis attacks is unknown. However, it is believed that their effects are mediated both locally (i.e. in muscle) and systemically. It is not known whether their effects are disease-modifying. Keveyis has received orphan drug exclusivity status in the United States through August 7, 2022.

Following FDA approval in August 2015, Keveyis was marketed by Taro. In May 2016, Taro announced the cessation of their commercial sales and related promotional activities for Keveyis. Taro supplied Keveyis to patients on a non-commercial basis through a single specialty pharmacy in the United States from May 2016 until our acquisition of the U.S. marketing rights to Keveyis in December 2016. We continued to supply Keveyis to patients on a non-commercial basis until launching Keveyis in April 2017. After acquiring the U.S. marketing rights for Keveyis, we established sales, marketing, market access and patient service capabilities.

We launched Keveyis using 12 experienced sales representatives, and in the fourth quarter of 2017 expanded

our sales force to 24 individuals consisting of three regional business directors and 21 sales representatives. Because a large percentage of the people who suffer from PPP remain undiagnosed or inadequately treated, we developed programs to educate the medical community and patients about this illness. In addition, we established a field-based force of medical science liaisons. We use a single, specialty pharmacy to provide reimbursement, clinical and distribution support for Keveyis and to develop cost-sharing and patient assistance programs to support qualified, commercially insured patients, federal- and state-insured patients, and uninsured or under-insured patients. We also donate money to independent charitable foundations dedicated to this cause. Our ultimate goal is to ensure that no PPP patient is denied access to Keveyis for financial reasons.

### ***Clinical Development of Keveyis***

The efficacy of KEVEYIS was evaluated in two clinical studies, Study 1 and Study 2.

#### *Study 1*

Study 1 was a 9-week, double blind, randomized, placebo-controlled, multi-center study. Study 1 consisted of two substudies: a substudy in patients with hypokalemic periodic paralysis (n=44), and a substudy in patients with hyperkalemic periodic paralysis (n=21). The primary efficacy endpoint in both substudies was the average number of self-reported attacks of muscle weakness per week over the final 8 weeks of the trial. Withdrawal from the study for acute severe worsening was also assessed as an endpoint.

In Study 1, the tested dose of Keveyis was 50 mg b.i.d. for treatment-naïve patients. Patients already receiving dichlorphenamide prior to the study continued on the same dose if randomized to Keveyis during the study. In patients taking acetazolamide prior to the study, the daily dose of Keveyis was set at 20% of the daily acetazolamide dose. Dose reduction for tolerability was permitted.

In the hypokalemic periodic paralysis substudy, median age of patients was 45 years and 73% of patients were male. Patients treated with Keveyis (n=24) had 2.2 fewer attacks per week than patients (n=20) treated with placebo (p=0.02). None of the patients randomized to Keveyis reached the endpoint of acute worsening, vs. five patients randomized to placebo. The mean dose of Keveyis at Week 9 was 94 mg/day.

In the hyperkalemic periodic paralysis substudy, median age of patients was 43 years and 43% of patients were male. During the double-blind treatment period, patients treated with Keveyis (n=12) had 3.9 fewer attacks per week than patients treated with placebo (n=9) (p=0.08). None of the patients randomized to Keveyis reached the endpoint of acute worsening, vs. two patients randomized to placebo. The mean dose of Keveyis at Week 9 was 82 mg/day.

#### *Study 2*

Study 2 was a 35-week, double blind, placebo-controlled, randomized, multi-center, two-period crossover study. Study 2 also consisted of two substudies: a substudy in patients with hypokalemic periodic paralysis (n=42), and a substudy in patients with hyperkalemic periodic paralysis (n=31), including patients with Paramyotonia Congenita (together termed potassium-sensitive periodic paralysis or PSPP). The primary endpoint in the hypokalemic periodic paralysis substudy was the incidence of acute intolerable worsening (based on attack frequency or severity) necessitating withdrawal. The primary endpoint in the hyperkalemic periodic paralysis substudy was the average number of self-reported attacks of muscle weakness per week. Dosing was determined similarly to Study 1.

In the hypokalemic periodic paralysis substudy, mean age of patients was 38 years and 79% of patients were male. Acute intolerable worsening was observed in 2 patients on Keveyis vs. 11 patients on placebo (p=0.02). The mean dose of Keveyis at the end of the study was 96 mg/day.

In the hyperkalemic periodic paralysis substudy, mean age of patients was 37 years and 58% of patients were male. Patients treated had 2.3 fewer attacks per week on Keveyis than on placebo (p=0.006). The mean dose of Keveyis at the end of the study was 73 mg/day.



## **Our Rare Endocrine Franchise**

Our rare endocrine franchise consists of Macrilen, Recorlev and veldoreotide. Macrilen is the first and only oral drug approved by the FDA for the diagnosis of patients with AGHD. Recorlev is being developed for the treatment of endogenous Cushing's syndrome, and veldoreotide is being developed for the treatment of acromegaly and potential additional applications in other conditions amenable to somatostatin receptor activation.

### ***Overview of Adult Growth Hormone Deficiency (AGHD) and Macrilen***

AGHD is a condition that is associated with premature mortality, as well as cardiovascular, neuromuscular, metabolic, nervous system, and skeletal abnormalities. The clinical features are nonspecific; growth hormone stimulation testing is required to diagnose AGHD. Growth hormone is produced by the pituitary gland and secreted in pulses, so random measurements of growth hormone levels in the blood are not useful for establishing a diagnosis of AGHD. Growth hormone stimulation testing provokes the pituitary gland to release levels of growth hormone above resting levels to determine the growth hormone release potential in a patient suspected of having AGHD.

On December 20, 2017, the FDA granted marketing approval for Macrilen, an orally available, peptidomimetic growth hormone secretagogue receptor agonist (or ghrelin receptor, GHSR-1a, agonist), to be used in the diagnosis of patients with AGHD, which affects approximately 60,000 adults in the U.S. and Canada. We acquired the U.S. and Canadian marketing rights to Macrilen from Aetema Zentaris GmbH in January 2018 and we intend to launch Macrilen in mid-2018. Macrilen is the first and only oral drug approved by the FDA for the diagnosis of patients with AGHD.

### ***Clinical Development of Macrilen***

The diagnostic efficacy of the Macrilen test was established in a randomized, open-label, single-dose, cross-over study. The objective of the study was to compare the level of agreement between Macrilen test results and insulin tolerance test ("ITT") results in adult patients with different pre-test probabilities of AGHD, including with healthy control subjects. The four groups of individuals evaluated were:

- **Group A:** Adults with a high likelihood of growth hormone deficiency (GHD)
  - Structural hypothalamic or pituitary lesions and low insulin-like growth factor 1 (IGF-1), and/or
  - Three or more pituitary hormone deficiencies and low IGF-1, or
  - Childhood onset GHD with structural lesions and low IGF-1.
- **Group B:** Adults with an intermediate likelihood of GHD
  - Eligible subjects not qualifying for either high or low likelihood.
- **Group C:** Adults with a low likelihood of GHD
  - One risk factor for GHD only, such as history of distant traumatic brain injury or one pituitary hormone deficiency only with otherwise normal pituitary function, or
  - Isolated idiopathic childhood onset GHD without additional pituitary deficits.
- **Group D:** Healthy adult controls
  - Healthy subjects matching Group A subjects by sex, age  $\pm$  5 years, body mass index ( $BMI \pm 2 \text{ kg/m}^2$ ), and estrogen status (females only).

For both the ITT and the Macrilen test, serum concentrations of growth hormone were measured at 30, 45, 60, and 90 minutes after drug administration. The test was considered positive (i.e., AGHD diagnosed) if the maximum serum growth hormone level observed anytime after stimulation was less than the pre-specified cut point value of 2.8 ng/mL for the Macrilen test or 5.1 ng/mL for the ITT.

The level of negative and positive agreement between the results of the ITT and the Macrilen test was used to evaluate the performance of the Macrilen test. In the study, the ITT test results were used as the benchmark (i.e., a negative ITT indicated absence of the disease and a positive ITT indicated presence of the disease). Negative agreement was the proportion of subjects with a negative ITT (i.e., those who did not have GHD per the ITT) who also had a negative Macrilen

test. The results showed a high level of negative agreement, demonstrating that the Macrilen test will not wrongly diagnose an individual without GHD (per the ITT) as having GHD. Positive agreement was the proportion of subjects with a positive ITT (i.e., those who had GHD per the ITT) who also had a positive Macrilen test. The results showed a high level of positive agreement, demonstrating that the Macrilen test will not wrongly diagnose an individual with GHD (per the ITT) as not having GHD. The agreement measures between the two tests are defined mathematically below (see Table 2).

**Table 2: Definition of Agreement between ITT and Macrilen**

		Insulin Tolerance Test		Total
		+	-	
Macrilen	+	a	b	a+b
	-	c	d	c+d
Total		a+c	b+d	a+b+c+d

Positive Agreement (%) =  $100\% \times \frac{a}{a+c}$   
 Negative Agreement (%) =  $100\% \times \frac{d}{b+d}$   
 Overall Agreement (%) =  $100\% \times \frac{(a+d)}{(a+b+c+d)}$

One hundred and fifty-seven subjects underwent at least one of the two tests in this study, 59% were male, 41% female, and 86% of white origin. The median age was 41 years (range: 18 – 66 years) and body mass index 27.5 kg/m<sup>2</sup> (range: 16 – 40 kg/m<sup>2</sup>). The study relied on a cross-over design and each participant was to undergo the two diagnostic tests and serve as his or her own control. Data on both tests were available for 140 subjects; 38 (27%) in Group A, 37 (26%) in Group B, 40 (29%) in Group C, and 25 (18%) in Group D. One out of 154 Macrilen tests (0.6%) performed failed due to a technical error and 27 out of 157 ITTs (17.2%) performed failed because induction of severe hypoglycemia (i.e., the stimulus) could not be achieved.

Two-by-two tables presenting the pre-specified primary analysis results for the ITT and Macrilen test are shown below for all subjects (Groups A, B, C, and D combined) and for each group separately (see Table 3). The estimates for negative and positive agreement between Macrilen and the ITT in the overall study population were 94% and 74% with lower 95% confidence interval bounds 85% and 63%, respectively. Negative and positive agreement between Macrilen and the ITT in subjects with intermediate or low risk (Groups B and C) were 93% and 61% with lower 95% confidence interval bounds 80% and 43%, respectively. These results are based on peak growth hormone values (maximum growth hormone concentrations across all measurement timepoints).

**Table 3: Diagnostic Outcomes for Macrilen and the ITT in all Subjects (Groups A, B, C, and D) and in Each Group Separately**

All Subjects		Insulin Tolerance Test		Total
		+	-	
Macrilen	+	55	4	59
	-	19	62	81
Total		74	66	140

Agreement Between ITT and Macrilen	
Positive	74%
Negative	94%
Overall	84%

Group A High likelihood of AGHD		Insulin Tolerance Test		Total
		+	-	
Macrilen	+	33	0	33
	-	4	1	5
Total		37	1	38

Positive	89%
Negative	100%
Overall	89%

Group B Intermediate likelihood of AGHD		Insulin Tolerance Test		Total		
		+	-			
Macrilen	+	20	1	21	Positive	67%
	-	10	6	16	Negative	86%
Total		30	7	37	Overall	70%

Group C Low likelihood of AGHD		Insulin Tolerance Test		Total		
		+	-			
Macrilen	+	2	2	4	Positive	33%
	-	4	32	36	Negative	94%
Total		6	34	40	Overall	85%

Group D Healthy control		Insulin Tolerance Test		Total		
		+	-			
Macrilen	+	0	1	1	Positive	0%
	-	1	23	24	Negative	96%
Total		1	24	25	Overall	92%

Repeatability was tested in a subset of 34 subjects who underwent two Macrilen tests. Agreement between the result of the first test and the second test was observed in 31 cases (91.2%).

### **Overview of Endogenous Cushing’s Syndrome and Recorlev**

#### *Overview of Endogenous Cushing’s Syndrome*

There are two variants of Cushing’s syndrome: exogenous, which is caused by factors outside the body (e.g., corticosteroid or cortisol-like medications) and endogenous, which is caused by factors within the body. The signs and symptoms may be the same in both forms. The more common form is exogenous Cushing’s syndrome, which is often found in people taking cortisol-like medications for long periods of time or for shorter periods of time using very potent forms. Cortisol-like medications are often used to treat inflammatory disorders such as asthma and rheumatoid arthritis. Unlike endogenous Cushing’s syndrome, exogenous Cushing’s syndrome may be alleviated by withdrawing the inciting medication.

Endogenous Cushing’s syndrome is a rare endocrine disorder characterized by sustained elevated blood cortisol. Cortisol is a hormone produced in the adrenal gland and is naturally secreted as an end-product of the activity of the hypothalamic-pituitary-adrenal axis. Corticotropin-releasing-hormone (“CRH”) is secreted from the hypothalamus and stimulates the secretion and release of adrenocorticotropin (“ACTH”) from the pituitary gland, which in turn stimulates cortisol (and other hormone) secretion from the adrenal gland. Cortisol itself exerts negative feedback control on both CRH in the hypothalamus and ACTH in the pituitary gland, thereby reducing CRH and ACTH secretion, keeping cortisol levels in a normal range.

The most common form of endogenous Cushing’s syndrome is called Cushing’s disease, which is typically caused by a benign pituitary tumor that secretes ACTH autonomously. Cushing’s disease represents approximately 70% to 80% of patients with endogenous Cushing’s syndrome. Other causes of endogenous ACTH-dependent Cushing’s syndrome include extrapituitary tumors producing ACTH, known as ectopic ACTH, or less often CRH (ectopic CRH). The source of ectopic ACTH/CRH secretion is most often small-cell carcinoma of the lung or bronchial carcinoid tumors but neuroendocrine tumors found in many different organs can also be sources. In a smaller number of cases, approximately 20%, endogenous Cushing’s syndrome is ACTH-independent, meaning that it does not arise through

tumor secretion of ACTH but rather results from excess secretion of cortisol itself in the adrenal gland by adrenocortical tumors, either benign or malignant, or by non-malignant enlargement of the adrenal glands called hyperplasia.

In patients with endogenous Cushing's syndrome, the normal feedback mechanisms of the hypothalamic-pituitary-adrenal axis are disrupted as a result of a tumor autonomously secreting ACTH, CRH or cortisol. This causes chronic exposure to high circulating cortisol levels that give rise to the clinical state of Cushing's syndrome. The most common signs and symptoms of the syndrome include: weight gain, especially in the upper body with a rounded face ("moon face") and extra fat on the upper back and above the collarbones; high blood sugar or diabetes mellitus; high blood pressure or hypertension; thin bones or osteoporosis; muscle loss or sarcopenia; thin, fragile skin that bruises easily; purple-red stretch marks called striae, usually over the abdomen and under the arms; depression and difficulty thinking clearly; too much facial hair, or hirsutism, usually noticed only in women; irregular or absent menstrual periods and infertility; reduced sex drive or libido; and in children, poor height growth.

An estimated 25,000 patients in the United States and 40,000 patients in Europe are diagnosed with endogenous Cushing's syndrome. When first diagnosed, patients are most commonly adults aged 20 to 50 and five times more often women than men. However, endogenous Cushing's syndrome is believed to be underdiagnosed due to lack of disease recognition, which often leads to a delay in diagnosis of six years on average. Endogenous Cushing's syndrome patients are believed to have a mortality risk two to three times that of the age-and-gender-matched general population, with cardiovascular disease, venous thrombosis and infections being the primary causes of death.

#### *Overview of Recorlev*

Recorlev (levoketoconazole) is a cortisol synthesis inhibitor that we are developing for the treatment of endogenous Cushing's syndrome, a rare endocrine disorder characterized by excessive production of the stress hormone cortisol. In endogenous Cushing's syndrome, elevated circulating cortisol gives rise to a severe disease with variable clinical signs and symptoms, including weight gain, characteristic changes in fat distribution, diabetes mellitus, hypertension, osteoporosis, muscle loss and depression. The active pharmaceutical ingredient in Recorlev, levoketoconazole exerts its therapeutic effect by blocking the synthesis of cortisol in the adrenal glands, leading to the reduction and, ideally, the normalization of blood cortisol. Recorlev has been granted orphan drug designation by the FDA and the EMA and is being developed using a dose regimen of twice daily oral administration.

Ketoconazole, used off-label in the United States, is the most frequently prescribed drug therapy for endogenous Cushing's syndrome. It is used to reduce blood cortisol and ameliorate comorbidities associated with Cushing's syndrome. Molecules of ketoconazole form as mirror images, referred to as enantiomers. Manufactured ketoconazole consists of two enantiomers, 2R,4S-ketoconazole and 2S,4R-ketoconazole, that are found in equal amounts, and is therefore referred to as a racemate. Recorlev is a pure form of one (2S,4R-ketoconazole) of the two enantiomers of ketoconazole. Single-enantiomer drugs, like Recorlev, may offer safety and efficacy advantages over racemates because one of the enantiomers in a racemate can have safety issues or be less effective in the treatment of the disorder or disease. The more therapeutically favorable enantiomer may be known as the eutomer. We believe that levoketoconazole is the eutomer of ketoconazole with respect to cortisol synthesis inhibition and treatment of endogenous Cushing's syndrome.

Recorlev inhibits the cortisol synthesis pathway at several points. In light of the shared mechanism of action with ketoconazole and the data from Phase 2 clinical trials, which were conducted in diabetes patients without Cushing's syndrome, we believe Recorlev may have a similar beneficial impact on the reduction of significant comorbidities of endogenous Cushing's syndrome, including those associated with cardiovascular disease risk, such as diabetes, weight gain, hypertension and elevation in LDL-cholesterol. In addition, based on preclinical data and human pharmacokinetics, we believe that Recorlev may offer an improved safety profile relative to existing approved drug therapies for endogenous Cushing's syndrome. Therefore, we believe that Recorlev has the potential to become a new standard of care for the chronic drug therapy of endogenous Cushing's syndrome.

### ***Current Treatment Landscape and Limitations on Current Treatment Options***

Treatment of endogenous Cushing's syndrome varies depending on the cause of the disease. For patients with Cushing's disease, initial treatment is almost always the attempted surgical removal of the pituitary tumor. In anticipation of surgery and when surgery is not effective or not feasible, drug or radiation therapy, or both, is used to suppress excessive cortisol production and the accompanying clinical symptoms.

A typical approach to drug therapy is to inhibit cortisol synthesis through the oral administration of an inhibitor of enzymes that regulate adrenal cortisol synthesis. Ketoconazole acts in this way and is the most widely used drug therapy for endogenous Cushing's syndrome in the United States. Although approved in the European Union for this indication, ketoconazole is not approved for this indication by the U.S. FDA and is therefore prescribed "off-label". The percentage of endogenous Cushing's syndrome patients treated with ketoconazole monotherapy who achieve normalized levels of cortisol, assessed by measuring urinary free cortisol ("UFC") has been reported from retrospective, uncontrolled studies, with varying definitions of normalization, to be between 33% and 100%. Data from a recent retrospective study of 200 patients in 14 French centers solely treated with ketoconazole for endogenous Cushing's syndrome between 1995 and 2012 suggested that ketoconazole controlled cortisol in approximately 50% of patients and likewise improved clinical symptoms. Also, beneficial effects of oral ketoconazole on clinical symptoms and signs that drive the morbidity and mortality of endogenous Cushing's syndrome have been reported including reduction in high blood pressure, improvement of diabetes, and normalization of hypokalemia, or low potassium blood levels. However, some patients treated with ketoconazole experience tolerability issues and, in some cases, liver injury (also known as hepatotoxicity). As a result of the hepatotoxicity risk the FDA has issued a boxed warning to prescribers concerning the use of ketoconazole to treat fungal infections, the only approved indication for ketoconazole in the United States. Although elevations in liver enzymes associated with ketoconazole are generally mild to moderate and reversible upon cessation of drug, in rare cases, severe hepatotoxicity may occur (estimated as one in every 10,000 to 15,000 patients). In extremely rare cases, ketoconazole-related liver injury may be irreversible and result in death or require liver transplantation. In July 2013, the Committee for Medical Products for Human Use ("CHMP") recommended that ketoconazole be withdrawn for use as an antifungal agent in the European Union. The EMA adopted the CHMP recommendation in August 2013, and the recommendation was subsequently confirmed by the European Commission. In September 2014, HRA Pharma received a recommendation of approval from the EMA for ketoconazole for the treatment of endogenous Cushing's syndrome, based on the well-established use of ketoconazole in medical practice as well as documentation from retrospective studies in the literature.

An alternative medical approach to treating Cushing's syndrome targets pituitary tumors that produce ACTH (i.e. in Cushing's disease). Among Cushing's disease patients, the dopamine agonist cabergoline, which is not approved for use to treat Cushing's disease in the United States, has been shown to achieve normalization of UFC levels, gold-standard evidence of disease control, in about 30% of patients. The SSA pasireotide, which is marketed as Signifor® for the treatment of Cushing's disease in the United States, has shown normalization of UFC levels with stable dosing in 15% of patients at a dosage of 600 µg twice-daily and in 26% of patients at a dosage of 900 µg twice-daily over a 6-month period. Certain SSAs, including Signifor, are known to have undesirable side effects on glucose metabolism. Forty percent of patients with Cushing's disease treated with Signifor in its Phase 3 clinical trial reported the occurrence of hyperglycemia-related adverse events, and in the cohort receiving Signifor 900 µg twice-daily, glycated hemoglobin (HbA1c) increased from 5.8% at baseline to 7.3% at Month 6.

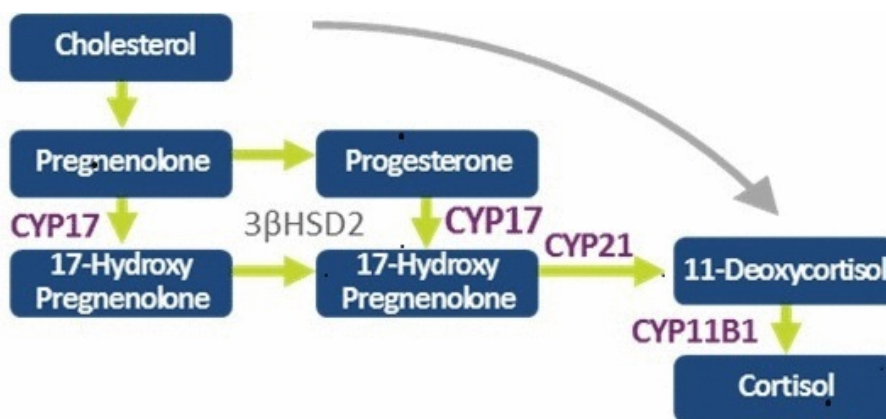
Another alternative, Korlym, or mifepristone, works by inhibiting the action of cortisol at the cortisol-receptor level but does not lower cortisol levels in the blood, which actually tend to increase during therapy. As a result of this mechanism of action, it is not possible to monitor response to Korlym by measuring UFC or cortisol levels (from blood or saliva), which are the standard ways clinicians monitor disease progression and response to treatment. As a result, Korlym is usually titrated and monitored through use of clinical signs and symptoms improvements, e.g. blood sugar reductions. Korlym has been approved in the United States to control hyperglycemia secondary to hypercortisolism in patients with endogenous Cushing's syndrome. Korlym is contraindicated in pregnant women and in women with a history of unexplained vaginal bleeding, as its side effects include termination of pregnancy, endometrial thickening and vaginal bleeding.

We believe that the efficacy and usage limitations and safety concerns associated with currently available drug therapies for endogenous Cushing's syndrome are an important reason why a significant unmet medical need exists among endogenous Cushing's syndrome patients with persistent or recurrent disease post-surgery. In a survey we commissioned in 2014 of 89 U.S. physicians treating patients with Cushing's syndrome, when asked, "Of your patients on medication to manage cortisol levels, what percentage are well controlled?", the physicians estimated that only approximately 37% of such patients were well controlled. A recent multicenter study of 230 Cushing's disease patients followed for up to 27.5 years and treated with any modality (i.e. surgery, radiation or drugs) found that only 49% had documented biochemical control. We believe that our potential addressable market for Recorlev includes diagnosed endogenous Cushing's syndrome patients that at any time are eligible for drug therapy, a figure that represents patients anticipating surgery, for whom surgery or radiation is not feasible, is contraindicated or has been unsuccessful. This unmet need may also be impacted by what we believe to be the current lack of disease awareness among physicians and patients, resulting in a relatively low rate of diagnosis.

#### **Our Solution—Recorlev**

We believe that Recorlev has the potential to become a new standard of care for the drug therapy of endogenous Cushing's syndrome because it may provide a favorable efficacy, safety and tolerability profile compared to current drug therapies, including ketoconazole, believed to be the most commonly used drug therapy for the treatment of endogenous Cushing's syndrome in the United States. We believe Recorlev, based on its similar mechanism of action to that of ketoconazole, may reduce UFC and blood pressure, in contrast to Korlym, and may have an anti-hyperglycemic effect, in contrast to Signifor. In addition, we believe Recorlev may have an improved safety profile compared with that of ketoconazole.

Recorlev, like ketoconazole, is a cortisol synthesis inhibitor that inhibits the cortisol synthesis pathway at multiple points. The following graphic illustrates the cortisol synthesis pathway:



Our preclinical and pharmacokinetic data suggest that Recorlev might have an efficacy profile at least as favorable as ketoconazole and might also confer less risk of liver injury:

- In *in vitro* studies, Recorlev was found to have higher potency than ketoconazole and its mirror-image enantiomer, 2R,4S-ketoconazole, in inhibiting the key enzymes in cortisol synthesis (CYP11B1, CYP17, and CYP 21). Thus, we believe Recorlev may have the same or improved efficacy compared to ketoconazole at lower dosages, which may in turn reduce relative drug exposure and potentially contribute to improved safety and tolerability.
- The pharmacokinetics of the enantiomers also suggest a potentially larger therapeutic index of Recorlev relative to ketoconazole. The two enantiomers found within ketoconazole are present in equal amounts, but

in a Phase 1 clinical study in healthy subjects, it was observed that administration of ketoconazole resulted in integrated blood concentrations (*i.e.*, exposure) of the single enantiomer, 2S,4R-ketoconazole (*i.e.*, Recorlev) that exceeded those of the other enantiomer, 2R,4S-ketoconazole, by approximately three times. This observation suggests but does not prove that 2R,4S-ketoconazole is extracted by the liver to a greater extent than the other single enantiomer, 2S,4R-ketoconazole (*i.e.*, Recorlev), and may therefore contribute more than Recorlev to the observed liver toxicity of ketoconazole.

- Compared with ketoconazole, it was observed in *in vitro* studies that Recorlev is less potent than the other enantiomer (*i.e.* its antipode, 2R,4S-ketoconazole) in inhibiting the activity of CYP7A. CYP7A is the first and rate-limiting enzyme for production of bile acids in the liver. While a role of CYP7A in liver injury is not established, this finding suggests a possible differential effect of the ketoconazole enantiomers on metabolic and detoxifying enzymes in the liver contributing to reduced hepatotoxicity potential of Recorlev.

Previously, levoketoconazole (then called DIO-902) was studied clinically for the treatment of type 2 diabetes. DiObex, our licensee from 2004 to 2008, initiated three clinical trials to investigate the use of levoketoconazole for treatment of type 2 diabetes and two clinical studies in healthy volunteers. In the Phase 2a clinical trial of type 2 diabetes patients, levoketoconazole demonstrated a significant dose response to reduce mean blood concentration levels of C-reactive protein (“CRP”), whereas for ketoconazole, an increase in CRP was observed. CRP tends to increase in the presence of inflammation. Thus, we believe that Recorlev may be associated with a decrease in inflammatory processes compared to ketoconazole. In the same study, levoketoconazole was also associated with dose-related reductions in cholesterol and body weight. Recorlev, with the same mechanism of action as ketoconazole to reduce blood cortisol, may also have beneficial effects on cardiovascular risk markers in Cushing’s syndrome including weight loss, reduction in blood sugar, lowering of cholesterol and reduction in blood pressure. Cardiovascular disease is the leading cause of excess mortality in endogenous Cushing’s syndrome.

#### ***Clinical and Preclinical Development of Recorlev***

In the United States, Recorlev is considered a new molecular entity. Upon completion of the clinical development program, we intend to file for marketing authorizations in the United States and elsewhere. In the United States, an NDA, which is a prerequisite to marketing authorization, can be submitted under one of a number of approval paths defined in the Federal Food, Drug, and Cosmetic Act. Following consultations with the FDA, we determined that the 505(b)(2) approval pathway, which permits an NDA applicant to rely on data from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference, is the appropriate pathway for a Recorlev NDA. Because a 505(b)(2) NDA approval can rely in part on data already accepted by the FDA or otherwise publicly available, an abbreviated and reduced development program may be possible. In the case of Recorlev, we intend to rely in our NDA on published literature and FDA’s prior findings concerning the safety and/or effectiveness of ketoconazole. A similar marketing authorization path is available in most of the rest of the world, and we anticipate that the studies supporting U.S. approval will likewise support approvals to market Recorlev elsewhere, including in the European Union. The FDA has acknowledged that no additional preclinical investigations will be required for Recorlev prior to an NDA filing. The EMA’s Committee for Medical Products for Human Use (“CHMP”), has requested a study of reproductive toxicity that may be completed prior to filing for marketing authorization in Europe, pending further discussions.

In July 2017, we completed enrollment of 94 patients in SONICS, a pivotal, multinational Phase 3 clinical trial for Recorlev investigating the safety and efficacy of Recorlev in subjects with endogenous Cushing’s syndrome. We anticipate top-line data for the primary efficacy analysis will be available in the mid-2018. In addition, we have initiated LOGICS, a second pivotal Phase 3 study of Recorlev for the treatment of endogenous Cushing’s syndrome. The LOGICS study will supplement the long-term efficacy and safety data from the ongoing SONICS study via a randomized, double-blind, placebo-controlled design that will randomize approximately 35 patients, of which up to approximately ½ will have completed the SONICS study. Enrollment in the LOGICS study is anticipated to begin in the first quarter of 2018 and top-line data are expected in the first quarter of 2019.

If SONICS can (1) demonstrate consistent and significant clinical benefit by meeting the primary endpoint of the trial, specifically the responder rate measured as normalization of UFC levels at the 6-month time point without need



for dose increase during the 6-month maintenance phase and (2) show consistent improvement of objectively quantifiable biomarkers of endogenous Cushing's syndrome comorbidities, such as blood glucose, blood lipids, blood pressure or weight, and improvement of other clinical signs and symptoms of endogenous Cushing's syndrome, we believe this would be regarded by regulators as adequate proof of efficacy in this rare disease with a high unmet medical need. Therefore, we consider LOGICS as a mechanism for providing independent evidence of efficacy of Recorlev, rather than serving as sole or primary evidence of efficacy for Recorlev in endogenous Cushing's syndrome. Furthermore, if successful, LOGICS has the potential to provide adequate evidence of efficacy durability beyond one year of therapy in the subset of subjects who were previously enrolled in SONICS. Finally, we believe that the combination of SONICS and LOGICS will provide an adequate demonstration of the long-term safety and tolerability of Recorlev in patients with endogenous Cushing's syndrome. In total over 100 unique subjects with this condition will have been treated with Recorlev during SONICS and LOGICS, and some subjects will be treated with a therapeutic dose of Recorlev for at least 1.5 years at the time of first NDA submission.

In addition to LOGICS, we intend to initiate a long-term open-label extension study with Recorlev to capture even longer-term safety, tolerability and efficacy data from subjects who complete either SONICS or LOGICS and who choose to continue therapy with Recorlev. The open-label extension, named OPTICS, is planned to begin enrollment in the second half of 2018 and will continue to accrue data indefinitely, at least until the drug is first marketed. We expect that we might be required by the FDA and the EMA to collect additional safety data post-approval.

### *Phase 3 Clinical Trials*

#### *SONICS Phase 3 Clinical Trial*

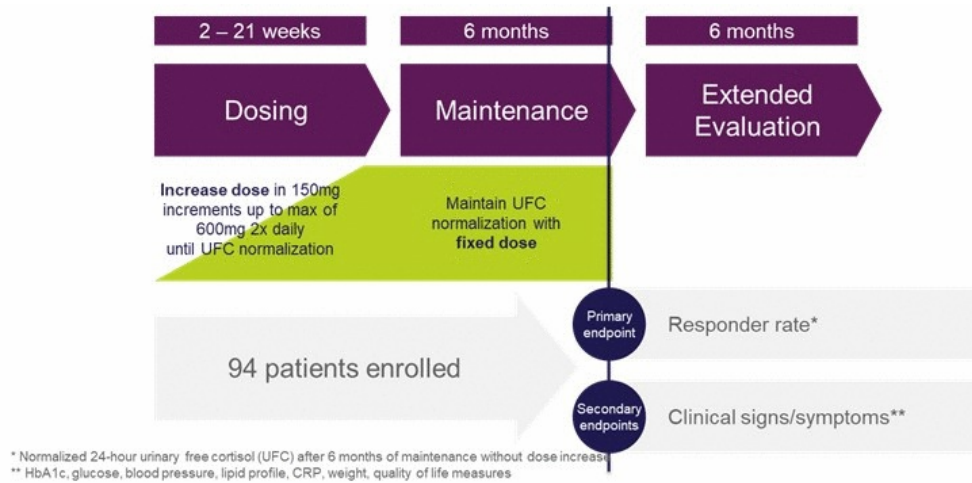
We enrolled 94 patients in our SONICS Phase 3 clinical trial in the United States, Canada, the European Union and the Middle East. This clinical trial is being conducted pursuant to a U.S. IND for Recorlev for the treatment of endogenous Cushing's syndrome that took effect in May 2013. We plan to collect safety and efficacy data over a treatment period of at least one year for all enrolled patients who complete the trial. If we are able to confirm a favorable safety profile of Recorlev in clinical use, we plan to discuss differentiated safety and tolerability labeling from ketoconazole with regulatory authorities.

Following a screening phase, SONICS has three distinct treatment phases. During the dose titration phase, patients start at 150 mg twice daily dosing (300 mg total daily dose) and titrate in 150 mg increments up to a maximum 600 mg twice daily dosing (1,200 mg total daily dose). Following the dose titration phase, once the therapeutic dose has been reached, patients enter the maintenance phase, during which the dose is fixed and cannot be changed other than for safety reasons, including loss of efficacy. At the end of the six-month maintenance phase, UFC levels are measured and the UFC responder rate, which is the primary endpoint of the clinical trial, is determined. Patients who have completed the maintenance phase may enter the extended evaluation phase, which we expect will provide additional safety and efficacy data. Throughout the entire clinical trial, various measurements for safety and efficacy are taken.

- The primary endpoint of the clinical trial is the proportion of subjects with UFC response to Recorlev, defined as a reduction in mean 24-hour UFC levels to levels that are equal to or less than the upper level of normal range following six months of treatment in the maintenance phase without a dose increase (during the maintenance phase).
- Key secondary endpoints include the number of patients with at least a 50% decrease in UFC levels, as well as changes in blood sugar, blood pressure, cholesterol and weight compared to baseline, and effects on clinical signs and symptoms of endogenous Cushing's syndrome, quality of life measures obtained from the endogenous Cushing's syndrome quality of life questionnaire and the severity of depression obtained from the Beck's Depression Inventory II.
- The clinical trial is also designed to investigate the pharmacokinetics of Recorlev in patients with endogenous Cushing's syndrome.



Below is a diagram of the SONICS clinical trial design:



Several elements of the SONICS clinical trial design were informed by the clinical development pathway of currently approved drug therapies in the United States and the European Union. Additionally, we incorporated advice from the CHMP and FDA into the design of the clinical trial. The FDA recommended use of a concurrent control group in SONICS. However, SONICS utilizes an open-label, single-arm design because use of a placebo control in a parallel-arm monotherapy design was considered unethical or infeasible to enroll, depending on the specific country or clinical trial site under consideration. Studies lacking a concurrent control group are more likely to be subject to unanticipated variability in study results that can potentially lead to flawed conclusions because they do not allow for discrimination of patient outcomes. As a result, even if we achieve the clinical trial's endpoints, the FDA or other regulatory authorities could view our study results as potentially biased. We have attempted to control for bias introduction in SONICS via the use of strict evidence of active disease at baseline based on objective measures, an objectively measured primary endpoint with repeated longitudinal assessments and implementation of a strict data restriction plan that severely limits exposure to efficacy data at the Sponsor.

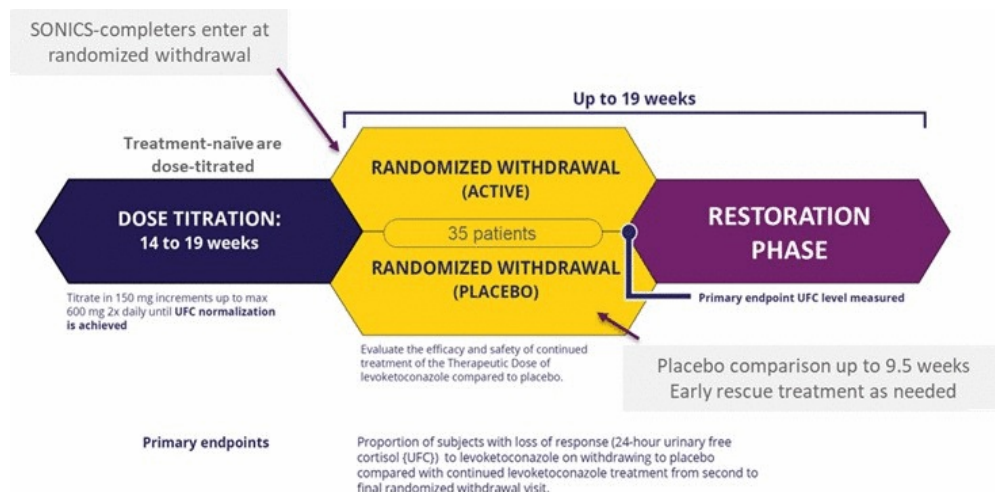
#### *LOGICS Phase 3 Clinical Trial*

Rather than alter the design of SONICS to facilitate regulatory authority requests for a concurrent control group with which to compare the efficacy and safety of Recorlev, we initiated LOGICS, a second Phase 3 pivotal study. LOGICS will include a concurrent comparison of Recorlev to matching placebo using a randomized, double-blind withdrawal design that we believe will be both feasible to enroll and ethical to conduct everywhere that SONICS is being conducted. LOGICS will randomize approximately 35 subjects, of which up to approximately one-half will have previously completed the SONICS study.

Following a screening phase, LOGICS has three distinct treatment phases for patients who did not participate in SONICS and two distinct phases for most of those who did participate in SONICS. The first phase, which is only intended for patients new to levoketoconazole or for those who require re-establishment of a therapeutic dose, is dose titration and maintenance. During the dose titration and maintenance phase, patients start at 150 mg twice daily dosing (300 mg total daily dose) and titrate in 150 mg increments up to a maximum 600 mg twice daily dosing (1,200 mg total daily dose) and remain at their individualized therapeutic dose. The total duration of this phase is approximately 14 weeks. SONICS-completers who are currently receiving a stable therapeutic dose skip dose titration and maintenance and proceed directly to the second phase, where they are joined by those who progressed through the first phase. The second phase is randomized-withdrawal, during which patients are randomly assigned to either continue active treatment with levoketoconazole or be switched to a matching placebo using the same tablet number. The primary efficacy endpoint comes at the end of the randomized-withdrawal period, which lasts no more than 9.5 weeks for each patient.

(and may end sooner if a “rescue” is needed). The primary endpoint is the proportion of patients with a loss of established UFC response in the placebo group compared with the proportion in the levoketoconazole group. The final phase of LOGICS is the restoration phase, during which all patients once again receive active therapy; however, in order to conceal the therapy in the randomized-withdrawal phase, it was necessary to blind the therapy during recovery using twice the number of tablets (one active and one placebo). Throughout the entire clinical trial, various measurements for safety and efficacy are taken.

Below is a diagram of the LOGICS clinical trial design:



### Clinical Trials in Type 2 Diabetes

Historically, levoketoconazole (then called DIO-902) was studied as a treatment for type 2 diabetes. An IND was filed in 2005 for investigation of the use of levoketoconazole in diabetes. DiObex, our licensee at the time, initiated three clinical trials to investigate the use of levoketoconazole for type 2 diabetes and two studies in healthy volunteers. A total of 159 subjects received at least one dose of levoketoconazole in these clinical trials, including 41 healthy subjects during Phase 1 clinical trials, and 118 patients with type 2 diabetes during Phase 2 clinical trials. Doses of levoketoconazole were administered over the range of 200 mg to 600 mg once a day, or QD, and 400 mg twice a day, or BID, for a single patient for up to 14 days, and 150 mg to 450 mg QD for up to four months.

The pharmacokinetics of levoketoconazole were studied in patients with type 2 diabetes and in normal volunteers in whom the effects of levoketoconazole on the pharmacokinetics of felodipine, a drug used to treat high blood pressure, and atorvastatin (Lipitor), a drug used to lower cholesterol, were evaluated. These drugs were chosen specifically as probes for interaction, because they were intended to be frequently used concomitantly during treatment of type 2 diabetes. In the completed Phase 2a clinical trial, dose dependent reductions from baseline in cholesterol levels contained in lipoproteins, in the form of low-density lipoprotein-cholesterol (“LDL-cho”), and cholesterol incorporated into high-density lipoprotein (“HDL-cho”), as well as total cholesterol were observed, but no differences in measures of glycemic control relative to placebo were detected. A Phase 2b randomized, double-blind, placebo-controlled, study in diabetes (DIO-502) was initiated to test doses of levoketoconazole up to 450 mg daily plus metformin as compared with atorvastatin 10 mg plus metformin in combination or placebo. Additionally, an open-label extension study (DIO-503) was started in parallel. However, in 2008, in light of negative safety reports for other diabetes treatments such as Avandia, DiObex made the decision to voluntarily terminate the development of levoketoconazole for the treatment of diabetes due to the perceived high regulatory and commercial hurdles for its approval and use in type 2 diabetes and considering the emerging efficacy and safety profile of levoketoconazole in type 2 diabetes (as described below).

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Thereafter, the IND was closed and DiObex terminated the two ongoing Phase 2 clinical trials. DiObex conducted the following five clinical trials with Recorlev in type 2 diabetes pursuant to an IND filed by them in November 2005:

<b>Clinical Trial Number</b>	<b>Clinical Trial Description</b>	<b>Subjects Enrolled</b>	<b>Year and Status</b>	<b>Location</b>	<b>Dose</b>
DIO-501	Phase 1/2a, Trial of Levoketoconazole or Placebo in Patients with Type 2 Diabetes Mellitus	37	2006/2007 Completed. Study report issued.	United States	200-600 mg QD; 400 mg BID
DIO-502	Phase 2b Trial of Levoketoconazole or Placebo in Addition to Metformin and Atorvastatin or Atorvastatin Placebo for Type 2 Diabetes Mellitus	133	2007/2008 Terminated early. Study report issued.	United States, Australia, New Zealand	150-450 mg QD
DIO-503	Phase 2 Open-Label Trial and Pharmacodynamic for 24-Week Study with Levoketoconazole in Combination with Metformin and Atorvastatin in Patients with Type 2 Diabetes Mellitus	13	2007/2008 Terminated early. Study report issued.	United States, Australia, New Zealand	150-450 mg QD
AA34509	Phase 1 Pharmacokinetic Drug Interaction Trial of Levoketoconazole with Felodipine in Healthy Adult Volunteers Under Fasting Conditions	18	2006/2007 Completed. Study report issued.	United States	400 mg QD
AA34510	Phase 1 Pharmacokinetic Drug Interaction Trial of Levoketoconazole and Ketoconazole with Atorvastatin in Healthy Adult Volunteers Under Fasting Conditions	24	2006/2007 Completed. Study report issued.	United States	400 mg QD

### *Phase 2 Clinical Trials*

#### *DIO-501 Clinical Trial*

The DIO-501 clinical trial was a double-blind, placebo-controlled, parallel-group clinical trial conducted in patients aged 18 to 70 with a diagnosis of type 2 diabetes. A total of 35 patients were treated: 21 with levoketoconazole (10 at 200 mg QD, six at 400 mg QD, four at 600 mg QD and one at 400 mg BID); eight with ketoconazole (400 mg QD); and six with placebo. Trial drugs were administered for 14 days.

In this clinical trial, the mean 12-hour plasma cortisol area under the concentration-time curve (“AUC”), levels were modestly reduced in the levoketoconazole treatment groups at day 15 compared to baseline, which is consistent with the known mechanism of action of levoketoconazole. However, counter-regulation in diabetic patients with a normal hypothalamic pituitary adrenal axis may have limited the observed cortisol suppression. A small, nonsignificant effect on glycated hemoglobin (HbA1c), and fasting glucose levels was observed. Consistent with the known inhibitory effect of ketoconazole on cholesterol synthesis, total cholesterol, LDL-cholesterol, and to a lesser extent HDL-cholesterol levels, but not triglycerides, were significantly decreased in a dose-dependent manner by levoketoconazole. The mean change from baseline in total cholesterol, LDL-cholesterol and HDL-cholesterol at a dose of 400 mg QD was similar to those observed in 400 mg QD ketoconazole and higher in the 600 mg QD levoketoconazole group. Also, for the levoketoconazole treatment groups, there was a statistically significant dose response in the reduction in mean levels of CRP on day 15 compared with baseline, with a p-value of 0.027. In contrast, mean levels of CRP increased in the ketoconazole-treated group and less so in the placebo group. CRP is an indicator of systemic inflammation, including vascular inflammation. The reduction in cholesterol and CRP observed in patients with type 2 diabetes may indicate a potential beneficial effect of levoketoconazole on cardiovascular risk factors. Notably, patients with endogenous Cushing’s syndrome tend to have elevated circulating CRP.

Plasma AUC and maximum concentration in blood (“C<sub>max</sub>”), increased in a non-proportional manner over the dose range of 200 mg to 400 mg on days one and 14. Clearance values were similar for the 200 mg and 400 mg doses of levoketoconazole, but significantly decreased at the 600 mg levoketoconazole dose, on days one and 14.

Levoketoconazole was generally well-tolerated. Headache and nausea were the most frequently reported adverse events, some of which were considered drug-related. There were no serious adverse events, and no clinically meaningful changes in hematology, blood chemistry and urinalysis were noted in any treatment group. No treatment-related changes in liver function tests (“LFTs”), were detected.

#### *DIO-502 and DIO-503 Clinical Trials*

The DIO-502 clinical trial was a four-month, double-blind, randomized, placebo-controlled, dose-ranging study of levoketoconazole with concomitant with metformin and atorvastatin (or atorvastatin placebo) that enrolled 133 of a planned 200 patients with type 2 diabetes, consisting of males and females between the ages of 18 and 70. Enrolled subjects were already receiving metformin treatment with a minimum daily dose of 500 mg and had a glycated hemoglobin (HbA1c) level of 7% to 10%. Additionally, all patients were treated with 10 mg atorvastatin or its placebo to evaluate the effect of levoketoconazole on lipid profiles given cholesterol-lowering drugs. Thus, patients were randomized into eight separate arms in the clinical trial: placebo or levoketoconazole at 150 mg; 300 mg; and 450 mg with either atorvastatin 10 mg or atorvastatin placebo; all received metformin concomitantly.

The DIO-503 clinical trial was an open-label, extension to DIO-502 to evaluate safety, tolerability and pharmacodynamics after 24 weeks of dosing with levoketoconazole in combination with metformin, with and without atorvastatin in subjects with type 2 diabetes.

DiObex terminated these clinical trials prior to their planned completion milestones. At the time of trial termination, a total of 133 patients were enrolled in the DIO-502 and DIO-503 trials, and 129 patients in total had been treated with a study drug, of which 97 patients received at least one dose of levoketoconazole. The investigators subsequently elected to defer efficacy and pharmacokinetics inferences based on incomplete datasets. The frequency of adverse events reported was generally similar across treatment arms. Diarrhea was the most frequently reported adverse event overall with administration of levoketoconazole. No serious adverse events were reported in the terminated studies.

A safety signal of elevated liver enzymes sufficiently abnormal to be classified as potentially clinically significant was identified in 10 (7.7%) of the 129 treated patients in the DIO-502 and DIO-503 trials combined. With respect to levoketoconazole treatment, in one of the ten, the LFT abnormality was first noted during placebo treatment, whereas in the other nine, the abnormality was first noted during active treatment. No case of Hy’s law (i.e., an increase of liver transaminases at or above three times the upper level of normal values; increase in total bilirubin at or above two times the upper level of the normal value; no or little sign of cholestasis; and absence of other reasons for liver injury, such as viral hepatitis) was observed. An observation of Hy’s Law would have indicated a high risk of potentially serious drug-related hepatotoxicity. Three of the treated patients were withdrawn from the clinical trials as required in the safety monitoring plan. In these three patients, LFT levels returned to normal after study drug was discontinued. In addition, three other patients had modest elevations in LFT levels. While these levels did not require termination by the trial protocol, the investigators elected to terminate these patients from the clinical trial. LFTs in these patients also returned to normal after the study drug was discontinued. Four additional patients required close monitoring per the protocol, and had resolution of their LFT abnormalities while on the study drug. The first case of elevated liver enzymes occurred in a patient who admitted to excessive alcohol consumption. The remaining cases developed over the following three months. An independent external safety review committee recommended continuation of the studies with no modifications.

Due to the design of these clinical trials, the independent data safety monitoring board for the trials stated that it was impossible to interpret which of the two drugs, levoketoconazole or atorvastatin, was primarily associated with the side effect profile observed (i.e. LFT abnormalities) in these trials. A more detailed analysis of the liver transaminase elevations in this clinical trial by an expert panel showed that there was no correlation between the dose of levoketoconazole and abnormal liver transaminases.

#### *Phase 1 Clinical Trials*

##### *AA34509 Clinical Trial*

The AA34509 clinical trial was designed primarily to evaluate the effect of levoketoconazole on the pharmacokinetics of concurrently administered felodipine. Healthy volunteers were administered 400 mg of

levoketoconazole or placebo QD for eight days. On the fifth day of the trial, subjects received a single 5 mg dose of felodipine. Beginning on day five, pharmacokinetics of levoketoconazole were monitored for 24 hours, and pharmacokinetics of felodipine were monitored for 72 hours. The trial was a cross-over trial involving 18 subjects, 16 of whom completed the trial.

*AA34510 Clinical Trial*

This clinical trial was designed primarily to evaluate the effect of concomitant administration of levoketoconazole or ketoconazole on the pharmacokinetics of atorvastatin. Healthy volunteers were administered 400 mg of levoketoconazole, 400 mg of ketoconazole or placebo daily for seven days. On day five, all subjects received a single 80 mg dose of atorvastatin. After administration of the racemate, ketoconazole, pharmacokinetics of the two single enantiomers 2R,4S-ketoconazole and 2S,4R-ketoconazole, were evaluated for 24 hours on day five using a chiral bioanalytical method, to distinguish the enantiomers in plasma (blood). Pharmacokinetics of atorvastatin were evaluated for 60 hours starting at the time of administration on day five. The trial was a cross-over trial involving 24 subjects, all of whom completed the clinical trial.

*Key Findings from the Clinical Trials of Recorlev (levoketoconazole)*

*Phase 2 Efficacy and Safety Trials in Diabetic Patients:*

- AUC and Cmax values were approximately 50% higher with levoketoconazole in comparison with ketoconazole at the same dose of 400 mg. All pharmacokinetic parameters were highly variable, in the sense that they differed within and among subjects.
- Following administration of ketoconazole, plasma levels (AUC or Cmax) of levoketoconazole (2S,4R-ketoconazole) were approximately three times those of the other enantiomer, 2R,4S-ketoconazole. Possible explanations could be reduced absorption of 2R,4S-ketoconazole or decreased uptake and metabolism of levoketoconazole in the liver compared to the other enantiomer.
- Levoketoconazole produced a decrease in some lipid measures, or blood fat, including reduced total cholesterol, LDL-chol and HDL-chol.
- A significant dose-related effect of levoketoconazole for reduction of CRP was observed.
- Trends for reductions in serum cortisol, measured as AUC (0-12 hours), were found after 14 days of treatment with levoketoconazole in diabetic patients.
- In the DIO-501 clinical trial, headache and nausea were the most frequently reported adverse events. No treatment related changes in LFTs were detected. In the DIO-502/503 clinical trials, diarrhea was the most frequently reported adverse event.
- LFTs were elevated in the DIO-502/503 clinical trials in 10 out of the 129 patients treated with either the combination of levoketoconazole and atorvastatin or levoketoconazole alone, in each case co-administered with metformin. The independent data safety monitoring board for the trial stated that it was impossible to interpret which of drugs was primarily associated with the side effect profile observed in the trial.

*Phase 1 Drug Interaction Clinical Trials in Normal Volunteers:*

- The AUC and the Cmax of felodipine were 10-fold higher when taken with levoketoconazole compared with felodipine alone.
- The AUC of atorvastatin was increased by 50% when administered with levoketoconazole compared with atorvastatin alone.
- A small, but statistically significant decrease of serum cortisol (AUC zero to six hours) was found for levoketoconazole compared with placebo and ketoconazole.

- Headache, nausea, dizziness and back pain were reported as the most frequent adverse events across the two studies.
- In the drug interaction study with atorvastatin, two subjects had elevated LFT values. The subjects had received levoketoconazole plus atorvastatin or ketoconazole plus atorvastatin in the immediately previous study periods in this cross-over study.

### **Veldoreotide Modified-Release —a Novel Somatostatin Analogue**

#### *Overview*

In June 2015, we acquired veldoreotide, a novel multi-receptor targeted SSA that was previously in Phase 2 development as an immediate-release formulation and has the potential to provide a new and differentiated treatment option for patients with acromegaly and potential additional applications in other conditions amenable to somatostatin receptor activation. We acquired veldoreotide as part of our strategy to build our rare endocrine franchise. At the time of acquisition, veldoreotide was in Phase 2 clinical development as a treatment for acromegaly in its original, immediate-release formulation. Acromegaly is a rare endocrine disorder that most commonly results from a benign tumor of the pituitary gland, leading to excess production of growth hormone and IGF-1. The treatment goal is the normalization of growth hormone and IGF-1, which is the main cause of the detrimental clinical signs and symptoms of acromegaly.

SSAs are peptides that are administered as deep subcutaneous or intramuscular injections, typically as long-acting formulations for monthly injections. They are the most commonly used drug therapy for the treatment of acromegaly and work by binding to specific subtypes of SSTRs that are expressed by the tumor. Binding of SSAs to these SSTRs leads to the beneficial inhibition of growth hormone secretion but can also result in the unwanted inhibition of secretion of other endocrine hormones such as insulin and glucagon in the pancreas and elsewhere. Like other SSAs, veldoreotide is a peptide that we are developing for subcutaneous injection. In contrast to approved SSAs, veldoreotide activates a different subset of SSTRs. Like pasireotide, it activates SSTR2 and SSTR5. However, in contrast to pasireotide, it possesses a similar affinity for SSTR2 than SSTR5. Veldoreotide is also the only SSA with a high affinity for SSTR4. Veldoreotide does not bind to SSTR3 or the opiate receptor at pharmacological concentrations. Although the functional consequences of the binding of SSAs to the opiate receptor are not fully understood, it has been suggested as a mechanism contributing to inhibition of insulin secretion by SSAs and may also influence their effect on gastrointestinal motility. *In vitro* data suggest that a higher number of adenomas are a target for growth hormone inhibition by veldoreotide as compared to octreotide, which is referred to as a single receptor targeted SSA that binds and activates predominantly via SSTR2, potentially resulting in an increased responder rate. Preclinical data from animal studies, and clinical data in healthy subjects and patients with acromegaly, showed that insulin secretion was less inhibited, potentially resulting in reduced side effects on blood glucose and an improved safety and tolerability profile. Preclinical data further suggest a reduced effect on gallbladder motility, or flow from the gallbladder.

Based on the differentiated activation pattern of immediate-release veldoreotide upon binding to SSTR subtypes and preclinical and clinical data, we believe that modified-release veldoreotide may offer an improved efficacy and safety profile relative to existing drug therapies for acromegaly and other conditions that are modifiable through activation of somatostatin receptors. In the five clinical studies of immediate-release veldoreotide completed to date outside the United States in healthy subjects and patients with acromegaly, a beneficial reduction of growth hormone was observed, and, when compared with immediate-release subcutaneous octreotide, there was less blunting of insulin in response to a mixed meal or oral glucose load. Veldoreotide has been granted orphan drug designation for the treatment of acromegaly by the FDA and the EMA.

We have completed the screening of potential modified-release technologies for veldoreotide and have selected a formulation based upon PLGA microspheres. PLGA is a well-known polymer, which has been widely applied in modified-release formulations due to its biocompatibility, biodegradability, and favorable release kinetics. We are in the process of securing intellectual property protection for the lead formulation, which could, if granted by the relevant patent authorities, extend the period of marketing exclusivity for the finished drug product. We expect to initiate a series of pre-clinical studies that seek to determine additional differentiating features of veldoreotide in both endocrine and non-endocrine conditions. Therefore, depending on the results of these studies, we may elect to pursue a development

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pathway for veldoreotide modified-release that includes a therapeutic use outside of endocrinology. Regardless of indication(s) to be pursued, further development will require preclinical safety (toxicology) studies as well as manufacturing scale-up before the newly formulated product can enter clinical testing. We anticipate that preclinical studies, once begun, will take at least 18 months to complete.

### *Completed Clinical Trials*

Five clinical trials of veldoreotide have been performed to date: three in healthy male volunteers and two in patients with acromegaly, all of which employed an immediate release, short-acting formulation injected subcutaneously. At the time, the clinical trials described below were conducted, veldoreotide was named DG3173. These trials were conducted by Aspireo Pharmaceuticals Ltd., other than DG3173-I-001, which was conducted by Develogen AG.

In four clinical trials with single subcutaneous injections or infusion and in one six-day clinical trial, all of which were conducted with an immediate release formulation of veldoreotide in healthy subjects or patients with acromegaly, veldoreotide was observed to have a tolerability profile comparable to that of octreotide. However, unlike octreotide, subjects treated with veldoreotide were observed to have less or no reduction in peak insulin secretion after a meal. We believe these preliminary clinical findings corroborate the profile of veldoreotide observed in preclinical studies, which suggested inhibition of growth hormone secretion without detrimental effects on post-meal insulin or glucose metabolism. These studies were too short to assess the effect on flow from the gallbladder. These preliminary findings contrast favorably with the well-described insulin and glucose perturbations caused by octreotide, lanreotide and pasireotide, and we intend to conduct additional clinical trials to evaluate the clinical profile of veldoreotide and its differentiation from existing SSAs. With the potentially superior efficacy, safety and tolerability profile suggested by preclinical studies and early clinical trials, we believe veldoreotide has the potential to become the standard-of-care SSA, with distinct therapeutic advantages relative to currently approved SSAs as treatment of acromegaly.



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The following table summarizes these trials.

Clinical Trial Number	Clinical Trial Descriptions	Subjects Enrolled	Year and Status	Location	Dose
DG3173-II-02	Phase 2 The Effect of Subcutaneous Infusion of Three Doses of Veldoreotide on Growth Hormone Levels in Untreated Acromegaly Patients	8	2013/2014 Completed. Bioanalytical report issued.	Ukraine	920-5520 µg continuous infusion over 23 hours
DG3173-II-01	Phase 2 Trial of the Effect of Veldoreotide and 300 µg Octreotide on Human Growth Hormone Levels in Untreated Acromegaly Patients	20	2012 Completed. Study report issued.	Ukraine	300-1800 µg QD
DG3173-I-003	Phase 1 Placebo-Controlled, Phase 1 Trial to Assess the Pharmacodynamics Effect on Glucose Metabolism of Single Doses Compared to Veldoreotide Octreotide and Placebo in Healthy Male Subjects	8	2013 Completed. Study report issued.	Switzerland	300-1800 µg QD
DG3173-I-002	Phase 1 Trial to Compare the Safety and Pharmacologic Activity of Repeated Doses of Veldoreotide and Veldoreotide Plus Octreotide with Octreotide and Placebo and Establish Their Pharmacokinetic Interaction in Healthy Male Subjects	42	2012/2013 Completed. Study report issued.	Switzerland	100-1800 µg TID
DG3173-I-001	Phase 1 Double-Blind Trial to Investigate Safety, Tolerability and Pharmacokinetics of Single Escalating Dosing of Veldoreotide in Healthy Male Subjects	72	2008 Completed. Study report issued.	Germany	10-2000 µg QD

The clinical trials involved 122 healthy subjects in the Phase 1 trials and 28 patients with acromegaly in the Phase 2 clinical trials. No serious adverse events were observed, and mostly mild adverse events typical for SSAs such as injection site reactions and gastrointestinal side effects were reported. There was no evidence that veldoreotide adversely affects the liver, kidneys or other organ systems, including the cardiovascular system. Data from the multiple ascending dose clinical trial in healthy subjects (Study I-002) showed inhibition of growth hormone comparable to octreotide, but no or less inhibition of insulin secretion and less effect on glucose levels. The single ascending dose trial in patients with acromegaly (Study II-01) and the continuous infusion study in patients with acromegaly (Study II-02) confirmed that veldoreotide also suppresses excessively produced growth hormone to a similar maximal extent as octreotide.

**Commercialization Strategy**

Our existing commercial infrastructure is limited and is focused on Keveyis. After acquiring the U.S. marketing rights for Keveyis in December 2016, we established sales, marketing, market access and patient service



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capabilities. We believe, based on our market research, that there are approximately 4,000 to 5,000 patients in the United States diagnosed with PPP and we believe that we can address the market by targeting physicians who are managing patients with PPP, including neuromuscular specialists, general neurologists and primary care physicians.

With the recent acquisition of Macrilen in January 2018, we are in the process of expanding our commercial infrastructure to support the planned product launch in mid-2018. We plan to build-out a separate and dedicated sales and marketing team to support the launch and ongoing commercialization of Macrilen. Further, we plan to leverage our current commercial operations infrastructure to support Macrilen. Based on our current market research, we believe there are approximately 50,000 adult growth hormone deficiency tests conducted per year. We plan to focus our launch activity on targeted pituitary centers and select community-based endocrinologists.

Given the current stage of product development of our product candidates, we do not have a commercialization infrastructure for those product candidates, although we do plan to leverage our current commercial infrastructure when possible. As with Keveys and Macrilen, we intend to independently commercialize our rare disease-focused product candidates, if approved, in the United States, the European Union and other key global markets. We believe that we can address the markets of our current product candidates by targeting endocrinologists that are focused on the diagnosis and treatment of rare pituitary disorders primarily stemming from benign tumors. Given the relatively concentrated specialty prescriber base, we plan to create a sales force of approximately 30 representatives in the United States as well in the European Union to market our endocrine product candidates, if approved. In building our sales force, we intend to recruit representatives with experience calling on endocrinologists and marketing orphan drug designated products.

Our commercial strategy for our product candidates, if approved, will encompass promoting their unique benefits, as well as a concerted effort to raise awareness about the underlying disease among the physician/patient community with the goal of increasing the rate of diagnosis when the symptoms may otherwise be overlooked. We believe the combination of our commercial efforts and our product candidate profiles will facilitate our ability to successfully penetrate our target markets.

### **Manufacturing**

We do not have internal manufacturing capabilities and intend to continue to rely on third parties to produce Keveys, Macrilen and our product candidates.

We have a supply agreement with Taro to produce Keveys. We are obligated to purchase certain annual minimum amounts of product totaling approximately \$29 million over a six-year period from Taro. The supply agreement may extend beyond the orphan exclusivity period unless terminated by either party pursuant to the terms of the agreement. If terminated by Taro at the conclusion of the orphan exclusivity period, we have the right to manufacture the product on our own or have the product manufactured by a third party on our behalf.

We have an interim supply agreement with Aetema Zentaris GmbH to purchase Macrilen materials (including drug substance, drug product, and finished goods) until such time that we can negotiate supply agreements directly with the third parties that manufacture these materials. We are obligated to purchase certain amounts of these Macrilen materials totaling approximately \$1.26 million over a nine-month period from Aetema Zentaris GmbH.

The manufacturing, packaging and distribution of Recorlev drug product for clinical trials following Good Manufacturing Practices ("GMPs"), is currently outsourced under contracts to experienced contract manufacturers. We expect to enter into similar arrangements for veldoreotide.

### **Intellectual Property of our Products and Product Candidates in Development**

We actively seek to protect the intellectual property and proprietary technology that we believe is important to our business, including seeking, maintaining, enforcing and defending patent rights for our product candidates and methods of treatment, whether developed internally or licensed from third parties. Our success will depend on our ability to obtain and maintain patent and other protection including data or market exclusivity for our product candidates and methods of treatment, preserve the confidentiality of any know-how and operate without infringing the valid and enforceable patents and proprietary rights of third parties.

Our policy is to seek to protect our proprietary position generally by filing patent applications initially at the USPTO. After this initial phase, patent applications claiming priority to the initial application are filed in various countries, including the United States, Europe and Canada. In each case, we determine the strategy and territories required after discussion with our patent professionals with the goal of obtaining relevant coverage in territories that are commercially important to us and our product candidates. We will additionally rely on data exclusivity and patent term extensions when available, including the relevant exclusivity through orphan drug designation. We also rely on trade secrets and know-how relating to our underlying product technologies. Prior to making any decision on filing any patent application, we consider with our patent professionals whether patent protection is the most sensible strategy for protecting the invention concerned or whether the invention should be maintained as confidential.

We own or license 53 granted patents, of which three are U.S. issued patents, and 7 pending patent applications, of which 6 are U.S. patent applications and one allowed U.S. patent application.

We have ten trademark registrations for Strongbridge Biopharma in the United States, Australia, Brazil, China, Europe, Israel, India, Japan, Mexico, and Turkey and one pending trademark application for Strongbridge Biopharma in Canada. We have five trademark registrations for Corynthia in Australia, China, Europe, Japan, Turkey and five pending trademark applications for Corynthia in the United States, Brazil, Canada, Israel and India. We have seven trademark registrations for Corynthia in Australia, China, Europe, India, Japan, Mexico and Turkey and four pending trademark applications for Recorlev in the United States, Brazil, Canada and Israel. We have one trademark registration for Normocort in Europe.

#### ***Keveyis***

We acquired U.S. marketing rights to Keveyis in late 2016. We are not aware of any issued patents or pending patent applications related to Keveyis. Although we intend to rely primarily on orphan exclusivity for Keveyis, we also expect to explore additional life cycle management opportunities.

#### ***Macrilen***

In January 2018, we acquired the U.S. and Canadian rights to manufacture and commercialize Macrilen. We also obtained a license to three U.S. patents, one Canadian patent and one U.S. patent application, as well as to the Macrilen trademark. The Canadian patent expires in 2021 and two of the U.S. patents expire in 2022. The third U.S. patent expires in 2027.

#### ***Recorlev***

We own 43 issued patents related to our product candidate, Recorlev. Issued claims in these patents are directed to methods of treatment of various diseases or conditions associated with elevated cortisol levels or activity using Recorlev. The patents have been granted in major territories including Europe, China and Japan and expire in 2026 and 2027. We have five pending U.S. patent applications and one allowed U.S. patent application directed to methods of treating a disease or condition associated with elevated cortisol levels or activity, including Cushing's syndrome, with Recorlev. The patent to issue from the allowed U.S. patent application will expire in 2026. We also have an issued patent in the United States directed to reducing C-reactive protein levels and systemic inflammation through administration of a once-daily dose of Recorlev that expires in 2030.

#### ***Veldoreotide***

While we own granted patents related to our product candidate veldoreotide in the United States and other major territories, including Europe and Canada, the terms of these patents may not extend beyond the launch date of this product candidate. We have also filed a PCT and U.S. application directed to various methods and formulations of veldoreotide. To the extent we are not able to obtain further patent exclusivity as a result of the PCT application or other future patent filings, we intend to rely on orphan and data/marketing exclusivity for veldoreotide.

### ***Laws and Regulations Regarding Patent Terms***

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional application. In the United States, a patent term may be shortened if a patent is terminally disclaimed over another patent or as a result of delays in a patent prosecution by the patentee. A patent's term may be lengthened by a patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent. The patent term of a European patent is 20 years from its effective filing date, which, unlike in the United States, is not subject to patent term adjustments in the same way as U.S. patents.

The term of a patent that covers a FDA-approved drug or biologic may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug or biologic is under regulatory review. Patent extensions cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other jurisdictions to extend the term of a patent that covers an approved drug, for example Supplementary Protection Certificates. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We anticipate that some of our issued patents may be eligible for patent term extensions but such extensions may not be available and therefore our commercial monopoly may be restricted.

### **Competition**

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our scientific knowledge, technology, and development experience provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing products and new products that may become available in the future. Many of our competitors, alone or with their strategic partners, have greater experience than we do in conducting preclinical studies and clinical trials, and obtaining FDA, EMA and other regulatory approvals, and have substantially greater financial, technical and other resources than we do, such as larger research and development, clinical, marketing and manufacturing organizations. As a result, these companies may obtain regulatory approval for competing products more rapidly than we are able and may be more effective in selling and marketing their products. Companies that complete clinical trials, obtain required regulatory authority approvals and commence commercial sale of their drugs before their competitors may achieve a significant competitive advantage, and our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Drugs resulting from our research and development efforts or from our joint efforts with collaboration partners therefore may not be commercially competitive with our competitors' existing products or products under development.

We are aware of several companies focused on developing or marketing therapies for rare neuromuscular and endocrine disorders. For our product candidates, the main competitors include:

- **Keveyis:** Acetazolamide, another oral carbonic anhydrase inhibitor, is used frequently off-label for the prophylactic and sometimes acute treatment of PPP. Potassium supplements, are indicated for use in hypokalemic periodic paralysis in the United States and are frequently used either chronically or for emergency treatment of episodes in that form of PPP. Several other types of drugs have been reported to have benefits for chronic or acute use in one or more than one PPP variant, including potassium-sparing diuretics, beta receptor agonists, mexelitin and other sodium channel blockers, and others. We are not aware of drugs currently in development for prophylactic chronic treatment of PPP. A Phase 2 clinical study of bumetanide, a loop diuretic, is underway in England for acute treatment of paralytic attacks.

- **Macrilen:** Measurement of blood levels of IGF-1, which is typically used as the first test when GHD is suspected. However, this test is not used to definitively diagnose GHD because many GHD patients show normal IGF-1 levels.

From a diagnostic performance perspective, the Insulin Tolerance Test (ITT) has historically been considered the reference standard for the evaluation of AGHD because of its high sensitivity and specificity. However, the ITT is inconvenient to both patients and physicians, administered intravenously (IV), and contra-indicated in certain patients, such as patients with coronary heart disease or seizure disorder, because it requires the patient to experience hypoglycemia to obtain a result. Some physicians will not induce full hypoglycemia, intentionally compromising accuracy to increase safety and comfort for the patient. Furthermore, administration of the ITT includes additional costs associated with the patient being closely monitored by a physician for the two- to four-hour duration of the test, and the test must be administered in a setting where emergency equipment is available and where the patient may be quickly hospitalized. The ITT is not used for patients with comorbidities, such as cardiovascular disease, seizure disorder or a history of brain cancer or for patients who are elderly and frail, due to safety concerns.

The Glucagon Stimulation Test (“GST”) is considered relatively safe by endocrinologists. The mechanism of action for this test is unclear. Like the ITT, this test takes at least three and up to four hours to complete and requires parenteral drug administration, typically intramuscular. It produces side effects in up to one-third of the patients with the most common being nausea during and after the test; delayed hypoglycemia also occurs uncommonly. The GST must be used in caution in the elderly as serious cardiovascular adverse effects have been reported. Interpretation of the GST is complicated by variability of the peak growth hormone response, which is strongly influenced by the patient’s body mass and glucose status (i.e. prediabetes, diabetes).

The GHRH + ARG test (growth hormone releasing hormone-arginine stimulation) is an easier test to perform in an office setting and has a good safety profile. The drug components are typically more expensive than insulin or glucagon. GHRH + ARG is used in the EU and has been proposed to be the best alternative to ITT, but GHRH in the form of GEREFF, a GHRH analog, is no longer marketed in the United States. This test is administered intravenously (IV).

- **Recorlev:** A number of therapies are currently approved and in various stages of development for endogenous Cushing’s syndrome. Currently, there are no therapies broadly marketed for the treatment of endogenous Cushing’s syndrome patients in the United States. Two therapies have limited indications in Cushing’s syndrome. Korlym (mifepristone) is a cortisol receptor blocker indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing’s syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Signifor (pasireotide) marketed by Novartis in the United States is indicated for the treatment of adult patients with Cushing’s disease (a subset of Cushing’s syndrome) for whom pituitary surgery is not an option or has not been curative.

Ketoconazole, metyrapone and mitotane are marketed by HRA Pharma in certain European countries. Novartis has submitted a NDA/MAA for Signifor (pasireotide) LAR in Cushing’s disease. Osilodrostat (LCI699), an 11 $\beta$ -HSD2 inhibitor, is currently in Phase 3 clinical development by Novartis in Cushing’s disease. Corcept is developing relacorilant (CORT125134), a selective glucocorticoid receptor antagonist, currently in Phase 2 for Cushing’s syndrome. HRA Pharma is developing metyrapone for the European market. Millendo is developing ATR-101, a selective acyl-CoA:cholesterol acyltransferase 1 (ACAT) inhibitor, currently in Phase 2. The University of Oxford, in collaboration with AstraZeneca is studying the selective 11 $\beta$ -HSD1 inhibitor, AZD4017, now in Phase 2. Cedars-Sinai is developing R-roscovitine in Phase 2.

- **Veldoreotide:** A number of acromegaly therapies are currently approved and in various stages of development. There are currently three approved SSA therapies for acromegaly in the United States: Sandostatin LAR (octreotide) marketed by Novartis; Signifor LAR (pasireotide) marketed by Novartis; and

Somatuline Depot (lanreotide) marketed by Ipsen. There is one growth hormone receptor antagonist, Somavert (pegvisomant), marketed by Pfizer. Chiasma had filed an NDA in the United States for RG-3806 (Mycapssa®), an oral octreotide formulation in 2015, and received a Complete Response Letter wherein FDA stated that it did not believe the company's application had provided substantial evidence of efficacy to warrant approval, and advised Chiasma that it would need to conduct another clinical trial in order to overcome this deficiency. Four additional therapies are in Phase 2 clinical development for acromegaly: octreotide long-acting depot (CAM-2029) developed by Novartis and Camurus; ITF-2984 developed by Italfarmaco; BIM-23B065 developed by Ipsen; and ATL-1103 developed by Antisense Therapeutics.

## **Government Regulation**

### ***Product Approval Process***

The safety, clinical testing, manufacturing, quality, labeling, storage, distribution, record keeping, advertising, promotion, import, export and marketing, among other things, of our product candidates are subject to extensive regulation by governmental authorities in the United States and other countries. The FDA under the Federal Food, Drug, and Cosmetic Act regulates pharmaceutical products in the United States. The steps required before a drug may be approved for marketing in the United States generally include:

- the completion of preclinical laboratory tests and animal tests conducted under Good Laboratory Practices, ("GLPs"), and other applicable regulations;
- the submission to the FDA of an IND application for human clinical testing, which must be reviewed by the FDA and become effective before human clinical trials commence;
- the successful performance of adequate and well-controlled human clinical trials conducted in accordance with cGCP to establish the safety and efficacy of the product candidate for each proposed indication;
- analysis of clinical trial data and preparation of submission to the FDA of an NDA;
- the submission to the FDA of an NDA;
- the FDA's acceptance of the NDA;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made to assess compliance with cGMPs to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of FDA inspections of clinical trial sites and GLP toxicology studies; and
- the FDA's review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

The testing and approval process requires substantial time, effort and financial resources, and the receipt and timing of any approval is uncertain.

Preclinical studies include laboratory evaluations of the product candidate, as well as animal studies to assess the potential safety and efficacy of the product candidate. The results of the preclinical studies, together with manufacturing information, analytical data and a proposed clinical trial protocol, are submitted to the FDA as part of the IND, which must become effective before clinical trials may be commenced. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the clinical trials as outlined in the IND prior to that time and places the IND on clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. A clinical hold may occur at any time during the life of an IND, due to safety concerns or non-compliance, and may affect one or more specific studies or all studies conducted under the IND.

Clinical trials involve the administration of the product candidates to healthy volunteers or patients with the disease to be treated under the supervision of a qualified principal investigator. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board ("IRB"), either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution. Progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors must also report to the FDA serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigation brochure, or any findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

Clinical trials are typically conducted in three sequential phases prior to approval, but the phases may overlap. These phases generally include the following:

- Phase 1. Phase 1 clinical trials represent the initial introduction of a product candidate into human subjects, frequently healthy volunteers. In Phase 1, the product candidate is usually tested for safety, including adverse effects, dosage tolerance, absorption, distribution, metabolism, excretion and pharmacodynamics.
- Phase 2. Phase 2 clinical trials usually involve studies in a limited patient population to (1) evaluate the efficacy of the product candidate for specific indications, (2) determine dosage tolerance and optimal dosage, and (3) identify possible adverse effects and safety risks.
- Phase 3. Phase 3 clinical trials are conducted to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population at geographically dispersed clinical trial sites, and to provide sufficient data for the statistically valid evidence of safety and efficacy.

Phase 4 clinical trials are conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations, or when otherwise requested by the FDA in the form of post-market requirements or commitments. Failure to promptly conduct any required Phase 4 clinical trials could result in withdrawal of approval.

Clinical trials are inherently uncertain and any phase may not be successfully completed. A clinical trial may be suspended or terminated by the FDA, IRB or sponsor at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides ongoing oversight and safety reviews to determine whether or not a clinical trial may move forward at designated check points based on access to certain data from the clinical trial. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Sponsors have the opportunity to meet with the FDA at certain points during the development of a new drug to share information about the data gathered to date and for the FDA to provide advice on the next phase of development. These meetings may be held prior to the submission of an IND, at the end of Phase 2 and/or before an NDA is submitted. Meetings may be requested at other times as well.

The results of preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information on the manufacture, composition and quality of the product, proposed labeling and other relevant information are submitted to the FDA in the form of an NDA requesting approval to market the product. The NDA must be accompanied by a significant user fee payment. The FDA has substantial discretion in the approval process and may refuse to accept any application, for example if the NDA is not sufficiently complete, or decide that the data is insufficient for approval and require additional preclinical, clinical or other studies.

In addition, under the Pediatric Research Equity Act (“PREA”), an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan drug designation has been granted. However, if only one indication for a product has orphan drug designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

Once the NDA submission has been submitted, the FDA has 60 days after submission of the NDA to conduct an initial review to determine whether it is sufficient to accept for filing. NDAs receive either a standard or priority review. Under the Prescription Drug User Fee Act, the FDA sets a goal date by which it plans to complete its review. For a standard review, this is typically 10 months from the date of submission of the NDA application. The review process is often extended by FDA requests for additional information or clarification. Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facility complies with cGMPs and may also inspect clinical trial sites for integrity of data supporting safety and efficacy. The FDA may also convene an advisory committee of external experts to provide input on certain review issues relating to risk, benefit and interpretation of clinical trial data. The FDA is not bound by the recommendations of an advisory committee, but generally follows such recommendations in making its decisions. The FDA may delay approval of an NDA if applicable regulatory criteria are not satisfied and/or the FDA requires additional testing or information. The FDA may require post-marketing testing and surveillance to monitor safety or efficacy of a product.

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter generally outlines the deficiencies in the NDA submission and may require substantial additional clinical testing, such as an additional pivotal Phase 3 clinical trial(s), clinical data, and/or other significant, expensive and time consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

The FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy (“REMS”), plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization.

#### ***Orphan Drug Designation***

Under the Orphan Drug Act of 1983, the FDA may grant orphan drug designation to a drug or biological product intended to treat an orphan disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting an NDA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as demonstrating clinical superiority to the product with orphan exclusivity. The designation of such drug also entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Competitors, however, may receive approval of



different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug product designated as an orphan product receives regulatory approval for an indication broader than that for which it is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar but not identical benefits in that jurisdiction.

### ***Post-Approval Requirements***

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product distribution, advertising and promotion, and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval and may require additional clinical trials and NDA submissions. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained, or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, but are not limited to:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Moreover, the recently enacted federal Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new federal legislation, manufacturers will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product



identifier, and keep certain records regarding the drug product. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

### ***Foreign Regulation***

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

### ***Other Healthcare Laws***

In addition to FDA restrictions on the marketing of pharmaceutical products, federal and state healthcare laws restrict certain business practices in the biopharmaceutical industry. Although we currently do not have any products on the market, we may be subject, and once our product candidates are approved and we begin commercialization, will be subject to additional healthcare laws and regulations enforced by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. These laws include, but are not limited to, anti-kickback, false claims, data privacy and security, and transparency statutes and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, purchasing, leasing, arranging for, ordering or recommending any good, facility, item or service for which payment is made, in whole or in part, under Medicare, Medicaid or any other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and our future practices may not in all cases meet all of the criteria for a statutory exception or safe harbor protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable regulatory safe harbor does not make the conduct *per se* illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare program covered business, the statute has been violated. Additionally, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the “PPACA”), amended the intent requirement under the Anti-Kickback Statute and criminal healthcare fraud statutes (discussed below) such that a person or entity no longer needs to have actual knowledge of the statute or the specific intent to violate it in order to have committed a violation. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below). Due to the breadth of these federal and state anti-kickback laws, and the potential for

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additional legal or regulatory change in this area, it is possible that our current and future sales and marketing practices and/or our future relationships with physicians might be challenged under these laws, which could cause harm to us.

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal false claims laws prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of the product for unapproved, and thus non-covered, uses.

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of, or payment for, healthcare benefits, items or services.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s security standards directly applicable to business associates— independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, and newly empowered state attorneys general with the authority to enforce HIPAA. In January 2013, the Office for Civil Rights of the U.S. Department of Health and Human Services issued the Final Omnibus Rule under HIPAA pursuant to HITECH that makes significant changes to the privacy, security, and breach notification requirements and penalties. The Final Omnibus Rule generally took effect in September 2013 and enhances certain privacy and security protections, and strengthens the government’s ability to enforce HIPAA. The Final Omnibus Rule also enhanced requirements for both covered entities and business associates regarding notification of breaches of unsecured protected health information. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways. These state laws may not have the same effect and often are not preempted by HIPAA, thus complicating compliance efforts.

Additionally, PPACA also included the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to comply with required reporting requirements could subject applicable manufacturers and others to substantial civil money penalties.

Also, many states have similar healthcare statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Certain states require pharmaceutical companies to implement a comprehensive compliance program that includes a limit or outright ban on

expenditures for, or payments to, individual medical or health professionals and/or require pharmaceutical companies to track and report gifts and other payments made to physicians and other healthcare providers.

Because we intend to commercialize products that could be reimbursed under federal and other governmental healthcare programs, we plan to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and healthcare program requirements. Although compliance programs and adherence thereto may mitigate the risk of violation of and subsequent investigation and prosecution for violations of the above laws, the risks cannot be entirely eliminated. If our operations are found to be in violation of any of the health care laws or regulations described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion of products from reimbursement under government programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and/or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products will be sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

#### ***Pharmaceutical Coverage, Pricing and Reimbursement***

In both domestic and foreign markets, our sales of any future approved products, if and when commercialized, will depend in part on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, if approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of our products will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid by third-party payors. These third-party payors are increasingly focused on containing healthcare costs by challenging the price and examining the cost-effectiveness of medical products and services.

In addition, significant uncertainty exists as to the coverage and reimbursement status of newly approved healthcare product candidates. The market for our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. Furthermore, third-party payor reimbursement to providers for our product candidates may be subject to a bundled payment that also includes the procedure administering our products. To the extent there is no separate payment for our product candidates, there may be further uncertainty as to the adequacy of reimbursement amounts. Because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time consuming, costly and sometimes unpredictable process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval would be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness and/or medical necessity of our products. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. We cannot be certain that our product candidates will be considered cost-effective or medically necessary. Because coverage and reimbursement determinations are made on a payor-by-payor basis, obtaining acceptable coverage and reimbursement from one payor does not guarantee the Company will obtain similar acceptable coverage or reimbursement from another payor. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. If we are unable to obtain coverage of, and adequate reimbursement and payment levels for, our product candidates from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition and future success.

Furthermore, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with our own products, which could negatively impact our profitability.

### ***Healthcare Reform***

In the United States and foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future business and operations if and when we begin to directly commercialize our products.

In particular, there have been and continue to be a number of initiatives at the U.S. federal and state level that seek to reduce healthcare costs. Initiatives to reduce the federal deficit and to reform healthcare delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative controls on healthcare spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups, price controls on pharmaceuticals and other fundamental changes to the healthcare delivery system. Any proposed or actual changes could limit or eliminate our spending on development projects and affect our ultimate profitability.

In March 2010, PPACA was signed into law. PPACA has substantially changed the way healthcare is financed by both governmental and private insurers. PPACA, among other things: established an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs; revised the methodology by which rebates owed by manufacturers for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated; increased the statutory minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; extended the Medicaid Drug Rebate Program to prescriptions of individuals enrolled in Medicaid managed care organizations; required manufacturers to offer 50% point-of-sale discounts on negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. For years the U.S. Congress has been assessing new legislation designed to repeal and replace core sections of the PPACA. On December 22, 2017, for instance, the President signed into law the Tax Cuts and Jobs Act of 2017, which repealed the "individual mandate" of the PPACA. The repeal of the individual mandate is expected to cause millions fewer Americans to be insured in 2027 and premiums in insurance markets may rise. The Trump Administration has also taken executive actions to undermine or delay implementation of the PPACA. In January 2017, the President signed an Executive Order directing applicable federal agencies to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices.

In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit the prices we will be able to charge for our product candidates, or the amounts of reimbursement available for our product candidates. If future legislation were to impose direct governmental price controls and access restrictions, it could have a significant adverse impact on our business. Managed care organizations, as well as Medicaid and other government agencies, continue to seek price discounts. Some states have implemented, and other states are considering, measures to reduce costs of the Medicaid program, and some states are considering implementing measures that would apply to broader segments of their populations that are not Medicaid-eligible. Due to

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the volatility in the current economic and market dynamics, we are unable to predict the impact of any unforeseen or unknown legislative, regulatory, payor or policy actions, which may include cost containment and healthcare reform measures. Such policy actions could have a material adverse impact on our profitability.

### **Segment and Geographical Information**

For the year ended December 31, 2017 revenue from product sales were derived entirely from the United States. We did not have revenue for the years ended December 31, 2016 or 2015.

We held long-lived assets in Ireland with a carrying value of \$35.2 million, \$40.2 million, and \$0 in 2017, 2016, and 2015, respectively. We held long-lived assets in the United States with a carrying value of \$0, \$0, and \$5.2 million in 2017, 2016, and 2015, respectively. We held long-lived assets in the Cayman Islands with a carrying value of \$0, \$20.7 million, and \$31.3 in 2017, 2016, and 2015, respectively.

### **Employees**

As of December 31, 2017, we had 66 full-time employees, each of whom is working in the United States. Of these full-time employees, 12 were engaged in research and development, 35 were engaged in commercial activities including sales, marketing and market access, and 19 were engaged in other general and administrative activities.

### **Corporate Information**

Strongbridge Biopharma plc, an Irish public limited company, was established on May 26, 2015 under the name Cortendo plc. On September 4, 2015, Cortendo plc changed its name to Strongbridge Biopharma plc.

Our principal executive offices are located at 900 Northbrook Drive, Suite 200, Trevose, Pennsylvania, 19053 and our telephone number is +1 610-254-9200. For the purposes of Irish law, our registered office is Arthur Cox Building, Ten Earlsfort Terrace, Dublin 2, Ireland.

Our website is [www.strongbridgebio.com](http://www.strongbridgebio.com). The information on, or that can be accessed through, our website is not part of and should not be incorporated by reference into this Annual Report.

### **Available Information**

We file with the SEC annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy and information statements and amendments to reports filed or furnished pursuant to Sections 13(a), 14 and 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Prior to becoming a domestic filer on January 1, 2018, we also filed annual reports on Form 20-F and Reports on Form 6-K. The public may obtain copies of these filings at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549 or by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website at <http://www.sec.gov> that contains reports, proxy and information statements and other information regarding Strongbridge Biopharma plc and other companies that file materials with the SEC electronically. As soon as practicable after filing with the SEC, we make copies of these reports available to the public, free of charge, through the investor relations tab on our web site, [www.strongbridgebio.com](http://www.strongbridgebio.com). The information found on our website is not part of this or any other report that we file with or furnish to the SEC.

## ITEM 1A. RISK FACTORS

*Certain factors may have a material adverse effect on our business, financial condition and results of operations. You should carefully consider the risks and uncertainties described below, in addition to other information contained in this Annual Report, including our consolidated financial statements and related notes. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occurs and, as a result, the market price of our ordinary shares could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may have similar adverse effects on us.*

### **Risks Related to Our Limited Operating History**

***We have a limited operating history on which to assess our business, have incurred significant losses over the last several years, and anticipate that we will continue to incur losses until achieving sufficient revenues from Keveyis, Macrilen, or one or more of our product candidates, if approved.***

Until we acquired the U.S. marketing rights to Keveyis, in December 2016, we were a development-stage biopharmaceutical company. We have a limited operating history and have not yet demonstrated an ability to successfully complete a large-scale, pivotal clinical trial, obtain regulatory approval, or manufacture and commercialize a product candidate. Other than our limited commercial experience with Keveyis, which we launched in April 2017, we have no meaningful prior commercial operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

Since inception, we have incurred significant operating losses. We have devoted substantially all of our financial resources to identifying, in-licensing, acquiring and developing our product candidates, conducting clinical trials, commercializing Keveyis, and providing general and administrative support for these operations. In January 2018, we acquired an exclusive license to the intellectual property rights relating to Macrilen in order to carry out the development, manufacturing, registration and commercialization of Macrilen, or any pharmaceutical product containing the active pharmaceutical ingredient in Macrilen, macimorelin acetate, in the United States and Canada, and ownership of all product registrations related to Macrilen in these countries.

To achieve commercial success of Keveyis, Macrilen and any product candidates that are approved, we will have to expand our sales, marketing and supply capabilities or outsource these activities to a third party.

To date, we have financed our operations primarily through private placements of equity securities, the proceeds from our initial public offering of ordinary shares in the United States in October 2015 and follow-on public offerings in October 2017 and January 2018, our at-the-market facility, and debt financings. The amount of our future net losses will depend, in part, on whether we successfully commercialize Keveyis, Macrilen or one of our other product candidates, if approved, and the rate of our future expenditures as well as our ability to obtain funding through strategic collaborations or grants. To become and remain profitable, we must successfully commercialize Keveyis, Macrilen or one or more of our product candidates, if approved.

***We have never been, and may never be, profitable.***

We have only two products, Keveyis and Macrilen, approved for commercialization, and two product candidates in development. We did not generate any revenue until we launched Keveyis in April 2017. Our ability to generate significant future revenue from product sales and become profitable depends heavily on our success in many areas, including, but not limited to:

- Integrating Keveyis and Macrilen and any other products or product candidates that we in-license or acquire, as well as completing research, formulation and process development, and preclinical or clinical development, as applicable, of those product candidates, including successfully completing clinical trials of those product candidates;

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- obtaining regulatory approval of our product candidates;
- maintaining supply and manufacturing relationships with third parties that can timely provide adequate, in amount and quality, products to support clinical development of our product candidates and the market demand for Keveyis and Macrilen and any other product candidates that are approved;
- obtaining market acceptance of Keveyis and Macrilen and our product candidates, if approved, and persuading adequate numbers of physicians to prescribe or utilize our products and other product candidates, if approved;
- addressing any competing technological and market developments;
- identifying, assessing, in-licensing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining adequate numbers of qualified sales and marketing personnel.

We are currently advancing two product candidates through clinical development, Recorlev (levoketoconazole) and veldoreotide. Development of product candidates is expensive, and we expect our research and development expenses to increase in connection with our ongoing activities, particularly as we continue our ongoing trials and initiate new nonclinical studies and clinical trials of Recorlev, veldoreotide and any other product candidates we may seek to develop.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. It may be several years, if ever, before we receive regulatory approval and have a product candidate, other than Keveyis and Macrilen, approved for commercialization. Our future revenue from Keveyis and Macrilen and from any other product candidates approved for commercialization will depend upon the size of the markets in which our product candidates are marketed, or in which they may receive approval, and our ability to achieve market acceptance and adequate market share for our product candidates in those markets.

Given the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. We expect to continue to incur significant expenses and operating losses until we successfully commercialize Keveyis, Macrilen or one or more of our product candidates. We anticipate that our expenses will increase substantially if and as we:

- continue to grow our sales, marketing and distribution infrastructure;
- continue research and nonclinical and clinical development of our product candidates, including advancing our programs from preclinical development into clinical trials and increasing the number and size of our current clinical trials and preclinical studies;
- make up-front, milestone or other payments under any asset acquisition, supply, or license arrangements;
- seek to identify, assess, in-license, acquire and develop additional product candidates;
- change or add manufacturers or suppliers;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;



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- seek to maintain, protect and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a U.S. listed company and our product development and commercialization efforts; and
- experience any delays or encounter issues with any of the above, including, but not limited to, failed preclinical studies or clinical trials, complex results, safety issues or other regulatory challenges that may require either longer follow-up of existing preclinical studies or clinical trials or limitation of additional preclinical studies or clinical trials in order to pursue regulatory approval.

Further, the net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Moreover, if we incur substantial losses, we could be liquidated, and the value of our shares might be significantly reduced or the shares might be of no value.

We have incurred, and anticipate we will continue to incur, significant costs associated with commercializing Keveyis. We will incur additional costs related to our development, manufacturing, registration and commercialization of Macrilen, as well as any of our other product candidates that are approved. Further, our revenue will be dependent, in part, upon the size of the markets in the territories for which we have received regulatory approval, the accepted price for the product, the ability to obtain coverage and adequate reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of our product candidates. If we are not able to generate sufficient revenue from the sale of any of our approved products, we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to successfully execute any of the foregoing would decrease the value of our company and could impair our ability to raise capital, expand our business or continue our operations. A decline in the value of our company could cause you to lose all or part of your investment.

***We expect that we will need substantial additional funding before we can expect to complete the development of our two product candidates.***

We are currently advancing two product candidates through clinical development, Recorlev (levoketoconazole) and veldoreotide. Development of product candidates is expensive, and we expect our research and development expenses to increase in connection with our ongoing activities, particularly as we continue our ongoing trials and initiate new nonclinical studies and clinical trials of Recorlev, veldoreotide and any other product candidates we may seek to develop. Although we believe the combination of our existing cash and cash equivalents and additional borrowings under our credit facility is sufficient to fund planned operations at least through the regulatory approval and commercial launch of Recorlev, if successful, we expect that we will require additional capital to obtain regulatory approval for, and to commercialize, both of our product candidates. Our future funding requirements will depend on many factors, including, but not limited to:

- the amount of revenue that we receive from sales of Keveyis and Macrilen;
- the cost of expanding our sales, marketing, distribution and administrative capabilities;
- the scope, rate of progress, results and cost of our clinical trials, nonclinical testing, and other related activities;
- the cost of formulation, process development, manufacturing of clinical supplies, and establishing commercial supplies of our product candidates and any other product candidates that we may develop, in-license or acquire;



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- whether we borrow any additional amounts under our credit facility;
- the number and characteristics of product candidates that we pursue, including any additional product candidates we may in-license or acquire;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the cost, timing and outcomes of regulatory approvals;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any required milestone and royalty payments thereunder; and
- the emergence of competing technologies and their achieving commercial success before we do or other adverse market developments.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may compromise our ability to develop and commercialize our product candidates, if approved. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ordinary shares to decline.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product or product candidates that is approved, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired.

***Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our intellectual property or future revenue streams.***

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of product revenue, equity offerings, debt financings, grants, and license and development agreements in connection with any collaborations. We have borrowed \$85 million under our credit facility. An additional \$15 million may be borrowed if we satisfy certain product revenue and market capitalization conditions. We do not have any committed external source of funds. In the event we seek additional funds, we may raise additional capital through the sale of equity or convertible debt securities. In such an event, the ownership interests of our current shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that would adversely affect their rights as shareholders. Debt financing, if available, could result in increased fixed payment obligations and may involve agreements that include restrictive covenants, such as limitations on our ability to incur additional debt, make capital expenditures, acquire, sell or license intellectual property rights or declare dividends, and other operating restrictions that could hurt our ability to conduct our business.

Further, if we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property or future revenue streams. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***We are expanding our organization and may experience difficulties in managing this growth, which could disrupt our operations.***

As our development, commercialization, in-licensing, and acquisition plans and strategies develop, and as we commercialize Keveyis and Macrilen and advance the clinical and preclinical development of our product candidates, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of managerial, operational, sales, marketing, financial, legal and other resources. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Any such growth could require significant capital expenditures and may divert financial resources from other projects, such as the in-licensing, acquisition and development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

***In order to increase adoption and sales of Keveyis and Macrilen and other product candidates we may commercialize, we will need to continue developing our commercial organization as well as recruit and retain qualified sales representatives.***

Part of our strategy is to continue to build a biopharmaceutical company to successfully execute the commercialization of our products. We may not be able to successfully commercialize our products in the United States or in any other territories where we have commercial rights. Prior to our launch of Keveyis in April 2017, we had no experience commercializing products on our own. In order to successfully commercialize our approved products, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. Although we have established a sales force consisting of approximately 21 orphan disease sales representatives focused on Keveyis, our resources are still limited compared to some of our competitors. For example, we will need to hire additional sales representatives to focus on commercialization of Macrilen. The continued development of our commercial organization to market our products and any additional products we may acquire will be expensive and time-consuming. We also cannot be certain that we will be able to continue to successfully develop this capability.

***If we are unable to effectively train and equip our sales force, our ability to successfully commercialize our products will be harmed.***

The members of our sales force have limited experience promoting Keveyis and no experience promoting Macrilen, which we only recently acquired. We have expended significant time and resources to train our sales force to be effective in their sales efforts for Keveyis and will need to devote significant additional time and resources to hire new individuals and train them with respect to Macrilen. For example, we must train our sales force to ensure that consistent and appropriate messages about Keveyis and Macrilen are being delivered to our potential customers. Our sales representatives may also experience challenges promoting Keveyis or Macrilen when we call on physicians and their office staff. We are likely to experience turnover of the sales representatives that we have hired or will hire, requiring us to train new sales representatives. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate physicians about the benefits of our products and their proper administration and label indication, as well as our patient access programs, our efforts to successfully commercialize our products could be put in jeopardy, which could have a material adverse effect on our financial condition, share price and operations.

***We may not be successful in executing our research programs or business development efforts.***

Research programs and business development efforts to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product

candidates that ultimately prove to be unsuccessful. Our research programs, business development efforts or licensing attempts may fail to yield additional complementary or successful product candidates for clinical development and commercialization for a number of reasons, including, but not limited to, the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates with a high probability of success for development progression;
- we may not be able or willing to assemble sufficient resources or expertise to in-license, acquire or discover additional product candidates;
- we may not be able to agree to acceptable terms with the licensor or owner of any product candidates we seek to in-license or acquire;
- our product candidates may not succeed in preclinical studies or clinical trials;
- we may not succeed in formulation or process development;
- our product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive regulatory approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates that we develop may be covered by third parties' patents or other exclusive rights;
- product candidates that we develop may not allow us to leverage our expertise and our development and commercial infrastructure as currently expected;
- the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occurs, we may not be successful in executing our growth strategy or our growth strategy may not deliver the anticipated results.

***We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

We have limited financial and managerial resources. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

***If we acquire other businesses or in-license or acquire other product candidates and are unable to integrate them successfully, our financial performance could suffer.***

If we are presented with appropriate opportunities, we may acquire other businesses or product candidates. We have had limited experience integrating other businesses or product candidates, or in-licensing or acquiring other product candidates. The recent acquisitions of the U.S. and Canadian marketing rights of Macrilen in January 2018 and the U.S.

marketing rights of Keveyis in December 2016 are still being integrated into our business. The integration process following these or any future transactions may produce unforeseen operating difficulties and expenditures, and may absorb significant management attention that would otherwise be directed to the ongoing development of our business. Also, in any future in-licensing or acquisition transactions, we may issue shares of stock that would result in dilution to existing shareholders, incur debt, assume contingent liabilities or create additional expenses related to amortizing intangible assets, any of which might harm our financial results and cause our stock price to decline. Any financing we might need for future transactions may be available to us only on terms that restrict our business or impose costs that reduce our net income.

***We are highly dependent on our key personnel, including our chief executive officer and chief medical officer, as well as our ability to recruit, retain and motivate additional qualified personnel.***

We are highly dependent on Matthew Pauls, our President and Chief Executive Officer, and Dr. Fredric Cohen, our Chief Medical Officer. Some members of our management team, including Mr. Pauls, have only been our employees since August 2014. As a result, they have limited experience working for us and working together as a team. Any member of management or employee can terminate his or her relationship with us at any time. Although we have included non-compete provisions in their respective employment or consulting agreements, as the case may be, such arrangements might not be sufficient for the purpose of preventing such key personnel from entering into agreements with any of our competitors. The inability to recruit and retain qualified personnel, or the loss of Mr. Pauls or Dr. Cohen, could result in competitive harm as we could experience delays in reaching our in-licensing, acquisition, development and commercialization objectives.

We also depend substantially on highly qualified managerial, sales and technical personnel who are difficult to hire and retain. There is currently a shortage of skilled personnel in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in preclinical studies or clinical trials may make it more challenging to recruit and retain qualified personnel. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will be critical to our success.

***Our business and operations would suffer in the event of system failures.***

Our computer systems, as well as those of our clinical research organizations (“CROs”), and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, including hurricanes, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of preclinical study or clinical trial data from completed, ongoing or planned preclinical studies or clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

#### **Risks Related to Our Business**

***We depend entirely on the success of Keveyis, Macrilen and our two product candidates, which are still in clinical development. If we do not successfully commercialize Keveyis or Macrilen or obtain regulatory approval for and successfully commercialize one or more of our product candidates or we experience significant delays in doing so, we may never become profitable.***

We currently have two products approved for sale, Keveyis and Macrilen, and two product candidates in development. We have invested, and continue to expect to invest, a significant portion of our efforts and financial resources in the development of our two product candidates, which are still in clinical development. Our ability to generate product revenues will depend heavily on our successful commercialization of Keveyis and Macrilen and our eventual commercialization, if approved, of one or more of our product candidates currently in development. We are not

permitted to market or promote any product candidate before we receive regulatory approval from the FDA, EMA or any comparable foreign regulatory agency, and we may never receive such regulatory approval for our product candidates currently in development. The success of Recorlev and veldoreotide will depend on several additional factors, including, but not limited to, the following:

- successfully completing clinical trials that demonstrate the efficacy and safety of our product candidates;
- successfully completing formulation and process development activities;
- acceptance of our product candidates by patients and the medical community;
- a continued acceptable safety profile following approval;
- obtaining and maintaining healthcare coverage and adequate reimbursement; and
- competing effectively with other therapies, including with respect to the sales and marketing of our product candidates, if approved.

Many of these factors are beyond our control, including clinical development, the regulatory submission process, potential threats to our intellectual property rights and changes in the competitive landscape. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete clinical trials or eventually commercialize our product candidates, if approved.

***Clinical trials are very expensive, time consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.***

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and earlier clinical trials may not be predictive of the results of later-stage clinical trials. For example, the results generated to date in preclinical studies or clinical trials for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. Further, we have limited clinical data for each of our product candidates and have not completed Phase 3 clinical trials for any of our product candidates. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials.

Companies in the biopharmaceutical industry may suffer setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials. For example, levoketoconazole was previously studied for the treatment of type 2 diabetes. In December 2005, prior to the initiation of the first clinical trial by DiObex, our licensee, the FDA placed a clinical hold relating to a safety concern for use of a dosage above 600 mg/day. DiObex modified the clinical trial protocol to limit the highest dose to 600 mg/day, and the clinical hold was lifted by the FDA in February 2006. Furthermore, levoketoconazole did not demonstrate a reduction in blood glucose levels in a small Phase 2 clinical trial in patients with type 2 diabetes mellitus, the original indication for which it was being developed. We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of subjects or patients on time or be completed on schedule, if at all. Clinical trials may be delayed, suspended or terminated for a variety of reasons, including delay or failure to:

- obtain authorization from regulators or IRBs to commence a clinical trial at a prospective clinical trial site;
- reach agreements on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;

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- recruit and enroll a sufficient number of patients in clinical trials to ensure adequate statistical power to detect statistically significant treatment effects;
- address any noncompliance with regulatory requirements or safety concerns that arise during the course of a clinical trial;
- have patients complete clinical trials or return for post-treatment follow-up;
- have CROs or other third parties comply with regulatory requirements, adhere to the trial protocol or meet contractual obligations in a timely manner or at all;
- identify a sufficient number of clinical trial sites and initiate them within the planned timelines; and
- manufacture sufficient quantities of the product candidate to complete clinical trials.

Positive or timely results from preclinical or early stage clinical trials do not ensure positive or timely results in late stage clinical trials or regulatory approval by the FDA, EMA or any comparable foreign regulatory agency. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for the product candidates. The FDA, EMA and any comparable foreign regulatory agency have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA or any comparable foreign regulatory agency.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the administration regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. In the case of our late stage clinical product candidates, results may differ in general on the basis of the larger number of clinical trial sites and additional countries involved in Phase 3 clinical trials. Different countries have different standards of care and different levels of access to care for patients, which in part drives the heterogeneity of the patient populations that enroll in our studies.

In June 2015, we acquired veldoreotide and were not involved in and had no control over the preclinical and clinical development of this product candidate prior to such acquisition. As a result, we are dependent on the prior research and development of veldoreotide having been conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, the accuracy of reported results of all clinical trials conducted prior to our acquisition and the correct interpretation of collected data from these clinical trials. These factors could result in increased costs and delays in the development of veldoreotide, which could hurt our ability to generate future revenues from this product candidate.

***The regulatory approval process of the FDA, EMA or any comparable foreign regulatory agency may be lengthy, time consuming and unpredictable.***

Our future success is dependent upon our ability to successfully develop, obtain regulatory approval for and then successfully commercialize one or more of our product candidates. Although certain of our employees have prior experience with submitting marketing applications to the FDA, EMA and comparable foreign regulatory agencies, we, as a company, have not submitted such applications for our product candidates. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Applications for any of our product candidates could fail to receive regulatory approval for many reasons, including, but not limited to, the following:

- the FDA, EMA or any comparable foreign regulatory agency may disagree with the design or implementation of our clinical trials or our interpretation of data from nonclinical trials or clinical trials;

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- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval, including reliance on foreign clinical data;
- the data collected from clinical trials of our product candidates may not be sufficient to support a finding that has statistical significance or clinical meaningfulness or support the submission of a NDA or other submission, or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, EMA or any comparable foreign regulatory agency that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or any comparable foreign regulatory agency may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or any comparable foreign regulatory agency may significantly change in a manner rendering our clinical data insufficient for approval.

Any of our current or future product candidates could take a significantly longer time to gain regulatory approval than expected or may never gain regulatory approval. This could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our product candidates.

Several elements of the SONICS Phase 3 clinical trial design for Recorlev were informed by the clinical development pathway of currently approved drug therapies in the United States and the European Union. Additionally, we incorporated advice from the CHMP and FDA into the design of the clinical trial. In communication we had with the FDA, they recommended use of a concurrent control group in SONICS. However, SONICS utilizes an open-label, single-arm design because use of a placebo control in a parallel-arm monotherapy design was considered unethical or infeasible to enroll, depending on the specific country or clinical trial site under consideration. Studies lacking an active control group are more likely to be subject to unanticipated variability in study results that can potentially lead to flawed conclusions because they do not allow for discrimination of patient outcomes. As a result, even if we achieve the clinical trial's endpoints, the FDA or other regulatory authorities could view our study results as potentially biased.

We intend to seek formal advice and guidance from the FDA and the EMA prior to advancing veldoreotide into further studies and pivotal clinical trials. If the feedback we receive is different from what we currently anticipate, this could delay the development and regulatory approval process for this product candidate.

We generally plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union and other key global markets. To obtain regulatory approval in other countries, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing and distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. Failure to obtain marketing authorization for our product candidates will result in our being unable to market and sell such products. If we fail to obtain approval in any jurisdiction, the geographic market for our product candidates could be limited. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

***If we or others identify previously unknown, serious side effects of Keveyis or Macrilen, we may be required to perform lengthy additional clinical trials, change their labeling or withdraw them from the market.***

If we or others identify previously unknown, serious side effects of Keveyis or Macrilen:

- regulatory authorities may withdraw their approvals;
- we may be required to conduct additional clinical trials, make changes in labeling, implement changes to or obtain re-approvals of facilities that manufacture Keveyis or Macrilen;



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- we may experience a significant drop in the sales of Keveyis or Macrilen;
- our reputation in the marketplace may suffer; and
- we may become the target of lawsuits, including class action lawsuits.

Any of these events could harm or prevent sales of Keveyis and Macrilen or could increase the costs and expenses of commercializing and marketing Keveyis and Macrilen.

***Physicians may accept Keveyis and/or Macrilen slowly or may never accept them, which would adversely affect our financial results.***

Physicians will prescribe Keveyis only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is preferable to other treatments, even if those products are not approved for PPP. Because PPP is rare, most physicians are inexperienced in the care of patients with the illness and it may be difficult to persuade them to prescribe Keveyis. Other factors that may affect the commercial success of Keveyis include:

- the preference of some physicians for more familiar, long-standing, off-label treatments for PPP, such as acetazolamide;
- competition from alternative therapies, such as potassium supplements, diuretics, beta receptor agonists, mexiletine and other sodium channel blockers;
- the cost-effectiveness of Keveyis and the availability of third-party insurance coverage and reimbursement; and
- the product labeling required by the FDA.

Physicians will prescribe Macrilen only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is preferable to other diagnostic methods, even if those methods are not approved for diagnosing AGHD. Because AGHD is rare, most physicians are inexperienced in the diagnosis of patients with the illness and it may be difficult to persuade them to prescribe Macrilen.

- the preference of some physicians to utilize Arginine, an injectable product that is the only other FDA-approved product indicated for use in diagnosing AGHD, or one of several other products that are used off-label to diagnose AGHD, of which the two most frequently prescribed products are the injectables glucagon and insulin;
- the cost-effectiveness of Macrilen and the availability of third-party insurance coverage and reimbursement; and
- the product labeling required by the FDA.

The failure of Keveyis and Macrilen to achieve commercial success could prevent us from generating sufficient revenue to fully fund our commercial and development activities.

***If serious adverse, undesirable or unacceptable side effects are identified during the development of our product candidates or following regulatory approval, if any, we may need to abandon our development of such product candidates.***

If our product candidates are associated with serious adverse, undesirable or unacceptable side effects, we may need to abandon their development or limit development to certain uses or sub-populations in which such side effects are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in preclinical or early stage testing have later been found to cause side effects that restricted their use and prevented further development of the compound for larger indications.

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For example, in our clinical trials of Recorlev to date, adverse events have included headache, nausea, back pain, dizziness, diarrhea and liver enzyme elevations. For veldoreotide, which is given by subcutaneous injections, adverse events have included injection site reaction such as swelling, itching and pain. In addition, headache and gastrointestinal effects such as nausea and diarrhea were observed for veldoreotide. These adverse events can be dose-dependent and may increase in frequency and severity if we increase the dose to increase efficacy. Occurrence of serious treatment-related side effects could impede clinical trial enrollment, require us to halt the clinical trial, and prevent receipt of regulatory approval from the FDA, EMA or any comparable foreign regulatory agency. They could also adversely affect physician or patient acceptance of our product candidates.

Discovery of previously unknown problems, or increased focus on a known problem, with an approved product may result in restrictions on its permissible uses, including withdrawal of the medicine from the market. Currently, ketoconazole is required to include a "black box" warning on its label for use as an antifungal related to liver toxicity in the United States. Manufactured ketoconazole consists of two enantiomers, 2R,4S-ketoconazole and 2S,4R-ketoconazole, that are found in equal amounts, and is therefore referred to as a racemate mixture. Recorlev is a single-enantiomer drug, a pure form of one of the two enantiomers (2S,4R-ketoconazole) of ketoconazole. If Recorlev is required to include a similar "black box" warning on its label, it may limit our ability to commercialize the product, if approved.

Additionally, if one or more of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product(s), a number of potentially significant negative consequences could result, including, but not limited to:

- withdrawal by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product;
- requirement by regulatory authorities of additional warnings on the label, such as a black box warning;
- requirement that we create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive additional safety studies prior to launch as a prerequisite of approval by regulatory authorities of such product;
- commitment to expensive post-marketing studies as a prerequisite of approval by regulatory authorities of such product;
- initiation of legal action against us claiming to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, financial condition, and results of operations.

***We may find it difficult to enroll patients in our clinical trials given the limited number of patients who have the diseases for the treatment of which our product candidates are being studied. Difficulty in enrolling patients in our clinical trials could delay or prevent clinical trials of our product candidates.***

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. Clinical trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the clinical trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is

investigating, and clinicians' and patients' perceptions as to the safety and potential advantages of the product candidate being studied in relation to other available therapies.

Because we are focused on addressing rare diseases, there are limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process, and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that may lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

***We may become exposed to costly and damaging liability claims, either in connection with the sale of Keveyis, Macrilen or other approved products or when testing our product candidates in the clinic, and our product liability insurance may not cover all damages from such claims.***

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. The current and future use of product candidates by us in clinical trials, and the sale of Keveyis and Macrilen and any approved products, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend, and could compromise the market acceptance of Keveyis and Macrilen, our product candidates or any prospects for commercialization of our product candidates, if approved.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If Keveyis, Macrilen or any of our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with product instructions or may ignore warnings regarding potential adverse effects and patients who should not use our products.

We have limited product liability insurance that offers coverage we believe to be appropriate for a company marketing a single pharmaceutical product and developing others. We intend to extend our product liability insurance coverage to any product candidate for which we obtain marketing approval. However, this insurance may be prohibitively expensive or may not fully cover our potential liabilities. Our inability to obtain adequate insurance coverage at an acceptable cost could prevent or inhibit the commercialization of Keveyis, Macrilen or other product candidates that are approved, or result in meaningful underinsured or uninsured liability. Defending a lawsuit could be costly and significantly divert management's attention from conducting our business. If we were sued successfully, our liability could exceed our total assets.

***We may not be able to build an effective sales and marketing team.***

We currently have a very limited sales force and marketing and distribution capabilities. To achieve commercial success of Keveyis, Macrilen and any product candidates that are approved, we will have to continue to develop and expand our sales and marketing capabilities or outsource these activities to a third party.

Factors that may affect our ability to successfully commercialize Keveyis, Macrilen and our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment and is time consuming. We may not be able to build an effective sales and marketing organization in the United States, the European Union or other key global markets. If we are unable to establish effective sales and marketing capabilities or to find suitable partners for the commercialization of Keveyis, Macrilen and our product candidates, we may not generate revenues from them.

***We operate in a highly competitive and rapidly changing industry, which may result in our competitors discovering, developing or commercializing competing products before or more successfully than we do, or our entering a market in which a competitor has commercialized an established competing product, and we may not be successful in competing with them.***

The development and commercialization of new drug products is highly competitive and subject to significant and rapid technological change. Our success is highly dependent upon our ability to in-license, acquire, develop and obtain regulatory approval for new and innovative drug products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies who already possess a large share of the market, specialty pharmaceutical companies and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in Europe, the United States and other jurisdictions.

Keveyis is an oral carbonic anhydrase inhibitor, that was approved in the United States to treat hyperkalemic, hypokalemic and related variants of PPP. Acetazolamide, another oral carbonic anhydrase inhibitor, is used frequently off-label for the prophylactic and sometimes acute treatment of PPP. Potassium supplements, are indicated for use in hypokalemic periodic paralysis in the United States and are frequently used either chronically or for emergency treatment of episodes in that form of PPP. Several other types of drugs have been reported to have benefits for chronic or acute use in one or more than one PPP variant, including potassium-sparing diuretics, beta receptor agonists, mexelitine and other sodium channel blockers, and others. We are not aware of drugs currently in development for prophylactic chronic treatment of PPP. A Phase 2 clinical study of bumetanide, a loop diuretic, is underway in England for acute treatment of paralytic attacks.

Macrilen is an orally available ghrelin agonist, approved in the United States December 20, 2017 for use in the diagnosis of patients with AGHD. Arginine, an injectable product, is the only other FDA approved product indicated for use in diagnosing AGHD. However, several other products are used off-label for this use also, of which the two most frequently prescribed products are the injectables glucagon and insulin. We are not aware of any drugs currently in development for use in diagnosing AGHD.

We are currently aware of various companies that are marketing existing drugs that may compete with Recorlev such as Corcept Therapeutics and Novartis. The treatment of endogenous Cushing's syndrome patients who fail or are ineligible for surgery in the United States and Europe are: Korlym (mifepristone) marketed by Corcept Therapeutics in the United States; Signifor (pasireotide) marketed by Novartis in the United States and European Union; and ketoconazole, metyrapone and mitotane marketed by HRA in the European Union. Novartis has submitted an NDA/MAA for Signifor (pasireotide) LAR in Cushing's disease. Additionally, LCI-699 (osilodrostat) is currently in Phase 3 clinical development by Novartis in Cushing's disease patients. Corcept is developing CORT125134, a second-generation glucocorticoid receptor modulator; currently in Phase 2. HRA Pharma is developing metyrapone for the US market; currently in Phase 2. Millendo is developing ATR-101, a selective acyl-CoA:cholesterol acyltransferase 1 (ACAT) inhibitor, currently in Phase 2. In addition, Ketoconazole is believed to be the most commonly prescribed drug therapy for the treatment of endogenous Cushing's syndrome, even though it is not approved for this use in the United States. Regulatory approval of ketoconazole in the United States for the treatment of endogenous Cushing's syndrome could significantly increase competition for Recorlev due to their similar mechanisms of action.

We are currently aware of various companies that are marketing existing drugs that may compete with veldoreotide such as Novartis, Ipsen and Pfizer. In addition, a number of acromegaly therapies are in various stages of development. There are currently three approved SSA therapies for acromegaly in the United States: Sandostatin LAR (octreotide) marketed by Novartis; Signifor LAR (pasireotide) marketed by Novartis; and Somatuline Depot (lanreotide) marketed by Ipsen. There is one growth hormone receptor antagonist, Somavert (pegvisomant), marketed by Pfizer. Chiasma had filed an NDA in the United States for RG-3806 (Mycapssa®), an oral octreotide formulation in 2015, and received a Complete Response Letter wherein FDA stated that it did not believe the company's application had provided substantial evidence of efficacy to warrant approval, and advised Chiasma that it would need to conduct another clinical trial in order to overcome this deficiency. Four additional therapies are in Phase 2 clinical development for acromegaly: octreotide long-acting depot (CAM-2029) developed by Novartis and Camurus; ITF-2984 developed by Italfarmaco; BIM-23B065 developed by Ipsen; and ATL-1103 developed by Antisense Therapeutics.

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We anticipate this competition to increase in the future as new companies enter the neuromuscular, endocrinology and rare diseases markets. In addition, the health care industry is characterized by rapid technological change, and new product introductions or other technological advancements could make some or all of our products obsolete.

The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete or non-competitive. Our competitors may, among other things:

- have similar or better product candidates or technologies;
- possess greater financial and human resources as well as supporting clinical data;
- develop and commercialize products that are safer, more effective, less expensive, or more convenient or easier to administer;
- obtain regulatory approval more quickly;
- establish superior proprietary positions;
- have access to greater manufacturing capacity;
- seek patent protection that competes with our product candidates;
- implement more effective approaches to sales and marketing; or
- enter into more advantageous collaborative arrangements for research, development, manufacturing and marketing of products.

***Additional competitors could enter the market with generic versions of our products, which may result in a decline in sales of affected products.***

Under the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application (“ANDA”), seeking approval of a generic copy of an approved innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA under section 505(b)(2) that references the FDA's prior approval of the innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. Hatch-Waxman also provides for certain periods of regulatory exclusivity, which preclude FDA approval, or, in some circumstances, FDA filing and reviewing, of an ANDA or 505(b)(2) NDA. These include, subject to certain exceptions, the period during which an FDA-approved drug is subject to orphan drug exclusivity. Although Recorlev is being developed as a new chemical entity (“NCE”), we intend to rely on orphan drug exclusivity rather than NCE exclusivity for nonpatent protection of Recorlev. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations,” known as the “Orange Book.” If there are patents listed in the Orange Book, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in the ANDA what is known as a “Paragraph IV certification,” challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the innovator, too, and if within 45 days of receiving notice the innovator sues to protect its patents, approval of the ANDA is stayed for 30 months, or as lengthened or shortened by the court.

Accordingly, if Recorlev or any of our other product candidates is approved, competitors could file ANDAs for generic versions of our product candidates, or 505(b)(2) NDAs that reference our product candidates, respectively. If there are patents listed for our product candidates in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict whether any patents issuing from our pending patent applications will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any patents that are granted and listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially. Should sales decline, we may have to write off a portion or all of the intangible assets associated with the affected product and our ability to generate revenue could be compromised.

***The successful commercialization of our products and product candidates that are approved will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage and reimbursement levels and pricing policies.***

The successful commercialization of Keveyis, Macrilen and our product candidates, if approved, will depend, in part, on the extent to which coverage and reimbursement for our products will be available from government and health administration authorities, private health insurers and other third-party payors. To manage healthcare costs, many governments and third-party payors increasingly scrutinize the pricing of new therapies and require greater levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage and adequate reimbursement to such new technologies. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the “Medicare Modernization Act”) changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly under a new Part D and introduced a new reimbursement methodology based on average sale prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost-reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors. In light of such challenges to prices and increasing levels of evidence of the benefits and clinical outcomes of new technologies, we cannot be sure that coverage will be available for Keveyis, Macrilen and/or any product candidate that we commercialize, and, if available, that the reimbursement rates will be adequate. If we are unable to obtain adequate levels of coverage and reimbursement for Keveyis, Macrilen and/or our product candidates, our ability to generate revenue will be compromised.

Because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time consuming, costly and sometimes unpredictable process. We may be required to provide scientific and clinical support, medical necessity or both for the use of Keveyis, Macrilen or any product to each third-party payor separately with no assurance that approval would be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness, medical necessity or both of our products. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results.

Third-party payors may deny coverage and reimbursement status altogether of a given drug product, or cover the product, but may also establish prices at levels that are too low to enable us to realize an appropriate return on our investment in product development. Because the rules and regulations regarding coverage and reimbursement change frequently, in some cases on short notice, even when there is favorable coverage and reimbursement, future changes may occur that adversely impact such favorable coverage and reimbursement status. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

The unavailability or inadequacy of third-party coverage and reimbursement could negatively affect the market acceptance of Keveyis, Macrilen and our product candidates and the future revenues we may expect to receive from these products. In addition, we are unable to predict what additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on our business.

***Our products may not gain market acceptance, in which case we may not be able to generate product revenues.***

Even if the FDA, EMA or any comparable foreign regulatory agency approves the marketing of any product candidates that we develop, physicians, healthcare providers, patients or the medical community may not accept or use them. Efforts to educate the medical community and third-party payors on the benefits of our products or product candidates may require significant resources and may not be successful. If Keveyis, Macrilen, Recorlev, veldoreotide or any other product candidate that we develop does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of Keveyis, Macrilen,

Recorlev, veldoreotide or any other product candidates that are approved for commercial sale will depend on a variety of factors, including, but not limited to:

- whether clinicians and potential patients perceive our products or product candidates to have better efficacy, safety and tolerability profile, and ease of use compared with alternative therapies;
- the timing of market introduction;
- the number of competing products;
- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- relative convenience and ease of administration;
- cost-effectiveness;
- patient diagnostics and screening infrastructure in each market;
- marketing and distribution support; and
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-party payors, both public and private.

In addition, the potential market opportunity for Keveyis, Macrilen, Recorlev, veldoreotide or any other product candidate we may develop is difficult to estimate precisely. Our estimates of the potential market opportunity are predicated on several key assumptions such as industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions may be inaccurate. If any of the assumptions proves to be inaccurate, then the actual market for Keveyis, Macrilen, Recorlev or our other product candidates could be smaller than our estimates of the potential market opportunity. If the actual market for Keveyis, Macrilen, Recorlev or our other product candidates is smaller than we expect, or if the products fail to achieve an adequate level of acceptance by physicians, health care payors and patients, our product revenue may be limited and we may be unable to achieve or maintain profitability. Further, given the limited number of treating physicians, if we are unable to convince a significant number of such physicians of the value of our products or product candidates, we may be unable to achieve a sufficient market share to make our products profitable.

***The Orphan Drug designation for Keveyis, Macrilen and our product candidates may not prevent competition from companies that develop other compounds for the treatment of the same condition. These companies may have significantly more resources than we do. Competition from them could limit our revenue from the commercialization of Keveyis, Macrilen and/or our other product candidates.***

Although Keveyis, Macrilen and our product candidates have received Orphan Drug designation in the United States, and in the case of Recorlev and veldoreotide in Europe, we cannot be assured that we will realize the potential benefits of the designation. Even after an orphan drug is approved for its orphan indication, the FDA or EMA can subsequently approve a different drug for the same condition if it concludes that the later drug is safer, more effective or makes a major contribution to patient care. Upon expiration of the orphan drug exclusivity period, we may be subject to competition from manufacturers offering a generic form of Keveyis, Macrilen or our other products at a lower price, in



which case our business could be harmed.

For example, Corcept's Korlym has an Orphan Drug designation in the United States and is approved for the control of hyperglycemia secondary to hypercortisolism in patients with endogenous Cushing's syndrome who have type 2 diabetes or glucose intolerance and have failed surgery or are not candidates for surgery. However, in 2012 Novartis received approval in both the United States and the European Union (EU) to market its somatostatin analogue Signifor for adult patients with Cushing's disease (a subset of Cushing's syndrome that accounts for approximately 70 percent of all Cushing's syndrome patients) for whom pituitary surgery is not an option or has not been curative.

Laboratoire HRA Pharma (HRA) received Orphan Drug designation in the United States and the EU for the use of mifepristone to treat a subtype of Cushing's syndrome. HRA began and terminated a Phase 2 clinical trial in Europe and the United States for this indication. Exelgyn Laboratories, which operates as a subsidiary of Medi Challenge (Pty) Ltd., received Orphan Drug designation for mifepristone to treat Cushing's syndrome in the EU, but it has stated that it has not yet conducted any clinical trials.

***The terms of our credit facility place restrictions on our operating and financial flexibility.***

Our term loan agreement with CRG includes affirmative and negative covenants applicable to us and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals necessary for us and our subsidiaries to perform our respective businesses and obligations under the term loan agreement, deliver certain financial reports to the lenders, maintain insurance coverage, and comply with certain financial covenants. The negative covenants include, among others, restrictions on our transferring collateral, changing our business, engaging in mergers or acquisitions, incurring additional indebtedness, paying dividends or making other distributions, making investments, creating liens, or entering into transactions with affiliates, in each case subject to certain exceptions.

The term loan agreement also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 4.0% and would provide the lenders holding more than 50% of the aggregate commitments under the credit facility, and CRG, as collateral agent, with the right to exercise remedies against us and the collateral securing the credit facility, including foreclosure against our assets securing the credit facility, including our cash. These events of default include, among others, our failure to pay any amounts due under the term loan agreement, a breach of covenants under the term loan agreement, a material adverse change, our insolvency, the occurrence of a default under any material agreement with a third party, and/or one or more judgments are rendered against us or our subsidiaries in an amount greater than \$250,000 individually or in the aggregate.

Our ability to make scheduled payments on or to refinance our indebtedness depends on our future performance and ability to raise additional sources of cash, which is subject to economic, financial, competitive and other factors beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. If we desire to refinance our indebtedness, our ability to do so will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

**Risks Related to Our Reliance on Third Parties**

***We have no manufacturing capabilities and currently depend on one supplier to manufacture Keveyis and a single set of suppliers to manufacture Macrilen. We also depend on a limited number of other suppliers to manufacture our product candidates for use in clinical trials. If these suppliers are unable or unwilling to continue manufacturing for us and we are unable to contract quickly with alternative sources, or if these third-party manufacturers fail to comply with FDA regulations or otherwise fail to meet our requirements, our business will be harmed.***

Taro Pharmaceuticals North America, Inc. produces all of our requirements for Keveyis. We rely on a single set of suppliers to produce all of our requirements for Macrilen. We rely on other third-parties to manufacture our product

candidates for use in clinical trials. If any of these vendors is unable or unwilling to meet our future requirements, we may not be able to manufacture our products in a timely manner. Our current arrangements with these manufacturers are terminable by such manufacturers, subject to certain notice provisions.

The facilities used by our vendors to manufacture our product and product candidates must be approved by the FDA. We do not control the manufacturing processes of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements known as current good manufacturing practices (cGMPs). If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict requirements of the FDA or others, they will not be able to maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our products or if it withdraws any such approval, we may need to find alternative manufacturing facilities, which would significantly hamper our ability to develop, obtain regulatory approval for or market our products. In addition, sanctions could be imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could harm our business. If our suppliers fail to manufacture Keveyis, Macrilen or our product candidates on a timely basis in the quantities that we require, or fail to maintain manufacturing capabilities that meet FDA standards, we may exhaust our Keveyis and/or Macrilen inventory and not be able to generate revenue, or clinical development programs may be delayed.

***We and our collaborators and contract manufacturers are subject to significant regulation with respect to the manufacturing of Keveyis, Macrilen and our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands.***

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our products and product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaborators or our contract manufacturers must supply all necessary documentation in support of an NDA or foreign equivalent on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our contract manufacturers have never produced a commercially-approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our collaborators and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our collaborators and third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility.

If we, our collaborators or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or another applicable regulatory authority could impose regulatory sanctions including, among other things, refusal to approve a pending application our product candidates, withdrawal of an approval or suspension of production.

Additionally, if the supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA supplement or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

***We rely on third parties to conduct our nonclinical and clinical trials and if these third parties perform in an unsatisfactory manner, our business could be substantially harmed.***

We have relied upon and plan to continue to rely upon third-party CROs to conduct and monitor and manage data for our ongoing nonclinical and clinical programs, and may not currently have all of the necessary contractual relationships in place to do so. Once we have established contractual relationships with such third-party CROs, we will have only limited control over their actual performance of these activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory, environmental and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs and other vendors are required to comply with current Good Manufacturing Practices (“cGMP”), current Good Clinical Practices (“cGCP”), and Good Laboratory Practice (“GLP”), which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Union and any comparable foreign regulatory agency for all of our product candidates in nonclinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, trial sites and other contractors. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our nonclinical and clinical trials may be deemed unreliable and the FDA, EMA or any comparable foreign regulatory agency may require us to perform additional nonclinical and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that all of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Our business involves the controlled use of hazardous materials, chemicals, biologicals and radioactive compounds. Substantially all such use is outsourced to third-party CRO manufacturers and clinical sites. Although we believe that our third-party CROs safety procedures for handling and disposing of such materials comply with industry standards, there will always be a risk of accidental contamination or injury. By law, radioactive materials may only be disposed of at certain approved facilities. If liable for an accident, or if it suffers an extended facility shutdown, we or our CROs could incur significant costs, damages or penalties.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing nonclinical and clinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Our CROs may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. If we are able to replace a CRO, switching or adding additional CROs involves additional cost and requires management time and focus and there is a natural transition period when a new CRO commences work. As a result, delays could occur, which could hurt our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future.

***Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.***

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business.

#### **Risks Related to Our Intellectual Property**

***If we or our licensors are unable to obtain and maintain effective patent or license rights for our technologies, product candidates or any future product candidates, or if the scope of the patent or license rights obtained is not sufficiently broad, we may not be able to compete effectively in our markets.***

In addition to the exclusivity provided for Keveyis, Macrilen and our product candidates with regulatory orphan drug status, we rely upon a combination of patents, trade secret protection, license rights and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our and our licensors' ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries, as well as license rights, with respect to our proprietary technology, products and product candidates.

We have sought to protect our proprietary position by filing, where possible, patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development and manufacturing processes before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our products or product candidates in the United States or in foreign countries. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions remain confidential for a period of time after filing, and some remain so until issued. Therefore, we cannot be certain that we were the first to file any patent application related to our products or product candidates, or whether we were the first to make the inventions claimed in our owned patents or pending patent applications, nor can we know whether those from whom we license patents were the first to make the inventions claimed or were the first to file. As a result, the issuance, scope, validity, enforceability

and commercial value of our patent rights are highly uncertain. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our products or product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, found unenforceable or invalidated, which could allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our products or product candidates, prevent others from designing around our claims or provide us with a competitive advantage. Any of these outcomes could impair our ability to prevent competition from third parties.

We and/or our licensors or partners have filed several patent applications covering various aspects of our products and product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether any issued patents will be found invalid and unenforceable or will be challenged by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance, or the loss or other impairment of any license rights relating to our products or product candidates, could deprive us of rights necessary for the successful commercialization of any products or product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product or product candidate under patent protection could be reduced.

***We may not have sufficient patent terms to effectively protect our products and business.***

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is first filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage. Even if patents covering our products or product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications.

Although patent term extensions in the United States and under supplementary protection certificates in the European Union may be available to extend the patent exclusivity term for our products or product candidates, we cannot provide any assurances that any such patent term extension will be obtained and, if so, for how long.

***Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.***

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to invent the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act (the "AIA"), enacted on September 16, 2011, the United States has moved to a first inventor to file system. The AIA also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the United States Patent and Trademark Office (the "USPTO") is still implementing various regulations, the courts have yet to address many of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the U.S. Congress, the

federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

***Third-party claims of intellectual property infringement may expose us to substantial liability or prevent or delay our development and commercialization efforts.***

Our commercial success depends in part on our ability to develop, manufacture, market and sell Keveyis, Macrilen and our product candidates, if approved, and use our proprietary technology without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we will market Keveyis and Macrilen and are developing product candidates. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products and product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods of treatment related to the use or manufacture of Keveyis, Macrilen or our product candidates. We cannot be sure that we know of each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of Keveyis, Macrilen or our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents upon which our products or product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our products or product candidates, any compositions formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product or product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product or product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize Keveyis, Macrilen or one or more of our product candidates, if approved. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

***Although we are not currently involved in any litigation, we may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe upon our patents or the patents of our licensors. Although we are not currently involved in any litigation, if we or one of our licensing partners were to initiate legal proceedings against a third party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim that the patent



covering our product or product candidate is invalid and/or unenforceable, or request declaratory judgment that there is no infringement. In patent litigation in the United States, defendant counterclaims alleging invalidity, noninfringement and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, nonobviousness or non-lack of enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs, and distract our management and other employees. In addition, the uncertainties associated with litigation could compromise our ability to successfully market Keveyis and/or Macrilen raise the funds necessary to continue our clinical trials, continue our research programs, and license necessary technology from third parties or enter into development partnerships that would help us bring our product candidates to market, if approved.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could hurt the market price of our ordinary shares.

***Failure to secure or maintain adequate protection for our trademarks could adversely affect our business.***

We have filed a U.S., Canadian, Brazilian and International (Madrid Protocol) trademark application designating Australia, China, European Community, India, Israel, Japan, Mexico and Turkey for the mark, "Strongbridge Biopharma." If the U.S. or any foreign trademark offices raise any objections, we may be unable to overcome such objections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Oppositions or cancellation proceedings have been filed and may in the future be filed against our trademarks, and our trademarks may not survive such proceedings.

Furthermore, third parties may allege in the future, that a trademark or trade name that we elect to use for our product candidates may cause confusion in the marketplace. We evaluate such potential allegations in the course of our business, and such evaluations may cause us to change our commercialization or branding strategy for our product candidates, which may require us to incur additional costs. Moreover, any name we propose to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, domain names or copyrights may be ineffective and could result in substantial costs and diversion of resources.

In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks alleging that the use of a corporate name or logo, product names or other signs by which we



distinguish our products and services are infringing their trademark rights. The outcome of such claims is uncertain and may adversely affect our freedom to use our corporate name or other relevant signs. If litigation arises in this area, it may lead to significant costs and diversion of management and employee attention.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

We may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, and we are not currently subject to any claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***We may be subject to claims challenging the inventorship of our patents and other intellectual property.***

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on our products or product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

#### **Risks Related to Government Oversight and Regulation**

*We will be subject to ongoing obligations and continued regulatory requirements, which may result in significant additional expense.*

Keveyis, Macrilen and any of our product candidates that obtain regulatory approval will remain subject to continual regulatory review. Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA, the EMA or any comparable foreign regulatory authority approves any of our product candidates, we will be subject to ongoing regulatory obligations and oversight by regulatory authorities, including with respect to the manufacturing processes, labeling, packing, distribution, adverse event reporting, storage, advertising and marketing restrictions, and recordkeeping and, potentially, other post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize such products. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-regulatory approval. Because our two Phase 3 clinical trials of Recorlev will collect safety data for approximately 125 patients, we currently expect that we would be required by the FDA and the EMA to collect additional safety data post-approval.

In addition, approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product;
- withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, disgorgement of profits or revenues, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us;
- suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements. The policies of the FDA, the EMA or any comparable foreign regulatory agency may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, which would compromise our ability to achieve or sustain profitability.

***Although we have obtained orphan drug designation for Keveyis, Macrilen and our key product candidates from the FDA and EMA, orphan drug designation may not ensure that we will enjoy market exclusivity in a particular market, and if we fail to obtain or maintain orphan drug exclusivity for Keveyis, Macrilen or our product candidates, we may be subject to earlier competition and our potential revenue will be reduced.***

Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan drug if it is intended to treat an orphan disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan drug designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the European Union, orphan drug designation entitles a party to financial incentives such as a reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Keveyis has been granted orphan drug designation for the treatment of hyperkalemic, hypokalemic, and related variants of PPP in the United States. Macrilen has been granted orphan drug designation for the diagnosis of AGHD. Recorlev has been granted orphan drug designation for the treatment of endogenous Cushing's syndrome in the United States and Europe. Veldoreotide has been granted orphan drug designation for the treatment of acromegaly in the United States and in Europe. Even though we have obtained orphan drug designation for our key product candidates, we may not be the first to obtain regulatory approval for any particular orphan indication due to the uncertainties associated with developing biopharmaceutical products. For example, ketoconazole was granted orphan drug exclusivity in Europe and is now being marketed for the treatment of endogenous Cushing's syndrome. Therefore, Recorlev will need to show significant benefit compared to ketoconazole in order to be marketed in Europe prior to the expiration of the ketoconazole orphan drug exclusivity. Further, even though we have obtained orphan drug designation for our key product candidates, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

***Enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our product candidates, and may affect the prices we may set.***

In the United States and the European Union, there have been a number of legislative, regulatory and proposed changes regarding the healthcare system. These changes could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to sell profitably any products for which we obtain regulatory approval and begin to commercialize.

As a result of legislative proposals and the trend toward managed health care in the United States, third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. In the United States, the Medicare Modernization Act changed the way Medicare covers and pays for

pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly under a new Part D and introduced a new reimbursement methodology based on average sale prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost-reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow the Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, a sweeping law intended, among other things, to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms. PPACA, among other things: increased the statutory minimum Medicaid rebates a manufacturer must pay under the Medicaid Drug Rebate Program; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; and established a new Medicare Part D coverage gap discount program in which manufacturers must provide 50% point-of-sale discounts on negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Part D and implemented payment system reforms, including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Further, the PPACA imposed a significant annual nondeductible fee on entities that manufacture or import specified branded prescription drug products and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs. We expect that additional healthcare reform measures will likely be adopted in the future, any of which may increase our regulatory burdens and operating costs and limit the amounts that federal, state and foreign governments will reimburse for healthcare products and services, which could result in reduced demand for our products, if approved, or additional pricing pressures.

Moreover, other legislative changes have also been proposed and adopted in the United States since PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021 was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could compromise the ability of patients and third-party payors to purchase our product candidates.

In 2017, the U.S. Congress has been assessing new legislation designed to repeal and replace core sections of the PPACA. We expect the U.S. Congress to continue to review and assess this legislation, referred to as the American Health Care Act (AHCA), along with other alternative health care reform proposals throughout 2017. Recent Congressional efforts such as the AHCA proposal adds to the uncertainty of the legislative changes enacted as part of PPACA. These changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the PPACA. There is no assurance that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In the European Union, proposed new clinical trial regulations will centralize clinical trial approval, which eliminates redundancy, but in some cases this may extend timelines for clinical trial approvals due to potentially longer wait times. Proposals to require specific consents for use of data in research, among other measures, may increase the

costs and timelines for our product development efforts. Austerity measures in certain European nations may also affect the prices we are able to seek if our products are approved, as discussed below.

Both in the United States and in the European Union, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, whether the regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our product candidates, if any, may be.

***Pricing for pharmaceutical products has come under increasing scrutiny by governments, legislative bodies and enforcement agencies. These activities may result in actions that have the effect of reducing our revenue or harming our business or reputation.***

Pharmaceutical product pricing is subject to enhanced government and public scrutiny and calls for reform. There has recently been intense publicity regarding the pricing of pharmaceutical products generally, including publicity and pressure resulting from the prices charged for new products as well as price increases for older products that the government and public deem excessive. We may experience downward pricing pressure on the price of our products due to social or political pressure to lower the cost of drugs, which could reduce our revenue and future profitability. Many companies in our industry have received governmental requests for documents and information relating to drug pricing and patient support programs. On December 19, 2017, we received letters from the offices of United States Senators Amy Klobuchar, Susan Collins and Tammy Baldwin, and Senator Claire McCaskill, Ranking member of Homeland Security and Governmental Affairs Committee, that request information relating to the marketing and sales of Kevevix. The letters request information principally relating to the pricing of Kevevix, among other things. We are cooperating with these voluntary requests for information. We could incur significant expense and experience reputational harm as a result of these or other similar future inquiries, as well as reduced market acceptance and demand for our products, which could harm our ability to market our products in the future. These factors could also result in changes in our product pricing and distribution strategies, reduced demand for our products and/or reduced reimbursement of products, including by federal health care programs such as Medicare and Medicaid and state health care programs. In addition, the Trump Administration has indicated an interest in taking measures pertaining to drug pricing, including potential proposals relating to Medicare price negotiations, and importation of drugs from other countries. At this time, it is unclear whether any of these proposals will be pursued and how they would impact our products or our future product candidates.

***Our relationships with customers, consultants and payors will be subject to applicable fraud and abuse, privacy and security, transparency and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we may in the future obtain regulatory approval and commercialize. Our current and future arrangements with third-party payors, consultants, customers, physicians and others may expose us to broadly applicable fraud and abuse and other healthcare federal and state laws and regulations, including in the United States, that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain regulatory approval. Potentially applicable healthcare laws and regulations include, but are not limited to, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for, purchasing, leasing, ordering, arranging for, or recommending the purchase, lease, or order of, any good, facility, item or service for which payment may be made under U.S. government healthcare programs such as Medicare and Medicaid;
- the federal civil and criminal false claims laws and civil monetary penalties laws, including civil whistleblower or qui tam actions, which prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal

government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government;

- the Privacy Rule or the Security Rule of HIPAA, as amended by HITECH, and its implementing regulations, which impose various obligations with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the health care fraud provisions of HIPAA, which impose criminal liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of, or payment for, healthcare benefits, items or services;
- the federal Physician Payments Sunshine Act under PPACA and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies to annually report to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value made by such manufacturers to physicians and teaching hospitals, and ownership and investment interests held by physicians or their immediate family members; and
- analogous laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements, research, distribution and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state requirements for manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures and other restrictions on drug manufacturer marketing practices.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute and analogous state laws, it is possible that some of our current and future business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, PPACA, among other things, amends the intent requirement of the U.S. federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to be in violation. Moreover, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to, without limitation, significant civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, imprisonment, disgorgement, enhanced government reporting and oversight, contractual damages, reputational harm, diminished profits and future earnings and/or the curtailment or restructuring of our operations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses or divert our management's attention from the operations of our business. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to similar penalties, including, without limitation, criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

***We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations which can harm our business.***

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

### **Risks Related to Our Ordinary Shares**

***The price of our ordinary shares may be volatile and may fluctuate due to factors beyond our control.***

The market price of our ordinary shares may be volatile and subject to wide fluctuations in response to a variety of factors, many of which are beyond our control, including:

- revenues from sales of Keveyis and Macrilen;
- positive or negative results of testing and clinical trials by us, strategic partners or competitors;
- delays in in-licensing or acquiring additional complementary product candidates;
- any delay in the commencement, enrollment and the ultimate completion of clinical trials;
- technological innovations or commercial product introductions by us or competitors;
- failure to successfully develop and commercialize any of our product candidates, if approved;
- changes in government regulations;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of any of our product candidates;
- financing or other corporate transactions, or inability to obtain additional funding;
- failure to meet or exceed expectations of the investment community;
- announcements of significant licenses, acquisitions, strategic partnerships or joint ventures by us or our competitors;
- publication of research reports or comments by securities or industry analysts; or
- general market conditions in the pharmaceutical industry or in the economy as a whole.



The share price of publicly traded emerging biopharmaceutical and drug discovery and development companies has been highly volatile and is likely to remain highly volatile in the future. In addition, the stock market in general has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of individual companies. Broad market and industry factors may hurt the market price of companies' stock, including ours, regardless of actual operating performance.

***If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, the price of our ordinary shares and our trading volume could decline.***

The trading market for our ordinary shares depends in part on the research and reports that securities or industry analysts publish about us or our business. If too few securities or industry analysts commence or continue coverage of our company, the trading price for our ordinary shares would likely be negatively affected. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our ordinary shares or publish inaccurate or unfavorable research about our business, the price of our ordinary shares would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our ordinary shares could decrease, which might cause the price of our ordinary shares and trading volume to decline.

***Future sales, or the possibility of future sales, of a substantial number of our ordinary shares could adversely affect the price of our ordinary shares.***

Future sales of a substantial number of our ordinary shares, or the perception that such sales will occur, could cause a decline in the market price of our ordinary shares. We currently have 45,504,848 ordinary shares outstanding. We have also filed a Registration Statement on Form S-8, registering ordinary shares that we may issue under our equity compensation plans. These ordinary shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements. If a large number of our ordinary shares or securities convertible into our ordinary shares are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our ordinary shares and impede our ability to raise future capital.

***An active market in our ordinary shares may not be liquid enough for investors to resell our ordinary shares.***

The listing of our ordinary shares on the Nasdaq Global Select Market does not assure that a meaningful, consistent and liquid trading market exists. In general trading volume in our ordinary shares has been limited and an active trading market for our shares may not be sustained. If an active market for our ordinary shares is not sustained, it may be difficult for investors to sell their shares without depressing the market price for the shares or at all.

***We have never paid cash dividends, do not expect to pay dividends in the foreseeable future and our ability to pay dividends, or repurchase or redeem our ordinary shares, is limited by law.***

We have not paid any dividends since our inception and do not anticipate paying any dividends on our ordinary shares in the foreseeable future. Even if future operations lead to significant levels of distributable profits, we currently intend that any earnings will be reinvested in our business and that dividends will not be paid until we have an established revenue stream to support continuing dividends. The proposal to pay future dividends to shareholders will in addition effectively be at the sole discretion of our board of directors after taking into account various factors our board of directors deems relevant, including our business prospects, capital requirements, financial performance and new product development. In addition, payment of future dividends is subject to certain limitations under the Irish Companies Act 2014 (the "Irish Companies Act"). The Irish Companies Act, among other requirements, requires Irish companies to have distributable reserves available for distribution equal to or greater than the amount of the proposed dividend. Accordingly, investors cannot rely on dividend income from our ordinary shares and any returns on an investment in our ordinary shares will likely depend entirely upon any future appreciation in the price of our ordinary shares.

***We believe we were classified as a passive foreign investment company (“PFIC”) for U.S. federal income tax purposes in past years and we may be classified as a PFIC in future years, which could result in adverse U.S. federal income tax consequences to U.S. Holders of our ordinary shares.***

A non-U.S. corporation generally will be classified as a PFIC for U.S. federal income tax purposes for any taxable year if either (1) 75% or more of its gross income for such year consists of certain types of "passive" income or (2) 50% or more of the value of its assets (determined on the basis of a quarterly average) during such year produce or are held for the production of passive income. For this purpose, "passive income" generally includes, among other items of income, dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income, and a non-U.S. corporation is treated as owning a proportionate share of the assets and earning a proportionate share of the income of any other corporation in which such non-U.S. corporation owns, directly or indirectly, more than 25% of the value of such other corporation's stock. Based on our income, assets and activities in past years, we believe that we were a PFIC in past years, and we may be classified as a PFIC for the current taxable year and for future years depending on the income, assets, and activities in such taxable years. A U.S. Holder that holds ordinary shares during any taxable year in which we are a PFIC would be subject to substantially increased U.S. federal income tax liability, including upon the receipt of any "excess distributions" from us and upon the sale or other disposition of our ordinary shares. Although certain elections may be available to mitigate the adverse impact of the PFIC rules, such elections may result in a current U.S. federal tax liability prior to any distribution on or disposition of our ordinary shares. Further, there can be no assurances that we will supply U.S. Holders with information that such U.S. Holders are required to report under the rules governing such elections. Accordingly, the acquisition of our ordinary shares may not be an appropriate investment for certain holders that are not tax-exempt organizations. U.S. Holders should consult their tax advisers regarding the application of the PFIC rules to an investment in our ordinary shares.

***As of January 1, 2018, we are required to comply with the Exchange Act's domestic reporting regime and Nasdaq's requirements for domestic issuers, which may cause us to incur increased legal, accounting and other expenses.***

Prior to January 1, 2018, we were a foreign private issuer and were, therefore, not required to comply with the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. As of the end of our second fiscal quarter in 2017, however, we determined that we no longer satisfied the eligibility requirements of a foreign private issuer. As a result, effective January 1, 2018 we are required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers, and are no longer eligible for certain exemptions from Nasdaq's corporate governance requirements. The Exchange Act's disclosure and reporting requirements for domestic issuers are generally more detailed and extensive than the requirements for foreign private issuers. To satisfy these requirements, we may be required to make changes to our corporate governance practices to comply with SEC and stock exchange rules. The costs for us to comply with these regulatory requirements may be significantly higher than the costs we have generally incurred as a foreign private issuer. Further, we are now subject to procedural requirements, including Nasdaq rules requiring shareholder approval for certain types of equity offerings, that may impede our ability to conduct certain types of financings or otherwise delay our ability to take corporate actions. We also expect that complying with the rules and regulations applicable to domestic issuers may make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

***Our shareholder's rights are governed by Irish law and differ from the rights of shareholders under U.S. law.***

We are a public limited company incorporated under the laws of Ireland. Therefore, the rights of holders of ordinary shares are governed by Irish law and by our memorandum and articles of association. These rights differ from the typical rights of shareholders in U.S. corporations. In certain cases, facts that, under U.S. law, would entitle a shareholder in a U.S. corporation to claim damages may not give rise to a cause of action under Irish law entitling a shareholder in an Irish company to claim damages. For example, the rights of shareholders to bring proceedings against us or against our directors or officers in relation to public statements are more limited under Irish law than under the civil liability provisions of the U.S. securities laws.

Our shareholders may have difficulties enforcing, in actions brought in courts in jurisdictions located outside the United States, judgments obtained in the U.S. courts under the U.S. securities laws. In particular, if a shareholder sought to bring proceedings in Ireland based on U.S. securities laws, the Irish court might consider that:

- it did not have jurisdiction;
- it was not the appropriate forum for such proceedings;
- applying Irish conflict of laws rules, U.S. laws (including U.S. securities laws) did not apply to the relationship between you and us or our directors and officers; or
- the U.S. securities laws were of a penal nature or violated Irish public policy and should not be enforced by the Irish court.

Our shareholders should also be aware that Irish law does not allow for any form of legal proceedings directly equivalent to the class action available in the United States.

***Because the PCAOB is not permitted to inspect registered public accounting firms in Ireland, you do not have the benefit of such inspections to the extent our financial statements are audited by a registered public accounting firm in Ireland.***

Auditors of U.S. public companies, including our independent registered public accounting firm, are required by the laws of the United States to undergo periodic PCAOB inspections to assess their compliance with U.S. law and professional standards in connection with performance of audits of financial statements filed with the SEC. The laws of certain European Union countries, including Ireland, do not currently permit the PCAOB to conduct inspections of accounting firms established and operating in such European Union countries. Accordingly, to the extent our financial statements will be audited by a registered public accounting firm in Ireland, the PCAOB would be prevented from fully evaluating the effectiveness of our independent registered public accounting firm's audit procedures or quality control procedures. Unlike shareholders or potential shareholders of most U.S. public companies, our shareholders would be deprived of the possible benefits of such PCAOB inspections.

***A future transfer of our ordinary shares, other than one effected by means of the transfer of book-entry interests in DTC, may be subject to Irish stamp duty.***

The rate of Irish stamp duty, when applicable, on the transfer of shares in an Irish-incorporated company is 1% of the price paid, or the market value of the shares acquired, whichever is greater. Payment of Irish stamp duty is generally a legal obligation of the transferee. We expect that most of our ordinary shares will be traded through the Depository Trust Company ("DTC"), or through brokers who hold such shares on behalf of customers through DTC. As such, the transfer of ordinary shares should be exempt from Irish stamp duty based on established practice of the Irish Revenue Commissioners. We received written confirmation from the Irish Revenue Commissioners on June 22, 2015 that a transfer of our ordinary shares held through DTC and transferred by means of a book-entry interest would be exempt from Irish stamp duty. However, if you hold your ordinary shares directly of record, rather than beneficially through DTC, or through a broker that holds your ordinary shares through DTC, any transfer of your ordinary shares may be subject to Irish stamp duty. The potential for Irish stamp duty to arise could adversely affect the price and liquidity of our ordinary shares. In addition, the terms of our eligibility agreement with DTC requires us to provide certain indemnities relating to Irish stamp duty to third parties. If liability were to arise as a result of the indemnities provided under the terms of the eligibility agreement, we may face significant unexpected costs.

***Anti-takeover provisions in our Articles and under Irish law could make an acquisition of us more difficult, limit attempts by our shareholders to replace or remove our current directors and management team, and limit the market price of our ordinary shares.***

Our Articles contain provisions that may delay or prevent a change of control, discourage bids at a premium over the market price of our ordinary shares and adversely affect the market price of our ordinary shares and the voting

and other rights of the holders of our ordinary shares. These provisions include:

- dividing our board of directors into three classes, with each class serving a staggered three-year term;
- permitting our board of directors to issue preference shares without shareholder approval, with such rights, preferences and privileges as they may designate;
- provisions which allow our board of directors to adopt a shareholder rights plan upon such terms and conditions as it deems expedient and in our best interests;
- establishing an advance notice procedure for shareholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors; and
- the ability of our board of directors to fill vacancies on our board in certain circumstances.

These provisions do not make us immune from takeovers. However, these provisions will apply even if the offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management team by making it more difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

***Irish law differs from the laws in effect in the United States with respect to defending unwanted takeover proposals and may give our board of directors less ability to control negotiations with hostile offerors.***

We are subject to the Irish Takeover Rules. Under the Irish Takeover Rules, our board of directors is not permitted to take any action that might frustrate an offer for our ordinary shares once our board of directors has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as (1) the issue of shares, options, restricted share units or convertible securities, (2) material acquisitions or disposals, (3) entering into contracts other than in the ordinary course of business or (4) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which our board of directors has reason to believe an offer is or may be imminent. These provisions may give our board of directors less ability to control negotiations with hostile offerors than would be the case for a corporation incorporated in the United States.

***We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to "emerging growth companies" will make our ordinary shares less attractive to investors.***

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, exemptions from the requirements to provide certain executive compensation disclosures, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation or seeking shareholder approval of any golden parachute payments not previously approved. As an "emerging growth company," in our initial registration statement, we were required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We could be an "emerging growth company" for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our ordinary shares held by non-affiliates exceeds \$700 million as of any June 30 before that time, in which case we would no longer be an "emerging growth company" as of the following December 31, our fiscal year end. We cannot predict if investors will find our ordinary shares less attractive because we may rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and the price of our ordinary shares may be more volatile.

***Certain provisions of the warrants issued in our 2016 private placement could impede a sale of the company.***

In the event of a sale of the company, the terms of the warrants issued to investors in our December 2016 private placement require us to use our best efforts to ensure the holders of such warrants will have a continuing right to purchase shares of the acquirer and, if our efforts are unsuccessful, to make a payment to such warrant holders based on a Black-Scholes valuation (using variables as specified in the warrant agreements). Such payment must be made in cash in the event that the acquisition results in our shareholders receiving cash from the acquirer at the closing of the transaction, and must be made in shares of the Company (with the value of each ordinary share determined according to the calculation specified in the warrant agreements) in the event that the acquisition results in our shareholders receiving shares in the acquirer or other entity at the closing of the transaction. In the event that our shareholders receive both cash and shares at the closing of the transaction, such payment to the warrant holders shall also be made in both cash and shares in the same proportion as the consideration received by the shareholders.

Notwithstanding the foregoing, in the event that as a result of an acquisition the warrants will be exercisable for anything other than shares or securities that are listed on a regulated market (within the meaning of the Markets in Financial Instruments Directive (2004/39(EC))) or a United States national securities exchange, the warrant holders will be entitled to demand to receive a cash payment in an amount equal to the Black-Scholes Value per warrant (calculated in accordance with the warrants) contemporaneously with or promptly after the consummation of such acquisition.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None

**ITEM 2. PROPERTIES**

For our corporate headquarters, we lease 22,069 square feet of office space at 900 Northbrook Drive, Suite 200 and Suite 250, Trevose, Pennsylvania 19053. We believe that our existing facility is adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms. We also lease 3,173 square feet of office space in Radnor, Pennsylvania, which was subleased in September 2015.

**ITEM 3. LEGAL PROCEEDINGS**

From time to time, we are a party to legal proceedings arising in the ordinary course of business. We are not currently a party to any other legal proceedings that we believe could have a material adverse effect on financial condition or results of operations.

**ITEM 4. MINE SAFETY DISCLOSURE**

Not applicable.

## ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

### Market Information

The Company's common stock is listed on the Nasdaq Global Select Market under the symbol "SBBP". The following table sets forth, for the periods indicated, the range of high and low sales prices per ordinary share as reported by Nasdaq:

	High	Low
<b>Year ended December 31, 2017</b>		
Quarter ended December 31, 2017	\$ 7.60	\$ 5.20
Quarter ended September 30, 2017	\$ 8.85	\$ 5.40
Quarter ended June 30, 2017	\$ 7.90	\$ 3.50
Quarter ended March 31, 2017	\$ 4.75	\$ 2.00
<b>Year ended December 31, 2016</b>		
Quarter ended December 31, 2016	\$ 5.42	\$ 2.05
Quarter ended September 30, 2016	\$ 6.24	\$ 3.73
Quarter ended June 30, 2016	\$ 6.39	\$ 3.30
Quarter ended March 31, 2016	\$ 7.99	\$ 3.51

### Stockholders

As of December 31, 2017, there were approximately 31 stockholders of record of our ordinary shares. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

### Dividend Policy

We have never declared or paid any cash dividends on our capital stock. As per our loan agreement, we are restricted to pay dividends or other distributions with respect to any shares of our capital stock. We do not intend to pay cash dividends on our common stock for the foreseeable future.

### Securities Authorized for Issuance Under Equity Compensation Plans

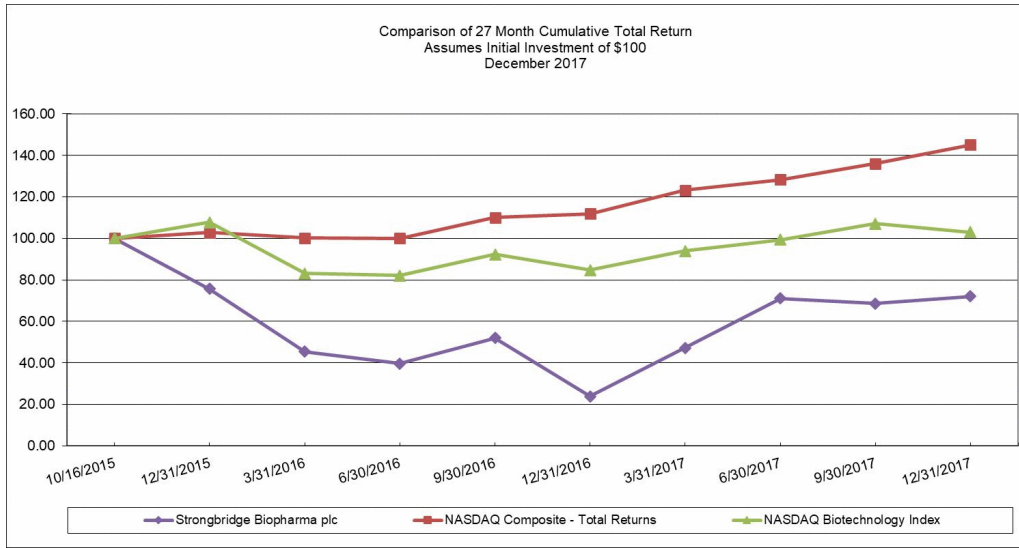
See Part III, Item 12. "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" for information relating to our equity compensation plans.

### Performance Graph

The performance graph below compares the cumulative total stockholder return on our common stock beginning on October 15, 2015, the date our stock began trading on the Nasdaq Global Market, and for each subsequent quarter period end through and including December 31, 2017, with the cumulative return of the Nasdaq Composite Index and Nasdaq Biotechnology Index.

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The performance graph comparison assumes \$100 was invested in our common stock and in each of the other indices described above October 15, 2015. The stock performance shown on the graph below is not necessarily indicative of future price performance.



**Recent Sale of Unregistered Securities and Use of Proceeds**

As a condition to the Loan Agreement, on July 14, 2017, we sold an aggregate of 429,799 ordinary shares to CRG for an aggregate purchase price of \$3.0 million. We also issued to CRG a warrant to purchase up to an aggregate of 394,289 ordinary shares, at an exercise price of \$7.37 per share.

We believe that the issuance of the ordinary shares and warrants to CRG were exempt from registration under the Securities Act pursuant to Section 4(a)(2) of the Securities Act regarding transactions not involving a public offering.

**Purchases of Equity Securities By the Issuer and Affiliated Purchasers**

None.



**ITEM 6. SELECTED FINANCIAL DATA**

The following tables set forth a summary of our consolidated financial data. We have derived the consolidated statement of operations data for the years ended December 31, 2017, 2016, 2015, 2014 and 2013 and the balance sheet data as of December 31, 2017, 2016 and 2015 from our consolidated audited financial statements. You should read this data together with the consolidated financial statements and related notes appearing elsewhere in this Annual Report and the section in this filing titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” The historical results are not necessarily indicative of the results to be expected for any future periods. All of our operations are continuing operations and we have not proposed or paid dividends in any of the periods presented.

	December 31,				
	2017	2016	2015	2014	2013
(in thousands)					
<b>Consolidated Statement of Operations Data:</b>					
Revenues:					
Net product sales	\$ 7,046	\$ —	\$ —	\$ —	\$ —
Cost and expenses:					
Cost of sales (excluding amortization of intangible asset)	\$ 1,483	\$ —	\$ —	\$ —	\$ —
Selling, general and administrative	36,292	14,875	22,719	4,588	2,658
Research and development	17,268	20,023	20,135	5,844	2,534
Amortization of intangible asset	5,022	—	—	—	—
Impairment of intangible assets	20,723	15,828	—	—	—
Total cost and expenses	80,788	50,726	42,854	10,432	5,192
Operating loss	(73,742)	(50,726)	(42,854)	(10,432)	(5,192)
Total other income (expense), net	(37,970)	(631)	(1,229)	282	(288)
Loss before income taxes	(111,712)	(51,357)	(44,083)	(10,150)	(5,480)
Income tax (expense) benefit	(1,771)	2,638	450	480	—
Net loss	(113,483)	(48,719)	(43,633)	(9,670)	(5,480)

	December 31,		
	2017	2016	2015
(in thousands)			
<b>Consolidated Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 57,510	\$ 66,837	\$ 51,623
Total assets	103,925	137,531	97,330
Long-term debt	37,794	18,434	—
Total liabilities	115,839	70,559	6,403
Total stockholders’ (deficit) equity	(11,914)	66,972	90,927

## **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion summarizes the significant factors affecting the operating results, financial condition, liquidity and cash flows of our company as of and for the periods presented below. The following discussion and analysis should be read in conjunction with the financial statements and the related notes thereto included elsewhere in this Annual Report. The statements in this discussion regarding industry outlook, our expectations regarding our future performance, liquidity and capital resources and all other non-historical statements in this discussion are forward-looking statements and are based on the current beliefs of our management, as well as assumptions made by, and information currently available to, our management. Actual results could differ materially from those discussed in or implied by forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Annual Report, particularly in the section titled "Risk Factors."*

### **Overview**

We are a global commercial-stage biopharmaceutical company focused on the development and commercialization of therapies for rare diseases with significant unmet needs.

Our first commercial product is Keveyis (dichlorphenamide), the first and only treatment approved by the U.S. Food and Drug Administration, or the FDA, for hyperkalemic, hypokalemic, and related variants of PPP, a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis. Keveyis, for which we hold the U.S. marketing rights, has orphan drug exclusivity status in the United States through August 7, 2022.

On January 16, 2018 we entered into a License and Assignment Agreement with Aetema Zentaris GmbH, pursuant to which we acquired the U.S. and Canadian rights to manufacture and commercialize Macrilen (macimorelin). Macrilen is an oral growth hormone secretagogue receptor agonist to be used in the diagnosis of patients with AGHD. Macrilen has been granted orphan drug designation in the United States and has patents with expiration dates through late 2027. We expect to launch Macrilen in the United States in mid-2018.

In addition to our two commercial products, we have two clinical-stage product candidates for rare endocrine diseases, Recorlev and veldoreotide. Recorlev (levoketoconazole) is a cortisol synthesis inhibitor currently being studied for the treatment of endogenous Cushing's syndrome. Veldoreotide is a next-generation somatostatin analog being investigated for the treatment of acromegaly, with potential additional applications in Cushing's syndrome and applications in other conditions amenable to somatostatin receptor activation. Both Recorlev and veldoreotide have received orphan designation from the FDA and the EMA.

Given the well-identified and concentrated prescriber base addressing our target markets, we intend to continue to use a small, focused sales force to effectively market Keveyis, Macrilen and any future products, in the United States, the European Union and other key global markets. We believe that our ability to execute on our strategy is enhanced by the significant commercial and clinical development experience of key members of our management team.

Since the introduction of our new management team in August 2014, we have been building a rare disease, franchise-based business model focused on expansion through a disciplined in-licensing and acquisition strategy. In pursuit of our growth strategy, we have raised over \$275 million in equity and debt financings since December 2014. We will continue to identify and evaluate the acquisition of products and product candidates that would be complementary to our existing rare neuromuscular and endocrine franchises or that would form the basis for new rare disease franchises. We believe this approach will enable us to maximize our commercial potential by further leveraging our existing resources and expertise. We incurred a net loss attributable to Strongbridge Biopharma plc of \$113.5 million for the year ended December 31, 2017. At December 31, 2017, our accumulated deficit was \$242.9 million.

In December 2017, we received letters from the offices of United States Senators Amy Klobuchar, Susan Collins and Tammy Baldwin, and Senator Claire McCaskill, Ranking Member of the Homeland Security and Governmental Affairs Committee, that request information relating to the marketing and sales of Keveyis. The letters request information principally relating to the pricing of Keveyis, among other things. We are cooperating with these

voluntary requests for information.

## **Financial Operations Overview**

### ***Net Revenue***

We sell Keveyis to one specialty pharmacy provider (the “Customer”), who is the exclusive distributor of Keveyis in the United States. The Customer subsequently resells Keveyis to patients, which are covered by payors that may provide for government-mandated or privately negotiated rebates with respect to the purchase of the Keveyis.

We recognize revenues from sales of Keveyis when we satisfy a performance obligation by transferring control of Keveyis to the Customer. Transfer of control occurs upon receipt of Keveyis by the Customer. We expense incremental costs related to the set-up of the contract with the Customer when incurred, as these costs did not meet the criteria for capitalization.

We expect to launch Macrilen in the United States in mid-2018 and will recognize revenue in accordance with the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 606, *Revenue Recognition*.

### ***Cost of Sales***

Cost of sales includes third-party acquisition costs, third-party warehousing and product distribution charges.

### ***Selling, General and Administrative Expenses***

Selling, general and administrative expenses include personnel costs, costs for outside professional services and other allocated expenses. Personnel costs consist of salaries, bonuses, benefits, travel and stock-based compensation. Outside professional services consist of legal, accounting and audit services, commercial evaluation and strategy services, sales, marketing and other consulting services. We expect to incur additional selling, general and administrative costs as a result of our initial and on-going commercial activities in support of Keveyis and Macrilen.

### ***Research and Development Expenses***

Our research and development expenses consist primarily of costs incurred in connection with the development of our product candidates, including:

- personnel-related costs, such as salaries, bonuses, benefits, travel and other related expenses, including stock-based compensation;
- expenses incurred under our agreements with CROs, clinical sites, contract laboratories, medical institutions and consultants that plan and conduct our preclinical studies and clinical trials, including, in the case of consultants, stock-based compensation;
- costs associated with regulatory filings;
- upfront and milestone payments under in-license or acquisition agreements with third parties;
- costs of acquiring preclinical study and clinical trial materials, and costs associated with formulation and process development; and
- depreciation, maintenance and other facility-related expenses.

We expense all research and development costs as incurred. Clinical development expenses for our product candidates are a significant component of our current research and development expenses as we progress our product candidates into and through clinical trials. Product candidates in later stage clinical development generally have higher

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research and development costs than those in earlier stages of development, primarily due to increased size and duration of the clinical trials. We recognize costs for each grant project, preclinical study or clinical trial that we conduct based on our evaluation of the progress to completion, including the use of information and data provided to us by our external research and development vendors and clinical sites.

We expect our research and development expenses to increase in absolute dollars in the future as we continue to in-license or acquire product candidates and as we advance our existing and any future product candidates into and through clinical trials and pursue regulatory approval of our product candidates. The process of conducting the necessary clinical research to obtain regulatory approval of a product candidate is costly and time consuming. The probability that any of our product candidates receives regulatory approval and eventually is able to generate revenue depends on a variety of factors, including the quality of our product candidates, early clinical data, investment in our clinical program, competition, manufacturing capability and commercial viability. As a result of these uncertainties, we are unable to determine the duration and completion costs of our research and development projects or if, when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates, if approved. We may never succeed in achieving regulatory approval for any of our product candidates.

We do not allocate personnel-related research and development costs, including stock-based compensation or other indirect costs, to specific programs, as they are deployed across multiple projects under development.

### ***Interest Expense***

Interest expense represents interest paid to our lenders throughout 2017, amortization of our debt discount, and issuance costs associated with loan and security agreements.

### ***Amortization of Intangible Asset***

Amortization of intangible asset relates to the amortization of our product rights to Keveyis, which we acquired in December of 2016. This intangible asset is being amortized over an eight-year period using the straight-line method.

### ***Other Income (Expense), Net***

Other income (expense), net, consists of unrealized (loss)/gain on the remeasurement of the fair value of warrant liability, interest expense recognized on our long-term debt, the loss on the early extinguishment of our pre-existing long-term debt, interest income generated from our cash and cash equivalents, foreign exchange gains and losses and gains and losses on investments.

Our consolidated financial statements are reported in U.S. dollars, which is also our functional currency. Transactions in foreign currencies are remeasured into our functional currency at the rate of exchange prevailing at the date of the transaction. Any monetary assets and liabilities arising from these transactions are remeasured into our functional currency at exchange rates prevailing at the balance sheet date or on settlement. Resulting gains and losses are recorded in foreign currency loss in other income (expense) in our consolidated statements of operations.

### **Critical Accounting Policies and Significant Judgments and Estimates**

This operating and financial review of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be the most critical to the judgments and estimates used in the preparation of our financial statements.

### ***Revenue Recognition***

Revenues from sales of Keveyis are recognized when we satisfy a performance obligation by transferring control of Keveyis to the Customer. Transfer of control occurs upon receipt of Keveyis by the Customer. We expense incremental costs related to the set-up of the contract with the Customer when incurred, as these costs did not meet the criteria for capitalization.

### ***Warrant Liability***

The fair values of certain outstanding warrants were measured using the Black-Scholes option-pricing model. Inputs used to determine estimated fair value of the warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. The significant unobservable inputs used in the fair value measurement of the warrant liabilities were the fair value of the underlying stock at the valuation date and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement.

### ***Intangible Assets***

Certain intangible assets were acquired as part of an asset purchase, and have been capitalized at their acquisition date at fair value. Acquired definite life intangible assets are amortized using the straight-line method over their respective estimated useful lives or another appropriate method. The Company evaluates the potential impairment of intangible assets if events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate.

In connection with the Asset Purchase and Supply Agreement we entered into with Taro Pharmaceuticals North America, Inc., we paid Taro an upfront payment in two installments of \$1 million in December 2016 and \$7.5 million in March 2017. We have concluded that the supply price payable by us exceeds fair value and, therefore, have used a discounted cash flow method with a probability assumption to value the payments in excess of fair value at \$29.3 million, for which we have recorded an intangible asset and corresponding liability. This liability will be amortized as we purchase inventory over the term of the agreement. In addition, we incurred transaction costs of \$2.4 million resulting in the recording of an Intangible Asset of \$40.2 million. This intangible asset is being amortized over an eight-year period using the straight-line method.

Purchased identifiable intangible assets with indefinite lives, such as in-process research and development, are evaluated for impairment annually in accordance with our policy and whenever events or changes in circumstances indicate that it is more likely than not that the fair value of these assets has been reduced. To test these assets for impairment, we compare the fair value of the asset to its carrying value. The method we use to estimate the fair value measurements of indefinite-lived intangible assets is based on the income approach. For the impairment analysis for the year ended December 31, 2017, significant unobservable inputs used in the income approach valuation method include discount rates, royalty rates and probabilities of product candidate advancement from one clinical trial phase to the next. The probabilities of product candidate advancement we used were based on standalone statistical analysis on a phase-by-phase basis.

As of December 31, 2017, there were material events that led to the impairment of our intangible assets. We recorded a \$20.7 million impairment for our veldoreotide in-process research and development ("IPR&D") for the year ended December 31, 2017.

### ***Goodwill***

We test goodwill for impairment on an annual basis or whenever events occur that may indicate possible impairment. This analysis requires us to make a series of critical assumptions to (1) evaluate whether any impairment exists and (2) measure the amount of impairment.

Because we have one operating segment, when testing for a potential impairment of goodwill, we are required to estimate the fair value of our business as a whole and determine the carrying value. If the estimated fair value is less than the carrying value of our business, then we are required to estimate the fair value of all identifiable assets and liabilities in a manner similar to a purchase price allocation for an acquired business. Only after this process is completed can the goodwill impairment be determined, if any.

We did not record a charge for impairment for the years ended December 31, 2017, 2016 and 2015. As of December 31, 2017, there were no events or changes in circumstances indicating possible impairment.

### ***Stock-Based Compensation***

We account for stock based compensation awards in accordance with FASB ASC Topic 718, Compensation—Stock Compensation (“ASC 718”). ASC 718 requires all stock based payments including grants of stock options and restricted stock and modifications to existing stock options, to be recognized in the consolidated statements of operations based on their fair values.

Our stock based awards are subject to either service based or performance based vesting conditions. Vesting of certain awards could also be accelerated upon achievement of defined market based vesting conditions. Certain awards also contain a combination of service and market conditions or performance and market conditions.

We account for employee stock based awards at grant date fair value. If we issue awards with an exercise price denominated in a currency other than our functional currency, trading currency or the currency for which we compensate our employee, we account for these as liabilities. We account for non employee and liability-classified stock based awards based on the then current fair values at each financial reporting date until the performance is complete for non employee awards, or until the award is settled (exercised) for liability-classified awards. Changes in the amounts attributed to these awards between the reporting dates are included in stock based compensation expense (credit) in our statements of operations. We include liability-classified stock options in non current liabilities in our balance sheets as their settlement (exercise) does not require use of cash, cash equivalents or other current assets.

We record compensation expense for service based awards over the vesting period of the award on a straight-line basis. Compensation expense related to awards with performance based vesting conditions is recognized over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. For those awards in which the performance condition was the completion of our initial public offering (“IPO”), we did not recognize compensation expense until the close of the IPO as we did not deem the IPO probable until it occurred.

Compensation expense for awards with service and market-based vesting conditions is recognized using the accelerated attribution method over the shorter of the requisite service period or the implied period associated with achievement of the market based vesting provisions.

We estimate the fair value of our awards with service conditions using the Black Scholes option pricing model, which requires the input of subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of historical and implied volatility data of our common stock, we based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. We selected companies with comparable characteristics to us, including enterprise value, risk profiles and position within the industry, and with historical share price information sufficient to meet the expected term of the stock based awards. We compute historical volatility data using the daily closing prices for the selected companies’ shares during the equivalent period of the calculated expected term of the stock based awards.

We estimate the fair value of our awards with market conditions using a Monte Carlo simulation to determine the probability of satisfying the market condition. We make this estimate using the conditions that exist at the grant date. The derived service period, which may be the requisite service period, is also determined at this time. Compensation cost for our awards with a market condition is recognized ratably using the accelerated attribution method if the award is

subject to graded vesting over the requisite service period. The compensation cost for our awards with a market condition is not reversed if the market condition is not satisfied.

We have estimated the expected term of employee service-based stock options using the “simplified” method, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option, due to our lack of sufficient historical data. We have estimated the expected term of employee awards with service and market conditions using a Monte Carlo simulation model. This approach involves generating random stock price paths through a lattice type structure. Each path results in a certain financial outcome, such as accelerated vesting or specific option payout. We have estimated the expected term of nonemployee service and performance based awards based on the remaining contractual term of such awards.

The risk free interest rates for periods within the expected term of the option are based on the Swedish Government Bond rate or the U.S. Treasury Bond rate with a maturity date commensurate with the expected term of the associated award. We have never paid dividends, and do not expect to pay dividends in the foreseeable future.

We account for forfeitures as they occur as opposed to estimating forfeitures. We record stock based compensation expense only for those awards that are expected to vest.

### ***Income Taxes***

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the “Tax Act”). The Tax Act makes broad and complex changes to the U.S. tax code, including, but not limited to, reducing the top U.S. federal corporate tax rate from 35 percent to 21 percent; requiring companies to pay a one-time transition tax on certain un-repatriated earnings of foreign subsidiaries; generally eliminating U.S. federal income taxes on dividends from foreign subsidiaries; requiring a current inclusion in U.S. federal taxable income of certain earnings of controlled foreign corporations; eliminating the corporate alternative minimum tax (AMT) and changing how existing AMT credits can be realized; creating the base erosion anti-abuse tax (BEAT), a new minimum tax; creating a new limitation on deductible interest expense; and changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017.

The Tax Act reduces our U.S. corporate income tax rate from 34% to 21%, effective January 1, 2018. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. As a result of the reduction in the U.S. corporate income tax rate from 34% to 21% under the Tax Act, we revalued our ending net deferred tax assets and liabilities at December 31, 2017.

The Tax Act provided for a one-time transition tax on the deemed repatriation of post-1986 undistributed foreign subsidiary earnings and profits (“E&P”). Strongbridge did not have to recognize any income tax expense related to the transition tax as they own no controlled foreign corporations.

The global intangible low-taxed income tax and base erosion provisions are effective for taxable years beginning after December 31, 2017. The Company does not currently expect these provisions to have a material impact on its tax rate as they do not own any controlled foreign corporations and they are currently below the gross receipts threshold for purposes of the base erosion provisions.

Due to the timing of the new tax law and the substantial changes it brings, the Staff of the Securities and Exchange Commission (the “SEC”) issued Staff Accounting Bulletin No. 118 (“SAB 118”), which provides registrants a measurement period to report the impact of the new US tax law. During the measurement period, provisional amounts for the effects of the law are recorded to the extent a reasonable estimate can be made. To the extent that all information necessary is not available, prepared or analyzed, companies may recognize provisional estimated amounts for a period of up to one year following enactment of the TCJA. The Company recorded amounts as provisional and will continue to monitor for future updates to guidance or interpretations issued by the IRS.



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We recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2017, 2016 and 2015, we had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in our statements of operations.

**Results of Operations**

**Comparison of the Years Ended December 31, 2017 and 2016**

The following table sets forth our results of operations for the years ended December 31, 2017 and 2016.

	Year Ended December 31,		Change
	2017	2016	\$
(in thousands)			
<b>Revenues:</b>			
Net product sales	\$ 7,046	\$ —	\$ 7,046
Total revenues	<u>7,046</u>	<u>—</u>	<u>7,046</u>
<b>Cost and operating expenses:</b>			
Cost of sales (excluding amortization of intangible asset)	\$ 1,483	\$ —	\$ 1,483
Selling, general and administrative	36,292	14,875	21,417
Research and development	17,268	20,023	(2,755)
Amortization of intangible asset	5,022	—	5,022
Impairment of intangible assets	20,723	15,828	4,895
Total cost and expenses	<u>80,788</u>	<u>50,726</u>	<u>30,062</u>
Operating loss	(73,742)	(50,726)	(23,016)
Other expense, net	(37,970)	(631)	(37,339)
Loss before income taxes	(111,712)	(51,357)	(60,355)
Income tax (expense) benefit	(1,771)	2,638	(4,409)
Net loss	(113,483)	(48,719)	(64,764)
Net loss attributable to non-controlling interest	—	122	(122)
Net loss attributable to Strongbridge	<u>\$(113,483)</u>	<u>\$(48,597)</u>	<u>\$(64,886)</u>

*Net Revenue and Cost of Sales.*

Net revenue of \$7.0 million and cost of sales of \$1.5 million for the year ended December 31, 2017 resulted from our initial commercial sales of Kevevis following our product launch in April 2017.

*Selling, General and Administrative Expenses*

The following table summarizes our selling, general and administrative expenses during the years ended December 31, 2017 and 2016:

	Year Ended December 31,		Change
	2017	2016	\$
(in thousands)			
Outside professional and consulting services	\$ 17,115	\$ 5,626	\$ 11,489
Compensation and other personnel costs	14,743	4,888	9,855
Stock-based compensation expense	4,027	4,006	21
Facility costs	407	355	52
Total selling, general and administrative expenses	<u>\$ 36,292</u>	<u>\$ 14,875</u>	<u>\$ 21,417</u>

Total selling, general and administrative expenses were \$36.3 million and \$14.9 million for the years ended December 31, 2017 and 2016, respectively. The \$11.5 million increase during 2017 in outside professional and

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consulting services was primarily due to costs incurred for the launch and subsequent commercialization of Keyeyis. Compensation and related personnel costs increased by \$9.9 million during 2017 primarily due to increased headcount of commercial personnel.

#### Research and Development Expenses

The following table summarizes our research and development expenses during the years ended December 31, 2017 and 2016:

	Year Ended December 31,		Change
	2017	2016	\$
	(in thousands)		
Product development and supporting activities	\$12,488	\$16,183	\$ (3,695)
Compensation and other personnel costs	3,640	3,239	401
Stock-based compensation expense	1,140	601	539
Total research and development expenses	<u>\$17,268</u>	<u>\$20,023</u>	<u>\$ (2,755)</u>

Total research and development expenses were \$17.3 million and \$20.0 million for the years ended December 31, 2017 and 2016, respectively. The \$3.7 million decrease during 2017 in expenses for product development and supporting activities was primarily due to a \$2.3 million decrease in expenses for veldoreotide development activity and a \$1.6 million decrease in development expenses related to programs we discontinued during 2016 (COR-004 and BioPancreate). Compensation and other personnel costs increased by \$0.4 million during 2017 due to increased headcount in research and development. Stock-based compensation expense increased by \$0.5 million during 2017 due to the granting of new awards to newly hired employees during 2017.

#### Amortization of Intangible Asset

Amortization of intangible asset was \$5.0 million for the year ended December 31, 2017 as we began amortizing the Keyeyis product rights acquired in December 2016. We recorded no amortization of intangible asset for the year ended December 31, 2016.

#### Impairment of Intangible Asset

Impairment of intangible assets was \$20.7 million and \$15.8 million for the years ended December 31, 2017 and 2016, respectively. The increase was due to a \$20.7 million impairment charge recorded in the third quarter of 2017 related to our veldoreotide in-process research and development offset by impairment charges recorded in 2016.

#### Other Income (Expense), Net

	Year Ended December 31,		Change
	2017	2016	\$
	(in thousands)		
Unrealized (loss) gain on fair value of warrants	\$(30,218)	\$ 638	\$(30,856)
Interest expense	(4,313)	(20)	(4,293)
Foreign exchange loss	(41)	(69)	28
Loss on early extinguishment of debt	(3,545)	—	(3,545)
Other income (expense), net	147	(1,180)	1,327
Total other income (expense), net	<u>\$(37,970)</u>	<u>\$ (631)</u>	<u>\$(37,339)</u>

Total other income (expense), net, increased by \$37.3 million for the year ended December 31, 2017 as compared to the year ended December 31, 2016. The increase was primarily due to a \$30.9 million change in the fair value of our warrant liability, primarily resulting from an increase in our stock price, \$4.3 million in interest expense and \$3.5 million of expense relating to the loss on the early extinguishment of debt.

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*Income Tax (Expense) Benefit*

We recorded income tax expense of \$1.8 million for the year ended December 31, 2017 as a result of recording full valuation allowances against our deferred tax asset and deferred tax liability. We recorded income tax benefit of \$2.6 million for the year ended December 31, 2016 primarily due to impairment of the value of intellectual property held by our BioPancreate subsidiary and certain permanent deductions at Strongbridge U.S. Inc.

**Comparison of the Years Ended December 31, 2016 and 2015**

The following table sets forth our results of operations for the years ended December 31, 2016 and 2015.

	Year Ended		Change
	December 31,		
	2016	2015	\$
	(in thousands)		
Operating expenses:			
Selling, general and administrative	\$ 14,875	\$ 22,719	\$ (7,844)
Research and development	20,023	20,135	(112)
Impairment of intangible assets	15,828	—	15,828
Total operating expenses	<u>50,726</u>	<u>42,854</u>	<u>7,872</u>
Operating loss	(50,726)	(42,854)	(7,872)
Other expense, net	(631)	(1,229)	598
Loss before income taxes	(51,357)	(44,083)	(7,274)
Income tax benefit	2,638	450	2,188
Net loss	(48,719)	(43,633)	(5,086)
Net loss attributable to non-controlling interest	122	53	69
Net loss attributable to Strongbridge	<u>\$(48,597)</u>	<u>\$(43,580)</u>	<u>\$(5,017)</u>

*Selling, General and Administrative Expenses*

The following table summarizes our selling, general and administrative expenses during the years ended December 31, 2016 and 2015:

	Year Ended		Change
	December 31,		
	2016	2015	\$
	(in thousands)		
Outside professional and consulting services	\$ 5,626	\$ 8,054	\$ (2,428)
Redomiciliation and IPO preparation costs	—	4,007	(4,007)
Corporate development and licensing transaction costs	—	3,390	(3,390)
Compensation and other personnel costs	4,888	3,783	1,105
Stock-based compensation expense	4,006	3,147	859
Facility costs	355	338	17
Total selling, general and administrative expenses	<u>\$ 14,875</u>	<u>\$ 22,719</u>	<u>\$(7,844)</u>

Total selling, general and administrative expenses were \$14.9 million and \$22.7 million for the years ended December 31, 2016 and 2015, respectively. The \$2.4 million decrease in outside professional and consulting services was primarily due to decreased legal fees in support of general corporate matters, employee recruiting fees, and consulting fees for general business efforts. Selling, general and administrative expenses for the year ended December 31, 2015 also included \$4.0 million of legal and accounting fees related to the redomiciliation of the Company from Sweden to Ireland and the indirect activities necessary to prepare the Company's financial records for the U.S. initial public offering completed in October 2015. Selling, general and administrative expenses for the year ended December 31, 2015 also included \$3.4 million of transaction fees and expenses related to the acquisition of veldoreotide from Aspireo Pharmaceuticals, the license of COR-004 from Antisense Therapeutics, and other business development

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activities. Compensation and other related personnel costs increased by \$1.1 million, and non-cash stock-based compensation by \$0.9 million, during the year ended December 31, 2016 due to increased headcount of administrative personnel during the 2016 period.

*Research and Development Expenses*

The following table summarizes our research and development expenses during the years ended December 31, 2016 and 2015:

	Year Ended		Change
	December 31,		
	2016	2015	\$
	(in thousands)		
Clinical development and supporting activities	\$16,183	\$13,537	\$ 2,646
Antisense Therapeutics license fee	—	3,899	(3,899)
Compensation and other personnel costs	3,239	1,906	1,333
Stock-based compensation expense	601	793	(192)
Total research and development expenses	<u>\$20,023</u>	<u>\$20,135</u>	<u>\$ (112)</u>

Total research and development expenses were \$20.0 million and \$20.1 million for the years ended December 31, 2016 and 2015, respectively. The \$2.6 million increase in clinical development and supporting activities was primarily attributed to a \$3.0 million increase in expense to the ongoing clinical trials for Recorlev, and a \$1.4 million increase due to the initiation of the development activity for veldoreotide, partially offset by reduced development spend due to discontinued programs for COR-004 and BioPancreate. Research and development expenses for the year ended December 31, 2015 included \$3.9 million of the \$5.0 million in aggregate cash paid to Antisense Therapeutics upon entering into a license agreement with them in May 2015, with the remaining \$1.1 million of cash paid recorded as the initial carrying value of our investment in the equity of Antisense therapeutics. Compensation and other personnel costs increased by \$1.3 million for the year ended December 31, 2016 as compared to the same period in 2015 due to increased headcount of research and development personnel during the 2016 period. Stock-based compensation expense decreased \$0.2 million due to the departure of certain research and development personnel.

*Other Expense, Net*

The following table summarizes our other expense, net, during the years ended December 31, 2016 and 2015:

	Year Ended		Change
	December 31,		
	2016	2015	\$
	(in thousands)		
Foreign exchange loss	\$ (69)	\$ (124)	\$ 55
Interest expense	(20)	—	(20)
Unrealized gain on fair value of warrants	638	—	638
Loss on termination of license agreement with Antisense Therapeutics	(1,051)	—	(1,051)
Other expense, net	(129)	(1,105)	976
Total other expense, net	<u>\$ (631)</u>	<u>\$ (1,229)</u>	<u>\$ 598</u>

Total other expense, net, increased for the year ended December 31, 2016 as compared to the year ended December 31, 2015. The decrease in other expense, is mostly due to the impairment of our Antisense investment in 2015 of \$.5 million as well as a loss on our Radnor lease of \$0.2 million, whereas in 2016 we returned the license to Antisense and incurred a loss on termination charge of \$1.1 million. We also recorded an unrealized gain on the fair value of our warrants.

*Income Tax Benefit*

We recorded income tax benefit of \$2.6 million for the year ended December 31, 2016 and \$0.5 million for the year ended December 31, 2015. For the year ended December 31, 2016, the benefit was primarily due to our subsidiary BioPancreate's write-off of intellectual property and certain permanent deductions at our subsidiary Strongbridge U.S. Inc. Additionally, Strongbridge U.S. Inc. is more likely than not to recognize its deferred tax assets. In December 31, 2015 the benefit was due to the generation of U.S. state and federal net operating loss carry forwards and federal tax credit carry forwards. The income tax benefit for U.S. state and federal net operating loss carry forwards and the federal tax credit carry forwards has been recognized to the extent it is supported by the deferred tax liabilities recorded in connection with the acquisition of BioPancreate.

*Net Loss Attributable to Non-Controlling Interest*

We recorded a net loss attributable to non-controlling interest of \$122,000 for the year ended December 31, 2016. The non-controlling interest resulted from the 0.418% of Cortendo AB shares not acquired by Strongbridge Biopharma plc pursuant to the exchange offer that expired September 3, 2015. In September 2016, the non-controlling interest was acquired by the Company.

**Liquidity and Capital Resources**

Our operations have been financed primarily by net proceeds from the issuance of ordinary shares and the issuance of debt. Our primary uses of capital have been third-party expenses associated with the commercialization of Keveyis, the planning and conduct of clinical trials, costs of process development services and manufacturing of our product candidates, and compensation-related expenses. We expect our funding requirements for operating activities to increase in 2018 and possibly beyond due to expenses associated with the commercialization of Keveyis and Macrilen, the execution of the Phase 3 SONICS and LOGICS clinical trials for Recorlev, and selling, general and administrative expenses. We also expect our cash needs to increase to fund potential in-licenses, acquisitions or similar transactions as we pursue our strategy. These expenses may be offset only in part by sales of Keveyis and Macrilen. In addition, beginning in September 2020, we may be required to make quarterly principal payments to repay amounts borrowed under our credit facility.

Cash used to fund operating expenses is affected by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We believe that our cash resources will be sufficient to allow us to fund planned operations for at least 12 months beyond the issuance date of these financial statements, which is after the expected receipt of data from the Recorlev SONICS and LOGICS Phase 3 clinical trials.

Our future funding requirements will depend on many factors, including the following:

- the amount of revenue that we receive from sales of Keveyis and Macrilen;
- the cost and timing of establishing sales, marketing, distribution and administrative capabilities;
- the scope, rate of progress, results and cost of our clinical trials testing and other related activities for Recorlev and veldoreotide;
- whether we borrow any additional amounts under our credit facility;
- the number and characteristics of product candidates that we pursue, including any additional product candidates we may in-license or acquire;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;

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- the cost, timing and outcomes of regulatory approvals;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any required milestone and royalty payments thereunder; and
- the emergence of competing technologies and their achieving commercial success before we do or other adverse market developments.

We expect to continue to incur losses. Our ability to achieve and maintain profitability is dependent upon the successful commercialization of Keveyis and Macrilen, the development, regulatory approval and commercialization of our product candidates and achieving a level of revenues adequate to support our cost structure. We may never achieve profitability, and unless and until we do, we will continue to need to raise additional capital. If we need to raise additional capital to fund our operations and complete our ongoing and planned clinical trials, funding may not be available to us on acceptable terms, or at all.

We plan to continue to fund our operations and capital funding needs through equity or debt financing, along with revenues from Keveyis and Macrilen, our proceeds from our term loan facility with CRG Servicing LLC (described below) and proceeds from our at-the-market (ATM) facility. The sale of additional equity would result in additional dilution to our shareholders. The incurrence of debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible or suspend or curtail planned programs. In addition, lack of funding would limit any strategic initiatives to in-license or acquire additional product candidates or programs.

### ***Term Loan Agreement with CRG Servicing LLC***

The Company and our subsidiaries are parties to a Term Loan Agreement with CRG Servicing LLC (“CRG”), as administrative and collateral agent, and the lenders named therein (the “Lenders”). Pursuant to the terms of the Term Loan Agreement, as amended (the “Loan Agreement”), we may borrow up to \$100 million from the Lenders under the Loan Agreement. We have borrowed \$85.0 million under the Loan Agreement as of the date of this Annual Report.

The Loan Agreement provides for additional disbursements of (i) up to \$10.0 million (the “Third Tranche”), contingent upon our achievement of certain revenue milestones and a market capitalization condition or before June 30, 2018, as described in the Loan Agreement and (ii) up to \$5.0 million (the “Fourth Tranche”), contingent upon our achievement of certain revenue milestones and a market capitalization condition on or before December 31, 2018, as described in the Loan Agreement.

The Loan Agreement has a six-year term with three and a half years (to December 31, 2020) of interest-only payments after which quarterly principal and interest payments will be due through the June 30, 2023 maturity date. Amounts borrowed under the Loan Agreement accrue interest at an annual fixed rate of 12.50%, of which 4.0% may, at our election, be deferred during the first three years of the term of the loan (which may be extended for the entire term of the loan subject to the satisfaction of certain conditions under the Loan Agreement) by adding such amount to the principal loan amount (PIK Loans). We are also required to pay the Lenders a final payment fee upon repayment of the loans in full.

We may prepay all or a portion of the outstanding principal and accrued unpaid interest under the Loan Agreement at any time upon prior notice to the Lenders subject to a prepayment fee during the first five years of the term of each loan (which reduces each year) and no prepayment fee thereafter. In certain circumstances, including a change of control and certain asset sales or licensing transactions, we are required to prepay all or a portion of the loan, including the applicable prepayment premium on the amount of the outstanding principal to be prepaid.

As security for its obligations under the Loan Agreement, we have entered into security agreements, whereby we have granted to CRG, as collateral agent, a lien on substantially all of our assets, including intellectual property.

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The Loan Agreement requires us to maintain cash and cash equivalents of \$3.0 million and, each year through the end of 2022, to meet a minimum total annual revenue threshold. In the event that we do not meet the minimum total annual revenue threshold for a particular year, then we can retroactively cure the shortfall by either issuing additional equity in exchange for cash or incurring certain additional permitted indebtedness, in each case, in an amount equal to twice the shortfall. Any such amounts are required to be applied to prepay the loans. The Loan Agreement also contains customary affirmative and negative covenants for a credit facility of this size and type, including covenants that limit or restrict our ability to, among other things, incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into transactions with affiliates, pay dividends or make distributions, license intellectual property rights on an exclusive basis or repurchase stock, in each case subject to customary exceptions.

The Loan Agreement includes customary events of default that include, among other things, non-payment, inaccuracy of representations and warranties, covenant breaches, a material adverse change (as defined in the Loan Agreement), cross default to material indebtedness or material agreements, bankruptcy and insolvency, material judgments, a change of control, certain ERISA-related events and certain injunctions applicable to the sale of our products. The occurrence and continuance of an event of default could result in the acceleration of the obligations under the Loan Agreement. Under certain circumstances, a default interest rate of an additional 4.00% per annum will apply on all outstanding obligations during the existence of an event of default under the Loan Agreement.

As a condition to the Loan Agreement, the Lenders purchased an aggregate of 429,799 of our ordinary shares from us for an aggregate purchase price of \$3.0 million. In addition, pursuant to the terms of the Loan Agreement, we have issued to CRG, or its designees, warrants to purchase an aggregate of (i) 394,289 ordinary shares at an exercise price of \$7.37 per share and (ii) 1,248,250 ordinary shares at an exercise price of \$10.00 per share.

If we borrow the Third Tranche, we must issue to CRG, or its designees, one or more additional warrants to purchase a number of our ordinary shares equal to an aggregate of 0.20% of our ordinary shares outstanding following such issuance on a fully diluted basis (inclusive of the ordinary shares underlying all such warrants issued), at an exercise price equal to 110% of the closing price of our ordinary shares on the date immediately preceding the Third Tranche disbursement date. If we borrow the Fourth Tranche, we must issue to the Lenders, or their designees, one or more additional warrants to purchase a number of our ordinary shares equal to an aggregate of 0.25% of our ordinary shares outstanding following such issuance on a fully diluted basis (inclusive of the ordinary shares underlying all such warrants issued), at an exercise price equal to 140% of the 10-day volume weighted average price (VWAP) per ordinary share for the consecutive 10-day trading period ending on the trading day immediately prior to the Fourth Tranche disbursement date.

Each of the warrants issued or to be issued to CRG will be exercisable at any time prior to seven years following its issue date and will contain customary provisions for assumption or exchange upon a change of control or a sale of all or substantially all of our assets.

### ***December 2016 Private Placement***

On December 22, 2016, we sold 14,000,000 ordinary shares at a price of \$2.50 per ordinary share, together with warrants to purchase 7,000,000 ordinary shares, in a private offering for approximately \$23.4 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

### ***October 2017 Public Offering of Ordinary Shares***

On October 6, 2017, we sold 4,000,000 ordinary shares in a public offering at a price to the public of \$6.25 per share for net proceeds of approximately \$23.4 million, after deducting underwriting discounts and commissions and offering expenses payable by us.



### **January 2018 Public Offering of Ordinary Shares**

On January 25, 2018, we sold 5,000,000 ordinary shares in a public offering at a price to the public of \$6.75 per ordinary share for net proceeds of approximately \$31.7 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

On February 26, 2018, we sold an additional 255,683 ordinary shares to the underwriters in connection with their partial exercise of the option to purchase additional shares that was granted to them under the underwriting agreement for additional net proceeds of approximately \$1.6 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

### **At-The-Market Facility**

We have entered into an Equity Distribution Agreement with JMP Securities LLC (“JMP Securities”), pursuant to which we may offer and sell ordinary shares having an aggregate offering price of up to \$40,000,000 from time to time through JMP Securities, acting as agent. As of December 31, 2017, we have issued an aggregate of 10,300 ordinary shares to JMP Securities under the Equity Distribution Agreement for aggregate net proceeds of approximately \$73,000 and paid fees to JMP of \$2,000.

### **Cash Flows**

#### **Comparison for the Years Ended December 31, 2017 and 2016:**

	Year Ended December 31	
	2017	2016
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (45,336)	\$ (31,714)
Investing activities	(7,500)	(3,392)
Financing activities	43,509	50,320
Net (decrease) increase in cash and cash equivalents	\$ (9,327)	\$ 15,214

#### *Operating Activities*

Net cash used in operating activities was \$45.3 million for the year ended December 31, 2017, compared to \$31.7 million for the year ended December 31, 2016. The increase in net cash used in operating activities resulted primarily from expenses during 2017 to support the commercialization of Keveyis.

#### *Investing Activities*

Net cash used in investing activities in 2017 was from our scheduled payment of \$7.5 million to Taro in connection with our acquisition of the U.S. marketing rights of Keveyis, and the \$3.4 million cash used in investing activities in 2016 was the result of our initial payment and transaction costs incurred with our acquisition of the U.S. marketing rights of Keveyis.

#### *Financing Activities*

Net cash provided by financing activities was \$43.5 million for the year ended December 31, 2017, a decrease of \$6.8 million from the year ended December 31, 2016. The decrease in net cash provided by financing activities resulted primarily from a decrease of \$5.9 million in proceeds received from the issuance of ordinary shares.

**Contractual Obligations and Other Commitments**

The following is a summary of our contractual obligations and other commitments as of December 31, 2017:

	Payments due by period				Total
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	
			(in thousands)		
Minimum contract purchases pursuant to supply agreement	\$ 2,033	\$ 7,901	\$ 16,217	\$ —	\$ 26,151
Debt payments	\$ —	\$ 7,466	\$ 26,828	\$ 6,465	\$ 40,759
Operating leases	\$ 357	\$ 492	\$ 323	\$ 69	\$ 1,241
Total contractual obligations	\$ 2,390	\$ 15,859	\$ 43,368	\$ 6,534	\$ 68,151

We enter into agreements in the normal course of business with CROs for clinical trials and with vendors for preclinical studies and other services and products for operating purposes, which are cancelable at any time by us, generally upon 30 days prior written notice. Future payment obligations under these agreements are not included in this table of contractual obligations.

We are obligated to make future payments to third parties under license agreements, including sublicense fees, royalties and payments that become due and payable upon the achievement of development and commercialization milestones. As the amount and timing of sublicense fees and the achievement and timing of these milestones are not probable and estimable, such commitments have not been included on our consolidated balance sheets or in the contractual obligations table above.

**Off-Balance Sheet Arrangements**

We do not have variable interests in variable interest entities or any off-balance sheet arrangements.

**Recent Accounting Pronouncements**

See Note 2 Summary of significant accounting policies and basis of presentation - Recently adopted accounting pronouncements to our consolidated financial statements.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are exposed to certain market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities as follows:

**Interest Rate Risk**

We had cash and cash equivalents of \$57.5 million as of December 31, 2017. Our cash and cash equivalents are held in a variety of interest-earning instruments, including money market funds. Such interest-earning instruments carry a degree of interest rate risk. To date, fluctuations in interest income have not been significant. We also had total outstanding long-term debt principal of \$40.8 million as of December 31, 2017, of which \$0 was due within 12 months. The interest rate of our borrowings under the term loan agreement with CRG is fixed. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

**ITEM 8. Financial Statements.**

The financial statements and supplementary data required by this item are listed in Item 15 – “Exhibits and Financial Statement Schedules” of this Annual Report.

**ITEM 9. CHANGE IN REGISTRANT’S CERTIFYING ACCOUNTANT**

None

**ITEM 9A. CONTROLS AND PROCEDURES**

***Disclosure Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2017 at the reasonable assurance level.

***Remediation of material weakness***

As identified in Item 15 of our Annual Report and 20-F for the year ended December 31, 2016, we identified a material weakness in internal control over financial reporting relating to the valuation of warrants that were issued in connection with our December 2016 private placement of ordinary shares. During 2017, management improved controls over the valuation of the warrants and controls over work performed by third parties and the material weakness has been remediated as of December 31, 2017.

***Management’s Annual Report on Internal Control over Financial Reporting***

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting refers to a process designed by, or under the supervision of, the principal executive and principal financial officer and effected by the board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company’s assets that could have a material effect on the financial statements.

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Under the supervision and with the participation of management, including the Chief Executive Officer and Chief Financial Officer, the Company carried out an evaluation of the effectiveness of its internal control over financial reporting as of December 31, 2017, based on the Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based upon this evaluation, management has concluded that, as of December 31, 2017, the Company's internal control over financial reporting was effective in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate due to changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

***Attestation Report of the Registered Public Accounting Firm***

This Annual Report does not include an attestation report of our registered public accounting firm regarding our internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to the rules of the SEC that permit us to provide only management's report in this Annual Report for so long as we qualify as an emerging growth company.

***Changes in Internal Control over Financial Reporting***

Other than the remediation efforts identified above to address the material weakness, there were no changes in the Company's internal control over financial reporting that occurred during the period covered by this Annual Report that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The following table presents information about our officers and directors as of March 1, 2018.

<u>NAME</u>	<u>AGE</u>	<u>POSITION</u>
<b>Executive Officers</b>		
Matthew Pauls	47	Chief Executive Officer and Director
A. Brian Davis	51	Chief Financial Officer
Fredric Cohen, M.D.	53	Chief Medical Officer
Stephen Long	52	Chief Legal Officer
<b>Non-Employee Directors</b>		
John H. Johnson	60	Director, Chairman of the Board
Richard S. Kollender	48	Director
Garheng Kong, M.D., Ph.D.	42	Director
Jeffrey W. Sherman, M.D., FACP	63	Director
Mårten Steen, M.D., Ph.D.	42	Director
Hilde H. Steineger, Ph.D.	51	Director

Unless otherwise indicated, the current business addresses for our executive officers and directors is 900 Northbrook Drive, Suite 200, Trevose, Pennsylvania 19053, United States.

## Executive Officers

**Matthew Pauls** has served as our Chief Executive Officer since August 2014 and as a member of our board of directors since September 2015. Mr. Pauls has served as a member of the board of directors of Savara Inc. (formerly Mast Therapeutics, Inc.), a publicly traded biopharmaceutical company, since October 2015. Prior to joining Strongbridge, Mr. Pauls was Chief Commercial Officer of Insmed, Inc., a publicly traded biopharmaceutical company, from April 2013 to August 2014. Prior to Insmed, Mr. Pauls worked at Shire Pharmaceuticals, a publicly traded specialty biopharmaceutical company, beginning in 2007 until March 2013, most recently as Senior Vice President, Head of Global Commercial Operations. Mr. Pauls also held positions at Bristol-Myers Squibb, a publicly traded pharmaceutical company, in Brand Management and Payor Marketing, and at Johnson & Johnson, a publicly traded medical devices, pharmaceutical and consumer packaged goods manufacturer, in various U.S. and global commercial roles. He is a volunteer board member of the Pennington School in Pennington, New Jersey, and the Boys & Girls Clubs of Philadelphia. Mr. Pauls holds B.S. and M.B.A. degrees from Central Michigan University and a J.D. from Michigan State University College of Law.

**A. Brian Davis** has served as our Chief Financial Officer since March 2015. Prior to joining Strongbridge, Mr. Davis served as Senior Vice President and Chief Financial Officer at Tengion, Inc., a publicly traded regenerative medicine company, from August 2010 to December 2014. In December 2014, Tengion, Inc. filed a petition for relief under Chapter 7 of Title 11 of the United States Bankruptcy Code. From 2009 to July 2010, Mr. Davis served in a consulting capacity as Chief Financial Officer of Neose Technologies, Inc., a biopharmaceutical company. Mr. Davis worked at Neose Technologies, Inc. from 1994 to 2009, where he held several positions of increasing responsibility, including Senior Vice President and Chief Financial Officer. Mr. Davis is licensed as a certified public accountant, and received a B.S. in accounting from Trenton State College and an M.B.A. from The Wharton School at the University of Pennsylvania.

**Fredric Cohen, M.D.** has served as our Chief Medical Officer since November 2016. Dr. Cohen joined Strongbridge in August 2015 and held roles of increasing responsibility, including Senior Vice President, Global Research and Development, and Vice President, Clinical Research and Development, prior to his promotion to Chief Medical Officer. Fred is an endocrinologist by training with more than 20 years of drug and business development experience, most recently focused in development and commercialization of rare disease and specialty products. Prior to joining Strongbridge, Fred provided strategic and operational counsel to life science companies, actively supporting their development and licensing functions. Prior to that, he served as Executive Director, Clinical Pipeline, at Aptalis Pharma, where he was responsible for innovation strategy as well as building and advancing the company's specialty pharma pipeline. He has also held research and development positions with Johnson & Johnson and Eli Lilly & Company. Fred holds an M.D. from Pennsylvania State University College of Medicine and an A.B. in biology from Franklin and Marshall College.

**Stephen Long** has served as our Chief Legal Officer since March 2015 and as Company Secretary since September 2015. Prior to joining Strongbridge, Mr. Long served as Counsel at the law firm of Reed Smith LLP, from April 2013 to February 2015. He previously served at C.R. Bard, Inc., a medical device manufacturing company, from October 2000 to May 2012 in the roles of Vice President, General Counsel, as Vice President, and Secretary, and as Associate General Counsel. Mr. Long also served as Assistant General Counsel, Consumer Healthcare, at Warner-Lambert Company, and as Counsel for the company's pharmaceutical division from February 1998 to September 2000. Mr. Long held positions earlier in his career at the law firm of Willkie Farr & Gallagher and Bankers Trust Company. Mr. Long received his B.S. from the School of Industrial and Labor Relations at Cornell University and his J.D. from Albany Law School of Union University.

## Non-Employee Directors

**John H. Johnson** has served as Chairman of our board of directors since March 2015. From January 2012 until August 2014, Mr. Johnson served as the President and Chief Executive Officer of Dendreon Corporation and as its Chairman from January 2012 until June 2014. From January 2011 until January 2012, he served as the Chief Executive Officer and a member of the board of Savient Pharmaceuticals, Inc. From November 2008 until January 2011, Mr. Johnson served as Senior Vice President and President of Eli Lilly and Company's Oncology unit. He was also

Chief Executive Officer of ImClone Systems Incorporated, which develops targeted biologic cancer treatments, from August 2007 until November 2008, and served on ImClone's board of directors until it was acquired by Eli Lilly in November 2008. From 2005 to 2007, Mr. Johnson served as Company Group Chairman of Johnson & Johnson's Worldwide Biopharmaceuticals unit, President of its Ortho Biotech Products LP and Ortho Biotech Canada units from 2003 to 2005, and Worldwide Vice President of its CNS, Pharmaceuticals Group Strategic unit from 2001 to 2003. Prior to joining Johnson & Johnson, he also held several executive positions at Parkstone Medical Information Systems, Inc., Ortho-McNeil Pharmaceutical Corporation and Pfizer, Inc. Mr. Johnson is the former Chairman of Tranzyme Pharma, Inc., and former lead independent director of Sucampo Pharmaceuticals, Inc. Mr. Johnson currently serves as a member of the board of directors of Melinta Pharmaceuticals, Inc., Aveo Pharmaceuticals, Inc., Histogenics Corporation, and Portola Pharmaceuticals, Inc. He previously served as a member of the board of directors for the Pharmaceutical Research and Manufacturers of America and the Health Section Governing Board of Biotechnology Industry Organization. Mr. Johnson holds a B.S. from the East Stroudsburg University of Pennsylvania.

**Richard S. Kollender** has served as a member of our board of directors since March 2015. Since January 2011, he has served as a Partner and Executive manager of Quaker Partners Management, LP, a healthcare investment firm, which he initially joined in 2003, and was promoted to Partner in 2005. Since August 2016, Mr. Kollender has served as Chief Business Officer and Chief Financial Officer of Rapid Micro Biosystems. Mr. Kollender previously served as a director of Celator Pharmaceuticals, Inc., Rapid Micro Biosystems, Inc., Insmed, Inc., Nupathe, Inc., TargetRx, Inc., and Precision Therapeutics, Inc. Mr. Kollender has held positions in sales, marketing and worldwide business development at GlaxoSmithKline or GSK, and served as investment manager at S.R. One, the corporate venture capital arm of GSK. Mr. Kollender holds a B.A. in accounting from Franklin and Marshall College and an M.B.A. and Health Administration and Policy Degree (with Honors) from the University of Chicago and practiced as a certified public accountant for six years at public accounting firms including KPMG.

**Garheng Kong, M.D., Ph.D.** has served as a member of our board of directors since September 2015. In July 2013, he founded, and has since served as managing partner of, HealthQuest Capital, a healthcare venture growth fund. Dr. Kong was a general partner at Sofinnova Ventures, a venture firm focused on life sciences, from September 2010 to December 2013. From May 2000 to September 2010, he worked at Intersouth Partners, a venture capital firm, serving most recently as a general partner. Dr. Kong currently serves as a director of Melinta Therapeutics, Inc., Histogenics Corporation, Alimera Sciences, Inc. and Laboratory Corporation of America Holdings. Dr. Kong holds a B.S. from Stanford University and an M.D., Ph.D. and M.B.A. from Duke University.

**Jeffrey W. Sherman, M.D., FACP**, has served as a member of our board of directors since October 2016. He currently serves as the Chief Medical Officer and Executive Vice President at Horizon Pharma plc. He brings than 25 years of research, clinical development, regulatory and commercialization experience within the biopharmaceutical industry. He is a member of a number of professional societies, a diplomat of the National Board of Medical Examiners and the American Board of Internal Medicine, and also serves on the Board of Advisors of the Center for Information and Study on Clinical Research Participation (CISCRP). He previously held positions at IDM Pharma Takeda Global Research and Development, Neopharm, Searle/Pharmacia, Bristol-Myers Squibb, and is past president of the Drug Information Association (DIA). Dr. Sherman earned his M.D. from the Rosalind Franklin University of Medicine and Science/The Chicago Medical School. He completed internship and residency programs at Northwestern University Feinberg School of Medicine, where he currently serves as an adjunct assistant professor, and a fellowship program at the University of California San Francisco. He received a B.A. in Biology from Lake Forrest College.

**Mårten Steen, M.D., Ph.D.** has served as a member of our board of directors since December 2014. Since April 2010, he has served as a Partner of HealthCap VI LP, a venture capital firm investing in life science companies. Prior to HealthCap, from February 2008 until March 2010, Dr. Steen served as director at Merck Serono SA, a biopharmaceutical company. Currently, he serves as a member of the board of directors of BioClin Therapeutics, Inc. He previously served on the boards of Ultragenyx Inc., Wilson Therapeutics AB, Altimmune, Inc. and FerroKin Biosciences. Dr. Steen holds a B.Sc. in Business Administration, an M.D., and a Ph.D. in Clinical Chemistry, all from Lund University.

**Hilde H. Steiniger, Ph.D.** has served as a member of our board of directors since January 2014. She is a Co-founder of NorthSea Therapeutics B.V., where she serves as Chief Operating Officer. She previously served as Head of

Strategic Innovation Management in the Nutrition & Health Division of BASF and as Head of Global Omega-3 Innovation Management at Pronova BioPharma ASA, a BASF company, from April 2013 to May 2015. From August 2007 to June 2010, Dr. Steineger was Head of Investor Relations for Pronova BioPharma and Vice President Business Development in Pronova BioPharma from November 2009 to April 2013. Dr. Steineger is a board member and Head of the Audit Committee of Nordic Nanovector ASA. Dr. Steineger also serves as a director of PCI Biotech AS. She previously served as a member of the board of directors of Aifew AS, Algeta ASA, Weifa AS, Invent2 AS, Alertis AS, Clavis Pharma ASA and Biotech Pharmacon ASA. Dr. Steineger holds a Ph.D. in medical biochemistry from University of Oslo and an M.Sc. in molecular biology/biotechnology.

### Section 16(a) Beneficial Ownership Reporting Compliance

We were a foreign private issuer until December 31, 2017. By virtue of our status as a foreign private issuer, for the fiscal year ended December 31, 2017 our directors, executive officers, and persons who owned more than 10% of our outstanding ordinary shares (collectively, the “Section 16 insiders”) were not required to file with the SEC initial reports of ownership of our ordinary shares and other equity securities on Form 3 or reports of changes in such ownership on Forms 4 or Form 5 prior to January 1, 2018. As result of our recent transition to domestic reporting status, the Section 16 insiders are now required to comply with Section 16(a) of the Exchange Act, effective as of January 1, 2018.

### Code of Business Conduct and Ethics

Our Code of Business Conduct and Ethics is applicable to all of our directors, officers and employees and is posted on the Investors section of our website, which is located at [www.strongbridgebio.com](http://www.strongbridgebio.com). Our Code of Business Conduct and Ethics provides that our directors, officers and employees are expected to avoid any action, position or interest that conflicts with the interests of our company or gives the appearance of a conflict. We expect that any amendment to this code, or any waivers of its requirements, will be disclosed on our website. Information contained on, or that can be accessed through, our website is not incorporated by reference into this document, and you should not consider information on our website to be part of this document.

### Audit Committee

The current members of our audit committee are, Richard S. Kollender, Hilde H. Steineger and Jeffrey Sherman, with Mr. Kollender serving as chairman. Our board of directors has determined that each member of our audit committee is independent under Rule 10A-3 of the Exchange Act and the applicable listing requirements of Nasdaq, and that each member of our audit committee satisfies the other listing requirements of Nasdaq for audit committee membership. Our board of directors has also determined that two of the three members of our audit committee, Mr. Kollender and Dr. Steineger, qualify as an “audit committee financial expert,” as such term is defined by the SEC, and that he or she has the requisite level of financial sophistication required by the continued listing standards of Nasdaq.

## ITEM 11. EXECUTIVE COMPENSATION

### Summary Compensation Table

The following table sets forth information concerning cash and non-cash compensation paid for 2017 and 2016 to certain of our executive officers (referred to herein as “our executive officers”).

Name and position	Year	Salary (\$)	Bonus (\$) <sup>(1)</sup>	Stock awards (\$) <sup>(2)</sup>	Restricted Share Units (\$) <sup>(3)</sup>	All Other Compensation (\$) <sup>(4)</sup>	Total
Matthew Pauls	2017	\$ 500,000	\$ 350,000	\$ 764,965	\$ -	\$ 10,124	\$ 1,625,089
Chief Executive Officer	2016	468,000	198,900	600,750	157,600	1,170	1,426,420
A. Brian Davis	2017	354,835	182,030	367,183	-	8,639	912,687
Chief Financial Officer	2016	334,750	123,858	173,550	78,800	1,038	711,996
Fredric Cohen, M.D. (5)	2017	395,200	200,366	352,904	-	8,089	956,559
Chief Medical Officer	2016	318,747	134,900	107,892	87,620	977	650,136



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- (1) The amounts in this column represent the discretionary bonuses paid with respect to 2017 and 2016 performance.
- (2) The fair value of all stock options granted during the periods covered by the table are calculated on the grant date in accordance with ASC 718-10-30-3 which represented the grant date fair value.
- (3) The fair value of the shares of restricted stock issued during the periods covered by the table are calculated on the grant date in accordance with ASC 718-10-30-3 which represented the grant date fair value.
- (4) All other compensation received that does not properly report in any other column of the table including insurance premiums paid by Strongbridge with respect to term life insurance, company match on employee's 401(k) contributions and club membership fees.
- (5) Dr. Cohen's employment commenced in August 2015 and he was promoted to Chief Medical Officer in November 2016.

### **Narrative to Summary Compensation Table**

We have entered into employment agreements with Matthew Pauls, A. Brian Davis and Fredric Cohen. The employment agreements outline the terms of the employment relationship, including any potential severance benefits. We believe that the employment agreements provide certainty to our management team and help to retain the leadership necessary for our company to succeed.

#### ***Employment Agreements***

We entered into an employment agreements with each of Messrs. Pauls and Davis and Dr. Cohen for their service as President and Chief Executive Officer, Chief Financial Officer and Chief Medical Officer, respectively. The agreements are effective until terminated by either the Company or the executive officer, in either case in accordance with the terms of the agreement. The agreements also provide for annual incentive bonus targets for Messrs. Pauls and Davis, and Dr. Cohen of 50%, 40% and 40%, respectively. Under the agreements, our executive officers are entitled to participate in benefits offered by us for similarly situated employees, including the Company's paid time-off policy.

Each employment agreement provides for severance benefits detailed below under "Potential Payments upon Terminations of Employment or Following a Change in Control." Each employment agreement also contains a non-competition provision, which applies during the term of employment and for one year following termination, and a restrictive covenant with respect to non-disclosure of confidential information, which remains in effect during the term of employment and at all times thereafter.

#### ***Other Benefits***

Our executive officers are eligible to participate in our employee benefit plans on the same basis as our other employees, including our health and welfare plans and our 401(k) plan. Under our 401(k) plan, participants may elect to make both pre- and post-tax contributions to their accounts in the plan, and we match 100% of those contributions up to 4% of compensation. Our executive officers are not eligible for retirement benefits other than under our 401(k) plan. The company is not required to, and has not, set aside any amounts relating to pension or retirements.

**Outstanding Equity Awards as of December 31, 2017**

The following table includes certain information with respect to option and restricted stock unit awards that were outstanding as of December 31, 2017 for our executive officers.

Name	Option Awards					Stock Awards	
	Number of Securities Underlying Unexercised Options (#)	Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Grant Date	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)(1)
Matthew Pauls	72,727	—	\$ 8.06	8/23/2014	8/23/2019	40,000	\$290,000 <sup>(6)</sup>
	72,727	—	\$10.74	8/23/2014	8/23/2019		
	81,818	—	\$13.43	8/23/2014	8/23/2019		
	180,020	274,525 <sup>(2)</sup>	\$15.71	5/26/2015	5/26/2025		
	37,751	126,562 <sup>(3)</sup>	\$ 3.94	2/26/2016	2/26/2026		
A. Brian Davis	—	304,687 <sup>(3)</sup>	\$ 2.90	2/23/2017	2/23/2027	20,000	\$145,000 <sup>(6)</sup>
	21,591	32,954 <sup>(2)</sup>	\$15.71	5/26/2015	5/26/2025		
	88,908	44,455 <sup>(4)</sup>	\$18.80	7/21/2015	7/21/2020		
	28,438	36,562 <sup>(5)</sup>	\$ 3.94	2/26/2016	2/26/2026		
Fredric Cohen, M.D.	33,750	146,250 <sup>(3)</sup>	\$ 2.90	2/23/2017	2/23/2027	22,000	\$159,500 <sup>(7)</sup>
	46,023	35,795 <sup>(5)</sup>	\$18.12	8/5/2015	8/5/2025		
	13,125	16,875 <sup>(3)</sup>	\$ 3.94	2/26/2016	2/26/2026		
	15,000	25,000 <sup>(5)</sup>	\$ 4.16	6/13/2016	6/13/2026		
	2,500	7,500 <sup>(5)</sup>	\$ 3.90	11/23/2016	11/23/2026		
	32,438	140,562 <sup>(3)</sup>	\$ 2.90	2/23/2017	2/23/2027		

- (1) The market value of shares of stock that have not vested is based on the closing price of our common stock on December 29, 2017, or \$7.25 per share.
- (2) These stock options vest in three separate tranches. The first tranche vests in 16 equal quarterly installments commencing the first quarter subsequent to the grant date; the second tranche vests in 16 equal quarterly installments commencing on the date on which our shares begin trading on NASDAQ; and the third tranche vests one-half on the date on which the closing price of our shares as reported on NASDAQ equals \$33.66 for Mr. Pauls, and \$31.46 for Mr. Davis, for 20 consecutive trading days, so long as this occurs prior to May 26, 2019, and one-half on the one year anniversary of such initial vesting date. All of these options will fully vest and become exercisable upon a change of control provided that the executive is employed on the date of such change in control.
- (3) These options vest in 16 equal quarterly installments commencing with the first quarter subsequent to the grant date. These options will fully vest and become exercisable upon a change of control provided that the executive is employed on the date of such change of control.
- (4) These options vest in three equal annual tranches. The first tranche of these options vested on March 23, 2016. The second tranche vests on March 23, 2017. The third tranche vests on March 23, 2018. These options will fully vest and become exercisable upon a change of control provided that the executive is employed on the date of such change of control.
- (5) These options vest with respect to one-fourth of the shares to vest on the one-year anniversary of the Date of Grant and the remaining three-fourths of shares to vest in 12 equal, quarterly installments after the one-year anniversary of the Date of Grant. These options will fully vest and become exercisable upon a change in control provided that the executive is employed on the date of such change in control.
- (6) The restricted stock units vested on February 26, 2018.
- (7) The restricted stock units vest as follows: 13,000 vest on February 26, 2018; 5,000 vest on June 13, 2018; and 4,000 vest on November 23, 2018.

Prior to September 3, 2015, we did not have an equity compensation plan. Grants of stock options to the executive officers and other individuals were made through individual grant agreements.

### **Stock Option and Restricted Stock Units Grants**

Our Compensation Committee granted stock options to Messrs. Pauls and Davis and Dr. Cohen in February 2017 in the amounts of 375,000, 180,000, and 173,000, respectively, with an exercise price equal to the fair market value of our stock on the date of grant. These options vest in 16 equal quarterly installments commencing with the first quarter subsequent to the grant date, and will accelerate and vest upon a change of control provided that the executive is employed on the date of such change of control.

In 2016, our board of directors granted stock options and restricted stock units, or RSUs, to Messrs. Pauls and Davis, and Dr. Cohen. Messrs. Pauls and Davis, and Dr. Cohen were granted stock options in the amounts of 225,000, 65,000, and 30,000, respectively, and RSUs in the amounts of 40,000, 20,000 and 13,000, respectively. In June 2016 and November 2016, our board of directors approved additional grants to Dr. Cohen of stock options in the amounts of 40,000 and 10,000 and RSUs in the amounts of 5,000 and 4,000, respectively.

The options granted in February 2016 vest in 16 equal quarterly installments commencing with the first quarter subsequent to the grant date. The options granted to Dr. Cohen in June 2016 and November 2016, vest with respect to one-fourth of the shares on the one-year anniversary of the Date of Grant and the remaining three-fourths of shares in 12 equal, quarterly installments after the one-year anniversary of the Date of Grant. All options will fully vest and become exercisable upon a change in control provided that the executive is employed on the date of such change in control. All RSUs vest, with respect to 100% of the grants, on the second anniversary following the date of grant, provided that the executive is employed by the Company on such vesting date and will fully vest upon a change of control of our company. If and when the RSUs vest, the Company will issue to the executive one ordinary share of the Company for each whole RSU that has vested, subject to satisfaction of the executive's tax withholding obligations. The RSUs will cease to be outstanding upon such issuance of shares.

### **Potential Payments Upon Terminations of Employment or Following a Change of Control**

The employment agreements with Messrs. Pauls and Davis, and Dr. Cohen provide that, upon a termination of employment by our company without "cause," or by the executive for "good reason," or due to the executive's death, subject to the execution of a release of claims, he or she will be entitled to (1) an amount equal to the sum of 18 months of base salary and the target bonus for Mr. Pauls, or 12 months of base salary and the target bonus for our other executive officers, paid in installments over the 18-month period following termination for Mr. Pauls or the 12-month period following termination for our other executive officers, (2) a pro rata portion of the annual bonus that he or she would have been entitled to receive for the calendar year that includes the termination date, based on the actual achievement of the applicable performance goals, and (3) medical and dental benefits provided by us that are at least equal to the level of benefits provided to other similarly situated active employees until the earlier of (a) 18 months following the termination date for Mr. Pauls, or 12 months following the termination date for our other executive officers and (b) the date the executive becomes covered under a subsequent employer's medical and dental plans.

In the event there is a change of control of our company and, during the 24-month period following the change of control, any of our executive officers is terminated by us without cause, by the executive for good reason, or due to the executive's death or, he or she will be entitled to the severance benefits detailed below and all unvested equity or equity-based awards held by the executive will accelerate and vest. The severance benefits include (1) an amount equal to the sum of 24 months base salary and the target bonus for Mr. Pauls, or the sum of 18 months base salary and the target bonus for our other executive officers, paid in installments over the 24-month period following termination for Mr. Pauls or the 18-month period following termination for our other executive officers; and (2) the medical and dental benefits provided by us until the earlier of (a) 18 months following the termination date for Mr. Pauls or one year following the termination date of our other executive officers and (b) the date the executive becomes covered under a subsequent employer's medical and dental plans.

Under the employment agreements, "cause" is defined as (1) the conviction of, or plea of guilty or nolo contendere to, any felony or any crime involving theft, embezzlement, dishonesty or moral turpitude, (2) any act constituting willful misconduct, deliberate malfeasance, dishonesty, or gross negligence in the performance of the individual's duties, (3) the willful and continued failure to perform any of the individual's duties, which has not been cured within 30 days following written notice from us, or (4) any material breach by the individual of the employment

agreement or any other agreement with us, which has not been cured within 30 days following written notice from us. “Good reason” is defined as any of the following reasons unless cured by us within a specified period: (1) a material reduction of the individual’s base salary, other than a reduction that is applicable to other senior executives in the same manner and proportion, (2) the assignment of duties or responsibilities which are materially inconsistent with the individual’s position, (3) a change in the principal location at which the individual performs his or her duties to a new location that is more than 50 miles from the prior location or (4) a material breach of the employment agreement by us. “Change of control” is defined as the occurrence of any of the following: (a) any person or group of persons becomes the beneficial owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company’s then outstanding securities; provided that if the person or group of persons is already deemed to own more than 50% of the total fair market value or total voting power, then the acquisition of additional stock by such person or group of persons shall not constitute an additional change of control; (b) the stockholders of the Company approve a plan of complete liquidation of the Company; (c) the sale or disposition of all or substantially all of the Company’s assets; or (d) a merger, consolidation or reorganization of the Company with or involving any other entity, other than a merger, consolidation or reorganization that would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) at least a 50% of the combined voting power of the Company (or such surviving entity) outstanding immediately after such merger, consolidation or reorganization owned in approximately the same proportion of such ownership by each of the prior shareholders as prior to the transaction. The following acquisitions are not considered to be a change of control of the Company: (A) an acquisition by the Company or entity controlled by the Company, or (B) an acquisition by an employee benefit plan (or related trust) sponsored or maintained by the Company.

The employment agreements also provide that, in the event that any of our other executive officers is subject to the excise tax under Section 4999 of the Code, the payments that would be subject to the excise tax will be reduced to the level at which the excise tax will not be applied unless such executive would be in a better net after-tax position by receiving the full payments and paying the excise tax.

### **Director Compensation**

Our board of directors’ compensation program for fiscal year 2017 provided for the following:

- Annual Cash Retainer—\$40,000
- Additional Annual Cash Retainers
  - Non-Executive Chairman of the Board Retainer—\$35,000
  - Audit Committee Chair Retainer—\$15,000
  - Compensation Committee Chair Retainer—\$10,000
  - Governance Committee Chair Retainer—\$7,500
  - Audit Committee Member (other than Chairman) Retainer—\$7,500
  - Compensation Committee Member (other than Chairman) Retainer—\$5,000
  - Governance Committee Member (other than Chairman) Retainer—\$3,750
- Equity Compensation
  - Initial Equity Grant—Option to purchase 60,000 shares, with one-third of the shares vesting on the first anniversary of the date of grant and the remaining two-thirds of the shares vesting in equal

monthly installments over the 24-month period that follows the first anniversary of the date of grant, provided that the director continues to provide services as a member of our board of directors continuously from the date of grant through the applicable vesting date

- Annual Equity Grant—Option to purchase 40,000 shares with such option vesting in full on the first anniversary of the date of grant, provided that the director continues to provide services as a member of our board of directors continuously from the date of grant through the vesting date

Our directors earned compensation in 2017 for their service on the board as summarized below:

Name	Year	Fees earned (\$)	Options Awards (1) (\$)	Total (\$)
John H. Johnson	2017	\$88,750	\$ 116,186	\$204,936
Richard S. Kollender	2017	60,000	116,186	176,186
Garheng Kong, M.D., Ph.D.	2017	48,750	116,186	164,936
Jeffrey W. Sherman, M.D., FACP	2017	47,500	116,186	163,686
Mårten Steen, M.D., Ph.D.	2017	47,500	116,186	163,686
Hilde H. Steineger, Ph.D.	2017	47,500	116,186	163,686

(1) Amounts shown represent the aggregate grant date fair value of the option awards, computed in accordance with FASB ASC Topic 718.

The following table includes a summary of outstanding stock options as of December 31, 2017 for our directors:

Name	Options Outstanding
John H. Johnson	147,767
Richard S. Kollender	117,188
Garheng Kong, M.D., Ph.D.	114,385
Jeffrey W. Sherman, M.D., FACP	100,000
Mårten Steen, M.D., Ph.D.	114,918
Hilde H. Steineger, Ph.D.	114,918

#### Non-Employee Director Equity Compensation Plan

Our board of directors has adopted and our shareholders have approved, the Non-Employee Director Equity Compensation Plan (the Non-Employee Director Plan). The Non-Employee Director Plan provides for the grant of nonstatutory stock options, stock awards, and restricted stock units to our non-employee directors. The Non-Employee Director Plan is effective as of September 3, 2015.

*Authorized Shares.* A total of 828,904 shares of our common stock have been reserved for issuance pursuant to the Non-Employee Director Plan. The shares of our common stock that we have reserved for issuance pursuant to the Non-Employee Director Plan (the “Share Pool”) will be increased on the first day of each fiscal year, in an amount equal to one-half percent (0.5%) of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year. The Share Pool will be reduced on the date of grant, by one share of our common stock for each award under the Non-Employee Director Plan; provided that awards that are valued by reference to shares of our common stock but are required to be paid in cash pursuant to their terms will not reduce the Share Pool. If and to the extent options terminate, expire, or are canceled, forfeited, exchanged, or surrendered without having been exercised, or if any stock awards or awards of restricted stock units (including restricted stock received upon the exercise of options) are forfeited, the shares of our common stock subject to such awards will again be available for awards under the Share Pool. Notwithstanding the foregoing, shares tendered by individual grantees, or withheld by us, as full or partial payment to us upon the exercise of options will not become available for issuance again under the Non-Employee Director Plan.

*Plan Administration.* Our board administers the Non-Employee Director Plan. Subject to the provisions of the Non-Employee Director Plan, our board has the power to determine the terms of the awards, including the exercise price, the number of shares of our common stock subject to each such award, the exercisability of the awards and the form of consideration, if any, payable upon exercise. To the maximum extent permitted by law, no member of our board will be liable for any action taken or decision made in good faith relating to the Non-Employee Director Plan or any award granted thereunder.

*Stock Options.* The exercise price of options granted under the Non-Employee Director Plan may be equal to or greater than the fair market value of our common stock on the date of grant. The term of an option may not exceed ten years. After the termination of service of a non-employee director for any reason other than death, disability or cause (as defined in the Non-Employee Director Plan), he or she may exercise the vested portion of his or her option for 90 days. If termination is due to death (or death occurs within 90 days after the director's termination date) or disability, the vested portion of the option will remain exercisable for one year. However, in no event may an option be exercised later than the expiration of its term. The entire option is forfeited upon a termination for Cause. In addition, if a non-employee director has engaged in conduct that constitutes cause, any shares acquired upon exercise of an option for which we have not yet delivered the share certificates shall be automatically forfeited to us in exchange for payment of the exercise price paid for such shares.

*Stock Awards.* Stock awards may be granted under the Non-Employee Director Plan. Stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the board. The board will determine the number of shares granted as stock awards to a non-employee director and the consideration, if any, to be paid for such shares. The board may impose whatever conditions to vesting it determines to be appropriate (for example, the board may set restrictions based on the achievement of specific performance goals or continued service to us); provided, however, that the board, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Shares of common stock subject to stock awards that do not vest are subject to forfeiture.

*Restricted Stock Units.* Restricted stock units may be granted under the Non-Employee Director Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. The board determines the terms and conditions of restricted stock units, including the vesting criteria (which may include accomplishing specified performance criteria or continued service to us) and the form and timing of payment. The amount payable as a result of the vesting of a restricted stock unit will be distributed as soon as practicable following the vesting date and in no event later than the fifteenth date of the third calendar month of the year following the vesting date of the restricted stock unit (or as otherwise permitted under Section 409A of the Internal Revenue Code); provided, however, that an individual grantee may, if and to the extent permitted by our board, elect to defer payment of restricted stock units in a manner permitted by Section 409A of the Internal Revenue Code. Notwithstanding the foregoing, the board, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

*Non-Transferability of Awards.* Unless our board provides otherwise, the Non-Employee Director Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime.

*Certain Adjustments.* In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the Non-Employee Director Plan, the board will adjust the number and class of shares that may be delivered under the Non-Employee Director Plan and/or the number, class and price per share of shares covered by each outstanding award.

*Change of Control.* The Non-Employee Director Plan provides that in the event of a change of control, as defined in the Non-Employee Director Plan, where we are not the surviving corporation (or we survive only as a subsidiary of another corporation), unless our board determines otherwise, all outstanding awards will be assumed by, or replaced with comparable awards by, the surviving corporation (or a parent or subsidiary of the surviving corporation). In the event the surviving corporation in such change of control (or a parent or subsidiary of the surviving corporation) does not assume or replace the outstanding awards with comparable awards, (i) we will provide written notice of such change of control to each individual grantee with outstanding awards; (ii) all outstanding options will automatically accelerate and become fully vested and exercisable; (iii) all outstanding stock awards will become vested and deliverable

in accordance with the Non-Employee Director Plan; and (iv) all outstanding restricted stock units will become vested and deliverable in accordance with the Non-Employee Director Plan.

Notwithstanding the foregoing, if there is a change of control, our board may require that grantees surrender outstanding options in exchange for a payment of cash or stock equal to the amount by which the fair market value of the shares exceeds the exercise price and/or, after giving grantees an opportunity to exercise options, terminate all unexercised options, with such surrender or termination taking place as of the date of the change of control or such other date that our board specifies.

*Amendment; Termination.* Our board has the authority to amend, suspend or terminate the Non-Employee Director Plan provided such action does not impair the existing rights of any participant. The Non-Employee Director Plan automatically terminates in 2025, unless we terminate it sooner. We will obtain shareholder approval of any amendment to the Non-Employee Director Plan as required by applicable law or listing requirements.

### **Equity Compensation Plan**

Our board of directors has adopted, and our shareholders have approved, the 2015 Equity Compensation Plan (the "2015 Plan"). The 2015 Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, to our employees and any parent or subsidiary corporations' employees, and for the grant of nonstatutory stock options, stock awards, and restricted stock units to our employees, directors and consultants and our parent or subsidiary corporations' employees and consultants. The 2015 Plan is effective as of September 3, 2015.

*Authorized Shares.* A total of 4,949,426 shares of our common stock have been reserved for issuance pursuant to the 2015 Plan. The shares of our common stock that we have reserved for issuance pursuant to the 2015 Plan (the "Share Pool"), will be increased on the first day of each fiscal year, in an amount equal to four percent (4.0%) of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year. A maximum of 1,000,000 shares of our common stock may be subject to awards made under the 2015 Plan to any individual during a calendar year, subject to adjustment as provided in the 2015 Plan. The maximum number of shares that may be issued under the 2015 Plan as incentive stock options is 4,949,426. The Share Pool will be reduced on the date of grant, by one share of our common stock for each award under the 2015 Plan; provided that awards that are valued by reference to shares of our common stock but are required to be paid in cash pursuant to their terms will not reduce the Share Pool. If and to the extent options terminate, expire, or are canceled, forfeited, exchanged, or surrendered without having been exercised, or if any stock awards or awards of restricted stock units (including restricted stock received upon the exercise of options) are forfeited, the shares of our common stock subject to such awards will again be available for awards under the Share Pool. Notwithstanding the foregoing, the following shares of our common stock will not become available for issuance under the 2015 Plan: (i) shares tendered by individual grantees, or withheld by us, as full or partial payment to us upon the exercise of options granted under the 2015 Plan and (ii) shares withheld by, or otherwise remitted to us to satisfy an individual grantee's tax withholding obligations upon the lapse of restrictions on stock awards, or the exercise of options granted under the 2015 Plan.

*Plan Administration.* Our compensation committee administers the 2015 Plan. Subject to the provisions of the 2015 Plan, our compensation committee has the power to determine the terms of the awards, including the exercise price, the number of shares of our common stock subject to each such award, the exercisability of the awards and the form of consideration, if any, payable upon exercise. To the maximum extent permitted by law, no member of our board or our compensation committee will be liable for any action taken or decision made in good faith relating to the 2015 Plan or any award granted thereunder.

*Stock Options.* The exercise price of options granted under the 2015 Plan may be equal to or greater than the fair market value of our common stock on the date of grant. The term of an option may not exceed ten years, except that the term of an incentive stock option granted to any employee who owns more than 10% of the voting power of all classes of our outstanding stock must not exceed five years and the exercise price must equal to at least 110% of the fair market value of our common stock on the grant date. After the termination of service of an employee, director or consultant for any reason other than death, disability or cause (as defined in the 2015 Plan), he or she may exercise the vested portion of his or her option for 90 days. If termination is due to death (or death occurs within 90 days after the individual's termination date) or disability, the vested portion of the option will remain exercisable for one year. However, in no event may an option be exercised later than the expiration of its term. The entire option is forfeited upon



a termination for Cause. In addition, if an employee, director or consultant has engaged in conduct that constitutes cause, any shares acquired upon exercise of an option for which we have not yet delivered the share certificates shall be automatically forfeited to us in exchange for payment of the exercise price paid for such shares.

*Stock Awards.* Stock awards may be granted under the 2015 Plan. Stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the compensation committee. The compensation committee will determine the number of shares of granted as stock awards to any employee, director, or consultant and the consideration, if any, to be paid for such shares. The compensation committee may impose whatever conditions to vesting it determines to be appropriate (for example, the compensation committee may set restrictions based on the achievement of specific performance goals or continued service to us); provided, however, that the compensation committee, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Shares of our common stock subject to stock awards that do not vest are subject to forfeiture.

*Restricted Stock Units.* Restricted stock units may be granted under the 2015 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. The compensation committee determines the terms and conditions of restricted stock units, including the vesting criteria (which may include accomplishing specified performance criteria or continued service to us) and the form and timing of payment. The amount payable as a result of the vesting of a restricted stock unit will be distributed as soon as practicable following the vesting date and in no event later than the fifteenth date of the third calendar month of the year following the vesting date of the restricted stock unit (or as otherwise permitted under Section 409A of the Internal Revenue Code); provided, however, that an individual grantee may, if and to the extent permitted by our compensation committee, elect to defer payment of restricted stock units in a manner permitted by Section 409A of the Internal Revenue Code. Notwithstanding the foregoing, the compensation committee, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

*Performance-Based Awards.* Certain stock awards or restricted stock units granted under the 2015 Plan may be granted in a manner that should be deductible by us under Section 162(m) of the Internal Revenue Code. These awards, referred to as performance-based awards, will be determined based on the attainment of written performance goals approved by the compensation committee. The performance-based awards will be based upon one or more of the following objective criteria: (i) consolidated earnings before or after taxes (including earnings before interest, taxes, depreciation and amortization); (ii) net income; (iii) operating income; (iv) earnings per share; (v) return on shareholders' equity; (vi) attainment of strategic and operational initiatives; (vii) customer income; (viii) economic value-added models; (ix) maintenance or improvement of profit margins; (x) stock price (including total shareholder return), including, without limitation, as compared to one or more stock indices; (xi) market share; (xii) revenues, sales or net sales; (xiii) return on assets; (xiv) book value per share; (xv) expense management; (xvi) improvements in capital structure; (xvii) costs; and (xviii) cash flow. The foregoing criteria may relate to the company, one or more of our subsidiaries or one or more of our divisions or units, or any combination of the foregoing, and may be applied on an absolute basis and/or be relative to one or more peer group companies or indices, or any combination thereof, all as determined by the compensation committee. In addition, to the degree consistent with the Internal Revenue Code, the performance criteria may be calculated without regard to extraordinary, unusual and/or non-recurring items. With respect to performance-based awards, (i) the compensation committee will establish the objective performance goals applicable to a given period of service while the outcome for that performance period is substantially uncertain and no later than 90 days after the commencement of that period of service (but in no event after 25% of that period of service has elapsed) and (ii) no awards will be granted to any participant for a given period of service until the compensation committee certifies that the objective performance goals (and any other material terms) applicable to that period have been satisfied.

*Non-Transferability of Awards.* Unless our compensation committee provides otherwise, the 2015 Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime.

*Certain Adjustments.* In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the 2015 Plan, the compensation committee will adjust the number and class of shares that may be delivered under the 2015 Plan and/or the number, class and price per share of shares covered by each outstanding award, and the numerical share limits set forth in the 2015 Plan.

*Change of Control.* The 2015 Plan provides that in the event of a change of control, as defined in the 2015 Plan, where we are not the surviving corporation (or we survive only as a subsidiary of another corporation), unless our compensation committee determines otherwise, all outstanding awards will be assumed by, or replaced with comparable awards by, the surviving corporation in such change of control (or a parent or subsidiary of the surviving corporation). In the event the surviving corporation (or a parent or subsidiary of the surviving corporation) in such change of control does not assume or replace the outstanding awards with comparable awards, (i) we will provide written notice of such change of control to each individual grantee with outstanding awards; (ii) all outstanding options will automatically accelerate and become fully vested and exercisable; (iii) all outstanding stock awards will become vested and deliverable in accordance with the 2015 Plan; and (iv) all outstanding restricted stock units will become vested and deliverable in accordance with the 2015 Plan.

Notwithstanding the foregoing, if there is a change of control, our board may require that grantees surrender outstanding options in exchange for a payment of cash or stock equal to the amount by which the fair market value of the shares exceeds the exercise price or, after giving grantees an opportunity to exercise options, terminate all unexercised options, with such surrender or termination taking place as of the date of the change of control or such other date that our board specifies.

*Amendment; Termination.* Our board has the authority to amend, suspend or terminate the 2015 Plan provided such action does not impair the existing rights of any participant. The 2015 Plan automatically terminates in 2025, unless we terminate it sooner. We will obtain shareholder approval of any amendment to the 2015 Plan as required by applicable law or listing requirements.

### **2017 Inducement Plan**

On February 23, 2017, our board of directors adopted the 2017 Inducement Plan (the “Inducement Plan”), pursuant to which we (along with our affiliates and subsidiaries) may grant equity-based awards to new employees. The purpose of the Inducement Plan is to attract valued employees by offering them a greater stake in our success and a closer identity with us, and to encourage ownership of our ordinary shares by such employees.

The Inducement Plan was adopted without shareholder approval pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules. In accordance with Rule 5635(c)(4) of the NASDAQ Listing Rules, awards under the Inducement Plan may only be made to individuals who were not previously an employee or a non-employee director of the Company or any of our subsidiaries (or who had a bona fide period of non-employment with the Company and our subsidiaries) who is hired by the Company or a subsidiary. Subject to adjustments described in the Inducement Plan, we may issue up to 2,500,000 of our ordinary shares in the form of stock options, stock awards and restricted stock units to eligible recipients.

*Administration.* Our compensation committee administers the Inducement Plan and is authorized to determine, among other things, the persons to whom inducement awards will be made and the terms of such awards.

*Stock Options.* The exercise price of options granted under the Inducement Plan will be equal to or greater than the fair market value of our ordinary shares on the date the options are granted and the term of any option will not exceed ten years from the date of the grant. After a termination of service for any reason other than death, disability or cause (as defined in the Inducement Plan), the grantee of an option award may exercise the vested portion of his or her option for 90 days. If termination is due to death (or death occurs within 90 days after the individual’s termination date) or disability, the vested portion of the option will remain exercisable for one year. However, in no event may an option be exercised later than the expiration of its term. The entire option will be forfeited upon a termination for cause. In addition, if an employee, director or consultant has engaged in conduct that constitutes cause, any shares acquired upon exercise of an option for which we have not yet delivered the share certificates will be automatically forfeited to us in exchange for payment of the exercise price paid for such shares.

*Stock Awards and Restricted Stock Units.* Ordinary shares issued or transferred pursuant to stock awards may be issued or transferred for consideration or for no consideration, and may be subject to restrictions or no restrictions, as determined by the compensation committee. Each restricted stock unit will be granted with respect to one ordinary share

or will have a value equal to the fair market value of one ordinary share. Restricted stock units will be paid in cash, ordinary shares, or other securities, other awards or other property, as determined by the compensation committee, upon the lapse of the restrictions applicable thereto. The amount payable as a result of the vesting of a restricted stock unit will be distributed as soon as practicable following the vesting date and in no event later than the fifteenth date of the third calendar month of the year following the vesting date of the restricted stock unit (or as otherwise permitted under Section 409A of the Internal Revenue Code); provided, however, that an individual grantee may, if and to the extent permitted by our compensation committee, elect to defer payment of restricted stock units in a manner permitted by Section 409A of the Internal Revenue Code. Except as otherwise set forth in an award agreement, if a grantee ceases to be employed by, or provide services to, us, any stock award or restricted stock units held by the grantee that are subject to transfer restrictions will be forfeited.

*Non-Transferability of Awards.* Except as otherwise permitted by an award agreement or by our compensation committee, the Inducement Plan generally does not allow for the transfer of awards made under the Inducement Plan, except by will or by the laws of descent and distribution.

*Certain Adjustments.* In the event of certain changes in our capitalization, to prevent dilution or enlargement of the benefits or potential benefits available under the Inducement Plan, the compensation committee will adjust the number and class of shares that may be delivered under the Inducement Plan and/or the number, class and price per share of shares covered by each outstanding award, and the numerical share limits set forth in the Inducement Plan.

*Change of Control.* The Inducement Plan provides that in the event of a change of control, as defined in the Inducement Plan, where we are not the surviving corporation (or we survive only as a subsidiary of another corporation), unless our compensation committee determines otherwise, all outstanding awards will be assumed by, or replaced with comparable awards by, the surviving corporation in such change of control (or a parent or subsidiary of the surviving corporation). In the event the surviving corporation (or a parent or subsidiary of the surviving corporation) in such change of control does not assume or replace the outstanding awards with comparable awards, (i) we will provide written notice of such change of control to each individual grantee with outstanding awards; (ii) all outstanding options will automatically accelerate and become fully vested and exercisable; (iii) all outstanding stock awards will become vested and deliverable in accordance with the Inducement Plan; and (iv) all outstanding restricted stock units will become vested and deliverable in accordance with the Inducement Plan.

Notwithstanding the foregoing, if there is a change of control, our board may require that grantees surrender outstanding options in exchange for a payment of cash or stock equal to the amount by which the fair market value of the shares exceeds the exercise price or, after giving grantees an opportunity to exercise options, terminate all unexercised options, with such surrender or termination taking place as of the date of the change of control or such other date that our board specifies.

*Amendment; Termination.* Our board has the authority to amend or terminate the Inducement Plan at any time; provided, however, that the board will not amend the Inducement Plan without shareholder approval if such approval is required in order to comply with applicable laws or stock exchange requirements. The Inducement Plan automatically terminates in 2027, unless we terminate it sooner.

## **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of March 1, 2018 by:

- each of our directors and director nominees;
- each of our “named executive officers”;
- all of our directors and executive officers as a group; and

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- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our ordinary shares.

The percentages in the columns entitled “Percentage of Shares Beneficially Owned” are based on a total of 45,504,848 ordinary shares outstanding as of March 1, 2018.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our ordinary shares. Our ordinary shares subject to options that are currently exercisable or exercisable within 60 days of March 1, 2018 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the ordinary shares beneficially owned by them, subject to community property laws, where applicable. Except as otherwise set forth below, the address of the beneficial owner is c/o Strongbridge Biopharma plc, 900 Northbrook Drive, Suite 200, Trevose, Pennsylvania 19053.

		Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
<b>5% Shareholders</b>			
Caxton Alternative Management LP	(1)	7,614,994	12.2%
Growth Equity Opportunities Fund III, LLC	(2)	5,141,308	8.2%
Vivo Capital VIII, LLC	(3)	3,952,397	6.3%
Broadfin	(4)	3,786,695	6.1%
HealthCap VI, L.P.	(5)	3,694,063	5.9%
<b>Executive Officers and Directors</b>			
Matthew Pauls	(6)	533,558	*
A. Brian Davis	(7)	249,229	*
Fredric Cohen, M.D.		135,860	*
John H. Johnson	(8)	107,767	*
Richard S. Kollender	(9)	77,188	*
Garheng Kong, M.D., Ph.D.	(10)	70,219	*
Jeffrey W. Sherman, M.D., F.A.C.P.	(11)	30,000	*
Mårten Steen, M.D., Ph.D.	(10)	70,752	*
Hilde H. Steineger, Ph.D.	(10)	70,752	*
<i>All current directors and executive officers as a group (10 persons)</i>		<b>1,589,600</b>	<b>3.8%</b>

\* less than one percent

- (1) Based on the information disclosed in a Schedule 13D/A filed with the SEC on October 10, 2017 by Caxton Corporation (“Caxton”), CDK Associates, L.L.C. (“CDK”) and Bruce Kovner, in which Caxton, the manager of CDK, and Mr. Kovner, the Chairman and sole shareholder of Caxton, each reported shared voting and dispositive power with respect to 7,614,994 ordinary shares, which includes 7,202,433 ordinary shares beneficially owned by CDK and 412,561 ordinary shares beneficially owned by employees of an affiliate of Caxton. CDK reported shared voting and dispositive power with respect to 7,202,433 ordinary shares. The 7,202,433 ordinary shares beneficially owned by CDK represent 5,102,433 ordinary shares and warrants to purchase up to an aggregate of 2,100,000 ordinary shares. The 412,561 ordinary shares beneficially owned by employees of an affiliate of Caxton represent 292,561 ordinary shares and warrants to purchase up to an aggregate of 120,000 ordinary shares. The reporting persons will be prohibited from exercising the warrants, if after giving effect to such exercise, they (together with any of their affiliates) would together beneficially own in excess of 4.99% of our ordinary shares outstanding immediately after giving effect to such exercise or 9.99% if the holder beneficially owns greater than 4.99% of the number of ordinary shares outstanding notwithstanding the ordinary shares issuable upon exercise of this warrant. The address of the reporting persons is 731 Alexander Road, Princeton, NJ, 08540.
- (2) Based on the information disclosed in a Schedule 13D/A filed with the SEC on January 6, 2017 by Growth Equity Opportunities Fund III, LLC (“GEO”), New Enterprise Associates 14, L.P. (“NEA 14”), NEA Partners 14, L.P. (“NEA Partners 14”), NEA 14 GP, LTD (“NEA 14 GP”), M. James Barrett, Peter J. Barris, Forest Baskett, Anthony A. Florence, Jr., Patrick J. Kerins, David M. Mott, Scott D. Sandell, Peter W. Sonsini, and Ravi Viswanathan, in which each reporting person reported shared voting and dispositive power with respect to 4,141,308 ordinary shares. The number reported in the table above includes warrants to purchase up to an aggregate of 1,000,000 ordinary shares, which became exercisable subsequent to the Schedule 13D/A filed by the reporting persons. The reporting persons will be prohibited from exercising the warrants, if after giving effect to such exercise, they (together with any of their affiliates) would together beneficially own in excess of 4.99% of our ordinary shares outstanding immediately after giving effect to such exercise or 9.99% if the holder beneficially owns greater than 4.99% of the number of

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ordinary shares outstanding notwithstanding the ordinary shares issuable upon exercise of this warrant. NEA 14 is the sole member of GEO, NEA Partners 14 is the sole general partner of NEA 14, and NEA 14 GP is the sole general partner of NEA Partners 14. Messrs. Barrett, Barris, Baskett, Florence, Kerins, Mott, Sandell, Sonsini and Viswanathan are the directors of NEA 14 GP. Each reporting person disclaims beneficial ownership of the ordinary shares reported other than those ordinary shares which such person owns of record. The address of each of GEO, NEA 14, NEA Partners 14, and NEA 14 GP is New Enterprise Associates, 1954 Greenspring Drive, Suite 600, Timonium, MD 21093. The address of the principal business office for each of Messrs. Barris, Florence, Kerins and Mott is New Enterprise Associates, 5425 Wisconsin Avenue, Suite 800, Chevy Chase, MD 20815. The address of the principal business officer for each of Messrs. Baskett, Sandell, Sonsini and Viswanathan is New Enterprise Associates, 2855 Sand Hill Road, Menlo Park, CA 94025.

- (3) Based on the information disclosed in a Schedule 13G/A filed with the SEC on February 12, 2018 by Vivo Capital VIII, LLC (“Vivo”), in which Vivo reported sole voting and dispositive power with respect to 3,952,397 ordinary shares. According to the Schedule 13G, the ordinary shares are held of record by Vivo Capital Fund VIII, L.P. (2,154,841 ordinary shares and 1,318,000 ordinary shares issuable upon exercise of 1,318,000 warrants exercisable within 60 days) and Vivo Capital Surplus Fund VIII, L.P. (297,556 ordinary shares and 182,000 ordinary shares issuable upon exercise of 182,000 warrants). The reporting persons will be prohibited from exercising the warrants, if after giving effect to such exercise, they (together with any of their affiliates) would together beneficially own in excess of 4.99% of our ordinary shares outstanding immediately after giving effect to such exercise or 9.99% if the holder beneficially owns greater than 4.99% of the number of ordinary shares outstanding notwithstanding the ordinary shares issuable upon exercise of this warrant. Vivo serves as the general partner for each of these entities. The address of Vivo is 505 Hamilton Street, Palo Alto, CA 94301.
- (4) Based on the information disclosed in a Schedule 13G/A filed with the SEC on February 13, 2018 by Broadfin Capital, LLC (“Broadfin Capital”), Broadfin Healthcare Master Fund, Ltd. (“Broadfin Fund”) and Kevin Kotler, in which each reporting person reported shared voting and dispositive power with respect to 3,786,695 ordinary shares. This number includes warrants to purchase up to an aggregate of 600,000 ordinary shares. The reporting persons will be prohibited from exercising the warrants, if after giving effect to such exercise, they (together with any of their affiliates) would together beneficially own in excess of 4.99% of our ordinary shares outstanding immediately after giving effect to such exercise or 9.99% if the holder beneficially owns greater than 4.99% of the number of ordinary shares outstanding notwithstanding the ordinary shares issuable upon exercise of this warrant. The address of Broadfin Capital and Mr. Kotler is Broadfin Capital, 300 Park Avenue, 25th floor, New York, NY 10022. The address of Broadfin Fund is 20 Genesis Close, Ansbacher House, Second Floor, PO Box 1344, Grand Cayman KY1-1108, Cayman Islands.
- (5) Based on the information disclosed in a Schedule 13G/A filed with the SEC on January 30, 2018 by HealthCap VI, L.P. (“HealthCap”) and HealthCap VI GP S.A. (“HealthCap GP”), in which each reporting person reported shared voting and dispositive power with respect to 3,694,063 ordinary shares, which includes (i) 67,973 ordinary shares issuable upon exercise of options that are exercisable within 60 days and (ii) a warrant to purchase up to an additional 400,000 ordinary shares. The reporting persons will be prohibited from exercising the warrants, if after giving effect to such exercise, they (together with any of their affiliates) would together beneficially own in excess of 4.99% of our ordinary shares outstanding immediately after giving effect to such exercise or 9.99% if the holder beneficially owns greater than 4.99% of the number of ordinary shares outstanding notwithstanding the ordinary shares issuable upon exercise of this warrant. HealthCap GP is the sole general partner of HealthCap. The address of HealthCap and HealthCap GP is 18, Avenue d’Ouchy, 1006 Lausanne, Switzerland.
- (6) This number includes 9,460 ordinary shares that are subject to options that are or will vest and become exercisable within 60 days.
- (7) This number includes 45,591 ordinary shares that are subject to options that are or will vest and become exercisable within 60 days.
- (8) This number includes 18,181 ordinary shares that are subject to options that are or will vest and become exercisable within 60 days.
- (9) This number includes 9,090 ordinary shares that are subject to options that are or will vest and become exercisable within 60 days.
- (10) This number includes 1,389 ordinary shares that are subject to options that are or will vest and become exercisable within 60 days.
- (11) This number includes 3,333 ordinary shares that are subject to options that are or will vest and become exercisable within 60 days.

**Equity Compensation Plan Information**

The table below sets forth information with respect to ordinary shares that may be issued under our equity compensation plans issued as of December 31, 2017:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding	Weighted- Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
	Options, Warrants and Rights		(a)
	(a)	(b)	(c)
Equity compensation plans approved by security holders	3,394,153 <sup>(1)</sup>	\$ 4.39	577,436
Equity compensation plans not approved by security holders <sup>(3)</sup>	1,206,650 <sup>(2)</sup>	4.89	293,350
<b>Total</b>	<b>4,600,803</b>		<b>870,786</b>

(1) This number includes the following: 2,766,790 ordinary shares subject to outstanding awards granted under the 2015 Equity Compensation Plan as of December 31, 2017, of which 2,527,540 ordinary shares were subject to outstanding stock options and 239,250 ordinary shares were subject to outstanding restricted stock unit awards; and 627,363 ordinary shares subject to outstanding awards granted in the form of options under the Non-Employee Director Equity Compensation Plan as of December 31, 2017.

(2) This number represents ordinary shares subject to outstanding awards granted under the 2017 Inducement Plan, of which 1,178,650 ordinary shares were subject to outstanding stock options and 28,000 ordinary shares were subject to outstanding restricted stock unit awards as of December 31, 2017.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

**Related Party Transactions**

On October 6, 2017, we sold 4,000,000 ordinary shares in a public offering. Two of our existing shareholders holding in excess of 5% of our outstanding shares prior to the public offering, Armistice Capital LLC and Broadfin Capital LLC, purchased shares in the public offering for \$6.0 million and \$2.5 million, respectively.

On January 25, 2018, we sold 5,000,000 ordinary shares in a public offering. One of our existing shareholders holding in excess of 5% of our outstanding shares prior to the public offering, Broadfin Capital LLC, purchased shares in the public offering for \$2.0 million.

**Policies and Procedures for Related Party Transactions**

We have adopted a policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our voting securities and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the prior consent of our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as

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a director, beneficial owner of more than 5% of any class of our voting securities or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds \$120,000 and such person would have a direct or indirect material interest, must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee is to consider the material facts of the transaction, including, but not limited to: the benefits to the Company; the impact on a director's independence in the event the transaction involves a director, an immediate family member of a director or an entity in which a director is a general partner, shareholder or executive officer; the availability of other sources for comparable products or services; the terms of the transaction; and the terms available to unrelated third parties or to employees generally. All of the transactions described above were entered into prior to the adoption of such policy, but after presentation, consideration and approval by our board of directors.

**Director Independence**

Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, our board of directors has determined that each of Messrs. Johnson and Kollender and Drs. Kong, Sherman, Steen and Steineger, representing six of our seven directors, is independent under the applicable rules and regulations of Nasdaq. In making such determinations, the board of directors considered the relationships that each such non-employee director has with the Company and all other facts and circumstances the board of directors deemed relevant in determining their independence.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

**Principal Accountant Fees and Services**

The following table sets forth the aggregate fees billed by Ernst & Young our independent registered public accounting firm as described below:

<b>Fee Category:</b>	<b>2017</b>	<b>2016</b>
	<b>(in thousands)</b>	
Audit Fees <sup>(1)</sup>	\$ 582	\$ 535
Audit-Related Fees <sup>(2)</sup>	162	80
Tax Fees <sup>(3)</sup>	—	—
All Other Fees	—	—
<b>Total Fees</b>	<b>\$ 744</b>	<b>\$ 615</b>

- (1) Audit fees consist of fees for the audit of our financial statements, the review of our interim financial statements and statutory audits.
- (2) Audit-related fees included fees for consultations concerning financial and accounting matters not classified as audit services.
- (3) Tax fees consists of fees incurred for tax compliance, tax advice and tax planning and includes fees for tax return preparation and tax consulting.

The aggregate fees included in the Audit Fees are billed for the fiscal year. The aggregate fees included in the Audit-related fees and Tax Fees are fees billed in the fiscal year.

All such accountant services and fees were pre-approved by our audit committee in accordance with the "Pre-Approval Policies and Procedures" described below.



## Pre-approval policies and procedures

The audit committee of our board of directors has adopted policies and procedures for the pre-approval of audit and non-audit services for the purpose of maintaining the independence of our independent auditor. We may not engage our independent auditor to render any audit or non-audit service unless either the service is approved in advance by the audit committee, or the engagement to render the service is entered into pursuant to the audit committee's pre-approval policies and procedures.

## ITEM 15. EXHIBITS

### EXHIBIT INDEX

- 3.1 [Constitution of Strongbridge Biopharma plc \(incorporated by reference to Exhibit 3.1 to the Form F-1/A \(No. 333-206654\) filed September 9, 2015\)](#)
- 3.2 [Articles of Association of Strongbridge Biopharma plc \(incorporated by reference to Exhibit 3.2 to the Form F-1/A \(No. 333-206654\) filed September 9, 2015\)](#)
- 10.1 [Sublease Agreement, dated March 30, 2015, by and between Insight Pharmaceuticals LLC and Cortendo AB \(incorporated by reference to Exhibit 10.1 to the Form F-1 \(No. 333-206654\) filed August 28, 2015\)](#)
- 10.2\* [Lease, dated November 21, 2017, by and between Northbrook TC Equities LLC, et. al. as Landlord, and Strongbridge U.S. Inc., as Tenant](#)
- 10.3 [Securities Purchase Agreement, dated December 22, 2016, by and among Strongbridge Biopharma plc and the several purchasers signatory thereto \(incorporated by reference to Exhibit 10.1 to the Form 6-K \(File No. 001-37569\) filed December 23, 2016\)](#)
- 10.4 [Asset Purchase Agreement, dated as of May 14, 2015, by and among Cortendo AB, and Aspireo Pharmaceuticals, Ltd. and TVM V Life Science Ventures GmbH & Co. KG \(incorporated by reference to Exhibit 10.3 to the Form F-1 \(No. 333-206654\) filed August 28, 2015\)](#)
- 10.5† [Asset Purchase Agreement, dated December 12, 2016, between Taro Pharmaceutical North America, Inc. and Strongbridge plc \(incorporated by reference to Exhibit 10.3 to the Form F-3 \(No. 333-215531\) filed January 12, 2017\)](#)
- 10.6† [Supply Agreement, dated December 12, 2016, between Taro Pharmaceutical North America, Inc. and Strongbridge plc \(incorporated by reference to Exhibit 10.4 to the Form F-3 \(No. 333-215531\) filed January 12, 2017\)](#)
- 10.7\* [Amended and Restated Employment Agreement, dated as of October 13, 2017, by and between Strongbridge U.S. Inc. and Matthew Pauls](#)
- 10.8\* [Form of Amended and Restated Employment Agreement, dated as of October 13, 2017, by and between Strongbridge U.S. Inc. and certain of its executive officers](#)
- 10.9 [Share Purchase Agreement, dated as of January 12, 2015, by and among Cortendo AB, BioPancreate Inc., Cortendo Invest AB and the Investors listed therein \(incorporated by reference to Exhibit 10.10 to the Company's Form F-1 \(No. 333-206654\) filed August 28, 2015\)](#)
- 10.10 [Investors' Rights Agreement, dated as of February 10, 2015, by and among Cortendo AB and the Investors listed therein \(incorporated by reference to Exhibit 10.11 to the Company's Form F-1 \(No. 333-206654\) filed August 28, 2015\)](#)
- 10.11 [Share Purchase Agreement, dated as of May 14, 2015, by and among Cortendo AB, BioPancreate Inc., Cortendo Invest AB and the Investors named therein \(incorporated by reference to Exhibit 10.12 to the Company's Form F-1 \(No. 333-206654\) filed August 28, 2015\)](#)
- 10.12 [Form of Indemnification Agreement \(incorporated by reference to Exhibit 10.13 to the Company's Form F-1/A \(No. 333-206654\) filed September 25, 2015\)](#)
- 10.13\* [Strongbridge Biopharma plc 2015 Equity Compensation Plan](#)
- 10.14\* [Strongbridge Biopharma plc Non-Employee Director Equity Compensation Plan](#)
- 10.15\* [Strongbridge Biopharma plc 2017 Inducement Plan](#)
- 10.16\* [Form of Incentive Stock Option Award Agreement under the Strongbridge Biopharma plc 2015 Equity Compensation Plan](#)

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10.17*	<a href="#">Form of Nonqualified Stock Option Award Agreement under the Strongbridge Biopharma plc 2015 Equity Compensation Plan</a>
10.18*	<a href="#">Form of Restricted Stock Unit Award Agreement under the Strongbridge Biopharma plc 2015 Equity Compensation</a>
10.19*	<a href="#">Form of Nonqualified Stock Option Award Agreement under the Strongbridge Biopharma plc Non-Employee Director Equity Compensation Plan (incorporated by reference to Exhibit 10.16 to the Company's Form 20-F (File No. 001-37569) filed March 24, 2016)</a>
10.20*	<a href="#">Form of Stock Option Award Agreement under the Strongbridge Biopharma plc 2017 Inducement Plan</a>
10.21*	<a href="#">Form of Restricted Stock Unit Award Agreement under the Strongbridge Biopharma plc 2017 Inducement Plan</a>
10.22	<a href="#">Form of Warrant Securities Agreement, by and among Strongbridge Biopharma plc and the several purchasers signatory thereto (incorporated by reference to Exhibit 10.3 to the Company's Form 6-K (File No. 001-37569) filed December 23, 2016)</a>
10.23	<a href="#">Form of Warrant Securities Agreement, by and among Oxford Finance LLC, Horizon Technology Finance Corporation, the other Lenders listed therein, and Strongbridge Biopharma plc, Cortendo Cayman Ltd, Cortendo AB (publ) and Strongbridge U.S. Inc. (incorporated by reference to Exhibit 10.20 to the Form 20-F (File No. 001-37569) filed April 4, 2017)</a>
10.24†	<a href="#">Term Loan Agreement, dated as of July 14, 2017, by and among Strongbridge U.S. Inc., Strongbridge Biopharma plc, Cortendo AB (publ), Cortendo Cayman Ltd., CRG Servicing LLC, as administrative agent and collateral agent, and the lenders named therein (incorporated by reference to Exhibit 10.1 to the Report on Form 6-K (File No. 001-37569) filed on July 17, 2017)</a>
10.25	<a href="#">Securities Purchase Agreement, dated as of July 14, 2017, by and among Strongbridge Biopharma plc, CRG Partners III L.P., CRG Partners III — Parallel Fund "A" L.P., CRG Partners III — Parallel Fund "B" (Cayman) L.P., CRG Partners III (Cayman) Lev AIV I L.P. and CRG Partners III (Cayman) Unlev AIV I L.P. (incorporated by reference to Exhibit 10.2 to the Report on Form 6-K (File No. 001-37569) filed on July 17, 2017)</a>
10.26	<a href="#">Form of Warrant to CR Group Lenders, dated July 14, 2017 (incorporated by reference to Exhibit 10.3 to the Report on Form 6-K (File No. 001-37569) filed on July 17, 2017)</a>
10.27	<a href="#">Amendment No. 1 to Securities Purchase Agreement, dated as of December 22, 2016, by and between Strongbridge Biopharma plc and the purchasers named therein (incorporated by reference to Exhibit 10.4 to the Report on Form 6-K (File No. 001-37569) filed on July 17, 2017)</a>
10.28*	<a href="#">License and Assignment Agreement, dated January 16, 2018, by and between Aetema Zentaris GmbH and Strongbridge Ireland Limited</a>
10.29*††	<a href="#">Amendment No. 1 to Term Loan Agreement, dated January 16, 2018, by and among Strongbridge U.S. Inc., Strongbridge Biopharma plc, Cortendo Cayman Ltd., Strongbridge Ireland Limited, Cortendo AB (Publ), CRG Servicing LLC, as administrative agent and collateral agent, and the lenders listed therein</a>
10.30*	<a href="#">Form of Warrant to CR Group Lenders, dated January 16, 2018</a>
21.1*	<a href="#">Subsidiaries of the Company</a>
23.1*	<a href="#">Consent of Ernst &amp; Young LLP</a>
31.1*	<a href="#">Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
31.2*	<a href="#">Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
32.1*	<a href="#">Certification of Chief Executive Officer and Chief Financial Officer pursuant to Exchange Act Rules 13a-14(b) and 15d-14(b) and 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definitions Linkbase Document

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\* Filed herewith.

† Confidential treatment granted as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

†† Portions of the exhibit are omitted pursuant to a confidential treatment request with the U.S. Securities and Exchange commission.

**ITEM 16. FORM 10-K SUMMARY**

None.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**STRONGBRIDGE BIOPHARMA PLC**

By: /s/ Matthew Pauls

Name: Matthew Pauls  
Title: *Chief Executive Officer and Director*

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Matthew Pauls and A. Brian Davis, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this report has been signed by the following persons on the dates and in the capacities indicated below:

<u>NAME</u>	<u>TITLE</u>	<u>DATE</u>
<u>/s/ Matthew Pauls</u> Matthew Pauls	President and Chief Executive Officer (principal executive officer) and Director	March 12, 2018
<u>/s/ A. Brian Davis</u> A. Brian Davis	Chief Financial Officer (principal financial officer and principal accounting officer) and authorized representative in the United States	March 12, 2018
<u>/s/ John H. Johnson</u> John H. Johnson	Chairman, Director	March 12, 2018
<u>/s/ Richard Kollender</u> Richard S. Kollender	Director	March 12, 2018
<u>/s/ Garheng Kong</u> Garheng Kong	Director	March 12, 2018

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<u>/s/ Jeffrey Sherman</u>	Director	March 12, 2018
Jeffrey Sherman		
<u>/s/ Marten Steen</u>	Director	March 12, 2018
Marten Steen		
<u>/s/ Hilde Steineger</u>	Director	March 12, 2018
Hilde Steineger		

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## **Report of Independent Registered Public Accounting Firm**

**To the Board of Directors and Shareholders of Strongbridge Biopharma plc**

### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Strongbridge Biopharma Plc. (the Company) as of December 31, 2017 and 2016, the related consolidated statements of operations and comprehensive loss, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2015.

Philadelphia, Pennsylvania

March 12, 2018



**STRONGBRIDGE BIOPHARMA plc**  
**Consolidated Balance Sheets**  
(In thousands, except share and per share data)

	December 31, 2017	December 31, 2016
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 57,510	\$ 66,837
Accounts receivable	1,584	—
Inventory	511	—
Prepaid expenses and other current assets	1,208	764
Total current assets	60,813	67,601
Property and equipment, net	15	25
Deferred tax asset	—	1,599
Intangible assets, net	35,155	60,900
Goodwill	7,256	7,256
Other assets	686	150
Total assets	<u>\$ 103,925</u>	<u>\$ 137,531</u>
<b>LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,247	\$ 1,089
Accrued liabilities	11,232	14,868
Total current liabilities	12,479	15,957
Long-term debt	37,794	18,434
Warrant liability	41,308	11,090
Supply agreement liability, noncurrent	24,258	25,078
Total liabilities	115,839	70,559
Commitments and contingencies (Note 9)		
Stockholders' (deficit) equity:		
Deferred shares, \$1.098 par value, 40,000 shares authorized, issued and outstanding at December 31, 2017 and December 31, 2016	44	44
Ordinary shares, \$0.01 par value, 600,000,000 shares authorized at December 31, 2017 and December 31, 2016; 40,149,812 and 35,335,026 shares issued and outstanding at December 31, 2017 and December 31, 2016	401	353
Additional paid-in capital	230,524	195,975
Accumulated deficit	(242,883)	(129,400)
Total stockholders' (deficit) equity	(11,914)	66,972
Total liabilities and stockholders' (deficit) equity	<u>\$ 103,925</u>	<u>\$ 137,531</u>

**The accompanying notes are an integral part of these consolidated financial statements.**

**STRONGBRIDGE BIOPHARMA plc**  
**Consolidated Statements of Operations and Comprehensive Loss**  
(In thousands, except share and per share data)

	Year Ended December 31		
	2017	2016	2015
<b>Revenues:</b>			
Net product sales	\$ 7,046	\$ —	\$ —
<b>Total revenues</b>	<b>7,046</b>	<b>—</b>	<b>—</b>
<b>Cost and expenses:</b>			
Cost of sales (excluding amortization of intangible asset)	\$ 1,483	\$ —	\$ —
Selling, general and administrative	36,292	14,875	22,719
Research and development	17,268	20,023	20,135
Amortization of intangible asset	5,022	—	—
Impairment of intangible assets	20,723	15,828	—
<b>Total cost and expenses</b>	<b>80,788</b>	<b>50,726</b>	<b>42,854</b>
Operating loss	(73,742)	(50,726)	(42,854)
<b>Other income (expense), net:</b>			
Unrealized (loss) gain on fair value of warrants	(30,218)	638	—
Interest expense	(4,313)	(20)	—
Foreign exchange loss	(41)	(69)	(124)
Loss on early extinguishment of debt	(3,545)	—	—
Other income (expense), net	147	(1,180)	(1,105)
<b>Total other income (expense), net</b>	<b>(37,970)</b>	<b>(631)</b>	<b>(1,229)</b>
Loss before income taxes	(111,712)	(51,357)	(44,083)
Income tax (expense) benefit	(1,771)	2,638	450
Net loss	(113,483)	(48,719)	(43,633)
Net loss attributable to non-controlling interest	—	122	53
<b>Net loss attributable to Strongbridge Biopharma</b>	<b>\$ (113,483)</b>	<b>\$ (48,597)</b>	<b>\$ (43,580)</b>
<b>Net loss attributable to ordinary shareholders:</b>			
Basic	\$ (113,483)	\$ (48,597)	\$ (43,580)
Diluted	\$ (113,483)	\$ (49,236)	\$ (43,580)
<b>Net loss per share attributable to ordinary shareholders:</b>			
Basic	\$ (3.11)	\$ (2.26)	\$ (2.62)
Diluted	\$ (3.11)	\$ (2.27)	\$ (2.62)
<b>Weighted-average shares used in computing net loss per share attributable to ordinary shareholders:</b>			
Basic	36,544,825	21,550,353	16,606,669
Diluted	36,544,825	21,655,564	16,606,669

**The accompanying notes are an integral part of these consolidated financial statements.**

**STRONGBRIDGE BIOPHARMA plc**  
**Consolidated Statements of Shareholders' Equity**  
(In thousands except share amounts)

	Ordinary Shares		Deferred Shares		Additional Paid-In Capital	Accumulated Deficit	Non- Controlling Interest	Total Shareholders' Equity
	Shares	Amount	Shares	Amount				
Balance—December 31, 2014	9,700,789	97	—	—	55,947	(37,223)	—	18,821
Net loss	—	—	—	—	—	(43,580)	(53)	(43,633)
Stock-based compensation	—	—	—	—	3,581	—	—	3,581
Reclass of stock-based liability award to equity	—	—	—	—	1,542	—	—	1,542
Issuance of shares	9,108,169	91	—	—	91,418	—	—	91,509
U.S. non-accredited shares repurchased	(24,955)	—	—	—	(412)	—	—	(412)
Issuance of shares in initial public offering, net	2,500,000	25	—	—	19,450	—	—	19,475
Non-controlling interest resulting from exchange offer	(78,621)	(1)	—	—	(616)	—	617	—
Beneficial shares issued	—	—	40,000	\$ 44	—	—	—	44
Balance—December 31, 2015	21,205,382	\$ 212	40,000	\$ 44	\$ 170,910	\$ (80,803)	\$ 564	\$ 90,927
Net loss	—	—	—	—	—	(48,597)	(122)	(48,719)
Stock-based compensation	—	—	—	—	4,606	—	—	4,606
Acquisition of non-controlling interest	—	—	—	—	(972)	—	(442)	(1,414)
Issuance of shares, net of offering costs	14,000,000	140	—	—	20,430	—	—	20,570
Exercise of stock options	129,644	1	—	—	119	—	—	120
Issuance of warrants related to the loan agreement	—	—	—	—	882	—	—	882
Balance—December 31, 2016	35,335,026	\$ 353	40,000	\$ 44	\$ 195,975	\$ (129,400)	\$ —	\$ 66,972
Net loss	—	—	—	—	—	(113,483)	—	(113,483)
Stock-based compensation	—	—	—	—	5,167	—	—	5,167
Issuance of shares, net of offering costs	4,429,799	44	—	—	26,340	—	—	26,384
Issuance of shares in connection with at-the-market facility, net of costs	10,300	*	—	—	73	—	—	73
Exercise of stock options	196,081	2	—	—	624	—	—	626
Exercise of warrants	178,606	2	—	—	(2)	—	—	—
Issuance of warrants related to loan agreements, net	—	—	—	—	2,347	—	—	2,347
Balance—December 31, 2017	40,149,812	\$ 401	40,000	\$ 44	\$ 230,524	\$ (242,883)	\$ —	\$ (11,914)

\* Represents an amount less than \$1.

**The accompanying notes are an integral part of these consolidated financial statements.**

**STRONGBRIDGE BIOPHARMA plc**  
**Consolidated Statements of Cash Flow**  
(In thousands)

	Year Ended December 31,		
	2017	2016	2015
<b>Cash flows from operating activities:</b>			
Net loss	\$ (113,483)	\$ (48,719)	\$ (43,633)
Adjustments to reconcile net loss to net cash used in operating activities:			
Change in fair value of warrant liability	30,218	(638)	—
Impairment of intangible assets	20,723	15,828	—
Stock-based compensation	5,167	4,606	3,940
Amortization of intangible asset	5,022	—	—
Loss on early extinguishment of debt	3,545	—	—
Interest paid in kind	896	—	—
Amortization of debt discounts and debt issuance costs	482	—	—
Deferred income tax expense (benefit)	1,958	(2,884)	(450)
Depreciation	10	10	11
Impairment/loss on investment in Antisense Therapeutics	—	550	551
Change in fair value of foreign currency forward contracts	—	—	438
Changes in operating assets and liabilities:			
Accounts receivable	(1,584)	—	—
Inventory	(511)	—	—
Prepaid expenses and other current assets	(444)	848	(1,165)
Other assets	(536)	(88)	(52)
Accounts payable	158	(1,702)	1,737
Accrued liabilities and other liabilities	3,043	475	1,263
Net cash used in operating activities	<u>(45,336)</u>	<u>(31,714)</u>	<u>(37,360)</u>
<b>Cash flows from investing activities:</b>			
Payment for acquisition	(7,500)	(3,392)	(3,168)
Investment in Antisense Therapeutics	—	—	(1,101)
Purchase of equipment	—	—	(25)
Net cash used in investing activities	<u>(7,500)</u>	<u>(3,392)</u>	<u>(4,294)</u>
<b>Cash flows from financing activities:</b>			
Proceeds from long-term debt	38,687	19,316	—
Repayment of long-term debt	(22,261)	—	—
Proceeds from issuance of ordinary shares and warrants, net	26,384	32,298	77,816
Proceeds from exercise of stock options	626	120	—
Proceeds from issuance of ordinary shares in connection with at-the-market offering	73	—	—
Acquisition of non-controlling interest	—	(1,414)	(412)
Net cash provided by financing activities	<u>43,509</u>	<u>50,320</u>	<u>77,404</u>
Effect of exchange rate changes on cash and cash equivalents	—	—	241
Net decrease in cash and cash equivalents	(9,327)	15,214	35,991
Cash and cash equivalents—beginning of period	66,837	51,623	15,632
Cash and cash equivalents—end of period	<u>\$ 57,510</u>	<u>\$ 66,837</u>	<u>\$ 51,623</u>
Supplemental disclosures of cash flow information			
Cash paid during the year for:			
Interest	\$ 2,935	\$ 20	—
Income taxes other, net of refunds	<u>\$ 127</u>	<u>\$ —</u>	<u>\$ —</u>

**The accompanying notes are an integral part of these consolidated financial statements.**

**STRONGBRIDGE BIOPHARMA plc**  
**Notes to Consolidated Financial Statements**

**1. Organization**

Strongbridge Biopharma plc is a global commercial-stage biopharmaceutical company focused on the development and commercialization of therapies for rare diseases with significant unmet needs. Our first commercial product is Keveyis® (dichlorphenamide), the first and only treatment approved by the U.S. Food and Drug Administration ("FDA") for hyperkalemic, hypokalemic, and related variants of primary periodic paralysis. Keveyis has orphan drug exclusivity status in the United States through August 7, 2022.

On January 16, 2018, we acquired the U.S. and Canadian rights to Macrilen (macimorelin), our second commercial product, from Aeterna Zentaris GmbH. Macrilen is an oral growth hormone secretagogue receptor agonist, and is the first and only oral drug approved by the FDA for the diagnosis of patients with AGHD. Macrilen has been granted orphan drug designation in the United States and has patents with expiration dates through late 2027. We expect to launch Macrilen in the United States in mid-2018.

In addition to our two commercial products, we have two clinical-stage product candidates for rare endocrine diseases, Recorlev and veldoreotide. Recorlev (levoketoconazole) is a cortisol synthesis inhibitor currently being studied for the treatment of endogenous Cushing's syndrome. Veldoreotide is a next-generation somatostatin analog being investigated for the treatment of acromegaly and potential additional applications in other conditions amenable to somatostatin receptor activation. Both Recorlev and veldoreotide have received orphan designation from the FDA and the European Medicines Agency ("EMA").

Given the well-identified and concentrated prescriber base addressing our target markets, we intend to continue to use a small, focused sales force to market Keveyis, Macrilen and any future products, in the United States, the European Union and other key global markets. We believe that our ability to execute on our strategy is enhanced by the significant commercial and clinical development experience of key members of our management team.

We will continue to identify and evaluate the potential acquisition of other products and product candidates that would be complementary to our existing rare neuromuscular and endocrine franchises or that would form the basis for new rare disease franchises. We believe this approach will enable us to maximize our commercial potential by further leveraging our existing resources and expertise.

In October 2015 we sold 2,500,000 ordinary shares in our initial U.S. public offering (IPO) at a price of \$10.00 per share. The aggregate net proceeds received by us from the IPO were \$19.5 million. Our shares began trading on The NASDAQ Global Select Market under the symbol "SBBP" on October 16, 2015. On October 20, 2015, trading ceased on the Norwegian Over-The-Counter Market.

*Exchange offer*

On May 26, 2015, Strongbridge Biopharma plc (then named Cortendo plc) was incorporated under the laws of Ireland.

On August 7, 2015, Strongbridge Biopharma plc initiated an exchange offer for the outstanding shares of Cortendo AB. The exchange offer was structured as a one-for-one exchange offer in which shareholders of Cortendo AB exchanged their common shares, with a par value of \$0.15, for beneficial interests in ordinary shares of Strongbridge Biopharma plc, with a par value of \$0.01, in the form of Norwegian depository receipts and, as the case may be, Swedish depository receipts (except for non-accredited investors who hold Cortendo AB shares located in the United States, who were offered cash in an amount equivalent to the value of the Strongbridge Biopharma plc shares such investors would otherwise receive for their Cortendo AB shares exchanged).

The exchange offer was settled on September 8, 2015, and Cortendo AB became a subsidiary with 99.582% of its shares being owned by Strongbridge Biopharma plc. Accordingly, Strongbridge Biopharma plc is a continuation of

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Cortendo AB, the predecessor, and the consolidated financial statements represent the assets, liabilities and results of operations of Cortendo AB, for all periods presented.

On September 8, 2015, Strongbridge Biopharma plc effected a 1-for-11 reverse stock split of its ordinary shares. Accordingly, the consolidated financial statements and notes retroactively reflect the capital structure of Strongbridge Biopharma plc after giving effect to the exchange offer and the reverse stock split. With affect from September 8, 2015, the 0.418% of Cortendo AB not owned by Strongbridge Biopharma plc, is accounted for as a non-controlling interest. In September 2016, we acquired the non-controlling interest in Cortendo AB, after which Cortendo AB became a wholly-owned subsidiary of Strongbridge Biopharma plc. Total consideration paid per share was \$13.66 resulting in an aggregate payment of \$1.4 million.

### ***Liquidity***

We believe that our cash resources of \$57.5 million at December 31, 2017 along with the completed subsequent financings from January and February 2018, will be sufficient to allow us to fund planned operations for at least 12 months beyond the issuance date of these financial statements, which is after the expected receipt of data from the Recorlev SONICS and LOGICS Phase 3 clinical trials. We expect our funding requirements for operating activities to increase in 2018 and possibly beyond due to expenses associated with the commercialization of Keveyis and Macrilen, the execution of the Phase 3 SONICS and LOGICS clinical trials for Recorlev, and selling, general and administrative expenses. We also expect our cash needs to increase to fund potential in-licenses, acquisitions or similar transactions as we pursue our strategy. These expenses may be offset only in part by sales of Keveyis and Macrilen. In addition, beginning in September 2020, we may be required to make quarterly principal payments to repay amounts borrowed under our credit facility.

In January 2018, we amended our loan agreement with CRG to increase availability from \$50 million to \$100 million. In January 2018 and February 2018, we sold 5,255,683 of our ordinary shares for net proceeds of approximately \$33.0 million (see Note 15).

We may never achieve profitability, and unless and until we do, we will continue to need to raise additional capital. We plan to continue to fund our operations and capital funding needs through equity or debt financing along with revenues from Keveyis and Macrilen. There can be no assurances, however, that additional funding will be available on terms acceptable to us.

Our loan and security agreement, under which outstanding borrowings were \$40.0 million at December 31, 2017 contains financial and non-financial covenants including minimum amounts of net revenue in 2018 and beyond. We achieved our 2017 financial covenant. Failure to comply with the covenants could result in the lenders declaring the loan immediately due and payable. Our liquidity requirements are predicated on maintaining compliance with the debt covenants and repaying outstanding borrowings in accordance with the loan term (see Note 7).

## **2. Summary of significant accounting policies and basis of presentation**

### ***Basis of presentation and principles of consolidation***

The accompanying consolidated financial statements include the accounts of our wholly owned subsidiaries, Strongbridge US Inc. (Trevose, Pennsylvania, United States), Strongbridge Ireland Limited (Dublin, Ireland), Cortendo AB (Gothenburg, Sweden) and Cortendo Cayman (Georgetown, Cayman Islands). All intercompany balances and transactions have been eliminated in consolidation. These audited consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States (U.S. GAAP). Any reference in these

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notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB).

### ***Revenue recognition***

Prior to the April 2017 launch of Keveyis, we did not generate any revenue. Therefore, we adopted Accounting Standards Codification (ASC), Topic 606, *Revenue from Contracts with Customers*, effective April 1, 2017. Topic 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We apply the five-step model to contracts only when it is probable that we will collect the consideration we are entitled to receive in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for net product revenue, (see Note 3).

### ***Inventory and cost of sales***

Inventory is stated at the lower of cost or market where cost is determined using the first-in, first-out method. Our inventory consists of only finished goods.

Cost of sales includes the cost of inventory sold, which includes third-party acquisition costs, third-party warehousing and product distribution charges.

### ***Foreign currency translation***

The consolidated financial statements are reported in United States dollars, which is the functional currency of our subsidiaries and Cortendo AB. Transactions in foreign currencies are remeasured into our functional currency at the rate of exchange prevailing at the date of the transaction. Any monetary assets and liabilities arising from these transactions are remeasured into our functional currency at exchange rates prevailing at the balance sheet date or on settlement. Resulting gains and losses are recorded in foreign exchange loss in our consolidated statements of operations.

### ***Use of estimates***

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. We must apply significant judgment in this process. Actual results could materially differ from those estimates.

### ***Segment information***

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions on how to allocate resources and assess performance. We view our operations and manage our business in one operating segment. Our material long-lived assets, reside in Ireland, Sweden and Cayman Islands. For the year ended December 31, 2017, revenue from product sales were derived entirely from the United States.



***Cash and cash equivalents***

We consider all short-term highly liquid investments with an original maturity at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents consist of account balances at banks and money market accounts, respectively.

***Concentration of credit risk and other risks and uncertainties***

As part of our cash and investment management processes, we perform periodic evaluations of the credit standing of the financial institutions with which we deposit our cash or purchase cash equivalents, and we have not sustained any credit losses from instruments held at these financial institutions.

***Fair value of financial instruments***

Fair value accounting is applied for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually).

We are required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, Fair Value Measurements and Disclosures (ASC 820), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of us. Unobservable inputs are inputs that reflect our assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described as follows:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that we have the ability to access at the measurement date.

Level 2—Valuations based on quoted prices for similar assets or liabilities, or quoted prices in markets that are not active, and for which all significant inputs are observable, either directly or indirectly.

Level 3—Valuations that require inputs that reflect our own assumptions that are both significant to the fair value measurement and unobservable. To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment we exercise in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

In December 2016, we issued warrants in connection with our private placement of ordinary shares. Pursuant to the terms of the warrant agreement, the Company could be required to settle the warrants in cash in the event of an acquisition of the Company and, as a result, the warrants are required to be measured at fair value and reported as a liability in the consolidated balance sheet. We recorded the fair value of the warrants upon issuance using the Black-Scholes Model and are required to revalue the warrants at each reporting date with any changes in fair value recorded on our statement of operations. The valuation of the warrants is considered under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. The change in the fair value of the Level 3 warrant liabilities is reflected in the statement of operations and comprehensive loss for the years ended December 31, 2017 and 2016.

***Property and equipment, net***

Property and equipment, net, consists of office equipment such as furniture, fixtures and computers. Depreciation expense for the years ended December 31, 2017 and 2016 was not significant. The following useful lives were used for the various classifications of property and equipment, net:

	<b>Amortization Periods</b>
Computer hardware	3 - 5 years
Computer software	2 - 5 years
Furniture and fixtures	2 - 5 years

***Business combinations***

When acquiring new enterprises over which we obtain control, the acquisition method is applied. Under this method, we identify assets and liabilities of these enterprises and measure them at fair value at the acquisition date. Allowance is made for the tax effect of the adjustments made.

The excess of the consideration transferred, the amount of the non-controlling interest in the acquiree and the acquisition date fair value of previous equity interest in the acquiree over the fair value of the identifiable net assets acquired is recorded as goodwill.

***Intangible assets***

Certain intangible assets were acquired as part of an asset purchase and have been capitalized at their acquisition date fair value. Acquired definite life intangible assets are amortized using the straight line method over their respective estimated useful lives. The Company evaluates the potential impairment of intangible assets if events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate.

Purchased identifiable intangible assets with indefinite lives are evaluated for impairment annually in accordance with our policy and whenever events or changes in circumstances indicate that it is more likely than not that the fair value of these assets may not be recovered.

To test these assets for impairment, we compare the fair value of the asset to its carrying value. The method we use to estimate the fair value measurements of indefinite-lived intangible assets is based on the income approach. For the impairment analysis for the year ended December 31, 2017, significant unobservable inputs used in the income approach valuation method including discount rates, royalty rates and probabilities of product candidate advancement from one clinical trial phase to the next. The determination of fair value of indefinite lived assets is considered Level 3 for fair value measurement.

***Goodwill***

We test goodwill for impairment on an annual basis or whenever events occur that may indicate possible impairment. This analysis requires us to make a series of critical assumptions to (1) evaluate whether any impairment exists and (2) measure the amount of impairment.

Because we have one operating segment, when testing for a potential impairment of goodwill, we are required to estimate the fair value of our business and determine the carrying value. If the estimated fair value is less than the carrying value of our business, then we are required to estimate the fair value of all identifiable assets and liabilities in a manner similar to a purchase price allocation for an acquired business. Only after this process is completed can the goodwill impairment be determined, if any.

To estimate the fair value of the business, primarily a market-based approach is applied, utilizing our public market value. We did not record a charge for impairment for our goodwill for the years ended December 31, 2017, 2016 and 2015.

***Research and development expenses***

Research and development costs are expensed as incurred. Research and development expenses consist of internal and external expenses. Internal expenses include compensation and related expenses. External expenses include development, clinical trials, report writing and regulatory compliance costs incurred with clinical research organizations and other third-party vendors. At the end of the reporting period, we compare payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that we estimate has been made as a result of the service provided, we may record net prepaid or accrued expense relating to these costs. Upfront and milestone payments made to third parties who perform research and development services on our behalf are expensed as services are rendered.

***Stock-based compensation***

We account for stock-based compensation awards in accordance with FASB ASC Topic 718, Compensation—Stock Compensation (ASC 718). ASC 718 requires all stock-based payments including grants of stock options and restricted stock and modifications to existing stock options, to be recognized in the consolidated statements of operations based on their fair values.

Our stock-based awards are subject to either service-based or performance-based vesting conditions. Vesting of certain awards could also be accelerated upon achievement of defined market-based vesting conditions. Certain awards also contain a combination of service and market conditions or performance and market conditions.

We record compensation expense for service-based awards over the vesting period of the award on a straight-line basis. Compensation expense related to awards with performance-based vesting conditions is recognized over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. For those awards in which the performance condition was the completion of our IPO, we did not recognize compensation expense until the close of the IPO as we did not deem the IPO probable until it occurred.

Compensation expense for awards with service and market-based vesting conditions is recognized using the accelerated attribution method over the shorter of the requisite service period or the implied period associated with achievement of the market-based vesting provisions.

We estimate the fair value of our awards with service conditions using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of historical and implied volatility data of our common stock, we based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. We selected companies with comparable characteristics to us, including enterprise value, risk profiles and position within the industry, and with historical share price information sufficient to meet the expected term of the stock-based awards. We compute historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards.

We estimate the fair value of our awards with market conditions using a Monte Carlo simulation to determine the probability of satisfying the market condition. We make this estimate using the conditions that exist at the grant date. The derived service period, which may be the requisite service period, is also determined at this time. Compensation cost for our awards with a market condition is recognized ratably using the accelerated attribution method if the award is subject to graded vesting over the requisite service period. The compensation cost for our awards with a market condition is not reversed if the market condition is not satisfied.

We have estimated the expected term of employee service-based stock options using the "simplified" method, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option, due to our lack of sufficient historical data. We have estimated the expected term of employee awards with market conditions using a Monte-Carlo simulation model. This approach involves generating random stock-price paths

through a lattice-type structure. Each path results in a certain financial outcome, such as accelerated vesting or specific option payout. We have estimated the expected term of nonemployee service- and performance-based awards based on the remaining contractual term of such awards.

The risk-free interest rates for periods within the expected term of the option are based on the Swedish Government Bond rate or the U.S. Treasury Bond rate with a maturity date commensurate with the expected term of the associated award. We have never paid dividends and do not expect to pay dividends in the foreseeable future.

We account for forfeitures as they occur.

### ***Income taxes***

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act makes broad and complex changes to the U.S. tax code, including, but not limited to, reducing the top U.S. federal corporate tax rate from 35 percent to 21 percent; requiring companies to pay a one-time transition tax on certain un-repatriated earnings of foreign subsidiaries; generally eliminating U.S. federal income taxes on dividends from foreign subsidiaries; requiring a current inclusion in U.S. federal taxable income of certain earnings of controlled foreign corporations; eliminating the corporate alternative minimum tax (AMT) and changing how existing AMT credits can be realized; creating the base erosion anti-abuse tax (BEAT), a new minimum tax; creating a new limitation on deductible interest expense; and changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017.

The Tax Act reduces our U.S. corporate income tax rate from 34% to 21%, effective January 1, 2018. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. As a result of the reduction in the U.S. corporate income tax rate from 34% to 21% under the Tax Act, we revalued our ending net deferred tax assets and liabilities at December 31, 2017.

The Tax Act provided for a one-time transition tax on the deemed repatriation of post-1986 undistributed foreign subsidiary earnings and profits ("E&P"). Strongbridge did not have to recognize any income tax expense related to the transition tax as they own no controlled foreign corporations.

The global intangible low-taxed income tax and base erosion provisions are effective for taxable years beginning after December 31, 2017. The Company does not currently expect these provisions to have a material impact on its tax rate as they do not own any controlled foreign corporations and they are currently below the gross receipts threshold for purposes of the base erosion provisions.

Due to the timing of the new tax law and the substantial changes it brings, the Staff of the Securities and Exchange Commission (the "SEC") issued Staff Accounting Bulletin No. 118 ("SAB 118"), which provides registrants a measurement period to report the impact of the new US tax law. During the measurement period, provisional amounts for the effects of the law are recorded to the extent a reasonable estimate can be made. To the extent that all information necessary is not available, prepared or analyzed, companies may recognize provisional estimated amounts for a period of up to one year following enactment of the TCJA. The Company recorded amounts as provisional and will continue to monitor for future updates to guidance or interpretations issued by the IRS.

We recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2017, 2016 and 2015, we had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in our statements of operations.

### ***Net loss per share***

Basic net loss per share is calculated by dividing the net loss attributable to shareholders by the weighted average number of ordinary shares outstanding during the period. Diluted net loss per share is calculated by dividing the net loss attributable to shareholders by the weighted-average number of ordinary shares outstanding for the period, including any dilutive effect from outstanding stock options or other equity-based awards. Shares used in the diluted net

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loss per share calculations exclude anti-dilutive ordinary share equivalents, which currently consist of outstanding stock options, unvested restricted stock units and warrants.

	Year Ended December 31,		
	2017	2016	2015
Warrants	7,555,003	7,000,000	—
Stock options issued and outstanding	6,104,715	3,249,784	2,591,520
Unvested restricted stock units	267,250	184,000	—

**Customer concentration**

For the year ended December 31, 2017, we sold Keveyis to one customer, who is the exclusive distributor of Keveyis in the United States.

**Recently issued accounting pronouncements**

In January 2017, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2017-04, *Intangibles - Goodwill and Other: Simplifying the Accounting for Goodwill Impairment*. ASU 2017-04 removes Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. A goodwill impairment will now be the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. This standard, which will be effective for the us beginning in the first quarter of fiscal year 2021, is required to be applied prospectively. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. We are currently evaluating the impact this new accounting guidance will have on our consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments*, which clarifies how certain cash receipts and cash payments are presented and classified in the statement of cash flows in order to reduce diversity in practice. The guidance is effective for us beginning in the first quarter of fiscal year 2018. Early adoption is permitted. We are currently evaluating the impact this new accounting guidance will have on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation - Improvements to Employee Share-Based Payment Accounting*, which affects all entities that issue share-based payment awards to their employees. The amendments in this ASU cover such areas as the recognition of excess tax benefits and deficiencies, the classification of those excess tax benefits on the statement of cash flows, an accounting policy election for forfeitures, the amount an employer can withhold to cover income taxes and still qualify for equity classification and the classification of those taxes paid on the statement of cash flows. This ASU is effective for annual and interim periods beginning after December 15, 2016. This guidance can be applied either prospectively, retrospectively or using a modified retrospective transition method. Early adoption is permitted. We have adopted the standard effective January 1, 2017 and have elected to account for forfeitures as they occur as opposed to estimating forfeitures. The adoption of this standard did not have a material impact on our financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, that discusses how an entity should account for lease assets and lease liabilities. The guidance specifies that an entity who is a lessee under lease agreements should recognize lease assets and lease liabilities for those leases classified as operating leases under previous FASB guidance. Accounting for leases by lessors is largely unchanged under the new guidance. The guidance is effective for us beginning in the first quarter of fiscal year 2019. Early adoption is permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. We are currently evaluating the impact this new accounting guidance will have on our consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, *Recognition and Measurement of Financial Assets and*

*Financial Liabilities*, that modifies certain aspects of the recognition, measurement, presentation, and disclosure of financial instruments. The accounting standard update is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, and early adoption is permitted. We are currently evaluating the impact this new accounting guidance will have on our consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*. ASU No. 2015-11 applies only to inventory for which cost is determined by methods other than last in, first-out and the retail inventory method, which includes inventory that is measured using first-in, first-out or average cost. Inventory within the scope of this standard is required to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. We adopted this standard on April 1, 2017. The adoption of this standard had no impact on the Company's consolidated financial statements, there was no accounting impact to previously issued financial statements based on our adoption.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*, which requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The new guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. We adopted this new standard on April 1, 2017 in conjunction with the launch of Keveyis. As we did not record revenue prior to adopting this standard, there was no accounting impact to previously issued financial statements based on our adoption of ASC Topic 606.

### **3. Revenue recognition**

#### ***Product revenue, net***

We sell Keveyis to one specialty pharmacy provider (the "Customer"), who is the exclusive distributor of Keveyis in the United States. The Customer subsequently resells Keveyis to patients, which are covered by payors that may provide for government-mandated or privately negotiated rebates with respect to the purchase of Keveyis.

#### ***Reserves for variable consideration***

Revenues from sales of Keveyis are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from rebates, co-pay assistance and other allowances that are offered between us and the patients' payors. There is no variable consideration reserve for returns as we do not accept returns of Keveyis. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the Customer) or a current liability (if the amount is payable to a party other than the Customer). Where appropriate, these estimates may take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. We reassess our estimates on an ongoing basis. If actual results in the future vary from our estimates, we will adjust our estimates. Any such adjustments would affect net product revenue and earnings in the period such variances become known.

*Trade discount:* We provide the Customer with a discount that is explicitly stated in our contract and is recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, we receive sales order management, data and distribution services from the Customer. To the extent, the services received are distinct from our sale of Keveyis to the Customer, these payments are classified in selling, general and administrative expenses in our consolidated statement of operations and comprehensive loss.

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*Funded Co-pay Assistance Program:* We contract with a third-party to manage the co-pay assistance program intended to provide financial assistance to qualified insured patients. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with Keveysis that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period. These payments are consideration payable to the customer and the related reserve is recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses on the consolidated balance sheet.

*Government rebates:* We are subject to discount obligations under state Medicaid programs and Medicare. We estimate our Medicaid and Medicare rebates based upon a range of possible outcomes that are probability-weighted for the estimated patient mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses on the consolidated balance sheet. For Medicaid, accruals are based on estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Center for Medicaid and Medicare Services. Effective January 1, 2011, manufacturers of pharmaceutical products are responsible for 50% of the patient's cost of branded prescription drugs related to the Medicare Part D Coverage Gap. In order to estimate the cost to us of this Medicare coverage gap responsibility, we estimate the number of patients in the prescription drug coverage gap for whom we will owe an additional liability under the Medicare Part D program. Our liability for these rebates consists of estimates of claims for the current quarter and estimated future claims that will be made for Keveysis that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

*Temporary Supply and Patient Assistance Programs:* We provide free Keveysis to uninsured patients who satisfy pre-established criteria for either the Temporary Supply Program or the Patient Assistance Program. Patients who meet the Temporary Supply Program eligibility criteria may receive a temporary supply of free Keveysis for no more than sixty days while we are determining the patient's third-party insurance, prescription drug benefit or other third-party coverage for Keveysis. The Patient Assistance Program provides free Keveysis for up to twelve months to patients that satisfy pre-established criteria for financial need. We do not recognize any revenue related to these free products and the associated costs are classified in selling, general and administrative expenses in our consolidated statements of operations and comprehensive loss.

#### 4. Fair value measurement

The following table sets forth the fair value measurements by level within the fair value hierarchy, that are measured on a recurring basis. Our level 3 instrument consist of the common stock warrant liability. The fair values of the outstanding warrants were measured using the Black-Scholes option-pricing model. Inputs used to determine estimated fair value of the warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. The significant unobservable inputs used in the fair value measurement of the warrant liabilities were the volatility rate and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement.

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis for the periods presented (in thousands):

	As of December 31, 2017			Total
	Level I	Level II	Level III	
Cash equivalents	57,024	—	—	57,024
Total assets	\$ 57,024	\$ —	\$ —	\$ 57,024
Warrant liability	—	—	41,308	41,308
Total liabilities	\$ —	\$ —	\$ 41,308	\$ 41,308



	As of December 31, 2016			
	Level I	Level II	Level III	Total
Warrant liability	—	—	11,090	11,090
Total liabilities	\$ —	\$ —	\$ 11,090	\$ 11,090

### 5. Intangible assets and goodwill

The gross carrying amount of in-process research and development, acquired developed product rights and goodwill is as follows (in thousands):

	As of December 31, 2017				
	Beginning of Period	Additions	Impairment	Amortization	End of Period
IPR&D	\$ 20,723	\$ —	\$ (20,723)	\$ —	\$ —
Acquired developed product rights	40,177	—	—	(5,022)	35,155
Goodwill	7,256	—	—	—	7,256
Total	\$ 68,156	\$ —	\$ (20,723)	\$ (5,022)	\$ 42,411

	As of December 31, 2016				
	Beginning of Period	Additions	Impairment	Amortization	End of Period
IPR&D	\$ 36,551	\$ —	\$ (15,828)	\$ —	\$ 20,723
Acquired developed product rights	—	40,177	—	—	40,177
Goodwill	7,256	—	—	—	7,256
Total	\$ 43,807	\$ 40,177	\$ (15,828)	\$ —	\$ 68,156

Estimated amortization of our acquired developed product rights intangible asset for the five years subsequent to December 31, 2017 is as follows (in thousands):

2018	\$ 5,022
2019	5,022
2020	5,022
2021	5,022
2022	5,022

Goodwill and in-process research and development resulted from our acquisition of BioPancreate and our 2015 acquisition of veldoreotide from Aspireo Pharmaceuticals, Ltd. In-process research and development is initially measured at its fair value and is not amortized until commercialization. Once commercialization occurs, in-process research and development will be amortized over its estimated useful life. We recorded \$20.7 million of impairment relating for our veldoreotide IPR&D during the year ended December 31, 2017. The significant inputs to the fair value measurement were future revenues expected to be generated, estimated costs to manufacture and appropriate risk adjusted discount rate. The impairment of veldoreotide is due to estimated increased development costs and longer time lines related to the development process; resulting in a decrease in the valuation of our intangible asset.

Our finite lived intangible asset consists of acquired developed product rights obtained from the asset acquisition of Keveyis (dichlorphenamide) from a subsidiary of Taro Pharmaceutical Industries Ltd. (“Taro”). In connection with the Asset Purchase and Supply Agreement we entered into with Taro Pharmaceutical Industries Ltd, we have paid Taro an upfront payment in two installments of \$1 million in December 2016 and \$7.5 million in March 2017. We concluded that the supply price payable by us exceeds fair value and, therefore, have used a discounted cash flow method with a probability assumption to value the payments in excess of fair value at \$29.3 million, for which we have recorded an intangible asset and corresponding liability. This liability will be amortized as we purchase inventory over the term of the agreement. In addition, we incurred transaction costs of \$2.4 million resulting in the recording of an

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Intangible Asset of \$40.2 million. This asset began being amortized in 2017 and is being amortized over an 8-year period.

**6. Accrued liabilities**

Accrued liabilities consist of the following (in thousands):

	December 31, 2017	December 31, 2016
Consulting and professional fees	\$ 3,207	\$ 1,110
Accrued payable due Taro Pharmaceuticals Industries Ltd.	—	7,500
Supply agreement - current portion	4,237	4,207
Employee compensation	3,668	1,554
Other	120	497
Total accrued liabilities	<u>\$ 11,232</u>	<u>\$ 14,868</u>

**7. Long-term debt**

On July 14, 2017, we entered into a \$50 million senior credit facility with CRG LP (“CRG”), a healthcare-focused investment firm, to retire our prior credit facility with Oxford Finance LLC and Horizon Technology Finance Corporation and provide additional capital to us. We initially borrowed \$40 million under the term loan agreement and have the option to borrow an additional \$10 million based upon the achievement of a certain revenue milestone on or prior to June 30, 2018. Concurrent with the initial borrowing, CRG purchased \$3 million of our ordinary shares at a price of \$6.98 per share. As a condition to the new credit facility, we issued warrants with a seven-year term to CRG to purchase 394,289 of our ordinary shares at an exercise price of \$7.37 per share.

The term loan agreement has a six-year term with three years of interest-only payments. The interest-only period may be extended to six years based upon the achievement of certain milestones during the first three years of the loan term. The loan agreement provides for interest payable at an annual rate of 12.5% and a final payment fee of 5% of the principal balance. The loan agreement includes a payment-in-kind (PIK) provision, which allows us to defer 4.0% of the 12.5% annual interest payable under the loan during the first three years of the term of the loan (which may be extended for the entire term of the loan, subject to the satisfaction of certain conditions) by adding such amount to the principal loan amount. We have granted a security interest in substantially all of our existing assets and assets acquired by us in the future, including intellectual property. The loan agreement contains facility and prepayment fees, and customary affirmative and negative covenants, including a financial covenant regarding minimum amounts of net revenue and restrictions on our ability to pay cash dividends, and a list of events that will constitute “events of default” under the loan agreement, and permit the lenders to declare all amounts under the loan agreement immediately due and payable, including a material adverse change in our business, operations or financial condition. We incurred \$2.5 million in debt discounts and \$0.8 million of debt issuance costs relating to this loan agreement which have been recorded as a reduction to the long-term debt. These amounts will be amortized over the outstanding period of the debt to interest expense using the effective interest rate method.

In connection with the retirement of our prior credit facility we incurred a final payment fee of \$1.6 million and a loss on early extinguishment of debt of \$3.5 million.

In January 2018, our term loan agreement was amended (see Note 15).

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Future principal payments due under the Loan Agreement are as follows (in thousands):

	<u>Principal Payments</u>
2018	\$ —
2019	—
2020	6,834
2021	13,667
2022	13,667
2023	6,591
Total future payments	<u>\$ 40,759</u>

## 8. Warrants

Common stock warrants are accounted for in accordance with applicable accounting guidance provided in ASC Topic 815, Derivatives and Hedging — Contracts in Entity's Own Equity (ASC Topic 815), as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement.

Warrants outstanding and warrant activity for the year ended December 31, 2017 is as follows:

	<u>Classification</u>	<u>Exercise Price</u>	<u>Expiration Date</u>	<u>Warrants Issued</u>	<u>Warrants Exercised</u>	<u>December 31, 2017</u>
Warrants in connection with private equity placement	Liability	\$ 2.50	6/28/2022	7,000,000	—	7,000,000
Warrants in connection with Horizon and Oxford loan agreement	Equity	\$ 2.45	12/28/2026	428,571	(267,857)	160,714
Warrants in connection with CRG loan agreement	Equity	\$ 7.37	7/14/2024	394,289	—	394,289
				<u>7,822,860</u>		<u>7,555,003</u>

## 9. Commitments and contingencies

### (a) Lease

On April 22, 2014, we entered into a 48-month building lease for approximately 3,000 square feet of space in Radnor, Pennsylvania. The lease has annual rent escalations. We obtained access to the newly leased space on August 1, 2014, and this was considered the lease commencement date for accounting purposes. Thus, rent expense began on this date and is recognized on a straight-line basis over the term of the lease.

In March 2015, the Company entered into a 52-month building sublease agreement for 14,743 square feet of office space in Trevose, Pennsylvania. The lease has annual rent escalations and is recognized on a straight-line basis over the term of the lease. As a result of this lease, we vacated the previously leased Radnor, Pennsylvania facility as of April 13, 2015 and determined that the Radnor, Pennsylvania facility was not likely to be utilized during the remaining lease term and as such we commenced efforts to sublease the facility. The Company recorded a liability as of the April 13, 2015 cease-use date of \$0.1 million for the estimated fair value of its obligations under the lease. The most significant assumptions used in determining the amount of the estimated liability are the potential sublease revenues and the credit-adjusted risk-free rate utilized to discount the estimated future cash flows.

In November 2017, the Company entered into a 60-month building lease agreement for an additional 7,326 square feet of office space in Trevose, Pennsylvania. The lease has annual rent escalations and is recognized on a straight-line basis over the term of the lease.

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As of December 31, 2017, future minimum commitments under facility operating leases were as follows (in thousands):

	<u>Operating leases</u>
2018	357
2019	336
2020	156
2021	160
2022	163
2023	69
Total minimum lease payments	<u>\$ 1,241</u>

Rent expense recognized under our operating lease, including additional rent charges for utilities, parking, maintenance and real estate taxes, was \$314,000, \$275,000 and \$254,000 for the years ended December 31, 2017, 2016 and 2015, respectively.

**(b) Commitments to Taro Pharmaceuticals Industries Ltd.**

In December 2016, we acquired the U.S. marketing rights to Keveyis® (dichlorphenamide) from a subsidiary of Taro Pharmaceutical Industries Ltd. (“Taro”). Keveyis is approved in the U.S. to treat hyperkalemic, hypokalemic and related variants of primary periodic paralysis, a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis. Keveyis has received orphan drug exclusivity status in the U.S. through August 7, 2022. Under the terms of an asset purchase agreement, we paid Taro an upfront payment in two installments of \$1 million in December 2016 and \$7.5 million in March 2017, and will pay an aggregate of \$7.5 million in potential milestones upon the achievement of certain product sales targets. Taro has agreed to continue to manufacture Keveyis for us under an exclusive supply agreement through the orphan exclusivity period. We are obligated to purchase certain annual minimum amounts of product totaling approximately \$29 million over a six-year period. The supply agreement may extend beyond the orphan exclusivity period unless terminated by either party pursuant to the terms of the agreement. If terminated by Taro at the conclusion of the orphan exclusivity period, we have the right to manufacture the product on our own or have the product manufactured by a third party on our behalf.

**10. Defined contribution plan**

Our 401(k) Employee Savings Plan “401(k) Plan” is available to all employees. We have elected a Safe-Harbor provision for the 401(k) Plan in which participants are always fully vested in their employer contributions. During 2017, we implemented a match, where we match 100% of the first 4% of participating employee contributions. In 2017, we contributed approximately \$173,000. Our contributions are made in cash. Our common stock is not an investment option available to participants in the 401(k) Plan.

**11. Income taxes**

For the years ended December 31, 2017, 2016 and 2015, the components of loss before income taxes were as follows (in thousands):

	<u>Year Ended December 31,</u>		
	<u>2017</u>	<u>2016</u>	<u>2015</u>
Sweden	\$ (19,249)	\$ (16,433)	\$ (33,960)
Ireland	(47,211)	(11,653)	(191)
Cayman Islands	(21,709)	(19,550)	(8,722)
U.S.	(23,543)	(3,721)	(1,210)
Total	<u>\$ (111,712)</u>	<u>\$ (51,357)</u>	<u>\$ (44,083)</u>

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The components of income tax expense (benefit) for the years ended December 31, 2017, 2016 and 2015 were as follows (in thousands):

	Year Ended December 31,		
	2017	2016	2015
Current tax (benefit) expense:			
Sweden	\$ —	\$ —	\$ —
Ireland	(22)	22	—
U.S.			
Federal	(151)	151	—
State	(14)	73	—
Total current tax (benefit) expense	<u>\$ (187)</u>	<u>\$ 246</u>	<u>\$ —</u>
Deferred tax expense (benefit):			
Sweden	\$ (4,586)	\$ (834)	\$ 212
Ireland	1,280	(1,547)	(24)
U.S.			
Federal	39	(3,412)	(17,543)
State	(2,392)	(678)	(1,233)
Change in valuation allowance	7,617	3,587	18,138
Total deferred tax expense (benefit)	<u>1,958</u>	<u>(2,884)</u>	<u>(450)</u>
Total tax expense (benefit)	<u>\$ 1,771</u>	<u>\$ (2,638)</u>	<u>\$ (450)</u>

With the exception of the newly formed U.S. Entity, we have incurred net operating losses since inception. For the Ireland and Swedish operations, we have not reflected any benefit of net operating loss carryforwards (NOLs) in the accompanying financial statements. Strongbridge US, Inc, as a result of the intercompany service agreements, was in taxable income and determined they were able to recognize all deferred tax assets in 2016. In 2017, Strongbridge US, Inc. generated book loss as the Company decided this entity will market and commercialize certain products. As such, given the expenses incurred, it is not more likely than not to recognize all deferred tax assets which results in the company establishing a full valuation allowance against its deferred tax assets.

Deferred taxes are recognized for temporary differences between the bases of assets and liabilities for financial statement and income tax purposes. The tax effect of temporary differences that give rise to significant portions of the deferred tax assets are as follows (in thousands):

	Year Ended December 31,	
	2017	2016
Deferred tax assets:		
Net operating loss carryforwards	\$ 28,570	\$ 24,433
Stock based compensation	2,824	1,870
Other deferred activity	617	96
Tax credits	9,182	9,135
Capitalized research and development costs	161	161
Total deferred tax assets	<u>41,354</u>	<u>35,695</u>
Valuation allowance	<u>(41,354)</u>	<u>(33,738)</u>
Deferred tax assets recognized	<u>—</u>	<u>1,957</u>
Deferred tax liabilities:		
Warrants	—	(358)
Acquired intangible assets	—	—
Total deferred tax liabilities	<u>—</u>	<u>(358)</u>
Net deferred tax assets (liabilities)	<u>\$ —</u>	<u>\$ 1,599</u>

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We have evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets. Based on our history of operating losses in Ireland and Sweden and also the current year operating losses in the U.S., we have concluded that it is more likely than not that the benefit of our deferred tax assets will not be realized. The valuation allowance increased by approximately \$7.6 million and \$3.6 million during the years ended December 31, 2017 and 2016, respectively, due primarily to net operating losses.

The Company's effective income tax rate differs from the ultimate parent company, Strongbridge Biopharma plc, Irish domestic statutory rate of 12.5% for the year ended December 31, 2017, 2016 and 2015.

	Year Ended December 31,		
	2017	2016	2015
Ireland statutory income tax rate	12.50 %	12.50 %	12.50 %
Foreign tax differential between Sweden, U.S., Cayman Island and Ireland	3.99	2.28	15.70
Federal tax credits	—	—	12.10
Change in valuation allowance	(6.82)	(6.69)	(41.20)
State income taxes	1.43	0.92	—
Permanent differences	(5.04)	1.59	—
Rate change - tax impact	(7.09)	—	—
Fx remeasurement of Swedish DTA	0.83	(5.42)	(5.41)
Provision to return	(1.33)	—	—
Other	(0.06)	(0.04)	7.31
Effective income tax rate	<u>(1.59)%</u>	<u>5.14 %</u>	<u>1.00 %</u>

At December 31, 2017, we had approximately \$56.0 million of Swedish NOLs and approximately \$2.3 million of Ireland NOLs, which have an indefinite life, and approximately \$53.4 million of U.S. federal and \$51.3 million of state NOLs, which begin to expire in 2031. Through December 31, 2015 we operated through a permanent establishment in both Sweden and the United States. Relief is granted by way of crediting the U.S. tax against the Swedish tax. This tax credit can never exceed the Swedish tax on the income. Since the tax rate is higher in the United States than in Sweden, the Swedish taxable carryforward losses of \$56.0 million can only generate a tax benefit if income is derived from sources other than the permanent establishment in the United States. Beginning January 1, 2016, the US operations that were not part of BioPancreate Inc occurred in a newly formed US corporation. There were no operating losses generated during 2016 in the U.S. except for a minor state NOL at BioPancreate.

At December 31, 2017, we had \$8.9 million of U.S. federal orphan drug tax credit carryforwards, which begin to expire in 2032, and \$84,000 of U.S. federal research and development tax credit carryforwards, which begin to expire in 2031. The orphan drug credit carryforward is attributable to the permanent establishment of the Swedish entity within the U.S.

Utilization of the NOLs may be subject to limitations under Swedish tax regulations or U.S. Internal Revenue Code Section 382 if there is a greater than 50% ownership change as determined under applicable regulations.

The Company files income tax returns in Sweden, the U.K., the United States, and various states within the United States. In the normal course of business, the Company is subject to examination by federal, state and foreign jurisdictions, where applicable. The Company's tax years are still open under statute from inception to present. All open years may be examined to the extent that tax credit or net operating loss carryforwards are used in future periods.

## 12. Ordinary shares

### *Voting rights and privileges*

As of December 31, 2017 and December 31, 2016, there are 600,000,000 authorized shares and 40,149,812 and 35,335,026 outstanding shares, respectively.

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The holders of our ordinary shares are entitled to one vote for each ordinary share held at all meetings of shareholders without limitation and written actions in lieu of meetings. The holders are entitled to receive dividends if and when declared by our Board of Directors. No dividends have been declared or paid since our inception. The holders are entitled to share ratably in our assets available for distribution to stockholders, in the event of any voluntary or involuntary liquidation.

In addition, on May 26, 2015 the Company issued 40,000 deferred shares with a €1.00 euro par value per share (US\$1.098). The deferred shares are issued in order to satisfy an Irish legislative requirement to maintain a minimum level of issued share capital denominated in euro. The deferred shares carry no voting rights and are not entitled to any dividend or distribution.

### ***Equity financings***

On October 6, 2017, we sold 4,000,000 ordinary shares in a public offering at a price to the public of \$6.25 per ordinary share for net proceeds of approximately \$23.4 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

Concurrent with the CRG credit facility from July 2017, CRG purchased 429,799 shares of our ordinary shares at a price of \$6.98 per share for total proceeds to us of approximately \$3.0 million.

We entered into an equity distribution agreement with JMP on April 28, 2017, pursuant to which we may sell, at our option, from time to time, up to an aggregate of \$40 million in ordinary shares of the Company through JMP, as sales agent. We will pay JMP a commission equal to 3% of the gross proceeds from the sale of ordinary shares under the ATM Facility. Pursuant to the terms of the equity distribution agreement, we reimbursed JMP for certain out-of-pocket expenses, including the fees and disbursements of counsel to JMP, incurred in connection with establishing the ATM Facility and have provided JMP with customary indemnification rights. During the year ended December 31, 2017, we sold an aggregate of 10,300 ordinary shares under the ATM Facility for net proceeds of approximately \$73,000 and paid fees to JMP of \$2,000.

On December 22, 2016, we raised \$32.7 million, net of transaction costs, in a private placement of ordinary shares and warrants. We issued and sold 14,000,000 ordinary shares of common stock at a purchase price of \$2.50 per ordinary share as well as warrants to purchase 7,000,000 shares. The warrants are exercisable at a price of \$2.50 per share beginning on June 28, 2017 and expire in five years from June 28, 2017. In the event of a sale of the Company, the terms of the warrants require us to use our best efforts to ensure the holders of such warrants will have a continuing right to purchase shares of the acquirer and, if our efforts are unsuccessful, to make a payment to such warrant holders based on a Black-Scholes valuation (using variables as specified in the warrant agreements). Therefore we are required to account for these warrants as liabilities and record them at fair value. Fair value for these warrants was initially determined upon issuance using the Black-Scholes Model and were revalued at fair value. The resulting change in fair value resulted in an unrealized loss of \$30.2 million for December 31, 2017 and a unrealized gain of \$0.6 million as of December 31, 2016. As of December 31, 2017, the fair value of these warrants of \$41.3 million was recorded as a long-term liability on our consolidated balance sheet.

On October 22, 2015, we closed on our initial U.S. public offering of 2,500,000 ordinary shares at a price to the public of \$10.00 per ordinary share for aggregate gross proceeds of \$25 million, before deducting the underwriting commission and estimated offering expenses of \$5.5 million. In June 2015, we raised \$32.6 million, net of transaction costs, in a private placement of 2,284,414 shares of our common stock. The subscription price was \$14.54 per share. In February 2015, we raised \$25.8 million, net of transaction costs, in a private placement of 4,761,078 shares of our common stock. The subscription price was \$5.54 per share.

### ***Shares reserved for issuance***

There were 728,411 and 1,951,022 shares of common stock reserved for future issuance upon exercise of stock options as of December 31, 2017 and 2016, respectively. As of December 31, 2017, we have 7,555,003 shares reserved for outstanding warrants.

### 13. Stock-based compensation

The Board of Directors approve the granting of awards to our officers, directors, employees and third party-consultants. Under these grants, the beneficiaries are given the right to acquire new shares of common stock at a pre-determined option price. The purpose of the grants is to assist us in attracting, retaining and motivating officers, employees, directors and consultants. In addition, these awards provide us with the ability to provide incentives that are directly linked to the performance of our business and the related increase in shareholder value.

Our awards have terms that range from five to ten years. As determined by our Board of Directors, our awards vest over service periods ranging up to four years or upon achievement of defined performance or market criteria such as the vesting of certain awards upon our IPO or awards that are accelerated when the fair value of our stock price reaches defined targets.

The exercise price for each stock option is determined by the Board of Directors based upon considerations such as the fair value of the underlying ordinary shares and certain market conditions. For options granted prior to our October 22, 2015, IPO, the determination of the fair value of our common stock takes into account the price at which our shares were being quoted on the Norwegian Over The Counter Market, recent equity financings and our valuations calculated with the assistance of third-parties.

A summary of the outstanding stock options activity for the year ended December 31, 2017 is as follows:

	<u>Options Outstanding</u>			
	<u>Number of Shares</u>	<u>Weighted-Average Exercise Price</u>	<u>Weighted-Average Remaining Contractual Term (Years)</u>	<u>Aggregate Intrinsic Value (in thousands)</u>
Outstanding—January 1, 2017	3,249,784	\$ 11.00	6.89	\$ —
Granted	3,260,350	\$ 3.73		
Forfeited and cancelled	(144,864)	\$ 7.22		\$ —
Exercised	(260,555)	\$ 4.08		
Outstanding—December 31, 2017	<u>6,104,715</u>	\$ 7.50	7.70	\$ 14,021
Vested and exercisable—December 31, 2017	<u>2,073,201</u>	\$ 10.68	5.69	\$ 2,533

Included in the stock options outstanding at December 31, 2017 are unvested stock options to purchase 88,908 shares at a weighted average exercise price of \$18.80 per share for which the vesting of certain tranches will accelerate if the fair value per share of our stock reaches \$31.46. In addition, the options outstanding include 97,652 shares that vest upon a market appreciation event, so long as it occurs prior to the date specified in the applicable award agreement and 97,652 shares that will vest upon the one year anniversary of the market appreciation event. The market appreciation event, which had not yet occurred as of December 31, 2017, is defined as the last trading day in the period in which our closing stock price on each of 20 consecutive trading days reported on NASDAQ has been at least \$30.14 or \$33.66 for the respective grantee.



**Stock-based compensation expense**

We recognized stock-based compensation expense for employees and non-employees in the accompanying consolidated statements of operations as follows (in thousands):

	Year Ended December 31,		
	2017	2016	2015
Selling, general and administrative	\$ 4,027	\$ 4,005	\$ 3,147
Research and development	1,140	601	793
Total stock-based compensation	<u>\$ 5,167</u>	<u>\$ 4,606</u>	<u>\$ 3,940</u>

Included in these amounts was stock compensation expense (credit) attributed to liability-classified awards of, \$0, \$0 and \$359,000, for the years ended December 31, 2017, 2016 and 2015, respectively. As of December 31, 2017, the total unrecognized compensation expense related to unvested options was \$10.1 million, which we expect to recognize over an estimated weighted-average period of 2.75 years.

In determining the estimated fair value of the stock-based awards, we use the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment.

The fair value of stock option awards was estimated with the following assumptions:

	Year Ended December 31,		
	2017	2016	2015
Expected term (in years)	5.98	5.9	3.23
Risk-free interest rate	1.78% - 2.26%	1.21% - 2.23%	0.0% - 0.6%
Expected volatility	78.2% - 85.0%	78.1% - 83.6%	79.0% - 83.1%
Dividend rate	—%	—%	—%

On February 26, 2016, our board of directors approved grants of restricted stock units (“RSUs”) to employees. These RSUs vest two years from the date of issuance, provided that the employee is employed by us on such vesting date. All RSUs will fully vest upon a change of control of our company. If and when the RSUs vest, we will issue one ordinary share for each whole RSU that has vested, subject to satisfaction of the employees’ tax withholding obligations. The RSUs will cease to be outstanding upon such issuance of ordinary shares. We recorded expense, which is included in the stock-based compensation table above, of \$436,000 and \$280,000 for the year ended December 31, 2017 and 2016, respectively. As of December 31, 2017, the total unrecognized compensation expense related to unvested RSUs is \$0.5 million, which we expect to recognize over an estimated weighted-average period of 1.39 years.

A summary of our unvested RSUs as of December 31, 2017 is as follows:

	Number of Shares
Unvested—January 1, 2017	184,000
Granted	92,250
Forfeited	(9,000)
Vested	—
Unvested—December 31, 2017	<u>267,250</u>

**14. Quarterly financial information (unaudited)**

This table summarizes the unaudited consolidated financial results of operations for the quarters ended:

(in thousands, except share and per share data)	March 31,	June 30,	September 30,	December 31,
<b>2017 Quarter Ended</b>				
Total revenues	\$ —	\$ 1,529	\$ 2,533	\$ 2,984
Cost of sales (excluding amortization of intangible asset)	—	377	591	515
Total costs and expenses	12,179	15,525	34,967	16,634
Other expenses	(15,712)	(15,910)	(2,885)	(3,463)
Income tax (expense) benefit	(1,594)	92	850	(1,119)
Net loss	(29,485)	(30,191)	(35,060)	(18,747)
Net loss per share of common stock, basic and diluted (1)	(0.83)	(0.86)	(0.98)	(0.47)
<b>2016 Quarter Ended</b>				
Total revenues	\$ —	\$ —	\$ —	\$ —
Cost of sales (excluding amortization of intangible asset)	—	—	—	—
Total costs and expenses	10,923	13,814	7,633	18,356
Other (expenses) income	(1,337)	47	15	643
Income tax benefit	55	871	—	1,712
Net loss	(12,154)	(12,841)	(7,601)	(16,001)
Net loss per share of common stock, basic (1)	(0.57)	(0.61)	(0.36)	(0.71)
Net loss per share of common stock, diluted (1)	(0.57)	(0.61)	(0.36)	(0.73)

(1) Net loss per share amounts may not agree to the per share for the full year due to the use of weighted average shares for each period.

**15. Subsequent events**

*Acquisition of U.S. and Canadian rights to Macrilen*

On January 16, 2018 we entered into a License and Assignment Agreement with Aeterna Zentaris GmbH, pursuant to which we acquired the U.S. and Canadian rights to manufacture and commercialize Macrilen (macimorelin) for \$24 million. Macrilen is an oral growth hormone secretagogue receptor agonist to be used in the diagnosis of patients with AGHD. Macrilen has been granted orphan drug designation in the United States and has patents with expiration dates through late 2027. We expect to launch Macrilen in the U.S. in mid-2018.

*Amendment to term loan agreement with CRG Servicing LLC*

On January 16, 2018 (the “Loan Amendment Effective Date”), we and our subsidiaries, Strongbridge U.S. Inc., Strongbridge Ireland Limited, Cortendo AB (publ) and Cortendo Cayman Ltd., entered into an amendment (the “Loan Amendment”), to the Term Loan Agreement (the “Loan Agreement”), dated July 14, 2017, with CRG, as administrative agent and collateral agent, and the lenders named therein (the “Lenders”).

The primary purpose of the Loan Amendment was to increase the total potential borrowing under the Term Loan Agreement from \$50 million to \$100 million. The Loan Amendment provides for (i) an additional disbursement of \$45.0 million (the “Second Tranche”), to the Company on the Loan Amendment Effective Date, and (ii) an additional disbursement of \$5.0 million (the “Fourth Tranche”), to us at our election, contingent upon our achievement of certain revenue milestones and a market capitalization condition on or before December 31, 2018, as described in the Loan

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Amendment. We continue to be eligible to borrow up to an additional \$10.0 million (the “Third Tranche”), contingent upon our achievement of certain revenue milestones on or before June 30, 2018, as previously provided in the Term Loan Agreement; provided, however, that under the Term Loan Agreement, as amended, the Third Tranche is now subject to market capitalization condition, as described in the Loan Amendment.

The term of the Term Loan Agreement, as amended, remains six years, although the interest-only period has been extended by six months to December 31, 2020. We have retained the option to extend the interest-only period to six years based upon the achievement of certain milestones during the interest-only period.

As a condition to the Second Tranche under the Term Loan Agreement, as amended, we issued to the Lenders on the Loan Amendment Effective Date warrants to purchase an aggregate of 1,248,250 of our ordinary shares, at an exercise price of \$10.00 per share. If we borrow the Third Tranche, we must issue to the Lenders, or their designees, one or more additional warrants to purchase a number of our ordinary shares equal to an aggregate of 0.20% of our ordinary shares outstanding following such issuance on a fully diluted basis (inclusive of the ordinary shares underlying all such warrants issued), at an exercise price equal to 110% of the closing price of our ordinary shares on the date immediately preceding the Third Tranche disbursement date. If we borrow the Fourth Tranche, we must issue to the Lenders, or their designees, one or more additional warrants to purchase a number of our ordinary shares equal to an aggregate of 0.25% of our ordinary shares outstanding following such issuance on a fully diluted basis (inclusive of the ordinary shares underlying all such warrants issued), at an exercise price equal to 140% of the 10-day volume weighted average price (VWAP) per ordinary share for the consecutive 10-day trading period ending on the trading day immediately prior to the Fourth Tranche disbursement date. Each of these warrants will be exercisable at any time prior to seven years following its issue date and will contain customary provisions for assumption or exchange upon a change of control or a sale of all or substantially all of our assets.

### *Equity financings*

On January 25, 2018, we sold 5,000,000 ordinary shares in a public offering at a price to the public of \$6.75 per ordinary share for net proceeds of approximately \$31.7 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

On February 26, 2018, we sold an additional 255,683 ordinary shares as part of our January 2018 public offering at a price of \$6.75 per ordinary share for net proceeds of approximately \$1.6 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

**STRONGBRIDGE BIOPHARMA PLC**  
**2015 EQUITY COMPENSATION PLAN**

The purpose of the Strongbridge Biopharma plc 2015 Equity Compensation Plan (the “Plan”) is to provide (i) designated employees of Strongbridge Biopharma plc (the “Company”) and its parents and subsidiaries; (ii) certain consultants and advisors who perform services for the Company or its parents or subsidiaries; and (iii) non-employee members of the Board of Directors of the Company (the “Board”) with the opportunity to receive grants of incentive stock options, nonqualified stock options and stock awards. The Company believes that the Plan will encourage the participants to contribute materially to the growth of the Company, thereby benefitting the Company’s shareholders, and will align the economic interests of the participants with those of the shareholders.

1. **Administration**

(a) **Committee**. The Plan shall be administered and interpreted by the Board or by a committee consisting of members of the Board, which shall be appointed by the Board. After an initial public offering of the Company’s stock as described in Section 19(b) (a “Public Offering”), the Plan shall be administered by a committee of Board members, which may consist of “outside directors” as defined under section 162(m) of the Internal Revenue Code of 1986, as amended (the “Code”), and related Treasury regulations, and “non-employee directors” as defined under Rule 16b-3 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). The Board, however, may ratify or approve any grants as it deems appropriate, and the Board shall approve and administer all grants made to non-employee directors. The committee may delegate authority to one or more subcommittees as it deems appropriate. To the extent that a committee or subcommittee administers the Plan, references in the Plan to the “Board” shall be deemed to refer to the committee or subcommittee.

(b) **Board Authority**. The Board shall have the sole authority to (i) determine the individuals to whom grants shall be made under the Plan; (ii) determine the type, size, and terms of the grants to be made to each such individual; (iii) determine the time when the grants will be made and the duration of any applicable exercise or restriction period, including the criteria for exercisability and the acceleration of exercisability; (iv) amend the terms of any previously issued grant; (v) accelerate the vesting, exercisability, or lapse of any forfeiture condition with respect to an Award; and (vi) deal with any other matters arising under the Plan.

(c) **Board Determinations**. The Board shall have full power and authority to administer, construe and interpret the Plan, correct any defect, supply any omission, or reconcile any inconsistency in the Plan or any Award or Award Agreement, make factual determinations and adopt or amend such rules, regulations, agreements, and instruments for implementing the Plan and for the conduct of its business as it deems necessary or advisable, in its sole discretion. The Board’s interpretations of the Plan and all determinations made by the Board pursuant to the powers vested in it hereunder shall be conclusive and binding on all persons having any interest in the Plan or in any awards granted hereunder. All powers of the Board shall be executed in its

sole discretion, in the best interest of the Company, not as a fiduciary, and in keeping with the objectives of the Plan and need not be uniform as to similarly situated individuals.

(d) Limitation of Liability. To the maximum extent permitted by law, no member of the Board shall be liable for any action taken or decision made in good faith relating to the Plan or any Award thereunder. The Board may employ counsel, consultants, accountants, appraisers, brokers or other persons. The Board, the Company, and the officers and directors of the Company shall be entitled to rely upon the advice, opinions or valuations of any such persons.

## 2. Awards

Awards under the Plan may consist of grants of incentive stock options as described in Section 5 (“Incentive Stock Options”), nonqualified stock options as described in Section 5 (“Nonqualified Stock Options”) (Incentive Stock Options and Nonqualified Stock Options are collectively referred to as “Options”), as stock awards as described in Section 6 (“Stock Awards”), and restricted stock units as described in Section 6 (“RSUs”) (hereinafter collectively referred to as “Awards”). All Awards shall be subject to the terms and conditions set forth herein and to such other terms and conditions consistent with the Plan as the Board deems appropriate and as are specified in writing by the Board to the individual in a grant instrument or an amendment to the grant instrument (the “Award Agreement”). The Board shall approve the form and provisions of each Award Agreement. Awards under a particular Section of the Plan need not be uniform as among the grantees.

## 3. Shares Subject to the Plan

(a) Shares Authorized. Subject to adjustment as described below, the aggregate number of ordinary shares of par value US\$0.01 each of the Company (“Company Stock”) that may be issued or transferred under the Plan is 4,949,426 (the “Share Pool”) and the maximum aggregate number of shares that may be issued under the Plan under Incentive Stock Options is 4,949,426. After a Public Offering, the maximum aggregate number of shares of Company Stock that shall be subject to Awards made under the Plan to any individual during any calendar year shall be 1,000,000 shares, subject to adjustment as described below. The shares may be authorized but unissued shares of Company Stock or reacquired shares of Company Stock, including shares purchased by the Company on the open market for purposes of the Plan.

(b) Automatic Share Pool Increase. The Share Pool shall be increased on the first day of each Fiscal Year beginning with the 2016 fiscal year, in an amount equal to four percent (4.0%) of the outstanding shares of Company Stock on the last day of the immediately preceding fiscal year.

(c) Adjustments to Share Pool. The Share Pool shall be reduced, on the date of grant, by one share for each Award granted under the Plan; provided that Awards that are valued by reference to shares of Company Stock but are required to be paid in cash pursuant to their terms shall not reduce the Share Pool. If and to the extent Options terminate, expire, or are canceled, forfeited, exchanged, or surrendered without having been exercised, or if any Stock Awards or RSUs (including restricted stock received upon the exercise of Options) are forfeited, the shares of Company Stock subject to such Awards shall again be available for Awards under the Share Pool. Notwithstanding the foregoing, the following shares of Company Stock shall not become

available for issuance under the Plan: (A) shares tendered by Grantees, or withheld by the Company, as full or partial payment to the Company upon the exercise of stock options granted under the Plan; and (B) shares withheld by, or otherwise remitted to, the Company to satisfy a Grantee's tax withholding obligations upon the lapse of restrictions on Stock Awards or the exercise of Options granted under the Plan.

(d) Adjustments. If there is any change in the number or kind of shares of Company Stock outstanding (i) by reason of a stock dividend, spinoff, recapitalization, stock split, or combination or exchange of shares; (ii) by reason of a merger, reorganization, or consolidation; (iii) by reason of a reclassification or change in par value; or (iv) by reason of any other extraordinary or unusual event affecting the outstanding Company Stock as a class without the Company's receipt of consideration, or if the value of outstanding shares of Company Stock is substantially reduced as a result of a spinoff or the Company's payment of an extraordinary dividend or distribution, the maximum number of shares of Company Stock available for Awards, the maximum number of shares of Company Stock that any individual participating in the Plan may be granted in any year, the number of shares covered by outstanding Awards, the kind of shares issued under the Plan, and the price per share of such Awards shall be adjusted by the Board to reflect any increase or decrease in the number of, or change in the kind or value of, issued shares of Company Stock to preclude the enlargement or dilution of rights and benefits under such Awards; provided, however, that any fractional shares resulting from such adjustment shall be eliminated. Any adjustments determined by the Board shall be final, binding, and conclusive.

#### 4. Eligibility for Participation

(a) Eligible Persons. All employees of the Company and its parents or subsidiaries ("Employees"), including Employees who are officers or members of the Board, and members of the Board who are not Employees ("Non-Employee Directors") shall be eligible to participate in the Plan. Consultants and advisors who perform services for the Company or any of its parents or subsidiaries ("Key Advisors") shall be eligible to participate in the Plan if the Key Advisors render bona fide services to the Company or its parents or subsidiaries, the services are not in connection with the offer and sale of securities in a capital-raising transaction, and the Key Advisors do not directly or indirectly promote or maintain a market for the Company's securities.

(b) Selection of Grantees. The Board shall select the Employees, Non-Employee Directors, and Key Advisors to receive Awards and shall determine the number of shares of Company Stock subject to a particular Award in such manner as the Board determines. Employees, Key Advisors, and Non-Employee Directors who receive Awards under the Plan shall hereinafter be referred to as "Grantees."

#### 5. Granting of Options

The Company may grant Options to purchase shares of Company Stock to Employees, Non-Employee Directors, and Key Advisors. The following provisions are applicable to Options.

(a) Number of Shares. The Board shall determine the number of shares of Company Stock that shall be subject to each Award of Options.

(b) Type of Option and Price.

(i) The Board may grant Incentive Stock Options that are intended to qualify as “incentive stock options” within the meaning of section 422 of the Code or Nonqualified Stock Options that do not qualify as Incentive Stock Options. Incentive Stock Options may be granted only to employees of the Company or its parents or subsidiaries, as defined in section 424 of the Code.

(ii) The purchase price (the “Exercise Price”) of Company Stock subject to an Option shall be determined by the Board and may be equal to or greater than the Fair Market Value (as defined below) of a share of Company Stock on the date the Option is granted. An Incentive Stock Option may not be granted to an Employee who, at the time of grant, owns stock possessing more than ten percent of the total combined voting power of all classes of stock of the Company or any parent or subsidiary of the Company, unless the Exercise Price per share is not less than 110% of the Fair Market Value of Company Stock on the date of grant.

(iii) If the Company Stock is publicly traded, the Fair Market Value per share shall be determined as follows: (x) if the principal trading market for the Company Stock is a national securities exchange or the Nasdaq National Market, the last reported sale price thereof on the relevant date or (if there were no trades on that date) the latest preceding date upon which a sale was reported, or (y) if the Company Stock is not principally traded on such exchange or market, the mean between the last reported “bid” and “asked” prices of Company Stock on the relevant date, as reported on Nasdaq or, if not so reported, as reported by the National Daily Quotation Bureau, Inc. or as reported in a customary financial reporting service, as applicable and as the Board determines.

(iv) If the Company Stock is not publicly traded or, if publicly traded, is not subject to reported transactions or “bid” or “asked” quotations as set forth above, the Fair Market Value per share shall be as determined by the Board. The Board shall determine the Fair Market Value based upon the application of a reasonable valuation method that considers all material information available to the Board. The Board may engage outside advisors, valuation experts and counsel to assist the Board in making a determination of Fair Market Value for purpose of the Plan.

(c) Option Term. The Board shall determine the term of each Option. The term of any Option shall not exceed ten years from the date of grant. An Incentive Stock Option that is granted to an Employee who, at the time of grant, owns stock possessing more than ten percent of the total combined voting power of all classes of stock of the Company, or any parent or subsidiary of the Company, however, may not have a term that exceeds five years from the date of grant.

(d) Exercisability of Options. Options shall become exercisable in accordance with such terms and conditions, consistent with the Plan, as may be determined by the Board and specified in the Award Agreement. The Board may accelerate the exercisability of any or all outstanding Options at any time for any reason. The Board may provide in an Award Agreement that the Grantee may elect to exercise part or all of an Option before it otherwise has become exercisable. Any shares so purchased shall be restricted shares and shall be subject to a repurchase

right in favor of the Company during a specified restriction period, with the repurchase price equal to the lesser of (A) the Exercise Price or (B) the Fair Market Value of such shares at the time of repurchase, and (C) any other restrictions determined by the Company.

(e) Termination of Employment, Disability, or Death.

(i) Except as provided below, an Option may only be exercised while the Grantee is employed by, or providing service to, the Employer (as defined below) as an Employee, Key Advisor, or member of the Board. In the event that a Grantee ceases to be employed by, or provide service to, the Employer for any reason other than Disability, death, or termination for Cause, any Option which is otherwise exercisable by the Grantee shall terminate unless exercised within 90 days after the date on which the Grantee ceases to be employed by, or provide service to, the Employer (or within such other period of time as may be specified by the Board), but in any event no later than the date of expiration of the Option term. Except as otherwise provided by the Board or in the Award Agreement, any of the Grantee's Options that are not otherwise exercisable as of the date on which the Grantee ceases to be employed by, or provide service to, the Employer shall terminate as of such date.

(ii) In the event the Grantee ceases to be employed by, or provide service to, the Employer on account of a termination for Cause by the Employer, any Option held by the Grantee shall terminate as of the date the Grantee ceases to be employed by, or provide service to, the Employer. In addition, notwithstanding any other provisions of this Section 5, if the Board determines that the Grantee has engaged in conduct that constitutes Cause at any time while the Grantee is employed by, or providing service to, the Employer or after the Grantee's termination of employment or service, any Option held by the Grantee shall immediately terminate, and the Grantee shall automatically forfeit all shares underlying any exercised portion of an Option for which the Company has not yet delivered the share certificates, upon refund by the Company of the Exercise Price paid by the Grantee for such shares. Upon any exercise of an Option, the Company may withhold delivery of share certificates pending resolution of an inquiry that could lead to a finding resulting in a forfeiture.

(iii) In the event the Grantee ceases to be employed by, or provide service to, the Employer because the Grantee is Disabled, any Option which is otherwise exercisable by the Grantee shall terminate unless exercised within one year after the date on which the Grantee ceases to be employed by, or provide service to, the Employer (or within such other period of time as may be specified by the Board), but in any event no later than the date of expiration of the Option term. Except as otherwise provided by the Board, any of the Grantee's Options which are not otherwise exercisable as of the date on which the Grantee ceases to be employed by, or provide service to, the Employer shall terminate as of such date.

(iv) If the Grantee dies while employed by, or providing service to, the Employer or within 90 days after the date on which the Grantee ceases to be employed or provide service on account of a termination specified in Section 5(f)(i) above (or within such other period of time as may be specified by the Board), any Option that is otherwise exercisable by the Grantee shall terminate unless exercised within one year after the date on which the Grantee ceases to be employed by, or provide service to, the Employer (or within such other period of time as may be specified by the Board), but in any event no later than the date of expiration of the Option term.



Except as otherwise provided by the Board, any of the Grantee's Options that are not otherwise exercisable as of the date on which the Grantee ceases to be employed by, or provide service to, the Employer shall terminate as of such date.

(v) For purposes of this Plan:

(A) The term "Employer" shall mean the Company and its parent and subsidiary corporations or other entities, as determined by the Board.

(B) "Employed by, or provide service to, the Employer" shall mean employment or service as an Employee, Key Advisor, or member of the Board (so that, for purposes of exercising Options and satisfying conditions with respect to Stock Awards or RSUs, a Grantee shall not be considered to have terminated employment or service until the Grantee ceases to be an Employee, Key Advisor, or member of the Board), unless the Board determines otherwise.

(C) "Disability" shall mean a Grantee's becoming disabled within the meaning of section 22(e)(3) of the Code, within the meaning of the Employer's long-term disability plan applicable to the Grantee, or as otherwise determined by the Board.

(D) "Cause" shall mean, except to the extent specified otherwise by the Board or as defined in any other agreement between the Grantee and the Company, a finding by the Board that the Grantee has (i) been convicted of a felony or crime involving moral turpitude; (ii) disclosed trade secrets or confidential information of the Employer to persons not entitled to receive such information; (iii) breached any written noncompetition or nonsolicitation agreement between the Grantee and the Employer; or (iv) engaged in willful and continued negligence in the performance of the duties assigned to the Grantee by the Employer, after the Grantee has received notice of and failed to cure such negligence.

(f) Exercise of Options. A Grantee may exercise an Option that has become vested and exercisable, in whole or in part, by delivering a notice of exercise to the Company. The Grantee shall pay the Exercise Price for an Option by the Board (i) in cash; (ii) by delivering shares of Company Stock owned by the Grantee (including Company Stock acquired in connection with the exercise of an Option, subject to such restrictions as the Board deems appropriate) and having a Fair Market Value on the date of exercise equal to the Exercise Price or by attestation (on a form prescribed by the Board) to ownership of shares of Company Stock having a Fair Market Value on the date of exercise equal to the Exercise Price; (iii) after a Public Offering, payment through a broker in accordance with procedures permitted by Regulation T of the Federal Reserve Board; or (iv) by such other method as the Board may approve. In addition, the Grantee may elect to settle the Option on a "net basis" by taking delivery of the number of Company Stock equal to Fair Market Value of the shares subject to any Option less the exercise price, any tax (or other governmental obligation) or other administration fees due. Shares of Company Stock used to exercise an Option shall have been held by the Grantee for the requisite period of time to avoid adverse accounting consequences to the Company with respect to the Option. The Grantee shall pay the Exercise Price and the amount of any withholding tax due (pursuant to Section 7) as specified by the Board.

(g) Limits on Incentive Stock Options. Each Incentive Stock Option shall provide that, if the aggregate Fair Market Value of the stock on the date of the grant with respect to which Incentive Stock Options are exercisable for the first time by a Grantee during any calendar year, under the Plan or any other stock option plan of the Company or a parent or subsidiary, exceeds \$100,000, then the Option, as to the excess, shall be treated as a Nonqualified Stock Option. An Incentive Stock Option shall not be granted to any person who is not an Employee of the Company or a parent or subsidiary (within the meaning of section 424(f) of the Code) of the Company.

## 6. Stock Awards and RSUs

The Company may issue or transfer shares of Company Stock to an Employee, Non-Employee Director, or Key Advisor under a Stock Award or RSU, upon such terms as the Board deems appropriate. The following provisions are applicable to Stock Awards and RSUs:

(a) General Requirements. Shares of Company Stock issued or transferred pursuant to Stock Awards may be issued or transferred for consideration or for no consideration, and subject to restrictions or no restrictions, as determined by the Board. The Board shall determine the number of shares of Company Stock subject to a Stock Award and the number of RSUs to be granted to a Grantee, the duration of the period during which, and the conditions, if any, under which, the Stock Award and RSUs may vest or may be forfeited to the Company and the other terms and conditions of such Awards. The Board may require different periods of service or different performance goals and objectives with respect to different Grantees holding different Stock Awards or RSUs or to separate, designated portions of shares constituting Stock Awards.

(b) Transfer Restrictions and Legend on Stock Certificate. Stock Awards and RSUs may not be sold, assigned, transferred, pledged or otherwise encumbered except as provided in the Plan or as may be provided in the applicable Award Agreement; provided, however, that the Board may determine that Stock Awards and RSUs may be transferred by the Grantee. Each certificate for Stock Awards shall contain a legend giving appropriate notice of the restrictions in the Award. The Grantee shall be entitled to have the legend removed from the stock certificate covering the shares subject to restrictions when all restrictions on such shares have lapsed. The Board may determine that the Company shall not issue certificates for Stock Awards until all restrictions on such shares have lapsed, or that the Company shall retain possession of certificates for Stock Awards until all restrictions on such shares have lapsed. Upon the lapse of the restrictions applicable to a Stock Award, the Company or other custodian, as applicable, shall deliver such certificates to the Grantee or the Grantee's legal representative.

(c) Payment/Lapse of Restrictions. Each RSU shall be granted with respect to one share of Company Stock or shall have a value equal to the Fair Market Value of one share of Company Stock. RSUs shall be paid in cash, shares of Company Stock, other securities, other Awards or other property, as determined in the sole discretion of the Board, upon the lapse of restrictions applicable thereto, or otherwise in accordance with the applicable Award Agreement. The amount payable as a result of the vesting of an RSU shall be distributed as soon as practicable following the vesting date and in no event later than the fifteenth date of the third calendar month of the year following the vesting date of the RSU (or as otherwise permitted under Section 409A of the Code); provided, however, that a Grantee may, if and to the extent permitted by the Board, elect to defer payment of RSUs in a manner permitted by Section 409A of the Code.

(d) Termination of Employment or Service. Except as otherwise set forth in the Award Agreement, if the Grantee ceases to be employed by, or provide service to, the Employer (as defined in Section 5(e)), any Stock Award or RSUs held by the Grantee that are subject to the transfer restrictions set forth in Section 6(b) above at such time shall be forfeited. The Board may, however, provide for complete or partial exceptions to this requirement as it deems appropriate.

(e) No Right to Vote and to Receive Dividends. Prior to the lapse of the transfer restrictions set forth in Section 6(b) above, the Grantee shall not have the right to vote shares subject to Stock Awards or to receive any dividends or other distributions paid on such shares, subject to any restrictions deemed appropriate by the Board.

## 7. Performance-Based Awards

Notwithstanding anything to the contrary herein, certain Stock Awards or RSUs granted under the Plan may be granted in a manner which is deductible by the Company under Section 162(m) of the Code (or any successor section thereto). Such Stock Awards or RSUs shall be designated “Performance-Based Awards”. The following provisions are applicable to Performance-Based Awards:

(a) Performance Goals. A Grantee’s Performance-Based Awards shall be determined based on the attainment of written performance goals approved by the Board for a performance period established by the Board (i) while the outcome for that performance period is substantially uncertain and (ii) no more than 90 days after the commencement of the performance period to which the performance goal relates or, if less, the number of days which is equal to 25 percent of the relevant performance period, or as otherwise permitted pursuant to Section 162(m) of the Code (or any successor section thereto). The performance goals, which must be objective, shall be based upon one or more of the following criteria: (i) consolidated earnings before or after taxes (including earnings before interest, taxes, depreciation and amortization); (ii) net income; (iii) operating income; (iv) earnings per share; (v) return on shareholders’ equity; (vi) attainment of strategic and operational initiatives; (vii) customer income; (viii) economic value-added models; (ix) maintenance or improvement of profit margins; (x) stock price (including total shareholder return), including, without limitation, as compared to one or more stock indices; (xi) market share; (xii) revenues, sales or net sales; (xiii) return on assets; (xiv) book value per share; (xv) expense management; (xvi) improvements in capital structure; (xvii) costs and (xviii) cash flow. The foregoing criteria may relate to the Company, one or more of its subsidiaries or one or more of its divisions or units, or any combination of the foregoing, and may be applied on an absolute basis and/or be relative to one or more peer group companies or indices, or any combination thereof, all as the Board shall determine. In addition, to the degree consistent with the Code, the performance goals may be calculated without regard to extraordinary, unusual and/or non-recurring items.

(b) Determination of Satisfaction of Performance Goals. The Board shall determine whether, with respect to a performance period, the applicable performance goals have been met with respect to a given Grantee and, if they have, so certify and ascertain the amount of the applicable Performance-Based Award. No Performance-Based Awards will be paid for such performance period until such certification is made by the Board. The amount of the Performance-Based Award actually paid to a given Grantee may be less than the amount determined by the

applicable performance goal formula, at the discretion of the Board. The amount of the Performance-Based Award determined by the Board for a performance period shall be paid to the Grantee at such time as determined by the Board in its sole discretion after the end of such performance period; provided, however, that a Grantee may, if and to the extent permitted by the Board and consistent with the provisions of Section 162(m) of the Code, elect to defer payment of a Performance-Based Award in a manner permitted by Section 409A of the Code. To the extent Section 162(m) of the Code (or any successor section thereto) provides terms different from the requirements of this Section 7, this Section 7 shall be deemed amended thereby

8. **Withholding of Taxes**

(a) **Required Withholding.** All Awards under the Plan shall be subject to applicable federal (including FICA), state, and local tax (or other governmental obligation) withholding requirements or other administration fees due. The Employer may require that the Grantee or other person receiving or exercising Awards pay to the Employer the amount of any federal, state, or local taxes (or other governmental obligations) that the Employer is required to withhold or any administration fees due with respect to such Awards, or the Employer may deduct from other wages paid by the Employer the amount of any withholding taxes, governmental obligations or administration fees due with respect to such Awards.

(b) **Election to Withhold Shares.** If the Board so permits, a Grantee may elect to satisfy the Employer's income tax (or other governmental obligation) withholding requirement and any administration fees due with respect to an Award by having shares withheld up to an amount that does not exceed the Grantee's minimum applicable withholding rate for federal (including FICA), state, and local tax (and other governmental obligation) liabilities plus any other administration fees due. The election must be in a form and manner prescribed by the Board and may be subject to the prior approval of the Board.

9. **Transferability of Awards**

(a) **Nontransferability of Awards.** Except as provided below, only the Grantee may exercise rights under an Award during the Grantee's lifetime. A Grantee may not transfer those rights except (i) by will or by the laws of descent and distribution or (ii) with respect to Awards other than Incentive Stock Options, if permitted in any specific case by the Board, pursuant to a domestic relations order or otherwise as permitted by the Board. When a Grantee dies, the personal representative or other person entitled to succeed to the rights of the Grantee may exercise such rights. Any such successor must furnish proof satisfactory to the Company of his or her right to receive the Award under the Grantee's will or under the applicable laws of descent and distribution.

(b) **Transfer of Nonqualified Stock Options.** Notwithstanding the foregoing, the Board may provide, in an Award Agreement, that a Grantee may transfer Nonqualified Stock Options to family members, or one or more trusts or other entities for the benefit of or owned by family members, consistent with applicable securities laws, according to such terms as the Board may determine; provided that the Grantee receives no consideration for the transfer of an Option and the transferred Option shall continue to be subject to the same terms and conditions as were applicable to the Option immediately before the transfer.

10. **Right of First Refusal; Repurchase Right**

(a) **Offer.** Prior to a Public Offering, if at any time an individual desires to sell, encumber, or otherwise dispose of shares of Company Stock that were distributed to him or her under the Plan and that are transferable, the individual may do so only pursuant to a bona fide written offer, and the individual shall first offer the shares to the Company by giving the Company written notice disclosing: (i) the name of the proposed transferee of the Company Stock; (ii) the certificate number and number of shares of Company Stock proposed to be transferred or encumbered; (iii) the proposed price; (iv) all other terms of the proposed transfer; and (v) a written copy of the proposed offer. Within 60 days after receipt of such notice, the Company shall have the option to purchase all or part of such Company Stock at the price and on the terms described in the written notice; provided that the Company may pay such price in installments over a period not to exceed four years, at the discretion of the Board.

(b) **Sale.** In the event the Company (or a shareholder, as described below) does not exercise the option to purchase Company Stock, as provided above, the individual shall have the right to sell, encumber, or otherwise dispose of the shares of Company Stock described in subsection (a) at the price and on the terms of the transfer set forth in the written notice to the Company, provided such transfer is effected within 15 days after the expiration of the option period. If the transfer is not effected within such period, the Company must again be given an option to purchase, as provided above.

(c) **Assignment of Rights.** The Board, in its sole discretion, may waive the Company's right of first refusal and repurchase right under this Section 10. If the Company's right of first refusal or repurchase right is so waived, the Board may, in its sole discretion, assign such right to the remaining shareholders of the Company in the same proportion that each shareholder's stock ownership bears to the stock ownership of all the shareholders of the Company, as determined by the Board. To the extent that a shareholder has been given such right and does not purchase his or her allotment, the other shareholders shall have the right to purchase such allotment on the same basis.

(d) **Purchase by the Company.** Prior to a Public Offering, if a Grantee ceases to be employed by, or provide service to, the Employer, the Company shall have the right to purchase, within 60 days of the date that Grantee ceases to be employed by, or provide services to, the Employer, all or part of any Company Stock distributed to Grantee under the Plan at the Fair Market Value (as defined in Section 5(b)) on the date that Grantee ceases to be employed by, or provide services to, the Employer (or at such other price as may be established in the Award Agreement); provided, however, that such repurchase shall be made in accordance with applicable accounting rules to avoid adverse accounting treatment.

(e) **Public Offering.** On and after a Public Offering, the Company shall have no further right to purchase shares of Company Stock under this Section 10.

(f) **Shareholder's Agreement.** Notwithstanding the provisions of this Section 10, if the Board requires that a Grantee execute a shareholder's agreement with respect to any Company Stock distributed pursuant to the Plan, which contains a right of first refusal or repurchase right, the provisions of this Section 10 shall not apply to such Company Stock.

## 11. **Change of Control of the Company**

As used herein, a “Change of Control” shall be deemed to have occurred if:

(a) Any “person” (as such term is used in sections 13(d) and 14(d) of the Exchange Act) (other than persons who are shareholders on the effective date of the Plan) becomes a “beneficial owner” (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing more than 50% of the voting power of the then outstanding securities of the Company; provided that a Change of Control shall not be deemed to occur as a result of a change of ownership resulting from the death of a shareholder, and a Change of Control shall not be deemed to occur as a result of a transaction in which the Company becomes a subsidiary of another corporation and in which the shareholders of the Company, immediately prior to the transaction, will beneficially own, immediately after the transaction, shares entitling such shareholders to more than 50% of all votes to which all shareholders of the parent corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote); or

(b) The consummation of (i) a merger or consolidation of the Company with another corporation where the shareholders of the Company, immediately prior to the merger or consolidation, will not beneficially own, immediately after the merger or consolidation, shares entitling such shareholders to more than 50% of all votes to which all shareholders of the surviving corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote); (ii) a sale or other disposition of all or substantially all of the assets of the Company; or (iii) a liquidation or dissolution of the Company.

(c) Notwithstanding the foregoing, the following acquisitions shall not constitute a Change of Control: (A) an acquisition by the Company or entity controlled by the Company, or (B) an acquisition by an employee benefit plan (or related trust) sponsored or maintained by the Company

## 12. **Consequences of a Change of Control**

(a) **Assumption of Awards.** Upon a Change of Control where the Company is not the surviving corporation (or survives only as a subsidiary of another corporation), unless the Board determines otherwise, all outstanding Awards shall be assumed by, or replaced with comparable Awards by, the surviving corporation (or a parent or subsidiary of the surviving corporation).

(b) **Termination of Awards.** Upon a Change of Control where the Company is not the surviving corporation (or survives only as a subsidiary of another corporation), in the event the surviving corporation (or a parent or subsidiary of the surviving corporation) does not assume or replace the Awards with comparable Awards, (i) the Company shall provide each Grantee with outstanding Awards written notice of such Change of Control; (ii) all outstanding Options shall automatically accelerate and become fully vested and exercisable; (iii) all outstanding Stock Awards shall become vested and deliverable in accordance with Section 6(b); and (iv) all outstanding RSUs shall become vested and deliverable in accordance with Section 6(c).

(c) Other Alternatives. Notwithstanding the foregoing, in the event of a Change of Control, the Board may take one or both of the following actions: the Board may (i) require that Grantees surrender their outstanding Options in exchange for a payment by the Company, in cash or Company Stock as determined by the Board, in an amount equal to the amount by which the then Fair Market Value of the shares of Company Stock subject to the Grantee's unexercised Options exceeds the Exercise Price of the Options; or (ii) after giving Grantees an opportunity to exercise their outstanding Options, terminate any or all unexercised Options at such time as the Board deems appropriate. Such surrender or termination shall take place as of the date of the Change of Control or such other date as the Board may specify.

13. **Requirements for Issuance or Transfer of Shares**

(a) Shareholder's Agreement. The Board may require that a Grantee execute a shareholder's agreement, with such terms as the Board deems appropriate, with respect to any Company Stock issued or distributed pursuant to the Plan.

(b) Limitations on Issuance or Transfer of Shares. No Company Stock shall be issued or transferred in connection with any Award hereunder unless and until all legal requirements applicable to the issuance or transfer of such Company Stock have been complied with to the satisfaction of the Board. The Board shall have the right to condition any Award made to any Grantee hereunder on such Grantee's undertaking in writing to comply with such restrictions on his or her subsequent disposition of such shares of Company Stock as the Board shall deem necessary or advisable, and certificates representing such shares may be legended to reflect any such restrictions. Certificates representing shares of Company Stock issued or transferred under the Plan shall be subject to such stop-transfer orders and other restrictions as may be required by applicable laws, regulations, and interpretations, including any requirement that a legend be placed thereon.

(c) Lock-Up Period. If so requested by the Company or any representative of the underwriters (the "Managing Underwriter") in connection with any underwritten offering of securities of the Company under the Securities Act of 1933, as amended (the "Securities Act"), a Grantee (including any successor or assigns) shall not sell or otherwise transfer any shares or other securities of the Company during the 30-day period preceding and the 180-day period following the effective date of a registration statement of the Company filed under the Securities Act for such underwriting (or such shorter period as may be requested by the Managing Underwriter and agreed to by the Company) (the "Market Standoff Period"). The Company may impose stop-transfer instructions with respect to securities subject to the foregoing restrictions until the end of such Market Standoff Period.

14. **Amendment and Termination of the Plan**

(a) Amendment. The Board may amend or terminate the Plan at any time; provided, however, that the Board shall not amend the Plan without shareholder approval if such approval is required in order to comply with the Code or other applicable laws or, after an Initial Public Offering, to comply with applicable stock exchange requirements.

(b) Termination of Plan. The Plan shall terminate on the day immediately preceding the tenth anniversary of its effective date, unless the Plan is terminated earlier by the Board or is extended by the Board with the approval of the shareholders.

(c) Termination and Amendment of Outstanding Awards. A termination or amendment of the Plan that occurs after an Award is made shall not materially impair the rights of a Grantee unless the Grantee consents or unless the Board acts under Section 20(b). The termination of the Plan shall not impair the power and authority of the Board with respect to an outstanding Award. Whether or not the Plan has terminated, an outstanding Award may be terminated or amended under Section 20(b) or may be amended by agreement of the Company and the Grantee consistent with the Plan.

(d) Governing Document. The Plan shall be the controlling document. No other statements, representations, explanatory materials or examples, oral or written, may amend the Plan in any manner. The Plan shall be binding upon and enforceable against the Company and its successors and assigns.

15. **Funding of the Plan**

The Plan shall be unfunded. The Company shall not be required to establish any special or separate fund or to make any other segregation of assets to assure the payment of any Awards under the Plan. In no event shall interest be paid or accrued on any Award, including unpaid installments of Awards.

16. **Rights of Participants**

Nothing in the Plan shall entitle any Employee, Key Advisor, Non-Employee Director, or other person to any claim or right to be granted an Award under the Plan. Neither the Plan nor any action taken hereunder shall be construed as giving any individual any rights to be retained by or in the employ of the Employer or any other employment rights.

17. **No Fractional Shares**

No fractional shares of Company Stock shall be issued or delivered pursuant to the Plan or any Award. The Board shall determine whether cash, other awards or other property shall be issued or paid in lieu of such fractional shares or whether such fractional shares or any rights thereto shall be forfeited or otherwise eliminated.

18. **Headings**

Section headings are for reference only. In the event of a conflict between a title and the content of a Section, the content of the Section shall control.

19. **Effective Date of the Plan**

(a) Effective Date. The Plan shall be effective on September 3, 2015.



(b) Public Offering. The provisions of the Plan that refer to a Public Offering, or that refer to, or are applicable to persons subject to, section 16 of the Exchange Act or section 162(m) of the Code, shall be effective, if at all, upon the initial registration of the Company Stock under section 12(g) of the Exchange Act, and shall remain effective thereafter for so long as such stock is so registered.

20. Miscellaneous

(a) Awards in Connection with Corporate Transactions and Otherwise. Nothing contained in the Plan shall be construed to (i) limit the right of the Board to make Awards under the Plan in connection with the acquisition, by purchase, lease, merger, consolidation, or otherwise, of the business or assets of any corporation, firm or association, including Awards to employees thereof who become Employees, or for other proper corporate purposes; or (ii) limit the right of the Company to grant stock options or make other awards outside of the Plan. Without limiting the foregoing, the Board may make an Award to an employee of another corporation who becomes an Employee by reason of a corporate merger, consolidation, acquisition of stock or property, reorganization, or liquidation involving the Company, the Parent, or any of their subsidiaries in substitution for a stock option, stock award or other type of applicable equity grants made by such corporation. The terms and conditions of the substitute grants may vary from the terms and conditions required by the Plan and from those of the substituted stock incentives. The Board shall prescribe the provisions of the substitute grants.

(b) Compliance with Law. The Plan, exercise of Options, restrictions of Stock Awards and obligations of the Company to issue or transfer shares of Company Stock under Awards shall be subject to all applicable laws and to approvals by any governmental or regulatory agency as may be required. With respect to persons subject to section 16 of the Exchange Act, after a Public Offering, it is the intent of the Company that the Plan and all transactions under the Plan comply with all applicable provisions of Rule 16b-3 or its successors under the Exchange Act. In addition, it is the intent of the Company that the Plan and applicable Awards under the Plan comply with the applicable provisions of sections 162(m), 409A and 422 of the Code. To the extent that any legal requirement of section 16 of the Exchange Act or sections 162(m), 409A or 422 of the Code as set forth in the Plan ceases to be required under section 16 of the Exchange Act or sections 162(m), 409A or 422 of the Code, that Plan provision shall cease to apply. The Board may revoke any Award if it is contrary to law or modify an Award to bring it into compliance with any valid and mandatory government regulation. The Board may also adopt rules regarding the withholding of taxes on payments to Grantees. The Board may, in its sole discretion, agree to limit its authority under this Section.

(c) Employees Subject to Taxation Outside the United States. With respect to Grantees who are subject to taxation in countries other than the United States, the Board may make Awards on such terms and conditions as the Board deems appropriate to comply with the laws of the applicable countries, and the Board may create such procedures, addenda, and subplans and make such modifications as may be necessary or advisable to comply with such laws.

(d) Governing Law. The validity, construction, interpretation, and effect of the Plan and Award Agreements issued under the Plan shall be governed and construed by and determined

in accordance with the laws of the State of Delaware, without giving effect to the conflict of laws provisions thereof.

**STRONGBRIDGE BIOPHARMA PLC**  
**NON-EMPLOYEE DIRECTOR EQUITY COMPENSATION PLAN**

The purpose of the Strongbridge Biopharma plc Non-Employee Director Equity Compensation Plan (the “Plan”) is to provide non-employee members of the Board of Directors (the “Board”) of Strongbridge Biopharma plc (the “Company”) with the opportunity to receive grants of nonqualified stock options and stock awards. The Company believes that the Plan will encourage the participants to contribute materially to the growth of the Company, thereby benefitting the Company’s shareholders, and will align the economic interests of the participants with those of the shareholders.

1. **Administration**

(a) **Administrator.** The Plan shall be administered and interpreted by the Board and all grants made hereunder shall be approved by the Board.

(b) **Board Authority.** The Board shall have the sole authority to (i) determine the individuals to whom grants shall be made under the Plan; (ii) determine the type, size, and terms of the grants to be made to each such individual; (iii) determine the time when the grants will be made and the duration of any applicable exercise or restriction period, including the criteria for exercisability and the acceleration of exercisability; (iv) amend the terms of any previously issued grant; (v) accelerate the vesting, exercisability, or lapse of any forfeiture condition with respect to an Award; and (vi) deal with any other matters arising under the Plan.

(c) **Board Determinations.** The Board shall have full power and authority to administer, construe and interpret the Plan, correct any defect, supply any omission, or reconcile any inconsistency in the Plan or any Award or Award Agreement, make factual determinations and adopt or amend such rules, regulations, agreements, and instruments for implementing the Plan and for the conduct of its business as it deems necessary or advisable, in its sole discretion. The Board’s interpretations of the Plan and all determinations made by the Board pursuant to the powers vested in it hereunder shall be conclusive and binding on all persons having any interest in the Plan or in any awards granted hereunder. All powers of the Board shall be executed in its sole discretion, in the best interest of the Company, not as a fiduciary, and in keeping with the objectives of the Plan and need not be uniform as to similarly situated individuals.

(d) **Limitation of Liability.** To the maximum extent permitted by law, no member of the Board shall be liable for any action taken or decision made in good faith relating to the Plan or any Award thereunder. The Board may employ counsel, consultants, accountants, appraisers, brokers or other persons. The Board, the Company, and the officers and directors of the Company shall be entitled to rely upon the advice, opinions or valuations of any such persons.

2. **Awards**

Awards under the Plan may consist of grants of nonqualified stock options as described in Section 5 (“Options”), as stock awards as described in Section 6 (“Stock Awards”), and restricted stock units as described in Section 6 (“RSUs”) (hereinafter collectively referred to as “Awards”).

All Awards shall be subject to the terms and conditions set forth herein and to such other terms and conditions consistent with the Plan as the Board deems appropriate and as are specified in writing by the Board to the individual in a grant instrument or an amendment to the grant instrument (the "Award Agreement"). The Board shall approve the form and provisions of each Award Agreement. Awards under a particular Section of the Plan need not be uniform as among the Grantees.

3. **Shares Subject to the Plan**

(a) Shares Authorized. Subject to adjustment as described below, the aggregate number of ordinary shares of par value US\$0.01 each of the Company ("Company Stock") that may be issued or transferred under the Plan is 828,904 (the "Share Pool"). The shares may be authorized but unissued shares of Company Stock or reacquired shares of Company Stock, including shares purchased by the Company on the open market for purposes of the Plan.

(b) Automatic Share Pool Increase. The Share Pool shall be increased on the first day of each Fiscal Year beginning with the 2016 fiscal year, in an amount equal to one-half percent (0.5%) of the outstanding shares of Company Stock on the last day of the immediately preceding fiscal year.

(c) Adjustments to Share Pool. The Share Pool shall be reduced, on the date of grant, by one share for each Award granted under the Plan; provided that Awards that are valued by reference to shares of Company Stock but are required to be paid in cash pursuant to their terms shall not reduce the Share Pool. If and to the extent Options terminate, expire, or are canceled, forfeited, exchanged, or surrendered without having been exercised, or if any Stock Awards or RSUs (including restricted stock received upon the exercise of Options) are forfeited, the shares of Company Stock subject to such Awards shall again be available for Awards under the Share Pool. Notwithstanding the foregoing, shares tendered by Grantees, or withheld by the Company, as full or partial payment to the Company upon the exercise of Options granted under the Plan, shall not become available for issuance under the Plan.

(d) Adjustments. If there is any change in the number or kind of shares of Company Stock outstanding (i) by reason of a stock dividend, spinoff, recapitalization, stock split, or combination or exchange of shares; (ii) by reason of a merger, reorganization, or consolidation; (iii) by reason of a reclassification or change in par value; or (iv) by reason of any other extraordinary or unusual event affecting the outstanding Company Stock as a class without the Company's receipt of consideration, or if the value of outstanding shares of Company Stock is substantially reduced as a result of a spinoff or the Company's payment of an extraordinary dividend or distribution, the maximum number of shares of Company Stock available for Awards, the maximum number of shares of Company Stock that any individual participating in the Plan may be granted in any year, the number of shares covered by outstanding Awards, the kind of shares issued under the Plan, and the price per share of such Awards shall be adjusted by the Board to reflect any increase or decrease in the number of, or change in the kind or value of, issued shares of Company Stock to preclude the enlargement or dilution of rights and benefits under such Awards; provided, however, that any fractional shares resulting from such adjustment shall be eliminated. Any adjustments determined by the Board shall be final, binding, and conclusive.

#### 4. **Eligibility for Participation**

(a) **Eligible Persons.** All members of the Board who are not employees (“**Non-Employee Directors**”) shall be eligible to participate in the Plan.

(b) **Selection of Grantees.** The Board shall select the Non-Employee Directors to receive Awards and shall determine the number of shares of Company Stock subject to a particular Award in such manner as the Board determines. Non-Employee Directors who receive Awards under the Plan shall hereinafter be referred to as “**Grantees.**”

#### 5. **Granting of Options**

The following provisions are applicable to Options.

(a) **Number of Shares.** The Board shall determine the number of shares of Company Stock that shall be subject to each Award of Options.

(b) **Type of Option and Price.**

(i) The purchase price (the “**Exercise Price**”) of Company Stock subject to an Option shall be determined by the Board and may be equal to or greater than the Fair Market Value (as defined below) of a share of Company Stock on the date the Option is granted.

(ii) If the Company Stock is publicly traded, the Fair Market Value per share shall be determined as follows: (x) if the principal trading market for the Company Stock is a national securities exchange or the Nasdaq National Market, the last reported sale price thereof on the relevant date or (if there were no trades on that date) the latest preceding date upon which a sale was reported, or (y) if the Company Stock is not principally traded on such exchange or market, the mean between the last reported “bid” and “asked” prices of Company Stock on the relevant date, as reported on Nasdaq or, if not so reported, as reported by the National Daily Quotation Bureau, Inc. or as reported in a customary financial reporting service, as applicable and as the Board determines.

(iii) If the Company Stock is not publicly traded or, if publicly traded, is not subject to reported transactions or “bid” or “asked” quotations as set forth above, the Fair Market Value per share shall be as determined by the Board. The Board shall determine the Fair Market Value based upon the application of a reasonable valuation method that considers all material information available to the Board. The Board may engage outside advisors, valuation experts and counsel to assist the Board in making a determination of Fair Market Value for purpose of the Plan.

(c) **Option Term.** The Board shall determine the term of each Option. The term of any Option shall not exceed ten years from the date of grant.

(d) **Exercisability of Options.** Options shall become exercisable in accordance with such terms and conditions, consistent with the Plan, as may be determined by the Board and specified in the Award Agreement. The Board may accelerate the exercisability of any or all outstanding Options at any time for any reason. The Board may provide in an Award Agreement

that the Grantee may elect to exercise part or all of an Option before it otherwise has become exercisable. Any shares so purchased shall be restricted shares and shall be subject to a repurchase right in favor of the Company during a specified restriction period, with the repurchase price equal to the lesser of (A) the Exercise Price or (B) the Fair Market Value of such shares at the time of repurchase, and (C) any other restrictions determined by the Company.

(e) Termination of Service, Disability, or Death.

(i) Except as provided below, an Option may only be exercised while the Grantee is providing service to the Company as a member of the Board. In the event that a Grantee ceases to provide service to the Company for any reason other than Disability, death, or termination for Cause, any Option which is otherwise exercisable by the Grantee shall terminate unless exercised within 90 days after the date on which the Grantee ceases to provide service to the Company (or within such other period of time as may be specified by the Board), but in any event no later than the date of expiration of the Option term. Except as otherwise provided by the Board or in the Award Agreement, any of the Grantee's Options that are not otherwise exercisable as of the date on which the Grantee ceases to provide service to the Company shall terminate as of such date.

(ii) In the event the Grantee ceases to provide service to the Company on account of a removal from the Board for Cause by the Company, any Option held by the Grantee shall terminate as of the date the Grantee ceases to provide service to the Company. In addition, notwithstanding any other provisions of this Section 5, if the a majority of disinterested members of the Board determines that the Grantee has engaged in conduct that constitutes Cause at any time while the Grantee is providing service to the Company or after the Grantee's termination of service, any Option held by the Grantee shall immediately terminate, and the Grantee shall automatically forfeit all shares underlying any exercised portion of an Option for which the Company has not yet delivered the share certificates, upon refund by the Company of the Exercise Price paid by the Grantee for such shares. Upon any exercise of an Option, the Company may withhold delivery of share certificates pending resolution of an inquiry that could lead to a finding resulting in a forfeiture.

(iii) In the event the Grantee ceases to provide service to the Company because the Grantee is Disabled, any Option which is otherwise exercisable by the Grantee shall terminate unless exercised within one year after the date on which the Grantee ceases to provide service to the Company (or within such other period of time as may be specified by the Board), but in any event no later than the date of expiration of the Option term. Except as otherwise provided by the Board, any of the Grantee's Options which are not otherwise exercisable as of the date on which the Grantee ceases to provide service to the Company shall terminate as of such date.

(iv) If the Grantee dies while providing service to the Company or within 90 days after the date on which the Grantee ceases to provide service on account of a termination specified in Section 5(f)(i) above (or within such other period of time as may be specified by the Board), any Option that is otherwise exercisable by the Grantee shall terminate unless exercised within one year after the date on which the Grantee ceases to provide service to the Company (or within such other period of time as may be specified by the Board), but in any event no later than the date of expiration of the Option term. Except as otherwise provided by the Board, any of the

Grantee's Options that are not otherwise exercisable as of the date on which the Grantee ceases to provide service to the Company shall terminate as of such date.

(v) For purposes of this Plan:

(A) "Provide service to the Company" shall mean service as a member of the Board (so that, for purposes of exercising Options and satisfying conditions with respect to Stock Awards or RSUs, a Grantee shall not be considered to have terminated service until the Grantee ceases to be a member of the Board), unless the Board determines otherwise.

(B) "Disability" shall mean a Grantee's becoming disabled within the meaning of section 22(e)(3) of the Internal Revenue Code of 1986, as amended (the "Code"), or as otherwise determined by the Board.

(C) "Cause" shall mean that the Grantee has been convicted of a felony or crime involving moral turpitude; or a determination by a majority of the disinterested members of the Board that the Grantee has engaged in any of the following: (i) malfeasance in office; (ii) gross misconduct or neglect; (iii) false or fraudulent misrepresentation inducing the Grantee's appointment to the Board; (iv) willful conversion of corporate funds; or (v) disclosure of trade secrets or confidential information of the Company to persons not entitled to receive such information.

(f) Exercise of Options. A Grantee may exercise an Option that has become vested and exercisable, in whole or in part, by delivering a notice of exercise to the Company. The Grantee shall pay the Exercise Price for an Option (i) in cash; (ii) by delivering shares of Company Stock owned by the Grantee (including Company Stock acquired in connection with the exercise of an Option, subject to such restrictions as the Board deems appropriate) and having a Fair Market Value on the date of exercise equal to the Exercise Price or by attestation (on a form prescribed by the Board) to ownership of shares of Company Stock having a Fair Market Value on the date of exercise equal to the Exercise Price; (iii) after an initial public offering of the Company's stock as described in Section 17(b) (a "Public Offering"), payment through a broker in accordance with procedures permitted by Regulation T of the Federal Reserve Board; or (iv) by such other method as the Board may approve. In addition, the Grantee may elect to settle the Option on a "net basis" by taking delivery of the number of Company Stock equal to Fair Market Value of the shares subject to any Option less the exercise price, any tax (or other governmental obligation) or other administration fees due. Shares of Company Stock used to exercise an Option shall have been held by the Grantee for the requisite period of time to avoid adverse accounting consequences to the Company with respect to the Option. The Grantee shall pay the Exercise Price as specified by the Board.

## 6. Stock Awards and RSUs

The following provisions are applicable to Stock Awards and RSUs:

(a) General Requirements. Shares of Company Stock issued or transferred pursuant to Stock Awards may be issued or transferred for consideration or for no consideration, and subject to restrictions or no restrictions, as determined by the Board. The Board shall determine

the number of shares of Company Stock subject to a Stock Award and the number of RSUs to be granted to a Grantee, the duration of the period during which, and the conditions, if any, under which, the Stock Award and RSUs may vest or may be forfeited to the Company and the other terms and conditions of such Awards. The Board may require different periods of service or different performance goals and objectives with respect to different Grantees holding different Stock Awards or RSUs or to separate, designated portions of shares constituting Stock Awards.

(b) Transfer Restrictions and Legend on Stock Certificate. Stock Awards and RSUs may not be sold, assigned, transferred, pledged or otherwise encumbered except as provided in the Plan or as may be provided in the applicable Award Agreement; provided, however, that the Board may determine that Stock Awards and RSUs may be transferred by the Grantee. Each certificate for Stock Awards shall contain a legend giving appropriate notice of the restrictions in the Award. The Grantee shall be entitled to have the legend removed from the stock certificate covering the shares subject to restrictions when all restrictions on such shares have lapsed. The Board may determine that the Company shall not issue certificates for Stock Awards until all restrictions on such shares have lapsed, or that the Company shall retain possession of certificates for Stock Awards until all restrictions on such shares have lapsed. Upon the lapse of the restrictions applicable to a Stock Award, the Company or other custodian, as applicable, shall deliver such certificates to the Grantee or the Grantee's legal representative.

(c) Payment/Lapse of Restrictions. Each RSU shall be granted with respect to one share of Company Stock or shall have a value equal to the Fair Market Value of one share of Company Stock. RSUs shall be paid in cash, shares of Company Stock, other securities, other Awards or other property, as determined in the sole discretion of the Board, upon the lapse of restrictions applicable thereto, or otherwise in accordance with the applicable Award Agreement. The amount payable as a result of the vesting of an RSU shall be distributed as soon as practicable following the vesting date and in no event later than the fifteenth date of the third calendar month of the year following the vesting date of the RSU (or as otherwise permitted under Section 409A of the Code); provided, however, that a Grantee may, if and to the extent permitted by the Board, elect to defer payment of RSUs in a manner permitted by Section 409A of the Code.

(d) Termination of Service. Except as otherwise set forth in the Award Agreement, if the Grantee ceases to provide service to the Company, any Stock Award or RSUs held by the Grantee that are subject to the transfer restrictions set forth in Section 6(b) above at such time shall be forfeited. The Board may, however, provide for complete or partial exceptions to this requirement as it deems appropriate.

(e) No Right to Vote and to Receive Dividends. Prior to the lapse of the transfer restrictions set forth in Section 6(b) above, the Grantee shall not have the right to vote shares subject to Stock Awards or to receive any dividends or other distributions paid on such shares, subject to any restrictions deemed appropriate by the Board.

## 7. Transferability of Awards

(a) Nontransferability of Awards. Except as provided below, only the Grantee may exercise rights under an Award during the Grantee's lifetime. A Grantee may not transfer those rights except (i) by will or by the laws of descent and distribution or (ii) if permitted in any specific



case by the Board, pursuant to a domestic relations order or otherwise as permitted by the Board. When a Grantee dies, the personal representative or other person entitled to succeed to the rights of the Grantee may exercise such rights. Any such successor must furnish proof satisfactory to the Company of his or her right to receive the Award under the Grantee's will or under the applicable laws of descent and distribution.

(b) Transfer of Nonqualified Stock Options. Notwithstanding the foregoing, the Board may provide, in an Award Agreement, that a Grantee may transfer Options to family members, or one or more trusts or other entities for the benefit of or owned by family members, consistent with applicable securities laws, according to such terms as the Board may determine; provided that the Grantee receives no consideration for the transfer of an Option and the transferred Option shall continue to be subject to the same terms and conditions as were applicable to the Option immediately before the transfer.

#### 8. **Right of First Refusal; Repurchase Right**

(a) Offer. Prior to a Public Offering, if at any time an individual desires to sell, encumber, or otherwise dispose of shares of Company Stock that were distributed to him or her under the Plan and that are transferable, the individual may do so only pursuant to a bona fide written offer, and the individual shall first offer the shares to the Company by giving the Company written notice disclosing: (i) the name of the proposed transferee of the Company Stock; (ii) the certificate number and number of shares of Company Stock proposed to be transferred or encumbered; (iii) the proposed price; (iv) all other terms of the proposed transfer; and (v) a written copy of the proposed offer. Within 60 days after receipt of such notice, the Company shall have the option to purchase all or part of such Company Stock at the price and on the terms described in the written notice; provided that the Company may pay such price in installments over a period not to exceed four years, at the discretion of the Board.

(b) Sale. In the event the Company (or a shareholder, as described below) does not exercise the option to purchase Company Stock, as provided above, the individual shall have the right to sell, encumber, or otherwise dispose of the shares of Company Stock described in subsection (a) at the price and on the terms of the transfer set forth in the written notice to the Company, provided such transfer is effected within 15 days after the expiration of the option period. If the transfer is not effected within such period, the Company must again be given an option to purchase, as provided above.

(c) Assignment of Rights. The Board, in its sole discretion, may waive the Company's right of first refusal and repurchase right under this Section 8. If the Company's right of first refusal or repurchase right is so waived, the Board may, in its sole discretion, assign such right to the remaining shareholders of the Company in the same proportion that each shareholder's stock ownership bears to the stock ownership of all the shareholders of the Company, as determined by the Board. To the extent that a shareholder has been given such right and does not purchase his or her allotment, the other shareholders shall have the right to purchase such allotment on the same basis.

(d) Purchase by the Company. Prior to a Public Offering, if a Grantee ceases to provide service to the Company, the Company shall have the right to purchase, within 60 days of

the date that Grantee ceases to provide services to the Company, all or part of any Company Stock distributed to Grantee under the Plan at the Fair Market Value (as defined in Section 5(b)) on the date that Grantee ceases to provide services to the Company (or at such other price as may be established in the Award Agreement); provided, however, that such repurchase shall be made in accordance with applicable accounting rules to avoid adverse accounting treatment.

(e) Public Offering. On and after a Public Offering, the Company shall have no further right to purchase shares of Company Stock under this Section 8.

(f) Shareholder's Agreement. Notwithstanding the provisions of this Section 8, if the Board requires that a Grantee execute a shareholder's agreement with respect to any Company Stock distributed pursuant to the Plan, which contains a right of first refusal or repurchase right, the provisions of this Section 8 shall not apply to such Company Stock.

## 9. Change of Control of the Company

As used herein, a "Change of Control" shall be deemed to have occurred if:

(a) Any "person" (as such term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) (other than persons who are shareholders on the effective date of the Plan) becomes a "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing more than 50% of the voting power of the then outstanding securities of the Company; provided that a Change of Control shall not be deemed to occur as a result of a change of ownership resulting from the death of a shareholder, and a Change of Control shall not be deemed to occur as a result of a transaction in which the Company becomes a subsidiary of another corporation and in which the shareholders of the Company, immediately prior to the transaction, will beneficially own, immediately after the transaction, shares entitling such shareholders to more than 50% of all votes to which all shareholders of the parent corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote); or

(b) The consummation of (i) a merger or consolidation of the Company with another corporation where the shareholders of the Company, immediately prior to the merger or consolidation, will not beneficially own, immediately after the merger or consolidation, shares entitling such shareholders to more than 50% of all votes to which all shareholders of the surviving corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote); (ii) a sale or other disposition of all or substantially all of the assets of the Company; or (iii) a liquidation or dissolution of the Company.

(c) Notwithstanding the foregoing, the following acquisitions shall not constitute a Change of Control: (A) an acquisition by the Company or entity controlled by the Company, or (B) an acquisition by an employee benefit plan (or related trust) sponsored or maintained by the Company

## 10. Consequences of a Change of Control

(a) Assumption of Awards. Upon a Change of Control where the Company is not the surviving corporation (or survives only as a subsidiary of another corporation), unless the Board determines otherwise, all outstanding Awards shall be assumed by, or replaced with comparable Awards by, the surviving corporation (or a parent or subsidiary of the surviving corporation).

(b) Termination of Awards. Upon a Change of Control where the Company is not the surviving corporation (or survives only as a subsidiary of another corporation), in the event the surviving corporation (or a parent or subsidiary of the surviving corporation) does not assume or replace the Awards with comparable Awards, (i) the Company shall provide each Grantee with outstanding Awards written notice of such Change of Control; (ii) all outstanding Options shall automatically accelerate and become fully vested and exercisable; (iii) all outstanding Stock Awards shall become vested and deliverable in accordance with Section 6(b); and (iv) all outstanding RSUs shall become vested and deliverable in accordance with Section 6(c).

(c) Other Alternatives. Notwithstanding the foregoing, in the event of a Change of Control, the Board may take one or both of the following actions: the Board may (i) require that Grantees surrender their outstanding Options in exchange for a payment by the Company, in cash or Company Stock as determined by the Board, in an amount equal to the amount by which the then Fair Market Value of the shares of Company Stock subject to the Grantee's unexercised Options exceeds the Exercise Price of the Options; or (ii) after giving Grantees an opportunity to exercise their outstanding Options, terminate any or all unexercised Options at such time as the Board deems appropriate. Such surrender or termination shall take place as of the date of the Change of Control or such other date as the Board may specify.

## 11. Requirements for Issuance or Transfer of Shares

(a) Shareholder's Agreement. The Board may require that a Grantee execute a shareholder's agreement, with such terms as the Board deems appropriate, with respect to any Company Stock issued or distributed pursuant to the Plan.

(b) Limitations on Issuance or Transfer of Shares. No Company Stock shall be issued or transferred in connection with any Award hereunder unless and until all legal requirements applicable to the issuance or transfer of such Company Stock have been complied with to the satisfaction of the Board. The Board shall have the right to condition any Award made to any Grantee hereunder on such Grantee's undertaking in writing to comply with such restrictions on his or her subsequent disposition of such shares of Company Stock as the Board shall deem necessary or advisable, and certificates representing such shares may be legended to reflect any such restrictions. Certificates representing shares of Company Stock issued or transferred under the Plan shall be subject to such stop-transfer orders and other restrictions as may be required by applicable laws, regulations, and interpretations, including any requirement that a legend be placed thereon.

(c) Lock-Up Period. If so requested by the Company or any representative of the underwriters (the "Managing Underwriter") in connection with any underwritten offering of securities of the Company under the Securities Act of 1933, as amended (the "Securities Act"), a

Grantee (including any successor or assigns) shall not sell or otherwise transfer any shares or other securities of the Company during the 30-day period preceding and the 180-day period following the effective date of a registration statement of the Company filed under the Securities Act for such underwriting (or such shorter period as may be requested by the Managing Underwriter and agreed to by the Company) (the “Market Standoff Period”). The Company may impose stop-transfer instructions with respect to securities subject to the foregoing restrictions until the end of such Market Standoff Period.

12. **Amendment and Termination of the Plan**

(a) Amendment. The Board may amend or terminate the Plan at any time; provided, however, that the Board shall not amend the Plan without shareholder approval if such approval is required in order to comply with the Code or other applicable laws or, after an Initial Public Offering, to comply with applicable stock exchange requirements.

(b) Termination of Plan. The Plan shall terminate on the day immediately preceding the tenth anniversary of its effective date, unless the Plan is terminated earlier by the Board or is extended by the Board with the approval of the shareholders.

(c) Termination and Amendment of Outstanding Awards. A termination or amendment of the Plan that occurs after an Award is made shall not materially impair the rights of a Grantee unless the Grantee consents or unless the Board acts under Section 18(b). The termination of the Plan shall not impair the power and authority of the Board with respect to an outstanding Award. Whether or not the Plan has terminated, an outstanding Award may be terminated or amended under Section 18(b) or may be amended by agreement of the Company and the Grantee consistent with the Plan.

(d) Governing Document. The Plan shall be the controlling document. No other statements, representations, explanatory materials or examples, oral or written, may amend the Plan in any manner. The Plan shall be binding upon and enforceable against the Company and its successors and assigns.

13. **Funding of the Plan**

The Plan shall be unfunded. The Company shall not be required to establish any special or separate fund or to make any other segregation of assets to assure the payment of any Awards under the Plan. In no event shall interest be paid or accrued on any Award, including unpaid installments of Awards.

14. **Rights of Participants**

Nothing in the Plan shall entitle any Non-Employee Director or other person to any claim or right to be granted an Award under the Plan. Neither the Plan nor any action taken hereunder

shall be construed as giving any individual any rights to be retained by the Company or any other employment rights.

15. **No Fractional Shares**

No fractional shares of Company Stock shall be issued or delivered pursuant to the Plan or any Award. The Board shall determine whether cash, other awards or other property shall be issued or paid in lieu of such fractional shares or whether such fractional shares or any rights thereto shall be forfeited or otherwise eliminated.

16. **Headings**

Section headings are for reference only. In the event of a conflict between a title and the content of a Section, the content of the Section shall control.

17. **Effective Date of the Plan**

(a) **Effective Date.** The Plan shall be effective on September 3, 2015.

(b) **Public Offering.** The provisions of the Plan that refer to a Public Offering, or that refer to, or are applicable to persons subject to, section 16 of the Exchange Act, shall be effective, if at all, upon the initial registration of the Company Stock under section 12(g) of the Exchange Act, and shall remain effective thereafter for so long as such stock is so registered.

18. **Miscellaneous**

(a) **Withholding.** To the extent required by applicable Federal, state or local law, a Grantee must make arrangements satisfactory to the Company for the payment of any withholding or similar tax obligations that arise in connection with the Plan.

(b) **Compliance with Law.** The Plan, exercise of Options, restrictions of Stock Awards and obligations of the Company to issue or transfer shares of Company Stock under Awards shall be subject to all applicable laws and to approvals by any governmental or regulatory agency as may be required. With respect to persons subject to section 16 of the Exchange Act, after a Public Offering, it is the intent of the Company that the Plan and all transactions under the Plan comply with all applicable provisions of Rule 16b-3 or its successors under the Exchange Act. In addition, it is the intent of the Company that the Plan and applicable Awards under the Plan comply with the applicable provisions of section 409A of the Code. To the extent that any legal requirement of section 16 of the Exchange Act or section 409A of the Code as set forth in the Plan ceases to be required under section 16 of the Exchange Act or section 409A of the Code, that Plan provision shall cease to apply. The Board may revoke any Award if it is contrary to law or modify an Award to bring it into compliance with any valid and mandatory government regulation. The Board may also adopt rules regarding the withholding of taxes on payments to Grantees. The Board may, in its sole discretion, agree to limit its authority under this Section.

(c) **Grantees Subject to Taxation Outside the United States.** With respect to Grantees who are subject to taxation in countries other than the United States, the Board may make Awards on such terms and conditions as the Board deems appropriate to comply with the laws of the

applicable countries, and the Board may create such procedures, addenda, and subplans and make such modifications as may be necessary or advisable to comply with such laws.

(d) Governing Law. The validity, construction, interpretation, and effect of the Plan and Award Agreements issued under the Plan shall be governed and construed by and determined in accordance with the laws of the State of Delaware, without giving effect to the conflict of laws provisions thereof.

**STRONGBRIDGE BIOPHARMA PLC**  
**2017 INDUCEMENT PLAN**

The purpose of the Strongbridge Biopharma plc 2017 Inducement Plan is to assist Strongbridge Biopharma plc and its affiliates and subsidiaries in attracting valued employees by offering them a greater stake in the Company's success and a closer identity with it, and to encourage ownership of the Company's stock by such employees.

1. **Definitions**

As used herein, the following definitions shall apply:

- (a) "Award" means a grant of Options, Stock Awards or Restricted Stock Units under the Plan.
- (b) "Award Agreement" means the written agreement, instrument or document evidencing an Award.
- (c) "Board" means the Board of Directors of the Company.
- (d) "Change of Control" means, after the Effective Date, any of the following events:

- (i) Any "person" (as such term is used in sections 13(d) and 14(d) of the Exchange Act) (other than persons who are shareholders on the Effective Date) becomes a "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing more than 50% of the voting power of the then outstanding securities of the Company; provided that a Change of Control shall not be deemed to occur as a result of a change of ownership resulting from the death of a shareholder, and a Change of Control shall not be deemed to occur as a result of a transaction in which the Company becomes a subsidiary of another corporation and in which the shareholders of the Company, immediately prior to the transaction, will beneficially own, immediately after the transaction, shares entitling such shareholders to more than 50% of all votes to which all shareholders of the parent corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote); or

- (ii) The consummation of (i) a merger or consolidation of the Company with another corporation where the shareholders of the Company, immediately prior to the merger or consolidation, will not beneficially own, immediately after the merger or consolidation, shares entitling such shareholders to more than 50% of all votes to which all shareholders of the surviving corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote); (ii) a sale or other disposition of all or substantially all of the assets of the Company; or (iii) a liquidation or dissolution of the Company.

- (iii) Notwithstanding the foregoing, the following acquisitions shall not constitute a Change of Control: (A) an acquisition by the Company or entity controlled by the

Company, or (B) an acquisition by an employee benefit plan (or related trust) sponsored or maintained by the Company.

(e) “Code” means the Internal Revenue Code of 1986, as amended, and the Treasury regulations promulgated thereunder. A reference to any provision of the Code or the Treasury regulations promulgated thereunder shall include reference to any successor provision of the Code or the Treasury regulations.

(f) “Committee” means the committee designated by the Board to administer the Plan under Section 2. The Committee shall consist of at least two members and each member shall be a Non-Employee Director and an “independent director” within the meaning of Rule 5605(a)(3) of the Nasdaq Stock Market Equity Rules.

(g) “Company” means Strongbridge BioPharma plc.

(h) “Company Stock” means the ordinary shares of the Company, par value US\$0.01 per share each.

(i) “Effective Date” has the meaning set forth in Section 17.

(j) “Eligible Individual” means any individual who was not previously an employee or a Non-Employee Director of the Company or any of its subsidiaries (or who had a bona fide period of non-employment with the Company and its subsidiaries) who is hired by the Company or a subsidiary.

(k) “Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules promulgated thereunder. A reference to any provision of the Exchange Act or rule promulgated under the Exchange Act shall include reference to any successor provision or rule.

(l) “Fair Market Value” means: (x) if the principal trading market for the Company Stock is a national securities exchange or the Nasdaq National Market, the last reported sale price thereof on the relevant date or (if there were no trades on that date) the latest preceding date upon which a sale was reported, or (y) if the Company Stock is not principally traded on such exchange or market, the mean between the last reported “bid” and “asked” prices of Company Stock on the relevant date, as reported on Nasdaq or, if not so reported, as reported by the National Daily



Quotation Bureau, Inc. or as reported in a customary financial reporting service, as applicable and as the Committee determines.

(m) “Grantee” means an Eligible Individual who receives an Award under the Plan.

(n) “Non-Employee Director” means a member of the Board who meets the definition of a “non-employee director” under Rule 16b-3(b)(4) promulgated by the Exchange Act.

(o) “Option” means a right to purchase a specified number of Company Stock at a specified price awarded by the Committee as described in Section 6 of the Plan.

(p) “Plan” means the Strongbridge BioPharma plc 2017 Inducement Plan.

(q) “Restricted Stock Unit” means the right to a payment in Company Stock or in cash, or in a combination thereof, awarded by the Committee under Section 7 of the Plan.

(r) “Stock Award” means the right to payment in Company Stock awarded by the Committee under Section 7 of the Plan.

## 2. Administration

(a) Administration and Authority. The Plan shall be administered by the Compensation Committee. The Committee shall have the sole authority to (i) determine the Eligible Individuals to whom Awards shall be made under the Plan; (ii) determine the type, size, and terms of the Award to be made to each such Eligible Individual; (iii) determine the time when the Awards will be made and the duration of any applicable exercise or restriction period, including the criteria for exercisability and the acceleration of exercisability; (iv) amend the terms of any previously issued Award; (v) accelerate the vesting, exercisability, or lapse of any forfeiture condition with respect to an Award; and (vi) deal with any other matters arising under the Plan.

(b) Committee Determinations. The Committee shall have full power and authority to administer, construe and interpret the Plan, correct any defect, supply any omission, or reconcile any inconsistency in the Plan or any Award or Award Agreement, make factual determinations and adopt or amend such rules, regulations, agreements, and instruments for implementing the Plan and for the conduct of its business as it deems necessary or advisable, in its sole discretion. The Committee’s interpretations of the Plan and all determinations made by the Committee pursuant to the powers vested in it hereunder shall be conclusive and binding on all persons having any interest in the Plan or in any Awards granted hereunder. All powers of the Committee shall be executed in its sole discretion, in the best interest of the Company, not as a fiduciary, and in keeping with the objectives of the Plan and need not be uniform as to similarly situated individuals.

(c) Limitation of Liability. To the maximum extent permitted by law, no member of the Committee shall be liable for any action taken or decision made in good faith relating to the Plan or any Award thereunder. The Committee may employ counsel, consultants, accountants, appraisers, brokers or other persons. The Committee, the Company, and the officers and directors

of the Company shall be entitled to rely upon the advice, opinions or valuations of any such persons.

3. **Awards**

Awards under the Plan may consist of grants of Options as described in Section 6, as Stock Awards as described in Section 7, and Restricted Stock Units as described in Section 7. All Awards shall be subject to the terms and conditions set forth herein and to such other terms and conditions consistent with the Plan as the Committee deems appropriate and as are specified in the Award Agreement. The Committee shall approve the form and provisions of each Award Agreement. Awards under a particular Section of the Plan need not be uniform as among the Grantees.

4. **Shares Subject to the Plan**

(a) **Shares Authorized.** Subject to adjustment as described below, the Company Stock available for Awards under the Plan is 2,500,000 (the "Share Pool"). The shares may be authorized but unissued shares of Company Stock or reacquired shares of Company Stock, including shares purchased by the Company on the open market for purposes of the Plan.

(b) **Adjustments to Share Pool.** The Share Pool shall be reduced, on the date of grant, by one share for each Award granted under the Plan; provided that Awards that are valued by reference to shares of Company Stock but are required to be paid in cash pursuant to their terms shall not reduce the Share Pool. If and to the extent Options terminate, expire, or are canceled, forfeited, exchanged, or surrendered without having been exercised, or if any Stock Awards or Restricted Stock Units (including restricted stock received upon the exercise of Options) are forfeited, the shares of Company Stock subject to such Awards shall again be available for Awards under the Share Pool. Notwithstanding the foregoing, the following shares of Company Stock shall not become available for issuance under the Plan: (A) shares tendered by Grantees, or withheld by the Company, as full or partial payment to the Company upon the exercise of stock options granted under the Plan; and (B) shares withheld by, or otherwise remitted to, the Company to satisfy a Grantee's tax withholding obligations upon the lapse of restrictions on Stock Awards or the exercise of Options granted under the Plan.

(c) **Adjustments.** If there is any change in the number or kind of shares of Company Stock outstanding (i) by reason of a stock dividend, spinoff, recapitalization, stock split, or combination or exchange of shares; (ii) by reason of a merger, reorganization, or consolidation; (iii) by reason of a reclassification or change in par value; or (iv) by reason of any other extraordinary or unusual event affecting the outstanding Company Stock as a class without the Company's receipt of consideration, or if the value of outstanding shares of Company Stock is substantially reduced as a result of a spinoff or the Company's payment of an extraordinary dividend or distribution, the maximum number of shares of Company Stock available for Awards, the maximum number of shares of Company Stock that any individual participating in the Plan may be granted in any year, the number of shares covered by outstanding Awards, the kind of shares issued under the Plan, and the price per share of such Awards shall be adjusted by the Committee to reflect any increase or decrease in the number of, or change in the kind or value of, issued shares of Company Stock to preclude the enlargement or dilution of rights and benefits under such Awards; provided, however, that any fractional shares resulting from such adjustment

shall be eliminated. Any adjustments determined by the Committee shall be final, binding, and conclusive.

5. **Eligibility for Participation**

Any Eligible Individual shall be eligible to participate in the Plan. The Committee shall select the Eligible Individuals to receive Awards and shall determine the number of shares of Company Stock subject to a particular Award in such manner as the Committee determines.

6. **Granting of Options**

The Company may grant Options to purchase shares of Company Stock to Eligible Individuals. The following provisions are applicable to Options.

(a) **Number of Shares.** The Committee shall determine the number of shares of Company Stock that shall be subject to each Award of Options.

(b) **Price.** The purchase price (the “Exercise Price”) of Company Stock subject to an Option shall be determined by the Board and shall be equal to or greater than the Fair Market Value of a share of Company Stock on the date the Option is granted.

(c) **Option Term.** The Committee shall determine the term of each Option. The term of any Option shall not exceed ten years from the date of grant.

(d) **Exercisability of Options.** Options shall become exercisable in accordance with such terms and conditions, consistent with the Plan, as may be determined by the Committee and specified in the Award Agreement. The Committee may accelerate the exercisability of any or all outstanding Options at any time for any reason. The Committee may provide in an Award Agreement that the Grantee may elect to exercise part or all of an Option before it otherwise has become exercisable. Any shares so purchased shall be restricted shares and shall be subject to a repurchase right in favor of the Company during a specified restriction period, with the repurchase price equal to the lesser of (A) the Exercise Price, or (B) the Fair Market Value of such shares at the time of repurchase, and (C) any other restrictions determined by the Company.

(e) **Termination of Employment, Disability, or Death.**

(i) Except as provided below, an Option may only be exercised while the Grantee is employed by, or providing service to, the Employer (as defined below) as an Eligible Individual. In the event that a Grantee ceases to be employed by, or provide service to, the Employer for any reason other than Disability, death, or termination for Cause, any Option which is otherwise exercisable by the Grantee shall terminate unless exercised within 90 days after the date on which the Grantee ceases to be employed by, or provide service to, the Employer (or within such other period of time as may be specified by the Committee), but in any event no later than the date of expiration of the Option term. Except as otherwise provided by the Committee or in the Award Agreement, any of the Grantee’s Options that are not otherwise exercisable as of the date on which the Grantee ceases to be employed by, or provide service to, the Employer shall terminate as of such date.

(ii) In the event the Grantee ceases to be employed by, or provide service to, the Employer on account of a termination for Cause by the Employer, any Option held by the Grantee shall terminate as of the date the Grantee ceases to be employed by, or provide service to, the Employer. In addition, notwithstanding any other provisions of this Section 6, if the Committee determines that the Grantee has engaged in conduct that constitutes Cause at any time while the Grantee is employed by, or providing service to, the Employer or after the Grantee's termination of employment or service, any Option held by the Grantee shall immediately terminate, and the Grantee shall automatically forfeit all shares underlying any exercised portion of an Option for which the Company has not yet delivered the share certificates, upon refund by the Company of the Exercise Price paid by the Grantee for such shares. Upon any exercise of an Option, the Company may withhold delivery of share certificates pending resolution of an inquiry that could lead to a finding resulting in a forfeiture.

(iii) In the event the Grantee ceases to be employed by, or provide service to, the Employer because the Grantee is Disabled (as defined below), any Option which is otherwise exercisable by the Grantee shall terminate unless exercised within one year after the date on which the Grantee ceases to be employed by, or provide service to, the Employer (or within such other period of time as may be specified by the Committee), but in any event no later than the date of expiration of the Option term. Except as otherwise provided by the Committee, any of the Grantee's Options which are not otherwise exercisable as of the date on which the Grantee ceases to be employed by, or provide service to, the Employer shall terminate as of such date.

(iv) If the Grantee dies while employed by, or providing service to, the Employer or within 90 days after the date on which the Grantee ceases to be employed or provide service on account of a termination specified in Section 6(e)(i) above (or within such other period of time as may be specified by the Committee), any Option that is otherwise exercisable by the Grantee shall terminate unless exercised within one year after the date on which the Grantee ceases to be employed by, or provide service to, the Employer (or within such other period of time as may be specified by the Committee), but in any event no later than the date of expiration of the Option term. Except as otherwise provided by the Committee, any of the Grantee's Options that are not otherwise exercisable as of the date on which the Grantee ceases to be employed by, or provide service to, the Employer shall terminate as of such date.

(v) For purposes of this Plan:

(A) The term "Employer" shall mean the Company and its parent and subsidiary corporations or other entities, as determined by the Committee.

(B) "Employed by, or provide service to, the Employer" shall mean employment or service as an Eligible Individual (so that, for purposes of exercising Options and satisfying conditions with respect to Stock Awards or Restricted Stock Units, a Grantee shall not be considered to have terminated employment or service until the Grantee ceases to be an Eligible Individual, unless the Committee determines otherwise).

(C) "Disability" shall mean a Grantee's becoming disabled within the meaning of section 22(e)(3) of the Code, within the meaning of the Employer's long-

term disability plan applicable to the Grantee, or as otherwise determined by the Committee.

(D) “Cause” shall mean, except to the extent specified otherwise by the Committee or as defined in any other agreement between the Grantee and the Company, a finding by the Committee that the Grantee has (i) been convicted of a felony or crime involving moral turpitude; (ii) disclosed trade secrets or confidential information of the Employer to persons not entitled to receive such information; (iii) breached any written noncompetition or nonsolicitation agreement between the Grantee and the Employer; or (iv) engaged in willful and continued negligence in the performance of the duties assigned to the Grantee by the Employer, after the Grantee has received notice of and failed to cure such negligence.

(f) Exercise of Options. A Grantee may exercise an Option that has become vested and exercisable, in whole or in part, by delivering a notice of exercise to the Company. The Grantee shall pay the Exercise Price for an Option by the Committee (i) in cash; (ii) by delivering shares of Company Stock owned by the Grantee (including Company Stock acquired in connection with the exercise of an Option, subject to such restrictions as the Committee deems appropriate) and having a Fair Market Value on the date of exercise equal to the Exercise Price or by attestation (on a form prescribed by the Committee) to ownership of shares of Company Stock having a Fair Market Value on the date of exercise equal to the Exercise Price; (iii) payment through a broker in accordance with procedures permitted by Regulation T of the Federal Reserve Board; or (iv) by such other method as the Committee may approve. In addition, the Grantee may elect to settle the Option on a “net basis” by taking delivery of the number of Company Stock equal to Fair Market Value of the shares subject to any Option less the exercise price, any tax (or other governmental obligation) or other administration fees due. The Grantee shall pay the Exercise Price and the amount of any withholding tax due (pursuant to Section 8) as specified by the Committee.

#### 7. Stock Awards and Restricted Stock Units

The Company may issue or transfer shares of Company Stock to an Eligible Individual under a Stock Award or Restricted Stock Unit, upon such terms as the Committee deems appropriate. The following provisions are applicable to Stock Awards and Restricted Stock Units:

(a) General Requirements. Shares of Company Stock issued or transferred pursuant to Stock Awards may be issued or transferred for consideration or for no consideration, and subject to restrictions or no restrictions, as determined by the Committee. The Committee shall determine the number of shares of Company Stock subject to a Stock Award and the number of Restricted Stock Units to be granted to a Grantee, the duration of the period during which, and the conditions, if any, under which, the Stock Award and Restricted Stock Units may vest or may be forfeited to the Company and the other terms and conditions of such Awards. The Committee may require different periods of service with respect to different Grantees holding different Stock Awards or Restricted Stock Units or to separate, designated portions of shares constituting Stock Awards.

(b) Transfer Restrictions and Legend on Stock Certificate. Stock Awards and Restricted Stock Units may not be sold, assigned, transferred, pledged or otherwise encumbered

except as provided in the Plan or as may be provided in the applicable Award Agreement; provided, however, that the Committee may determine that Stock Awards and Restricted Stock Units may be transferred by the Grantee. Each certificate for Stock Awards shall contain a legend giving appropriate notice of the restrictions in the Award. The Grantee shall be entitled to have the legend removed from the stock certificate covering the shares subject to restrictions when all restrictions on such shares have lapsed. The Committee may determine that the Company shall not issue certificates for Stock Awards until all restrictions on such shares have lapsed, or that the Company shall retain possession of certificates for Stock Awards until all restrictions on such shares have lapsed. Upon the lapse of the restrictions applicable to a Stock Award, the Company or other custodian, as applicable, shall deliver such certificates to the Grantee or the Grantee's legal representative.

(c) Payment/Lapse of Restrictions. Each Restricted Stock Unit shall be granted with respect to one share of Company Stock or shall have a value equal to the Fair Market Value of one share of Company Stock. Restricted Stock Units shall be paid in cash, shares of Company Stock, other securities, other Awards or other property, as determined in the sole discretion of the Committee, upon the lapse of restrictions applicable thereto, or otherwise in accordance with the applicable Award Agreement. The amount payable as a result of the vesting of an Restricted Stock Unit shall be distributed as soon as practicable following the vesting date and in no event later than the fifteenth date of the third calendar month of the year following the vesting date of the Restricted Stock Unit (or as otherwise permitted under Section 409A of the Code); provided, however, that a Grantee may, if and to the extent permitted by the Committee, elect to defer payment of Restricted Stock Units in a manner permitted by Section 409A of the Code.

(d) Termination of Employment or Service. Except as otherwise set forth in the Award Agreement, if the Grantee ceases to be employed by, or provide service to, the Employer (as defined in Section 6(e)), any Stock Award or Restricted Stock Units held by the Grantee that are subject to the transfer restrictions set forth in Section 7(b) above at such time shall be forfeited. The Committee may, however, provide for complete or partial exceptions to this requirement as it deems appropriate.

(e) No Right to Vote and to Receive Dividends. Prior to the lapse of the transfer restrictions set forth in Section 7(b) above, the Grantee shall not have the right to vote shares subject to Stock Awards or to receive any dividends or other distributions paid on such shares, subject to any restrictions deemed appropriate by the Committee.

## 8. Withholding of Taxes

(a) Required Withholding. All Awards under the Plan shall be subject to applicable federal (including FICA), state, and local tax (or other governmental obligation) withholding requirements or other administration fees due. The Employer may require that the Grantee or other person receiving or exercising Awards pay to the Employer the amount of any federal, state, or local taxes (or other governmental obligations) that the Employer is required to withhold or any administration fees due with respect to such Awards, or the Employer may deduct from other wages paid by the Employer the amount of any withholding taxes, governmental obligations or administration fees due with respect to such Awards.

(b) Election to Withhold Shares. If the Board so permits, a Grantee may elect to satisfy the Employer's income tax (or other governmental obligation) withholding requirement and any administration fees due with respect to an Award by having shares withheld up to an amount that does not exceed the Grantee's minimum applicable withholding rate for federal (including FICA), state, and local tax (and other governmental obligation) liabilities plus any other administration fees due. The election must be in a form and manner prescribed by the Committee and may be subject to the prior approval of the Committee.

9. **Transferability of Awards**

(a) Nontransferability of Awards. Except as provided below, only the Grantee may exercise rights under an Award during the Grantee's lifetime. A Grantee may not transfer those rights except by will or by the laws of descent and distribution. When a Grantee dies, the personal representative or other person entitled to succeed to the rights of the Grantee may exercise such rights. Any such successor must furnish proof satisfactory to the Company of his or her right to receive the Award under the Grantee's will or under the applicable laws of descent and distribution.

(b) Transfer of Stock Options. Notwithstanding the foregoing, the Committee may provide, in an Award Agreement, that a Grantee may transfer Options to family members, or one or more trusts or other entities for the benefit of or owned by family members, consistent with applicable securities laws, according to such terms as the Committee may determine; provided that the Grantee receives no consideration for the transfer of an Option and the transferred Option shall continue to be subject to the same terms and conditions as were applicable to the Option immediately before the transfer.

10. **Consequences of a Change of Control**

(a) Assumption of Awards. Upon a Change of Control where the Company is not the surviving corporation (or survives only as a subsidiary of another corporation), unless the Committee determines otherwise, all outstanding Awards shall be assumed by, or replaced with comparable Awards by, the surviving corporation (or a parent or subsidiary of the surviving corporation).

(b) Termination of Awards. Upon a Change of Control where the Company is not the surviving corporation (or survives only as a subsidiary of another corporation), in the event the surviving corporation (or a parent or subsidiary of the surviving corporation) does not assume or replace the Awards with comparable Awards, (i) the Company shall provide each Grantee with outstanding Awards written notice of such Change of Control; (ii) all outstanding Options shall automatically accelerate and become fully vested and exercisable; (iii) all outstanding Stock Awards shall become vested and deliverable in accordance with Section 7(b); and (iv) all outstanding Restricted Stock Units shall become vested and deliverable in accordance with Section 7(c).

(c) Other Alternatives. Notwithstanding the foregoing, in the event of a Change of Control, the Committee may take one or both of the following actions: the Committee may (i) require that Grantees surrender their outstanding Options in exchange for a payment by the

Company, in cash or Company Stock as determined by the Committee, in an amount equal to the amount by which the then Fair Market Value of the shares of Company Stock subject to the Grantee's unexercised Options exceeds the Exercise Price of the Options; or (ii) after giving Grantees an opportunity to exercise their outstanding Options, terminate any or all unexercised Options at such time as the Committee deems appropriate. Such surrender or termination shall take place as of the date of the Change of Control or such other date as the Committee may specify.

11. **Requirements for Issuance or Transfer of Shares**

(a) **Shareholder's Agreement.** The Committee may require that a Grantee execute a shareholder's agreement, with such terms as the Committee deems appropriate, with respect to any Company Stock issued or distributed pursuant to the Plan.

(b) **Limitations on Issuance or Transfer of Shares.** No Company Stock shall be issued or transferred in connection with any Award hereunder unless and until all legal requirements applicable to the issuance or transfer of such Company Stock have been complied with to the satisfaction of the Committee. The Committee shall have the right to condition any Award made to any Grantee hereunder on such Grantee's undertaking in writing to comply with such restrictions on his or her subsequent disposition of such shares of Company Stock as the Committee shall deem necessary or advisable, and certificates representing such shares may be legended to reflect any such restrictions. Certificates representing shares of Company Stock issued or transferred under the Plan shall be subject to such stop-transfer orders and other restrictions as may be required by applicable laws, regulations, and interpretations, including any requirement that a legend be placed thereon.

(c) **Lock-Up Period.** If so requested by the Company or any representative of the underwriters (the "**Managing Underwriter**") in connection with any underwritten offering of securities of the Company under the Securities Act of 1933, as amended (the "**Securities Act**"), a Grantee (including any successor or assigns) shall not sell or otherwise transfer any shares or other securities of the Company during the 30-day period preceding and the 180-day period following the effective date of a registration statement of the Company filed under the Securities Act for such underwriting (or such shorter period as may be requested by the Managing Underwriter and agreed to by the Company) (the "**Market Standoff Period**"). The Company may impose stop-transfer instructions with respect to securities subject to the foregoing restrictions until the end of such Market Standoff Period.

12. **Amendment and Termination of the Plan**

(a) **Amendment.** The Board may amend or terminate the Plan at any time; provided, however, that the Board shall not amend the Plan without shareholder approval if such approval is required in order to comply with the Code or other applicable laws or to comply with applicable stock exchange requirements.

(b) **Termination of Plan.** The Plan shall terminate on the day immediately preceding the tenth anniversary of its effective date, unless the Plan is terminated earlier by the Board or is extended by the Board.



(c) Termination and Amendment of Outstanding Awards. A termination or amendment of the Plan that occurs after an Award is made shall not materially impair the rights of a Grantee unless the Grantee consents or unless the Board acts under Section 20(b). The termination of the Plan shall not impair the power and authority of the Committee with respect to an outstanding Award. Whether or not the Plan has terminated, an outstanding Award may be terminated or amended under Section 20(b) or may be amended by agreement of the Company and the Grantee consistent with the Plan. Notwithstanding the foregoing, any such amendment or termination shall be subject to the approval of the Company's stockholders if such stockholder approval is required by any federal or state law or regulation or the rules of any stock exchange or automated quotation system on which the Company Stock may then be listed or quoted, in each case.

(d) Governing Document. The Plan shall be the controlling document. No other statements, representations, explanatory materials or examples, oral or written, may amend the Plan in any manner. The Plan shall be binding upon and enforceable against the Company and its successors and assigns.

13. **Funding of the Plan**

The Plan shall be unfunded. The Company shall not be required to establish any special or separate fund or to make any other segregation of assets to assure the payment of any Awards under the Plan. In no event shall interest be paid or accrued on any Award, including unpaid installments of Awards.

14. **Rights of Participants**

Nothing in the Plan shall entitle any Eligible Individual or other person to any claim or right to be granted an Award under the Plan. Neither the Plan nor any action taken hereunder shall be construed as giving any individual any rights to be retained by or in the employ of the Employer or any other employment rights.

15. **No Fractional Shares**

No fractional shares of Company Stock shall be issued or delivered pursuant to the Plan or any Award. The Committee shall determine whether cash, other awards or other property shall be issued or paid in lieu of such fractional shares or whether such fractional shares or any rights thereto shall be forfeited or otherwise eliminated.

16. **Headings**

Section headings are for reference only. In the event of a conflict between a title and the content of a Section, the content of the Section shall control.

17. **Effective Date of the Plan**

The Plan shall be effective on February 23, 2017.

18. **Miscellaneous**

(a) **Awards in Connection with Corporate Transactions and Otherwise.** Nothing contained in the Plan shall be construed to (i) limit the right of the Committee to make Awards under the Plan in connection with the acquisition, by purchase, lease, merger, consolidation, or otherwise, of the business or assets of any corporation, firm or association; or (ii) limit the right of the Company to grant stock options or make other awards outside of the Plan.

(b) **Compliance with Law.** The Plan, exercise of Options, restrictions of Stock Awards and obligations of the Company to issue or transfer shares of Company Stock under Awards shall be subject to all applicable laws and to approvals by any governmental or regulatory agency as may be required. With respect to persons subject to section 16 of the Exchange Act, it is the intent of the Company that the Plan and all transactions under the Plan comply with all applicable provisions of Rule 16b-3 or its successors under the Exchange Act. In addition, it is the intent of the Company that the Plan and applicable Awards under the Plan comply with the applicable provisions of section 409A of the Code. To the extent that any legal requirement of section 16 of the Exchange Act or section 409A of the Code as set forth in the Plan ceases to be required under section 16 of the Exchange Act or section 409A of the Code, that Plan provision shall cease to apply. The Committee may revoke any Award if it is contrary to law or modify an Award to bring it into compliance with any valid and mandatory government regulation. The Committee may also adopt rules regarding the withholding of taxes on payments to Grantees. The Committee may, in its sole discretion, agree to limit its authority under this Section.

(c) **Employees Subject to Taxation Outside the United States.** With respect to Grantees who are subject to taxation in countries other than the United States, the Committee may make Awards on such terms and conditions as the Committee deems appropriate to comply with the laws of the applicable countries, and the Committee may create such procedures, addenda, and subplans and make such modifications as may be necessary or advisable to comply with such laws.

(d) **Governing Law.** The validity, construction, interpretation, and effect of the Plan and Award Agreements issued under the Plan shall be governed and construed by and determined in accordance with the laws of the State of Delaware, without giving effect to the conflict of laws provisions thereof.

**STRONGBRIDGE BIOPHARMA PLC**  
**2015 EQUITY COMPENSATION PLAN**  
**INCENTIVE STOCK OPTION AWARD**

Strongbridge Biopharma plc (the “Company”) has granted you an Incentive Stock Option (the “Option”) under the 2015 Equity Compensation Plan (the “Plan”). The terms of the grant are set forth in the Incentive Stock Option Award Agreement provided to you (the “Agreement”). The following provides a summary of the key terms of the grant; however, you should read the entire Agreement, along with the terms of the Plan, to fully understand the grant.

**SUMMARY OF INCENTIVE STOCK OPTION AWARD**

**Grantee:** \_\_\_\_\_

**Date of Grant:**

**Vesting Schedule:** \_\_\_\_\_

**Exercise Price Per Share:** \_\_\_\_\_

**Total Number of Options Granted:**

**Term/Expiration Date:**

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**STRONGBRIDGE BIOPHARMA PLC**

**2015 EQUITY COMPENSATION PLAN**

**INCENTIVE STOCK OPTION AWARD AGREEMENT**

This **INCENTIVE STOCK OPTION AWARD AGREEMENT** (the "Agreement"), dated as of [ ] (the "Date of Grant"), is delivered by Strongbridge Biopharma plc (the "Company") to [ ] (the "Grantee").

**RECITALS**

A. The 2015 Equity Compensation Plan (the "Plan") provides for the grant of options to purchase shares of common stock of the Company ("Company Stock"). The Company has decided to make a stock option award as an inducement for the Grantee to promote the best interests of the Company and its stockholders. Capitalized terms that are used but not defined herein shall have the respective meanings accorded to such terms in the Plan.

B. The Plan is administered and interpreted by the Compensation Committee of the Board of Directors of the Company (the "Board") (or a subcommittee thereof), or such other committee of the Board (including, without limitation, the full Board) to which the Board has delegated power to act under or pursuant to the provisions of the Plan (the "Committee"). The Committee may delegate authority to one or more subcommittees as it deems appropriate. If a subcommittee is appointed, all references in this Agreement to the "Committee" shall be deemed to refer to the committee.

**NOW, THEREFORE**, the parties to this Agreement, intending to be legally bound hereby, agree as follows:

1. **Grant of Option.** Subject to the terms and conditions set forth in this Agreement and in the Plan, the Company hereby grants to the Grantee an Incentive Stock Option (the "Option") to purchase \_\_\_\_\_ shares of Company Stock at an exercise price of \$[ ] per share.

2. **Vesting.** The Option shall become vested and exercisable, according to the vesting schedule set forth on Attachment A, if the Grantee continues to be employed by, or provide service to, the Company (or its parent or subsidiary, as applicable) (the "Employer") from the Date of Grant until the applicable vesting date.

3. **Term of Option.**

(a) The Option shall have a term of ten (10) years from the Date of Grant and shall terminate at the expiration of that period, unless it is terminated at an earlier date pursuant to the provisions of this Agreement or the Plan.

(b) Unless a later termination date is provided for in a Company-sponsored plan, policy or arrangement, or any agreement to which the Employer is a party, the Option shall automatically terminate upon the happening of the first of the following events:

(i) The expiration of the ninety (90) day period after the Grantee ceases to be employed by, or provide service to, the Employer, if the termination is for any reason other than Disability (as defined in the Plan), death or Cause (as defined in the Plan).

(ii) The expiration of the one (1) year period after the Grantee ceases to be employed by, or provide service to, the Employer on account of the Grantee's Disability.

(iii) The expiration of the one (1) year period after the Grantee ceases to be employed by, or provide service to, the Employer, if the Grantee dies (x) while employed by, or providing service to, the Employer or (y) within ninety (90) days after the Grantee ceases to be so employed or provide such services on account of a termination described in subparagraph (i) above.

(iv) The date on which the Grantee ceases to be employed by, or provide service to, the Employer on account of a termination by the Employer for Cause. In addition, notwithstanding the prior provisions of this Paragraph 3, if the Board determines that the Grantee has engaged in conduct that constitutes Cause at any time while the Grantee is employed by, or providing service to, the Employer or after the Grantee's termination of employment or service, any Option held by the Grantee shall immediately terminate, and the Grantee shall automatically forfeit all shares underlying any exercised portion of an Option for which the Company has not yet delivered the share certificates, upon refund by the Company of the Exercise Price paid by the Grantee for such shares.

Notwithstanding the foregoing, in no event may the Option be exercised after the date that is immediately before the tenth anniversary of the Date of Grant. Any portion of the Option that is not vested and exercisable at the time the Grantee ceases to be employed by, or provide service to, the Employer shall immediately terminate.

#### 4. **Exercise Procedures**

(a) Subject to the provisions of Paragraphs 2 and 3 above, the Grantee may exercise part or all of the vested Option by delivering a written notice of exercise to the Company in the manner provided in this Agreement, specifying the number of shares of Company Stock as to which the Option is to be exercised. The Grantee shall pay the Exercise Price (i) in cash, (ii) by delivering shares of Company Stock owned by the Grantee (including Company Stock acquired in connection with the exercise of an Option, subject to such restrictions as the Committee deems appropriate) and having a Fair Market Value on the date of exercise equal to the Exercise Price or by attestation (on a form prescribed by the Committee) to ownership of shares of Company Stock having a Fair Market Value on the date of exercise equal to the Exercise Price; (iii) by payment through a broker in accordance with procedures permitted by Regulation T of the Federal Reserve Board; or (iv) by such other method as the Committee may approve. In addition, the Grantee may elect to settle the Option on a "net basis" by taking delivery of the number of Company Stock equal to Fair Market Value of the shares subject to any Option less the exercise price, any tax (or governmental obligation) or other administration fees due. The Company may impose from time to time such limitations as it deems appropriate on the use of shares of Company Stock to exercise the Option.

(b) The obligation of the Company to deliver shares of Company Stock upon exercise of the Option shall be subject to all applicable laws, rules, and regulations and such approvals by governmental agencies as may be deemed appropriate by the Company, including such actions as Company counsel shall deem necessary or appropriate to comply with relevant securities laws and regulations. The Company may require that the Grantee (or other person exercising the Option after the Grantee's death) represent that the Grantee is purchasing shares of Company Stock for the Grantee's own account and not with a view to or for sale in connection with any distribution of the shares of Company Stock, or such other representation as the Company deems appropriate.

(c) All obligations of the Company under this Agreement shall be subject to the rights of the Company as set forth in the Plan to withhold amounts required to be withheld for any taxes, if applicable. The Grantee may elect to satisfy any tax withholding obligation of the Company with respect to the Option by having shares of Company Stock withheld up to an amount that does not exceed the minimum applicable withholding tax rate for federal (including FICA), state and local tax liabilities.

5. **Designation as Incentive Stock Option.**

(a) This Option is designated an incentive stock option under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"). If the aggregate fair market value of the stock on the date of the grant with respect to which incentive stock options are exercisable for the first time by the Grantee during any calendar year, under the Plan or any other stock option plan of the Company or a parent or subsidiary, exceeds one hundred thousand dollars (\$100,000), then the Option, as to the excess, shall be treated as a nonqualified stock option that does not meet the requirements of Section 422. If and to the extent that the Option fails to qualify as an incentive stock option under the Code, the Option shall remain outstanding according to its terms as a nonqualified stock option.

(b) The Grantee understands that favorable incentive stock option tax treatment is available only if the Option is exercised while the Grantee is an employee of the Employer or within a period of time specified in the Code after the Grantee ceases to be an employee. The Grantee understands that the Grantee is responsible for the income tax consequences of the Option, and, among other tax consequences, the Grantee understands that he or she may be subject to the alternative minimum tax under the Code in the year in which the Option is exercised. The Grantee will consult with his or her tax adviser regarding the tax consequences of the Option.

(c) The Grantee agrees that the Grantee shall immediately notify the Company in writing if the Grantee sells or otherwise disposes of any Shares acquired upon the exercise of the Option and such sale or other disposition occurs on or before the later of (i) two (2) years after the Date of Grant or (ii) one (1) year after the exercise of the Option. The Grantee also agrees to provide the Company with any information requested by the Company with respect to such sale or other disposition.

6. **Change of Control.** Upon a Change of Control (as defined in the Plan), the Option shall automatically accelerate and become fully vested and exercisable, provided that the Grantee is employed by, or providing service to, the Employer on the date of such Change of Control.

7. **Restrictions on Exercise.** Except as the Company may otherwise permit pursuant to the Plan, only the Grantee may exercise rights under the Option during the Grantee's lifetime and, after the Grantee's death, the Option shall be exercisable (subject to the limitations specified in the Plan) solely by the personal representative or other person entitled to succeed to the rights of the Grantee, or by the person who acquires the right to exercise the Option by will or by the laws of descent and distribution, to the extent that the Option is vested and exercisable pursuant to this Agreement. Any such successor must furnish proof satisfactory to the Company of his or her right to receive the Option under the Grantee's will or under the applicable laws of descent and distribution.

8. **Adjustments.** The provisions of the Plan applicable to Adjustments (as described in Section 3 of the Plan) shall apply to the Option.

9. **Grant Subject to Plan Provisions.** This grant is made pursuant to the Plan, the terms of which are incorporated herein by reference, and in all respects shall be interpreted in accordance with the Plan. The grant and exercise of the Option are subject to interpretations, regulations and determinations concerning the Plan established from time to time by the Committee in accordance with the provisions of the Plan, including, but not limited to, provisions pertaining to (i) rights and obligations with respect to withholding taxes, (ii) the registration, qualification or listing of the shares of Company Stock, (iii) changes in capitalization of the Company and (iv) other requirements of applicable law. The Committee shall have the authority to interpret and construe the Option pursuant to the terms of the Plan, and its decisions shall be conclusive as to any questions arising hereunder.

10. **No Employment or Other Rights.** The grant of the Option shall not confer upon the Grantee any right to be retained by or in the employ or service of the Company and shall not interfere in any way with the right of the Company to terminate the Grantee's employment or service at any time. The right of the Company to terminate at will the Grantee's employment or service at any time for any reason is specifically reserved.

11. **No Shareholder Rights.** Neither the Grantee, nor any person entitled to exercise the Grantee's rights in the event of the Grantee's death, shall have any of the rights and privileges of a shareholder with respect to the shares of Company Stock subject to the Option, until certificates for shares of Company Stock have been issued upon the exercise of the Option.

12. **Assignment and Transfers.** Except as the Committee may otherwise permit pursuant to the Plan, the rights and interests of the Grantee under this Agreement may not be sold, assigned, encumbered or otherwise transferred except, in the event of the death of the Grantee, by will or by the laws of descent and distribution. In the event of any attempt by the Grantee to alienate, assign, pledge, hypothecate, or otherwise dispose of the Option or any right hereunder, except as provided for in this Agreement, or in the event of the levy or any attachment, execution or similar process upon the rights or interests hereby conferred, the Company may terminate the Option by notice to the Grantee, and the Option and all rights hereunder shall thereupon become null and void. The rights and protections of the Company hereunder shall extend to any successors or assigns of the Company and to the Company's parents, subsidiaries, and affiliates. This Agreement may be assigned by the Company without the Grantee's consent.

13. **Applicable Law.** The validity, construction, interpretation and effect of this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to the conflicts of laws provisions thereof.

14. **Notice.** Any notice to the Company provided for in this Agreement shall be addressed to the Company, in care of the Committee, and any notice to the Grantee shall be addressed to such Grantee at the current address shown on the payroll of the Company, or to such other address as the Grantee may designate to the Company in writing.



**IN WITNESS WHEREOF**, the Company has caused its duly authorized officer to execute this Agreement, and the Grantee has executed this Agreement, effective as of the Date of Grant.

Strongbridge Biopharma plc

By:

Name:

Title:

I hereby accept the Option described in this Agreement, and I agree to be bound by the terms of the Plan and this Agreement. I hereby further agree that all the decisions and determinations of the Committee shall be final and binding.

Grantee: \_

Date: \_

*(Signature Page to Incentive Stock Option Award Agreement)*

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**ATTACHMENT A**

The Option shall become vested and exercisable according to the following vesting schedule, if the Grantee continues to be employed by, or provide service to, the Employer from the Date of Grant until the applicable vesting date:

[VESTING SCHEDULE]

The vesting of the Option shall be cumulative, but shall not exceed 100% of the shares subject to the Option granted above. If the foregoing schedule would produce fractional shares, the portion of the Option that vests shall be rounded down to the nearest whole share.

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**STRONGBRIDGE BIOPHARMA PLC**  
**2015 EQUITY COMPENSATION PLAN**  
**NONQUALIFIED STOCK OPTION AWARD**

Strongbridge Biopharma plc (the “Company”) has granted you a Nonqualified Stock Option (the “Option”) under the 2015 Equity Compensation Plan (the “Plan”). The terms of the grant are set forth in the Nonqualified Stock Option Award Agreement provided to you (the “Agreement”). The following provides a summary of the key terms of the grant; however, you should read the entire Agreement, along with the terms of the Plan, to fully understand the grant.

**SUMMARY OF NONQUALIFIED STOCK OPTION AWARD**

**Grantee:** [NAME]

**Date of Grant:** \_\_\_\_\_

**Vesting Schedule:** 16 equal, quarterly installments following the Grant Date (provided employee is employed by the Company on each vesting date)

**Exercise Price Per Share:** \$ \_\_\_\_\_

**Total Number of Options Granted:** [#UNITS]

**Term/Expiration Date:** \_\_\_\_\_

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**STRONGBRIDGE BIOPHARMA PLC**

**2015 EQUITY COMPENSATION PLAN**

**NONQUALIFIED STOCK OPTION AWARD AGREEMENT**

This **NONQUALIFIED STOCK OPTION AWARD AGREEMENT** (the "Agreement"), dated as of \_\_\_\_\_ (the "Date of Grant"), is delivered by Strongbridge Biopharma plc (the "Company") to [NAME] (the "Grantee").

**RECITALS**

A. The 2015 Equity Compensation Plan (the "Plan") provides for the grant of options to purchase shares of common stock of the Company ("Company Stock"). The Company has decided to make a stock option award as an inducement for the Grantee to promote the best interests of the Company and its stockholders. Capitalized terms that are used but not defined herein shall have the respective meanings accorded to such terms in the Plan.

B. The Plan is administered and interpreted by the Compensation Committee of the Board of Directors of the Company (the "Board") (or a subcommittee thereof), or such other committee of the Board (including, without limitation, the full Board) to which the Board has delegated power to act under or pursuant to the provisions of the Plan (the "Committee"). The Committee may delegate authority to one or more subcommittees as it deems appropriate. If a subcommittee is appointed, all references in this Agreement to the "Committee" shall be deemed to refer to the committee.

**NOW, THEREFORE**, the parties to this Agreement, intending to be legally bound hereby, agree as follows:

1. **Grant of Option.** Subject to the terms and conditions set forth in this Agreement and in the Plan, the Company hereby grants to the Grantee a Nonqualified Stock Option (the "Option") to purchase [#UNITS] shares of Company Stock at an exercise price of \$\_\_\_\_\_ per share.

2. **Vesting.** The Option shall become vested and exercisable, according to the following vesting schedule, if the Grantee continues to be employed by, or provide service to, the Company (or its parent or subsidiary, as applicable) (the "Employer") from the Date of Grant until the applicable vesting date.

<b><u>Vesting Date</u></b>	<b><u>% of Option Vested</u></b>
16 equal, quarterly installments following the Grant Date (provided employee is employed by the Company on each vesting date)	100% of the Option

The vesting of the Option shall be cumulative, but shall not exceed 100% of the shares subject to the Option granted above. If the foregoing schedule would produce fractional shares, the portion of the Option that vests shall be rounded down to the nearest whole share.

3. **Term of Option.**

(a) The Option shall have a term of ten (10) years from the Date of Grant and shall terminate at the expiration of that period, unless it is terminated at an earlier date pursuant to the provisions of this Agreement or the Plan.

(b) Unless a later termination date is provided for in a Company-sponsored plan, policy or arrangement, or any agreement to which the Employer is a party, the Option shall automatically terminate upon the happening of the first of the following events:

(i) The expiration of the ninety (90) day period after the Grantee ceases to be employed by, or provide service to, the Employer, if the termination is for any reason other than Disability (as defined in the Plan), death or Cause (as defined in the Plan).

(ii) The expiration of the one (1) year period after the Grantee ceases to be employed by, or provide service to, the Employer on account of the Grantee's Disability.

(iii) The expiration of the one (1) year period after the Grantee ceases to be employed by, or provide service to, the Employer, if the Grantee dies (x) while employed by, or providing service to, the Employer or (y) within ninety (90) days after the Grantee ceases to be so employed or provide such services on account of a termination described in subparagraph (i) above.

(iv) The date on which the Grantee ceases to be employed by, or provide service to, the Employer on account of a termination by the Employer for Cause. In addition, notwithstanding the prior provisions of this Paragraph 3, if the Board determines that the Grantee has engaged in conduct that constitutes Cause at any time while the Grantee is employed by, or providing service to, the Employer or after the Grantee's termination of employment or service, any Option held by the Grantee shall immediately terminate, and the Grantee shall automatically forfeit all shares underlying any exercised portion of an Option for which the Company has not yet delivered the share certificates, upon refund by the Company of the Exercise Price paid by the Grantee for such shares.

Notwithstanding the foregoing, in no event may the Option be exercised after the date that is immediately before the tenth anniversary of the Date of Grant. Any portion of the Option that is not vested and exercisable at the time the Grantee ceases to be employed by, or provide service to, the Employer shall immediately terminate.

4. **Exercise Procedures**

(a) Subject to the provisions of Paragraphs 2 and 3 above, the Grantee may exercise part or all of the vested Option by delivering a written notice of exercise to the Company in the manner provided in this Agreement, specifying the number of shares of Company Stock as to

which the Option is to be exercised. The Grantee shall pay the Exercise Price (i) in cash, (ii) by delivering shares of Company Stock owned by the Grantee (including Company Stock acquired in connection with the exercise of an Option, subject to such restrictions as the Committee deems appropriate) and having a Fair Market Value on the date of exercise equal to the Exercise Price or by attestation (on a form prescribed by the Committee) to ownership of shares of Company Stock having a Fair Market Value on the date of exercise equal to the Exercise Price; (iii) by payment through a broker in accordance with procedures permitted by Regulation T of the Federal Reserve Board; or (iv) by such other method as the Committee may approve. In addition, the Grantee may elect to settle the Option on a "net basis" by taking delivery of the number of Company Stock equal to Fair Market Value of the shares subject to any Option less the exercise price, any tax (or governmental obligation) or other administration fees due. The Company may impose from time to time such limitations as it deems appropriate on the use of shares of Company Stock to exercise the Option.

(b) The obligation of the Company to deliver shares of Company Stock upon exercise of the Option shall be subject to all applicable laws, rules, and regulations and such approvals by governmental agencies as may be deemed appropriate by the Company, including such actions as Company counsel shall deem necessary or appropriate to comply with relevant securities laws and regulations. The Company may require that the Grantee (or other person exercising the Option after the Grantee's death) represent that the Grantee is purchasing shares of Company Stock for the Grantee's own account and not with a view to or for sale in connection with any distribution of the shares of Company Stock, or such other representation as the Company deems appropriate.

(c) All obligations of the Company under this Agreement shall be subject to the rights of the Company as set forth in the Plan to withhold amounts required to be withheld for any taxes, if applicable. The Grantee may elect to satisfy any tax withholding obligation of the Company with respect to the Option by having shares of Company Stock withheld up to an amount that does not exceed the minimum applicable withholding tax rate for federal (including FICA), state and local tax liabilities.

5. **Change of Control.** Upon a Change of Control (as defined in the Plan), the Option shall automatically accelerate and become fully vested and exercisable, provided that the Grantee is employed by, or providing service to, the Employer on the date of such Change of Control.

6. **Restrictions on Exercise.** Except as the Company may otherwise permit pursuant to the Plan, only the Grantee may exercise rights under the Option during the Grantee's lifetime and, after the Grantee's death, the Option shall be exercisable (subject to the limitations specified in the Plan) solely by the personal representative or other person entitled to succeed to the rights of the Grantee, or by the person who acquires the right to exercise the Option by will or by the laws of descent and distribution, or if permitted in any case by the Committee, pursuant to a domestic relations order or otherwise as permitted by the Committee, to the extent that the Option is vested and exercisable pursuant to this Agreement. Any such successor must furnish proof satisfactory to the Company of his or her right to receive the Option under the Grantee's will or under the applicable laws of descent and distribution.

7. **Adjustments.** The provisions of the Plan applicable to Adjustments (as described in Section 3 of the Plan) shall apply to the Option.

8. **Grant Subject to Plan Provisions.** This grant is made pursuant to the Plan, the terms of which are incorporated herein by reference, and in all respects shall be interpreted in accordance with the Plan. The grant and exercise of the Option are subject to interpretations, regulations and determinations concerning the Plan established from time to time by the Committee in accordance with the provisions of the Plan, including, but not limited to, provisions pertaining to (i) rights and obligations with respect to withholding taxes, (ii) the registration, qualification or listing of the shares of Company Stock, (iii) changes in capitalization of the Company and (iv) other requirements of applicable law. The Committee shall have the authority to interpret and construe the Option pursuant to the terms of the Plan, and its decisions shall be conclusive as to any questions arising hereunder.

9. **No Employment or Other Rights.** The grant of the Option shall not confer upon the Grantee any right to be retained by or in the employ or service of the Company and shall not interfere in any way with the right of the Company to terminate the Grantee's employment or service at any time. The right of the Company to terminate at will the Grantee's employment or service at any time for any reason is specifically reserved.

10. **No Shareholder Rights.** Neither the Grantee, nor any person entitled to exercise the Grantee's rights in the event of the Grantee's death, shall have any of the rights and privileges of a shareholder with respect to the shares of Company Stock subject to the Option, until certificates for shares of Company Stock have been issued upon the exercise of the Option.

11. **Assignment and Transfers.** Except as the Committee may otherwise permit pursuant to the Plan, the rights and interests of the Grantee under this Agreement may not be sold, assigned, encumbered or otherwise transferred except, in the event of the death of the Grantee, by will or by the laws of descent and distribution or if permitted in any specific case by the Committee, pursuant to a domestic relations order or otherwise as permitted by the Committee. In the event of any attempt by the Grantee to alienate, assign, pledge, hypothecate, or otherwise dispose of the Option or any right hereunder, except as provided for in this Agreement, or in the event of the levy or any attachment, execution or similar process upon the rights or interests hereby conferred, the Company may terminate the Option by notice to the Grantee, and the Option and all rights hereunder shall thereupon become null and void. The rights and protections of the Company hereunder shall extend to any successors or assigns of the Company and to the Company's parents, subsidiaries, and affiliates. This Agreement may be assigned by the Company without the Grantee's consent.

12. **Applicable Law.** The validity, construction, interpretation and effect of this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to the conflicts of laws provisions thereof.

13. **Notice.** Any notice to the Company provided for in this Agreement shall be addressed to the Company in care of the Committee, and any notice to the Grantee shall be addressed to such Grantee at the current address shown on the payroll of the Company, or to such other address as the Grantee may designate to the Company in writing.

**IN WITNESS WHEREOF**, the Company has caused its duly authorized officer to execute this Agreement, and the Grantee has executed this Agreement, effective as of the Date of Grant.

Strongbridge Biopharma plc

By: \_\_\_\_\_  
Name: Matthew Pauls  
Title: Chief Executive Officer

I hereby accept the Option described in this Agreement, and I agree to be bound by the terms of the Plan and this Agreement. I hereby further agree that all the decisions and determinations of the Committee shall be final and binding.

Grantee:

\_\_\_\_\_  
Name: [name]

Date: \_\_\_\_\_

*(Signature Page to Nonqualified Stock Option Award Agreement)*

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**STRONGBRIDGE BIOPHARMA PLC**  
**2015 EQUITY COMPENSATION PLAN**  
**RESTRICTED STOCK UNIT AWARD**

Strongbridge Biopharma plc (the “Company”) has determined to grant to you an award of restricted stock units (the “RSUs”) under the 2015 Equity Compensation Plan (the “Plan”). The terms of the grant are set forth in the attached Restricted Stock Unit Award Agreement (the “Agreement”). The following provides a summary of the key terms of the Agreement; however, you should read the entire Agreement along with the terms of the Plan, to fully understand the Agreement.

**SUMMARY OF RESTRICTED STOCK UNIT AWARD**

<b>Grantee:</b>	[name]
<b>Date of Grant:</b>	[date]
<b>Vesting Schedule:</b>	100% vest on 2-year anniversary of Date of Grant (provided employee is employed by the Company on such vesting date)
<b>Total Number of Restricted Stock Units Granted:</b>	[#units]

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## STRONGBRIDGE BIOPHARMA PLC

### 2015 EQUITY COMPENSATION PLAN

#### RESTRICTED STOCK UNIT AWARD AGREEMENT

This RESTRICTED STOCK UNIT AWARD AGREEMENT (the “Agreement”), dated as of [DATE], (the “Date of Grant”) is delivered by Strongbridge Biopharma plc (the “Company”), to [NAME] (the “Grantee”).

The Company has determined to provide the Grantee an award of restricted stock units under the 2015 Equity Compensation Plan (the “Plan”) and in accordance with the terms and conditions set forth in this Agreement. Capitalized terms that are used but not defined herein shall have the respective meanings accorded to such terms in the Plan.

The Plan is administered and interpreted by the Compensation Committee of the Board of Directors of the Company (the “Board”) (or a subcommittee thereof), or such other committee of the Board (including, without limitation, the full Board) to which the Board has delegated power to act under or pursuant to the provisions of the Plan (the “Committee”). The Committee may delegate authority to one or more subcommittees as it deems appropriate. If a subcommittee is appointed, all references in this Agreement to the “Committee” shall be deemed to refer to the committee.

The Company and Grantee, intending to be legally bound hereby, agree as follows:

**1. Grant of Restricted Stock Unit Award.** Subject to the terms and conditions set forth in this Agreement and the Plan, the Company hereby awards to the Grantee [#units] Restricted Stock Units (the “RSUs”) under the Plan. The Grantee accepts the RSUs and agrees to be bound by the terms and conditions of this Agreement and the Plan with respect to the award. Each vested RSU entitles the Grantee to receive one share of Company Stock, as described in Paragraph 2 below.

**2. Vesting of Award/Payment of Shares.**

(a) The RSUs shall vest in full on the second anniversary of the Date of Grant (the “Vesting Date”), if the Grantee continues to be employed by, or provide service to, the Company (or its parent or subsidiary, as applicable) (the “Employer”) from the Date of Grant until the Vesting Date.

(b) If and when the RSUs vest, the Company will issue to the Grantee one share of Company Stock for each whole RSU that has vested, subject to satisfaction of the Grantee’s tax withholding obligations as described in Paragraph 5 below. The RSUs shall cease to be outstanding upon such issuance of shares.

(c) Unless otherwise provided in a Company-sponsored plan, policy or arrangement, or any agreement to which the Employer is a party, the Grantee shall forfeit the unvested RSUs in

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the event the Grantee ceases to be employed by, or provide service to, the Employer prior to the Vesting Date.

**3. No Stockholder Rights Prior to Settlement; Issuance of Certificates.** The Grantee shall have no rights as a stockholder with respect to any shares of Company Stock represented by the RSUs until the date of issuance of the shares of Company Stock (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), if applicable. Except as otherwise required by the Plan, no adjustment shall be made for dividends, distributions, or other rights for which the record date is prior to the date, if any, that shares of Company Stock are issued.

**4. Change of Control.** Upon a Change of Control (as defined in the Plan), the RSUs shall accelerate and vest and shall be paid pursuant to Paragraph 2(b) above, provided that the Grantee is employed by, or providing service to, the Employer on the date of such Change of Control.

**5. Withholding.** The Grantee shall be required to pay to the Company, or make other arrangements satisfactory to the Company to provide for the payment of, any federal, state, local or other taxes that the Employer is required to withhold with respect to the grant or vesting of the RSUs, or the Employer may deduct from other wages paid by the Employer the amount of any withholding taxes due with respect to the RSUs. The Grantee may elect to satisfy any income tax withholding obligation of the Employer with respect to the RSUs by having shares of Company Stock withheld up to an amount that does not exceed the minimum applicable withholding tax rate for federal (including FICA), state, local and other tax liabilities. Unless the tax withholding obligations of the Company are satisfied, the Company shall have no obligation to deliver to the Grantee any Company Stock. In the event the Company's obligation to withhold arises prior to the delivery to the Grantee of shares of Company Stock or it is determined after the delivery of shares of Company Stock to the Grantee that the amount of the Company's withholding obligation was greater than the amount withheld by the Company, the Grantee agrees to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

**6. Adjustments.** The provisions of the Plan applicable to adjustments (as described in Section 3 of the Plan) shall apply to the RSUs.

**7. Assignment and Transfers.** The rights and interests of the Grantee under this Agreement may not be sold, assigned, encumbered or otherwise transferred except, in the event of the death of the Grantee, by will or by the laws of descent and distribution. In the event of any attempt by the Grantee to alienate, assign, pledge, hypothecate, or otherwise dispose of the RSUs or any right hereunder, or in the event of the levy or any attachment, execution or similar process upon the rights or interests hereby conferred, the Company may terminate the RSUs by notice to the Grantee, and the RSUs and all rights hereunder shall thereupon become null and void. The rights and protections of the Company hereunder shall extend to any successors or assigns of the Company and to the Company's parents, subsidiaries, and affiliates. This Agreement may be assigned by the Company without the Grantee's consent.

**8. Miscellaneous.**

( a ) No Right to Employment. The grant of the RSUs shall not be construed as giving the Grantee the right to be retained by or in the employ of the Employer or any other employment right.

( b ) Delivery Subject to Legal Requirements. The obligation of the Company to deliver stock shall be subject to the condition that if at any time the Board shall determine in its discretion that the listing, registration or qualification of the shares upon any securities exchange or under any state or federal law, or the consent or approval of any governmental regulatory body is necessary or desirable as a condition of, or in connection with, the issue of shares, the shares may not be issued in whole or in part unless such listing, registration, qualification, consent or approval shall have been effected or obtained free of any conditions not acceptable to the Board. The issuance of shares to the Grantee pursuant to this Agreement is subject to any applicable taxes and other laws or regulations of the United States or of any state having jurisdiction thereof.

( c ) RSUs Subject to Plan. By entering into this Agreement the Grantee agrees and acknowledges that the Grantee has received and read a copy of the Plan. The RSUs are subject to the terms and provisions of the Plan, as they may be amended from time to time, and such terms and provisions of the Plan are hereby incorporated herein by reference. In the event of a conflict between any term or provision contained herein and a term or provision of the Plan, the applicable terms and provisions of the Plan will govern and prevail.

( d ) Committee Authority. By entering into this Agreement the Grantee agrees and acknowledges that all decisions and determinations of the Committee shall be final and binding on the Grantee, his or her beneficiaries and any other person having or claiming an interest in the RSUs.

( e ) Severability. If any provision of this Agreement is or becomes or is deemed to be invalid, illegal or unenforceable in any jurisdiction or would disqualify this Agreement or the RSUs under any applicable law, such provision shall be construed or deemed amended to conform to applicable law (or if such provision cannot be so construed or deemed amended without materially altering the purpose or intent of this Agreement and the grant of the RSUs hereunder, such provision shall be stricken as to such jurisdiction and the remainder of this Agreement and the award shall remain in full force and effect).

( d ) Notices. Any notice to be given to the Company under the terms of this Agreement shall be addressed to the Company, at the attention of the Committee, at its principal place of business, and any notice to be given to Grantee may be sent to Grantee's address as it appears in the payroll records of the Company, or at such other addresses as either party may designate in writing to the other.

( e ) Section 409A. This Agreement and the RSUs granted hereunder are intended to fit within the "short-term deferral" exemption from Section 409A of the Code, as set forth in Treasury Regulation Section 1.409A-1(b)(4) or any successor provision, or to comply with, or otherwise be exempt from, Section 409A of the Code. This Agreement and the RSUs shall be administered, interpreted and construed in a manner consistent with Section 409A of the Code. Each amount

payable under this Agreement is designated as a separate identified payment for purposes of Section 409A of the Code. The payment of dividend equivalents under Paragraph 3 of this Agreement shall be construed as earnings and the time and form of payment of such dividend equivalents shall be treated separately from the time and form of payment of the underlying RSUs for purposes of Section 409A of the Code.

(f) Governing Law. The validity, construction, interpretation and effect of this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to the conflict of laws provisions thereof

(g) Interpretation. The Grantee accepts the RSUs subject to all the terms and provisions of this Agreement and the terms and conditions of the Plan.

(g) Headings. Headings are given to the paragraphs and subparagraphs of this Agreement solely as a convenience to facilitate reference. Such headings shall not be deemed in any way material or relevant to the construction or interpretation of this Agreement or any provision thereof.

(h) Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement. Facsimile or other electronic transmission of any signed original document or retransmission of any signed facsimile or other electronic transmission will be deemed the same as delivery of an original.

(i) Complete Agreement. Except as otherwise provided for herein, this Agreement and those agreements and documents expressly referred to herein embody the complete agreement and understanding among the parties and supersede and preempt any prior understandings, agreements or representations by or among the parties, written or oral, which may have related to the subject matter hereof in any way. The terms of this Agreement shall be binding upon the executors, administrators, heirs, successors and assigns of the Grantee.

*[Signature Page Follows]*

**IN WITNESS WHEREOF**, the Company and Grantee have executed this Agreement as of the grant date shown above.

**Strongbridge Biopharma plc**

By: \_\_\_\_\_  
Name: Matthew Pauls  
Title: Chief Executive Officer

I hereby accept the RSUs described in this Agreement, and I agree to be bound by the terms of the Plan and this Agreement. I hereby further agree that all the decisions and determinations of the Committee shall be final and binding.

**GRANTEE:**

\_\_\_\_\_  
Name: [name]

Date: \_\_\_\_\_

*(Signature Page to Restricted Stock Unit Award Agreement)*

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**STRONGBRIDGE BIOPHARMA PLC****2015 NON-EMPLOYEE DIRECTOR EQUITY COMPENSATION PLAN****NONQUALIFIED STOCK OPTION AWARD**

Strongbridge Biopharma plc (the “Company”) has granted you a Stock Option (the “Option”) under the Non-Employee Director Equity Compensation Plan (the “Plan”). The terms of the grant are set forth in the Stock Option Award Agreement provided to you (the “Agreement”). The following provides a summary of the key terms of the grant; however, you should read the entire Agreement, along with the terms of the Plan, to fully understand the grant.

**SUMMARY OF NONQUALIFIED STOCK OPTION AWARD**

<b>Grantee:</b>	[name]
<b>Date of Grant:</b>	[date]
<b>Vesting Schedule:</b>	To vest and become exercisable (i) on [date], provided that the applicable member of the Board continues to provide service as a member of the Board continuously from the date of grant through [date]; (ii) upon a change of control of the Company, provided the applicable member of the Board is a director of the Company on such date.
<b>Exercise Price Per Share:</b>	[price]
<b>Total Number of Options Granted:</b>	[#units]
<b>Term/Expiration Date:</b>	[date]

---

**STRONGBRIDGE BIOPHARMA PLC**

**NON-EMPLOYEE DIRECTOR EQUITY COMPENSATION PLAN**

**NONQUALIFIED STOCK OPTION AWARD AGREEMENT**

This **STOCK OPTION AWARD AGREEMENT** (the "Agreement"), dated as of [date] (the "Date of Grant"), is delivered by Strongbridge Biopharma plc (the "Company") to [name] (the "Grantee").

**RECITALS**

A. The Non-Employee Director Equity Compensation Plan (the "Plan") provides for the grant of options to purchase shares of common stock of the Company ("Company Stock"). The Company has decided to make a stock option award as an inducement for the Grantee to promote the best interests of the Company and its stockholders. Capitalized terms that are used but not defined herein shall have the respective meanings accorded to such terms in the Plan.

B. The Plan is administered and interpreted by the Board of Directors of the Company (the "Board").

**NOW, THEREFORE**, the parties to this Agreement, intending to be legally bound hereby, agree as follows:

1. **Grant of Option**. Subject to the terms and conditions set forth in this Agreement and in the Plan, the Company hereby grants to the Grantee a Stock Option (the "Option") to purchase \_\_\_\_\_ shares of Company Stock at an exercise price of \$[\_\_\_\_\_] per share.
2. **Vesting**. The Option shall become vested and exercisable, according to the following vesting schedule, if the Grantee continues to provide service to the Company from the Date of Grant until the applicable vesting date:

<b><u>Vesting Date</u></b>	<b><u>% of Option Vested</u></b>
To vest and become exercisable (i) on [date], provided that the applicable member of the Board continues to provide service as a member of the Board continuously from the date of grant through [date]; (ii) upon a change of control of the Company, provided the applicable member of the Board is a director of the Company on such date.	100%

The vesting of the Option shall be cumulative, but shall not exceed 100% of the shares subject to the Option granted above. If the foregoing schedule would produce fractional shares, the portion of the Option that vests shall be rounded down to the nearest whole share.



3. **Term of Option.**

(a) The Option shall have a term of ten (10) years from the Date of Grant and shall terminate at the expiration of that period, unless it is terminated at an earlier date pursuant to the provisions of this Agreement or the Plan.

(b) Unless a later termination date is provided for in a Company-sponsored plan, policy or arrangement, or any agreement to which the Company is a party, the Option shall automatically terminate upon the happening of the first of the following events:

(i) The expiration of the ninety (90) day period after the Grantee ceases to provide service to the Company, if the termination is for any reason other than Disability (as defined in the Plan), death or Cause (as defined in the Plan).

(ii) The expiration of the one (1) year period after the Grantee ceases to provide service to the Company on account of the Grantee's Disability.

(iii) The expiration of the one (1) year period after the Grantee ceases to provide service to the Company, if the Grantee dies (x) while providing service to the Company or (y) within ninety (90) days after the Grantee ceases to provide such services on account of a termination described in subparagraph (i) above.

(iv) The date on which the Grantee ceases to provide service to the Company on account of a removal for Cause. In addition, notwithstanding the prior provisions of this Paragraph 3, if a majority of disinterested members of the Board determines that the Grantee has engaged in conduct that constitutes Cause at any time while the Grantee is providing service to the Company or after the Grantee's termination of service, any Option held by the Grantee shall immediately terminate, and the Grantee shall automatically forfeit all shares underlying any exercised portion of an Option for which the Company has not yet delivered the share certificates, upon refund by the Company of the Exercise Price paid by the Grantee for such shares.

Notwithstanding the foregoing, in no event may the Option be exercised after the date that is immediately before the tenth anniversary of the Date of Grant. Any portion of the Option that is not vested and exercisable at the time the Grantee ceases to provide service to the Company shall immediately terminate.

4. **Exercise Procedures**

(a) Subject to the provisions of Paragraphs 2 and 3 above, the Grantee may exercise part or all of the vested Option by delivering a written notice of exercise to the Company in the manner provided in this Agreement, specifying the number of shares of Company Stock as to which the Option is to be exercised. The Grantee shall pay the Exercise Price (i) in cash, (ii) by delivering shares of Company Stock owned by the Grantee (including Company Stock acquired in connection with the exercise of an Option, subject to such restrictions as the Board deems appropriate) and having a Fair Market Value on the date of exercise equal to the Exercise Price or by attestation (on a form prescribed by the Board) to ownership of shares of Company Stock having a Fair Market Value on the date of exercise equal to the Exercise Price; (iii) after a Public Offering,

by payment through a broker in accordance with procedures permitted by Regulation T of the Federal Reserve Board; or (iv) by such other method as the Board may approve. In addition, the Grantee may elect to settle the Option on a “net basis” by taking delivery of the number of Company Stock equal to Fair Market Value of the shares subject to any Option less the exercise price, any tax (or governmental obligation) or other administration fees due. The Company may impose from time to time such limitations as it deems appropriate on the use of shares of Company Stock to exercise the Option.

(b) The obligation of the Company to deliver shares of Company Stock upon exercise of the Option shall be subject to all applicable laws, rules, and regulations and such approvals by governmental agencies as may be deemed appropriate by the Company, including such actions as Company counsel shall deem necessary or appropriate to comply with relevant securities laws and regulations. The Company may require that the Grantee (or other person exercising the Option after the Grantee’s death) represent that the Grantee is purchasing shares of Company Stock for the Grantee’s own account and not with a view to or for sale in connection with any distribution of the shares of Company Stock, or such other representation as the Company deems appropriate.

5. **Change of Control.** Upon a Change of Control (as defined in the Plan), the Option shall automatically accelerate and become fully vested and exercisable, provided that the Grantee is providing service to the Company on the date of such Change of Control.

6. **Restrictions on Exercise.** Except as the Company may otherwise permit pursuant to the Plan, only the Grantee may exercise rights under the Option during the Grantee’s lifetime and, after the Grantee’s death, the Option shall be exercisable (subject to the limitations specified in the Plan) solely by the personal representative or other person entitled to succeed to the rights of the Grantee, or by the person who acquires the right to exercise the Option by will or by the laws of descent and distribution, or if permitted in any case by the Board, pursuant to a domestic relations order or otherwise as permitted by the Board, to the extent that the Option is vested and exercisable pursuant to this Agreement. Any such successor must furnish proof satisfactory to the Company of his or her right to receive the Option under the Grantee’s will or under the applicable laws of descent and distribution.

7. **Adjustments.** The provisions of the Plan applicable to Adjustments (as described in Section 3 of the Plan) shall apply to the Option.

8. **Grant Subject to Plan Provisions.** This grant is made pursuant to the Plan, the terms of which are incorporated herein by reference, and in all respects shall be interpreted in accordance with the Plan. The grant and exercise of the Option are subject to interpretations, regulations and determinations concerning the Plan established from time to time by the Board in accordance with the provisions of the Plan, including, but not limited to, provisions pertaining to (i) rights and obligations with respect to withholding taxes, (ii) the registration, qualification or listing of the shares of Company Stock, (iii) changes in capitalization of the Company and (iv) other requirements of applicable law. The Board shall have the authority to interpret and construe the Option pursuant to the terms of the Plan, and its decisions shall be conclusive as to any questions arising hereunder.

9. **No Rights to Continued Service.** The grant of the Option shall not confer upon the Grantee any right to be retained by or in the service of the Company and shall not interfere in any way with the right of the Board to terminate the Grantee's service.

10. **No Shareholder Rights.** Neither the Grantee, nor any person entitled to exercise the Grantee's rights in the event of the Grantee's death, shall have any of the rights and privileges of a shareholder with respect to the shares of Company Stock subject to the Option, until certificates for shares of Company Stock have been issued upon the exercise of the Option.

11. **Assignment and Transfers.** Except as the Board may otherwise permit pursuant to the Plan, the rights and interests of the Grantee under this Agreement may not be sold, assigned, encumbered or otherwise transferred except, in the event of the death of the Grantee, by will or by the laws of descent and distribution or if permitted in any specific case by the Board, pursuant to a domestic relations order or otherwise as permitted by the Board. In the event of any attempt by the Grantee to alienate, assign, pledge, hypothecate, or otherwise dispose of the Option or any right hereunder, except as provided for in this Agreement, or in the event of the levy or any attachment, execution or similar process upon the rights or interests hereby conferred, the Company may terminate the Option by notice to the Grantee, and the Option and all rights hereunder shall thereupon become null and void. The rights and protections of the Company hereunder shall extend to any successors or assigns of the Company and to the Company's parents, subsidiaries, and affiliates. This Agreement may be assigned by the Company without the Grantee's consent.

12. **Applicable Law.** The validity, construction, interpretation and effect of this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to the conflicts of laws provisions thereof.

13. **Notice.** Any notice to the Company provided for in this Agreement shall be addressed to the Company in care of the Board, and any notice to the Grantee shall be addressed to such Grantee at the current address shown on the payroll of the Company, or to such other address as the Grantee may designate to the Company in writing.

**IN WITNESS WHEREOF**, the Company has caused its duly authorized officer to execute this Agreement, and the Grantee has executed this Agreement, effective as of the Date of Grant.

Strongbridge Biopharma plc

By:  
Name: Matthew Pauls  
Title: Chief Executive Officer

I hereby accept the Option described in this Agreement, and I agree to be bound by the terms of the Plan and this Agreement. I hereby further agree that all the decisions and determinations of the Board shall be final and binding.

**Grantee:**

Name: [name]

Date:

*(Signature Page to Nonqualified Stock Option Award Agreement)*

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LEASE

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NORTHBROOK TC EQUITIES LLC  
NORTHBROK 134 WEST 93 EQUITIES LLC  
NORTHBROOK LEMAD EQUITIES LLC  
NORTHBROOK CH EQUITIES LLC  
NORTHBROOK CLINTON EQUITIES LLC  
NORTHBROOK UK1 EQUITIES LLC  
NORTHBROOK LOKEN LLC  
NORTHBROOK HS DEVELOPMENT LLC  
NORTHBROOK HS RK LLC  
NORTHBROOK TEIDIF LLC

AS TENANTS IN COMMON  
*LANDLORD*

and

STRONGBRIDGE U.S., INC.

*TENANT*

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**OFFICE REFERENCE PAGE**

**BUILDING:** 900 Northbrook Drive  
Trevose, PA 19053

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**LANDLORD:** Northbrook TC Equities, Northbrook 134 West 93 Equities LLC,  
Northbrook Lemad Equities LLC, Northbrook CH Equities LLC,  
Northbrook Clinton Equities LLC, Northbrook UK1 Equities LLC,  
Northbrook Loken LLC, Northbrook HS Development LLC and  
Northbrook HS RK LLC, Northbrook TEIDIF LLC, as Tenants in  
**Common**

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**LANDLORD'S ADDRESS:** c/o  
Time Equities Inc.  
55 Fifth Avenue,  
New York, NY 10003

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**TENANT:** **STRONGBRIDGE U.S., INC.**

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**TENANT'S ADDRESS:** 900 Northbrook Drive, Suite 200, Trevose, PA 19053

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**LEASE EXECUTION DATE:** November 21, 2017

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**PREMISES:** Second Floor Suite 250

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**USE:** General Office Space

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**PREMISES RENTABLE AREA:** 7,326 RSF on the Second Floor of a 65,825 RSF building

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**RENT COMMENCEMENT DATE:** The earlier of (1) One Hundred  
Eighty (180) days from the Commencement Date or (2) upon  
Substantial Completion of Tenant's Work.

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**COMMENCEMENT DATE:** Upon Execution of this Lease.

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**TERMINATION DATE:** Five (5) years from Rent Commencement Date.

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**TERM:** Five (5) years from Rent Commencement Date.

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**ANNUAL RENT:** \$20.50/RSF Year 1 with \$.50/SF annual increases (see Exhibit "D-1"  
attached)

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**FREE RENT:** See Section 3.2

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**ANNUAL ESCALATION:** \$0.50 /SF

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**MONTHLY INSTALLMENTS OF  
RENT (PLUS UTILITIES):** \$12,515.25

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**TENANT'S PROPORTIONATE  
SHARE:** 11.13%

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**BASE YEAR (DIRECT  
EXPENSES):** Calendar 2018 Base Year

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**BASE YEAR (TAXES):** Calendar 2018 Base Year

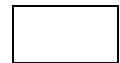
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**BROKER DUE COMMISSION:** CBRE, Inc. and NAI Geis Realty Group Inc.

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**ADDITIONAL RENT:** Any sum to be paid pursuant to the provisions of this Lease  
other than Annual Rent.

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Initials

The reference Page information is incorporated into and made part of the Lease. In the event of any conflict between any Reference Page information and the Lease, the Lease shall control. This Lease includes Exhibits "A" through "E" all which, are made a part hereof.

**LANDLORD:**

**TENANT:**

**NORTHBROOK TC EQUITIES LLC  
NORTHBROK 134 WEST 93 EQUITIES LLC  
NORTHBROOK LEMAD EQUITIES LLC  
NORTHBROOK CH EQUITIES LLC  
NORTHBROOK CLINTON EQUITIES LLC  
NORTHBROOK UK1 EQUITIES LLC  
NORTHBROOK LOKEN LLC  
NORTHBROOK HS DEVELOPMENT LLC  
NORTHBROOK HS RK LLC  
NORTHBROOK TEIDIF LLC  
As Tenants In Common**

**STRONGBRIDGE U.S., INC.**

By: \_\_\_\_\_

By: \_\_\_\_\_

Print: \_\_\_\_\_

Print: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

Initials

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# LEASE

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged and intending to be legally bound, by this Lease Landlord leases to Tenant and Tenant leases from Landlord the Premises in the Building as set forth and described on the Reference Page. The Reference Page, including all terms defined thereon, is incorporated as part of this Lease.

## 1. USE AND RESTRICTIONS ON USE.

1.1 The Premises are to be used solely for general office purposes. Tenant shall not do or permit anything to be done in or about the Premises which will unreasonably obstruct or interfere with the rights of other tenants or occupants of the Building or injure, annoy, or disturb them or allow the Premises to be used for any improper, immoral, unlawful, or objectionable purpose. Tenant shall not do, permit or suffer in, on, or about the Premises the sale of any alcoholic liquor without the written consent of Landlord first obtained, or the commission of any waste. Notwithstanding anything else contained above, Tenant's use of the Premises for ordinary office use shall not be in violation of the terms of this Section 1.1. Tenant shall comply with all governmental laws, ordinances and regulations applicable to the use of the Premises and its occupancy and shall promptly comply with all governmental orders and directions for the correction, prevention and abatement of any violations in or upon, or in connection with, the Premises, all at Tenant's sole expense. Tenant shall not do or permit anything to be done on or about the Premises or bring or keep anything into the Premises which will in any way increase the rate of, invalidate or prevent the procuring of any insurance protecting against loss or damage to the Building or any of its contents by fire or other casualty or against liability for damage to property or injury to persons in or about the Building or any part thereof.

1.2 Tenant shall not, and shall not direct, suffer or permit any of its agents, contractors, employees, licensees or invitees to at any time handle, use, manufacture, store or dispose of in or about the Premises or the Building any flammables, explosives, radioactive materials, hazardous wastes or materials, toxic wastes or materials, or other similar substances, petroleum products or derivatives or any substance subject to regulation by or under any Environmental Laws (collectively "Hazardous Materials"), nor shall Tenant suffer or permit any Hazardous Materials to be used in any manner not fully in compliance with all Environmental Laws, in the Premises or the Building and appurtenant land or allow the environment to become contaminated with any Hazardous Materials. Notwithstanding the foregoing, Tenant may handle, store, use or dispose of products containing small quantities of Hazardous Materials (such as aerosol cans containing insecticides, toner for copiers, paints, paint remover and the like) to the extent customary and necessary for the use of the Premises for general office purposes; provided that Tenant shall always handle, store, use, and dispose of any such Hazardous Materials in a safe and lawful manner and never allow such Hazardous Materials to contaminate the Premises, Building and appurtenant land or the environment. Tenant shall protect, defend, indemnify and hold each and all of the Landlord Entities (as defined in Article 30) harmless from and against any and all loss, claims, liability or costs (including court costs and attorney's fees) incurred by reason of any actual or asserted failure of Tenant to fully comply with all applicable Environmental Laws, or the presence, handling, use



Initials

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or disposition in or from the Premises of any Hazardous Materials (even though permissible under all applicable Environmental Laws or the provisions of this Lease), or by reason of any actual or asserted failure of Tenant to keep, observe, or perform any provision of this Section 1.2. For purposes of this Lease, "Environmental Laws" shall mean all federal, state and local laws and ordinances relating to the protection of the environment or the keeping, use or disposition of Hazardous Materials, presently in effect or hereafter adopted, all amendments to any of them, and all rules and regulations issued pursuant to any of such laws or ordinances.

**2. TERM.**

2.1 The Term of this Lease shall begin on the date ("Commencement Date"), as shown on the Reference Page. Landlord shall tender possession of the Premises, broom clean and vacant and (to the best knowledge of Landlord), free from any Hazardous Materials and otherwise in its as-is condition.

2.2 In the event Landlord shall permit Tenant to occupy the Premises prior to the Commencement Date, such occupancy shall be subject to all the provisions of this Lease except that no Rent shall be due in connection with such occupancy until the Rent Commencement Date (as set forth on the Reference Page). Notwithstanding the above, Additional Rent for electric service shall be due to Landlord as of Tenant's occupation of the Premises. Said early possession shall not advance the Rent Commencement Date or the Termination Date.

2.3 Landlord shall have the right to confirm the rentable and usable square footage of the Premises by independent measurement. For such purpose, the measurement of the Premises shall be in accordance with the method for determining "rentable area" and "usable area" under the Building Owners and Managers Association International, Office Buildings: Standard Methods of Measurement (ANSI/BOMA Z65.1 – 2010). Following such measurement, if the rentable square footage of the Premises differs from that set forth in the Basic Lease Information, Tenant and Landlord shall amend this Lease to revise the monthly installments of Annual Rent, the Tenant's Proportionate Share and to otherwise reflect such revised rentable area of the Premises. If Landlord has not, by the date that is sixty (60) days after the Commencement Date, notified Tenant that an adjustment to the rentable area recited in the Basic Lease Information is required, the parties conclusively agree that the rentable area set forth in the Office Reference Page is correct.

**3. RENT.**

3.1 Pursuant to the terms set forth on the Reference Page, Tenant agrees to pay to Landlord the Annual Rent in effect from time to time by paying the Monthly Installment of Rent then in effect on or before the first day of each full calendar month during the Term from and after the Rent Commencement Date.

3.2 The Monthly Installment of Rent in effect at any time shall be one-twelfth of the Annual Rent in effect at such time. Rent for any period during the Term, which is less than a full month shall be a prorated portion of the Monthly Installment of Rent based upon a thirty (30)-day month. Said Annual Rent shall be paid to Landlord, without deduction or offset and without notice



Initials

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or demand, at the Landlord's address, as set forth on the Reference Page, or to such other person or at such other place as Landlord may from time to time designate in writing. Provided Tenant is not in default of any of the terms and conditions of this lease beyond any applicable grace or cure period, the first four (4) months of Rent shall be abated. During this period, Tenant shall remain responsible for the payment of all Additional Rent, including electricity.

3.3 Tenant recognizes that late payment of any Annual Rent or other sum due under this Lease will result in administrative expense to Landlord, the extent of which additional expense is extremely difficult and economically impractical to ascertain. Tenant therefore agrees that if Annual Rent or any other sum is not paid within five (5) days after the applicable due date hereunder, a late charge shall be imposed in an amount equal to the greater of: (a) Fifty Dollars (\$50.00), or (b) a sum equal to five percent (5%) per month of the unpaid Annual Rent or other payment. The provisions of this Section 3.2 in no way relieve Tenant of the obligation to pay Annual Rent or other payments on or before the date on which they are due, nor do the terms of this Section 3.2 in any way affect Landlord's remedies pursuant to Article 19 of this Lease in the event said Annual Rent or other payment is unpaid after date due.

#### 4. RENT ADJUSTMENTS.

4.1 For the purpose of this Article 4, the following terms are defined as follows:

4.1.1 Lease Year: Each calendar year falling partly or wholly within the Term.

4.1.2 Direct Expenses: All direct costs of operation, maintenance, repair and management of the Building (including the amount of any credits which Landlord may grant to particular tenants of the Building in lieu of providing any standard services or paying any standard costs described in this Section 4.1.2 for similar tenants), as determined in accordance with generally accepted accounting principles ("GAAP") or other sound accounting principals consistently used by Landlord, including the following costs by way of illustration, but not limitation: water and sewer charges; insurance charges of or relating to all insurance policies and endorsements required to be maintained by Landlord pursuant to Section 11.2 hereof, utility costs, including, but not limited to, the cost of heat, power, steam, gas, and waste disposal; the cost of janitorial services; the cost of security and alarm services; window cleaning costs; labor costs; costs and expenses of managing the Building including management fees in an amount not to exceed 5% per annum; air conditioning maintenance costs; elevator maintenance fees and supplies; material costs; equipment costs including the cost of maintenance, repair and service agreements and rental and leasing costs; purchase costs of equipment other than capital items; current rental and leasing costs of items which would be amortizable capital items if purchased; tool costs; licenses, permits and inspection fees; wages and salaries of Landlord employees or agents directly engaged in the operation, maintenance, repair or management of the Building, and employee benefits and reasonable payroll taxes with regard to such Landlord employees; accounting and legal fees; any sales, use or service taxes incurred in connection therewith. Direct Expenses for any year during which average occupancy of the Building is less than one hundred percent (100%) shall be calculated based upon the Direct Expenses that would have been incurred if the Building had an average occupancy of one hundred percent (100%) during the entire calendar year. Direct



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Expenses shall not include any of the following: capital expenditures not permitted herein; legal fees for enforcing rights under other tenant leases in the Building or in defense of Landlord's title to the Building; depreciation or amortization of the Building or equipment in the Building except as expressly provided herein; loan principal or interest payments or rental payments on any ground or other underlying leases; costs of alterations of tenants' premises; leasing commissions, interest expenses on long-term borrowings; advertising and marketing costs; management salaries for executive personnel other than personnel directly engaged in the operation, maintenance, repair or management of the Building; interest or penalty charges incurred by Landlord due to the failure to timely pay obligations of Landlord (even if such obligation is reimbursed through Direct Expenses); the costs of Landlord's compliance with any Environmental Laws or the removal or abatement of any Hazardous Materials from the Premises or the Building (unless such costs arise out of the acts of Tenant during the Term); expenses for repair or other work occasioned by fire or other casualty which is covered under the casualty insurance policy described in Section 11.2 hereof; expenses for the replacement of any items covered by a manufacturer's or seller's warranty; costs of repair to the Premises necessitated by Landlord's gross negligence or willful misconduct, or of correcting any latent defects or original design defects in the construction of the Building or the materials and equipment used therefor; reserves; salaries of employees of Landlord above the grade of Building manager and/or employees of Landlord whose time is not substantially spent in the management and operation of the Building; new artwork installed in the Building the cost of which exceeds \$10,000 in the aggregate; charges for utility services separately metered to particular tenants in the Building; and fees and charges not reasonable and competitive with fees charged by unaffiliated entities for the performance of such services of comparable quality in comparable buildings in the area. In addition, Landlord shall be entitled to amortize and include as an Additional Rental adjustment: (i) an allocable portion of the cost of capital improvement items which are reasonably calculated to reduce operating expenses, as may be determined in accordance with GAAP or other applicable sound accounting or administrative practices; (ii) fire sprinklers and suppression systems and other life safety systems; and (iii) other capital expenses which are required under any governmental laws, regulations or ordinances which were not applicable to the Building at the time it was constructed. All such costs shall be amortized over the reasonable life of such improvements in accordance with such reasonable life and amortization schedules as shall be determined by Landlord in accordance with generally accepted accounting principles, with interest on the unamortized amount at one percent (1%) in excess of the prime lending rate announced from time to time as such by Chase Bank.

4.1.3 Taxes: Tenant agrees to pay Tenant's Proportionate Share of any and all increases in Taxes, as defined below, assessed and levied against the Building and the land appurtenant thereto above the taxes paid for the Base Year as well as any special assessment(s) imposed upon the Premises for any purpose whatsoever during the term, whether the increase in taxation results from a higher tax rate or an increase in the assessed valuation of the Premises, or both. Taxes shall be defined as real estate taxes and any other taxes, charges and assessments which are levied with respect to the Building or the land appurtenant to the Building, or with respect to any improvements, fixtures and equipment or other property of Landlord, real or personal, located in the Building and used in connection with the operation of the Building and said land, any payments to any ground lessor in reimbursement of tax payments made by such lessor; and all fees, expenses and costs incurred by Landlord in investigating, protesting, contesting

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or in any way seeking to reduce or avoid increase in any assessments, levies or the tax rate pertaining to any Taxes to be paid by Landlord in any Lease Year. Taxes shall not include any corporate franchise, or estate, inheritance or corporate net income tax or gross receipts or similar tax, any tax imposed upon any transfer by Landlord of its interest in this Lease or the Building or any late charges, fines or penalties incurred by Landlord with respect to the failure to pay any of the foregoing taxes in a timely manner.

4.2 If in any Lease Year, Tenant's Proportionate Share of Direct Expenses exceeds the Direct Expense Base Year as set forth in the Reference Page above, respectively, Tenant shall pay such excess as Additional Rent for such Lease Year as provided in Section 4.5 below.

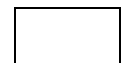
4.3 The annual determination of Direct Expenses shall be made by Landlord and if certified by a public accountants selected by Landlord shall be binding upon Landlord and Tenant, subject to the provisions of Section 4.7 below. In the event that during all or any portion of any Lease Year, the Building is not fully rented and occupied Landlord may make any appropriate adjustment in occupancy-related Direct Expenses for such year for the purpose of avoiding distortion of the amount of such Direct Expenses to be attributed to Tenant by reason of variation in total occupancy of the Building, by employing GAAP and other applicable sound accounting and management principles to determine Direct Expenses that would have been paid or incurred by Landlord had the Building been fully rented and occupied, and the amount so determined shall be deemed to have been Direct Expenses for such Lease Year.

4.4 Prior to the commencement date of any Lease Year other than the first Lease Year hereunder, Landlord shall estimate Tenant's liability for Direct Expenses and/or Taxes under Section 4.2, Article 6 and Article 29 ("Tenant's Estimated Share") for the Lease Year or portion thereof. Landlord will give Tenant written notification of the amount of such estimate at least fifteen (15) days prior to the commencement date of such Lease Year. Tenant agrees that it will pay, by increase of its Monthly Installments of Rent due in such Lease Year, Tenant's Estimated Share with respect to such Lease Year as Additional Rent in equal monthly installments of 1/12 of such estimate, through and until the end of such Lease Year. Any such increased rate of Monthly Installments of Rent pursuant to this Section 4.4 shall remain in effect through and until the end of the applicable Lease Year, and thereafter shall be subject to adjustment as provided in Section 4.5 below.

4.5 Within one hundred eighty (180) days after the expiration of each Lease Year in which Tenant paid its Estimated Share as provided in Section 4.4 above, Landlord shall communicate to Tenant in writing the actual determination of Tenant's liability for Direct Expenses and/or Taxes with regard to such Lease Year, in which instance the parties shall proceed as follows:

4.5.1 If the total Tenant's Estimated Share paid for such applicable Lease Year is less than the actual amount of Tenant's liability for Direct Expenses and/or Taxes, then Tenant shall pay such deficiency to Landlord as Additional Rent in one lump sum within thirty (30) days of the later of Tenant's receipt of Landlord's bill therefor or the conclusion of Tenant's audit proceedings with respect thereto pursuant to Section 4.7 below; or

4.5.2 If the total Tenant's Estimated Share paid for such applicable Lease Year is



more than the actual amount of Tenant's liability for Direct Expenses and/or Taxes, then Landlord shall credit the difference against the then next due payments to be made by Tenant under this Article 4. Tenant shall not be entitled to a credit by reason of actual Direct Expenses and/or Taxes in any Lease Year being less than the Base Year.

4.6 If the Commencement Date is other than January 1 or if the Termination Date is other than December 31, Tenant's liability for Direct Expenses and Taxes for the Lease Year in which said Date occurs shall be prorated based upon a three hundred sixty-five (365) day year.

4.7 Landlord shall keep accurate records showing in detail all Additional Rent charges provided for in this Lease for the duration of the Term. Tenant has the right, exercisable no more than once each Lease Year on not less than forty-five (45) days' prior written notice and at a time reasonably acceptable to Landlord, to cause an audit to be performed of Landlord's operations and/or books and records pertaining to the Direct Expenses and Taxes for the preceding Lease Year. In the event that (i) such audit determines that Tenant's Estimated Share exceeds the actual amount of Tenant's liability for Direct Expenses and/or Taxes by more than five percent (5%) for such prior Lease Year and (ii) provided no Event of Default is continuing at such time, then Landlord will reimburse Tenant for the costs of such audit and verification incurred by Tenant within thirty (30) days after demand therefor by Tenant accompanied by Tenant's reasonably detailed verification of such overcharges and paid invoices; provided, however, that Tenant shall not use a contingent fee auditor and if Tenant does, then to the extent Landlord shall be obligated hereunder to reimburse Tenant for the costs of such audit, Landlord shall pay the commercially reasonable hourly rate.

## 5. SECURITY DEPOSIT.

Tenant shall not be required to provide any security deposit to Landlord in connection with this Lease.

## 6. ALTERATIONS.

6.1 Except for those alterations specifically provided for in Exhibit "B" to this Lease or as provided in Section 6.5 below, Tenant shall not make or suffer to be made any alterations, additions, or improvements in, on, or to the Premises or any part thereof or the making of any improvements as required by Article 7, without the prior written consent of Landlord, which shall not be unreasonably withheld, conditioned or delayed. When applying for such consent, Tenant shall, if requested by Landlord, furnish complete plans and specifications for such alterations, additions and improvements. To the extent that Landlord's consent is required pursuant to this Section 6.1, Landlord shall communicate the same in writing to Tenant within thirty (30) days after application therefor and the provision of any and all required plans or specifications to Landlord (and any failure by Landlord to respond to such request within such 30-day period shall be deemed to be an approval of such alterations).

6.2 In the event Landlord's consent is required pursuant to Section 6.1 above and Landlord affirmatively consents to the making of any such alteration, addition or improvement by





Tenant, the same shall be made using a contractor reasonably acceptable to Landlord (“Landlord’s Contractor”) (unless Landlord agrees in writing otherwise) at Tenant's sole cost and expense. Any other alterations, additions or improvements by Tenant shall be made using a contractor selected by Tenant in its sole discretion. If Landlord enters into any contract or agreement during the Term restricting the use of non-union labor or suppliers in connection with any construction or alterations in or to the Building, Landlord shall promptly notify Tenant in writing of the same. Thereafter, if Tenant shall employ any contractor and such contractor or any subcontractor thereof shall employ any non-union labor or supplier, Tenant shall be responsible for and hold Landlord harmless from any and all delays, damages and extra costs directly suffered by Landlord as a result of any dispute with any labor unions employed at the Building concerning the wage, hours, terms or conditions of the employment of any such labor resulting from Tenant’s direct or indirect employment of such non-union labor or supplier at the Building.

6.3 All alterations, additions or improvements proposed by Tenant shall be constructed in accordance with all government laws, ordinances, rules and regulations and Tenant shall, prior to construction, provide any additional insurance required under Article 11 in such case, and also all such assurances to Landlord, including but not limited to, reasonable and customary waivers of lien, and if such alteration, addition or improvement is in excess of \$100,000 in the aggregate, reasonable and customary surety company performance bonds as Landlord shall reasonably require to assure payment of the costs thereof and to protect Landlord and the Building and appurtenant land against any loss from any mechanic's, materialmen's or other liens. Tenant shall as Additional Rent pay in addition to any sums due pursuant to Article 4, any increase in Taxes attributable directly to any such alteration, addition or improvement for so long, during the Term, as such increase is ascertainable, at Landlord's election said sums shall be paid in the same way as sums due under Article 4.

6.4 All alterations, additions, and improvements in, on, or to the Premises made or installed by Tenant, including carpeting, shall be and remain the property of Tenant during the Term but, excepting furniture, furnishings, movable partitions of less than full height from floor to ceiling and other trade fixtures, shall become a part of the realty and belong to Landlord without compensation to Tenant upon the expiration or sooner termination of the Term, at which time title shall pass to Landlord under this Lease as by a bill of sale, unless Landlord communicates to Tenant within thirty (30) days after the installation of such alterations, additions or improvements, that the same must be removed from the Premises upon the expiration or sooner termination of this Lease. If Landlord provides the foregoing notice to Tenant, Tenant shall upon the expiration or sooner termination of this Lease, at Tenant's sole cost and expense, remove any such alterations, additions or improvements which are designated by Landlord to be removed, and Tenant shall forthwith and with all due diligence, at its sole cost and expense, repair and restore the Premises to their original condition, reasonable wear and tear and damage by fire or other casualty excepted.

6.5 Notwithstanding anything to the contrary set forth in Section 6.1 above, Tenant shall have the right, without the consent of Landlord, to make alterations to the Premises which (i) are non-structural; (ii) which do not otherwise affect the structural integrity of the Premises, the Building, or Building utility services or plumbing and electrical lines; and (iii) cost less than \$30,000 in the aggregate during the Term.

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**7. REPAIR.**

7.1 It is the Landlord's responsibility to maintain and repair common areas, mechanical systems in the Building (including those serving the Premises) and public portions of the Building, interior and exterior, in good order and condition, reasonable wear and tear excepted. Landlord shall have no obligation to alter, remodel, improve, repair, decorate or paint the Premises, except as specified in Exhibit "B" attached hereto and made a part hereof and except that Landlord shall repair and maintain the structural portions of the Building, including the basic plumbing, air conditioning, heating and electrical systems installed or furnished by Landlord, including portions of such systems that may be located within the Premises. By taking possession of the Premises, Tenant accepts them as being in good order, condition and repair and in the condition in which Landlord is obligated to deliver them, except for the presence of any Hazardous Materials in the Premises. It is hereby understood and agreed that no representations respecting the condition of the Premises or the Building have been made by Landlord to Tenant, except as specifically set forth in this Lease.

7.2 Tenant shall, at all times during the Term, keep the Premises in good condition and repair, excepting reasonable wear and tear and damage by fire, or other casualty, and in compliance with all applicable governmental laws, ordinances and regulations, promptly complying with all governmental orders and directives for the correction, prevention and abatement of any violations or nuisances in or upon, or connected with, the Premises, all at Tenant's sole expense, except for any violations or nuisances resulting from any acts or omissions of Landlord or its agents or the presence of Hazardous Materials in the Premises.

7.3 Except as provide in Article 13 below, Landlord shall not be liable for any failure to make any repairs or to perform any maintenance unless such failure shall persist for an unreasonable time after written notice of the need of such repairs or maintenance is given to Landlord by Tenant.

7.4 Except as provided in Article 22 below, there shall be no abatement of Annual Rent or Additional Rent and no liability of Landlord by reason of any injury to or interference with Tenant's business arising from the making of any repairs, alterations or improvements in or to any portion of the Building or the Premises or to fixtures, appurtenances and equipment in the Building.

**8. LIENS.**

Tenant shall keep the Premises, the Building and appurtenant land and Tenant's leasehold interest in the Premises free from any liens arising out of any services, work or materials performed, furnished, or contracted for by Tenant, or obligations incurred by Tenant. In the event that Tenant shall not, within thirty (30) days following the imposition of any such lien, either cause the same to be released of record or provide Landlord with a bond or other customary insurance against the same in a customary amount, Landlord shall have the right to cause the same to be released by any customary means, including payment of the claim giving rise to such lien. All actual such sums paid by Landlord and all reasonable expenses incurred by it in connection

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therewith shall be considered Additional Rent and shall be payable to it by Tenant on demand.

**9. ASSIGNMENT AND SUBLETTING.**

9.1 Except as otherwise provided in this Article 9, Tenant shall not have the right to assign or pledge this Lease or to sublet the whole or any part of the Premises whether voluntarily or by operation of law, or permit the use or occupancy of the Premises by anyone other than Tenant, and shall not make, suffer or permit such assignment, subleasing or occupancy without the prior written consent of Landlord, which shall not be unreasonably withheld, conditioned or delayed, and said restrictions shall be binding upon any and all assignees of the Lease and subtenants of the Premises. In the event Tenant desires to sublet, or permit such occupancy of, the Premises, or any portion thereof, or assign this Lease, Tenant shall give written notice thereof to Landlord at least thirty (30) days but no more than one hundred eighty (180) days prior to the proposed commencement date of such subletting or assignment, which notice shall set forth the name of the proposed subtenant or assignee, the relevant terms of any sublease or assignment and copies of financial reports and other or relevant financial information of the proposed subtenant or assignee, to the extent disclosure of such financial reports or other information is not prohibited by the terms of such proposed sublease or assignment.

9.2 Notwithstanding any assignment or subletting, permitted or otherwise, Tenant shall at all times remain directly, primarily and fully responsible and liable for the payment of the Annual Rent and Additional Rent specified in this Lease and for compliance with all of its other obligations under the terms, provisions and covenants of this Lease. Upon the occurrence of an Event of Default (hereinafter defined), if the Premises or any part of them are then assigned or sublet, Landlord, in addition to any other remedies provided in this Lease or provided by law, may, at its option, collect directly from such assignee or subtenant all rents due and becoming due to Tenant under such assignment or sublease and apply such rent against any sums due to Landlord from Tenant under this Lease, and no such collection shall be construed to constitute a novation or release of Tenant from the further performance of Tenant's obligations under this Lease.

9.3 In addition to Landlord's right to approve of any subtenant or assignee as provided in Section 9.1 above, Landlord shall have the option, in its sole discretion, in the event of any proposed subletting or assignment, to terminate this Lease, or in the case of a proposed subletting of less than the entire Premises, to recapture the portion of the Premises to be sublet, as of the date the subletting or assignment is to be effective. The option shall be exercised, if at all, by Landlord giving Tenant written notice given by Landlord to Tenant within sixty (60) days following Landlord's receipt of Tenant's written notice as required above. If this Lease shall be terminated with respect to the entire Premises pursuant to this Section 9.3, the Term of this Lease shall end on the date stated in Tenant's notice as the effective date of the sublease or assignment as if that date had been originally fixed in this Lease for the expiration of the Term. If Landlord recaptures under this Section 9.3 only a portion of the Premises, the Annual Rent and the Additional Rent to be paid from time to time during the Term shall abate proportionately based on the proportion by which the approximate square footage of the remaining portion of the Premises shall be less than that of the Premises as of the date immediately prior to such recapture. Tenant shall, at Tenant's own cost and expense, discharge in full any outstanding commission obligation on the part of

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Landlord with respect to this Lease, and any commissions which may be due and owing as a result of any proposed assignment or subletting, whether or not the Premises are recaptured pursuant to this Section 9.3 and rented by Landlord to the proposed tenant or any other tenant.

9.4 In the event that Tenant sells, sublets, assigns or transfers this Lease except as provided in Section 9.7 hereof, Tenant shall pay to Landlord as Additional Rent an amount equal to fifty percent (50%) of any Increased Rent (as defined below) when and as such Increased Rent is received by Tenant. As used in this Section 9.4, "Increased Rent" shall mean the excess of the sum of (x) all rent and other consideration which Tenant is entitled to receive by reason of any sale, sublease, assignment or other transfer of this Lease, over (y) the Annual Rent and Additional Rent otherwise payable by Tenant under this Lease at such time, less (z) all reasonable costs incurred by Tenant to obtain such sublease or assignment. For purposes of the foregoing, any consideration received by Tenant in form other than cash shall be valued at its fair market value as determined by Landlord in good faith, unless prohibited by law.

9.5 Notwithstanding any other provision hereof, Tenant shall have no right to make (and Landlord shall have the absolute right to refuse consent to) any assignment of this Lease or sublease of any portion of the Premises if at the time of either Tenant's notice of the proposed assignment or sublease or the proposed commencement date thereof, there shall exist any Event of Default hereunder, or if the proposed assignee or sub-lessee is an entity: (a) with which Landlord is already in negotiation as evidenced by the issuance of a written proposal; (b) is already an occupant of the Building; (c) is a governmental agency; ~~;~~ or (d) would subject the Premises to a use which would: (i) involve a material increase in the number of occupants or degree of wear and tear upon the Building; (ii) violate any exclusive right granted to another tenant of the Building (which exclusive rights shall have been communicated by Landlord to Tenant in advance of Tenant's request for approval of such proposed sublease or assignment); (iii) require any material addition to or modification of the Premises or the Building in order to comply with building code or other governmental requirements; or (iv) involve a violation of Section 1.2 above.

9.6 Upon any request to assign or sublet which requires Landlord's consent hereunder, Tenant will pay to Landlord a fee equal to \$1,500, which shall serve as reimbursement of Landlord's costs, including attorney's fees, incurred in investigating and considering any proposed or purported assignment or pledge of this Lease or sublease of any of the Premises, regardless of whether Landlord shall consent to, refuse consent, or determine that Landlord's consent is not required for, such assignment, pledge or sublease.

9.7 Notwithstanding anything else contained in this Article 9, (i) Landlord shall not withhold consent to assignment or sublease based on the financial condition of proposed assignee or sublessee provided that Tenant remains liable under the terms of this Lease for the duration of the Term; and (ii) Landlord's consent shall not be required (and no fee shall be payable pursuant to Section 9.6 above) with respect to any proposed sublease or assignment of the Lease to an entity Controlled, in Control of or under common Control with Tenant or to any successor to Tenant by means of merger, consolidation or other similar transaction or any entity purchasing all or substantially all of the equity interests or assets of Tenant. For purposes of this Lease, the term "Control" or variations thereof shall mean the direct or indirect ownership of more than fifty



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percent (50%) of the issued and outstanding voting equity interests of an entity.

**10. INDEMNIFICATION.**

10.1 Tenant shall protect, indemnify and hold the Landlord Entities harmless from and against any and all loss, claims, liability or costs (including court costs and attorney's fees) incurred by reason of (a) any damage to any property (including but not limited to property of any Landlord Entity) or any injury (including but not limited to death) to any person occurring in, on or about the Premises or the Building to the extent that such injury or damage shall be caused by or arise from any actual or alleged act, neglect, fault, or omission by or of Tenant, its agents, servants, employees, invitees, or visitors to meet any standards imposed by any duty with respect to the injury or damage; (b) the conduct or management of any work or thing whatsoever done by the Tenant in or about the Premises or from transactions of the Tenant concerning the Premises; (c) Tenant's failure to comply with any and all governmental laws, ordinances and regulations applicable to the condition or use of the Premises or its occupancy; or (d) any breach or default on the part of Tenant in the performance of any covenant or agreement on the part of the Tenant to be performed pursuant to this Lease.

10.2 Landlord shall protect, indemnify and hold Tenant and its directors, managers, officers, employees, agents, invitees and licensees (each, a "Tenant Entity") harmless from and against any and all loss, claims, liability or costs (including court costs and attorney's fees) incurred by reason of (a) any damage to any property (including but not limited to property of any Tenant Entity) or any injury (including but not limited to death) to any person occurring in, on or about the Premises or the Building to the extent that such injury or damage shall be caused by or arise from any actual act, neglect, fault, or omission by or of any Landlord Entity to meet any standards imposed by any duty with respect to the injury or damage or : or (b) any breach or default on the part of Landlord in the performance of any covenant or agreement on the part of Landlord to be performed pursuant to this Lease.

10.3 The provisions of this Article 10 shall survive the termination of this Lease with respect to any claims or liability accruing prior to such termination.

**11. INSURANCE.**

11.1 During the Lease Term (and any period of early entry or occupancy or holding over by Tenant, if applicable), Tenant shall maintain the following types of insurance, in the amounts specified below:

11.1.1 Commercial Insurance. Tenant shall maintain commercial general liability (CGL) and, if necessary, commercial umbrella insurance, with a limit of not less than \$1,000,000 each occurrence. If such CGL insurance contains a general aggregate limit, it shall apply separately to this location.

11.1.1.1. CGL insurance shall be written on ISO occurrence form CG 00 01 12 07, or a substitute form providing coverage at least as broad, and shall

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cover liability arising from premises, operations, independent contractors, products-completed operations, personal injury and advertising injury, and liability assumed under an insured contract.

11.1.1.2. Landlord, Landlord's managing agent, and any mortgagee requested by Landlord shall be included as additional insureds under the CGL, using ISO additional insured endorsement CG 20 11 or a substitute providing coverage at least as broad, and under the commercial umbrella, if any. Tenant's insurance shall apply on a primary and noncontributory basis with respect to any other insurance or self-insurance programs afforded to Landlord. There shall be no endorsement or modification of the CGL to make it excess over other available insurance; alternatively, if the CGL states that it is excess or pro rata, the policy shall be endorsed to be primary and noncontributory with respect to the additional insureds.

11.1.2 Commercial Property Insurance. Tenant shall maintain commercial property insurance covering Tenant's property and improvements (including, without limitation, alterations or additions performed by Tenant pursuant hereto, but excluding those improvements, if any, made pursuant to Section 6 above), and other personal property (including property of others), in the Premises.

11.1.2.1 Commercial property insurance shall, at minimum, cover the perils insured under the ISO special causes of loss form (CP 10 30).

11.1.2.2 Commercial property insurance shall cover the replacement cost of the property insured.

11.1.2.3 The amount insured shall equal the full estimated replacement cost of the property insured.

11.1.2.4 Any coinsurance requirement in the policy shall be eliminated through the attachment of an agreed amount endorsement, the activation of an agreed value option, or as is otherwise appropriate under the particular policy form.

11.1.2.5 Tenant shall purchase business interruption coverage with a limit not less than an amount equal to one (1) year of Annual Rent hereunder as part of this commercial property insurance, and in no event shall Landlord be liable for any business interruption or other consequential loss sustained by Tenant, whether or not it is insured, even if such loss is caused by negligence of Landlord, its employees, officers, directors, or agents.

11.1.3 Worker's Compensation Insurance. Tenant shall maintain worker's compensation insurance in amounts required by applicable law. Tenant shall maintain employer's liability insurance with limits not less than \$1,000,000 each accident for bodily

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injury by accident and \$1,000,000 each employee for bodily injury by disease. The limit requirements can be satisfied through the combination of primary employer's liability and umbrella liability coverage.

11.1.4 Automobile Liability Insurance. If Tenant parks fleet vehicles at the Premises on a routine basis during the Term, Tenant shall maintain automobile liability with a limit of not less than \$1,000,000 each loss.

11.1.4.1 Such insurance shall cover liability arising out of any auto (including owned, hired, and non-owned autos), except that if Tenant does not own any autos, such insurance may cover only hired and non-owned autos at any time as Tenant continues not to own any autos.

11.1.4.2 Coverage shall be written on ISO form CA 00 01 10 13 or a substitute form providing coverage at least as broad.

11.1.5 Umbrella Liability Insurance. Tenant shall maintain commercial umbrella liability insurance, with a limit of not less than \$1,000,000 each loss. Coverage shall be written on ISO form CA 00 01 10 13 or a substitute form providing coverage at least as broad

All insurance required to be carried by Tenant hereunder shall be issued by one or more insurance companies reasonably acceptable to Landlord, licensed to do business in the State in which the Leased Premises is located and having an AM Best's rating of A IX or better, and Tenant will endeavor to provide no less than thirty (30) days' prior written notice to Landlord of any material change, cancellation, or lapse in the aforementioned coverage. On or before the Commencement Date (or the date of any earlier entry or occupancy by Tenant), and thereafter, within thirty (30) days prior to the expiration of each such policy, Tenant shall furnish Landlord with certificates of insurance in the form of ACORD 25 (or other evidence of insurance reasonably acceptable to Landlord), evidencing all required coverages (including all required endorsements), and that with the exception of Worker's Compensation insurance, such insurance is primary and non-contributory. If Tenant fails to carry such insurance and furnish Landlord with such certificates of insurance, Landlord may obtain such insurance on Tenant's behalf and Tenant shall reimburse Landlord upon demand for the cost thereof as Additional Rent. Upon Tenant's receipt of a request from Landlord, Tenant shall provide Landlord with copies of all endorsements, evidencing the coverages required hereunder. Landlord reserves the right from time to time to require Tenant to obtain higher minimum amounts or different types of insurance if it becomes customary for other landlords of similar buildings in the area to require similar sized tenants in similar industries to carry insurance of such higher minimum amounts or of such different types. By requiring insurance herein, Landlord does not represent that the coverage and limits will necessarily be adequate to protect Tenant, and such coverage and limits shall not be deemed as a limitation on Tenant's liability under the indemnities granted to Landlord in this Lease. If Tenant's policies do not contain the standard ISO separation of insureds provision, or a substantially similar clause, they shall be endorsed to provide cross-liability coverage. There shall be no provisions that limit Landlord's ability to pursue a claim against Tenant.

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11.2 Landlord's Insurance. During the Lease Term, Landlord shall maintain the following types of insurance, in the amounts specified below (the cost of which shall be included in Operating Expenses):

11.2.1 Commercial General and Umbrella Liability Insurance. Landlord shall maintain commercial general liability (CGL) and, if necessary, commercial umbrella insurance, with a limit of not less than \$1,000,000 each occurrence. If such CGL insurance contains a general aggregate limit, it shall apply separately to this location.

CGL insurance shall be written on ISO occurrence form CG 00 01 12 07, or a substitute form providing coverage at least as broad, and shall cover liability arising from premises, operations, independent contractors, products-completed operations, personal injury and advertising injury, and liability assumed under an insured contract.

11.2.2 Commercial Property Insurance. Landlord shall maintain commercial property insurance covering the Building, including, without limitation, any improvements, if any, made pursuant to Section 6 above, but excluding Tenant's personal property and any other items required to be insured by Tenant pursuant to Section 11.1 above.

11.2.2.2 Commercial property insurance shall, at minimum, cover the perils insured under the ISO special causes of loss form (CP 10 30).

11.2.2.3 Commercial property insurance shall cover the replacement cost of the property insured on an all-risk basis.

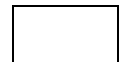
11.2.2.4 The amount insured shall equal the full estimated replacement cost of the property insured.

## **12. WAIVER OF SUBROGATION.**

Notwithstanding anything contained in this Lease to the contrary, Landlord (and its affiliates, property managers and mortgagees) and Tenant (and its affiliates) shall have no liability to one another, or to any insurer, by way of subrogation or otherwise, on account of any loss of or damage to their respective property, the Leased Premises, its contents, or other portions of the Building or Common Areas, regardless of whether such loss or damage is caused by the negligence of Landlord or Tenant, arising out of any of the perils or casualties insured against by the property insurance policies carried, or required to be carried, by the parties pursuant to this Lease. The insurance policies obtained by Landlord and Tenant pursuant to this Lease shall permit waivers of subrogation which the insurer may have against the non-insuring party. In the event the policy or policies do not allow waiver of subrogation prior to loss, either Landlord or Tenant shall deliver to the other party a waiver of subrogation endorsement containing an express waiver of any rights of subrogation by the insurance company against Landlord or Tenant, as applicable.

## **13. SERVICES AND UTILITIES.**

13.1 Provided Tenant shall not be in default under this Lease, and subject to the other





provisions of this Lease, Landlord agrees to furnish to the Premises during ordinary business hours (8:00AM to 6:00PM) on generally recognized business days (but exclusive in any event of Sundays and legal holidays), the following services and utilities subject to the rules and regulations of the Building prescribed from time to time: (a) water suitable for normal office use of the Premises; (b) heat and air conditioning required in Landlord's judgment for the use and occupation of the Premises; (c) cleaning and janitorial service; (d) elevator service by non-attended automatic elevators; (e) such window washing as may from in time to time in Landlord's judgment be reasonably required; and, (f) equipment to bring to Tenant's meter, electricity for lighting, convenience outlets and other normal office use. To the extent that Tenant is not billed directly by a public utility, Tenant shall pay, upon demand, as Additional Rent, for all electricity used by Tenant in the Premises and Tenant shall pay as Additional Rent, for Tenant's Proportionate Share of electricity used in the operation, maintenance, repair and management of the Building, including all common areas. The charge shall be at the rates charged for such services by the local public utility. Landlord shall use reasonable efforts to remedy any interruption in the furnishing of services and utilities. Landlord shall not be liable for, and Tenant shall not be entitled to, any abatement or reduction of rental by reason of Landlord's failure to furnish any of the foregoing; provided, however, in the event that (i) any heat, air conditioning, electric, water, or sewer (the "Primary Utilities") are not available for use by the Tenant at the Premises for a period of five (5) consecutive days, and the cause of such non availability is due to something in Landlord's control, or (ii) if the Building is not available for use for a period of five (5) consecutive days due to the violation or alleged violation of any Environmental Laws, then Tenant shall have the right thereafter to abate rent on a per diem basis for each day that any of the Primary Utilities or the Building are not available for use by the Tenant.

13.2 Should Tenant require any additional work or service, as described above, including services furnished outside ordinary business hours specified above, Landlord may, on terms to be agreed, upon reasonable advance notice by Tenant, furnish such additional service and Tenant agrees to pay to Landlord as Additional Rent such charges as may be agreed upon, including any tax imposed thereon, but in no event at a charge less than Landlord's actual cost plus overhead for such additional service and, where appropriate, a reasonable allowance for depreciation of any systems being used to provide such service. As of the date of this Lease, the after-hours charge for HVAC is \$40 per hour. This charge is subject to change during the term of the Lease.

13.3 Wherever heat-generating machines or equipment are used by Tenant in the Premises which affect the temperature otherwise maintained by the air conditioning system, Landlord reserves the right to install supplementary air conditioning units in or for the benefit of the Premises and the cost thereof, including the cost of installation and the cost of operations and maintenance, shall be paid by Tenant to Landlord upon demand as such Additional Rent.

13.4 Tenant will not, without the written consent of Landlord, use any apparatus or device in the Premises, including but not limited to, electronic data processing machines and machines using current in excess of 200 watts or 110 volts, which will in any way increase the amount of electricity or water usually furnished or supplied for use of the Premises for normal office use, nor connect with electric current, except through existing electrical outlets in the Premises, or water pipes, any apparatus or device for the purposes of using electrical current or

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water. If Tenant shall require water or electric current in excess of that usually furnished or supplied for use of the Premises as normal office use, Tenant shall procure the prior written consent of Landlord for the use thereof, which Landlord may refuse, and if Landlord does consent, Landlord may cause a water meter or electric current meter to be installed so as to measure the amount of such excess water and electric current. The cost of any such meters shall be paid for by Tenant as Additional Rent. Tenant agrees to pay as Additional Rent to Landlord promptly upon demand therefor, the cost of all such excess water and electric current consumed (as shown by said meters, if any, or, if none, as reasonably estimated by Landlord) at the rates charged for such services by the local public utility or agency, as the case may be, furnishing the same, plus any additional expense incurred in keeping account of the water and electric current so consumed.

13.5 Tenant reserves the right, at Tenant's sole cost and expense, to install a generator at the Building, upon written approval of Landlord, and subject to all local codes and regulations, and Tenant. Tenant shall pay for all costs associated with the installation, maintenance, and repair of such generator, and the associated pad and enclosure required to be installed. The specific location of the generator, and the plans and specifications for such equipment and its installation, shall be subject to Landlord's prior written approval, which shall not be unreasonably withheld, conditioned, or delayed. Tenant shall have access to the generator pursuant to the Building's Rules and Regulations provided Tenant supplies Landlord with forty-eight (48) hours prior notice. Upon vacating the Premises, at Landlord's sole discretion, Tenant shall remove the generator installed pursuant to this Section and shall restore the Building or the area where the generator is constructed, to substantially its condition prior to installation of the generator described herein, reasonable wear and tear and casualty damage excepted. With Landlord's approval as to location and manner of installation, which shall not be unreasonably withheld, conditioned, or delayed, Tenant shall be entitled to install, connect, run, and maintain connections to the generator, and other wiring within the Building which shall be reasonably located so as not materially to interfere with other tenants.

**14. HOLDING OVER.**

Tenant shall pay Landlord for each day Tenant retains possession of the Premises or part of them after termination of this Lease by lapse of time or otherwise at the rate ("Holdover Rate") which shall be 125% of the amount of the Annual Rent for the last month prior to the date of such termination plus all Rent Adjustments under Article 4 for the first thirty (30) days after the Expiration Date or early termination of the Lease and 150% of the amount of the Annual Rent for the last month prior to the date of such termination plus all Rent Adjustments under Article 4 thereafter.

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**15. SUBORDINATION.**

Without the necessity of any additional document being executed by Tenant for the purpose of effecting a subordination, this Lease shall be subject and subordinate at all times to ground or underlying leases and to the lien of any mortgages or deeds of trust now or hereafter placed on, against or affecting the Building, Landlord's interest or estate in the Building, or any ground or underlying lease; provided, however, that if the lessor, mortgagee, trustee, or holder of any such mortgage or deed of trust elects to have Tenant's interest in this Lease be superior to any such instrument, then, by notice to Tenant, this Lease shall be deemed superior, whether this Lease was executed before or after said instrument. Notwithstanding the foregoing, Tenant covenants and agrees to execute and deliver upon demand such further instruments evidencing such subordination or superiority of this Lease as may be required by Landlord, provided such instruments contain language reasonable acceptable to Tenant. Notwithstanding anything contained in the Lease to the contrary, Landlord shall obtain a subordination, non-disturbance and attornment agreement ("SNDA") to the benefit of Tenant from the holder of any current or future mortgage or lessor under any ground lease with respect to the Building (a "Lender"), using the specific Lender's SNDA form together with such modifications as may be reasonably agreed upon by Tenant and Lender. To the extent that any such mortgage or ground lease exists as of the Commencement Date, Landlord shall use commercially reasonable efforts to secure such SNDA. With respect to any future mortgage or ground lease with respect to the Building, Landlord shall secure such SNDA with respect to the same simultaneously with Landlord's execution and delivery of such mortgage or ground lease to Lender.

**16. RULES AND REGULATIONS.**

Tenant shall faithfully observe and comply with all the rules and regulations as set forth in Exhibit "C" attached to and made a part of this Lease and all reasonable modifications of and additions to them from time to time put into effect by Landlord. Landlord shall not be responsible to Tenant for the non-performance by any other tenant or occupant of the Building of any such rules and regulations.

**17. REENTRY BY LANDLORD.**

17.1 Landlord reserves and shall at all times have the right to re-enter the Premises to inspect the same, to supply janitor service and any other service to be provided by Landlord to Tenant under this Lease, and with twenty-four (24) hour advance notice, except in the case of an emergency where no notice is required, to show said Premises to prospective purchasers, mortgagees or, within the last twelve (12) calendar month of the Lease Term), to prospective tenants, and to alter, improve or repair the Premises and any portion of the Building, without abatement of Annual Rent or Additional Rent, and may for that purpose erect, use and maintain scaffolding, pipes, conduits and other necessary structures and open any wall, ceiling or floor in and through the Building and Premises where reasonably required by the character of the work to be performed, provided entrance to the Premises shall not be blocked thereby, and further provided that the business of Tenant shall not be interfered with unreasonably.

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17.2 Landlord shall have the right at any time to change the arrangement and/or locations of entrances, or passageways, doors and doorways, and corridors, windows, elevators, stairs, toilets or other public parts of the Building (provided that such changes do not materially interfere with any Tenant Entity's access to and from the Premises) and to change the name, number or designation by which the Building is commonly known. In the event that Landlord damages any portion of any wall or wall covering, ceiling, or floor or floor covering within the Premises, Landlord shall repair or replace the damaged portion to match the original as nearly as commercially reasonable but shall not be required to repair or replace more than the portion actually damaged.

17.3 For each of the aforesaid purposes, Landlord shall at all times have and retain a key with which to unlock all of the doors in the Premises, excluding Tenant's vaults and safes or special security areas (designated in advance), and Landlord shall have the right to use any and all means which Landlord may deem proper to open said doors in an emergency to obtain entry to any portion of the Premises. As to any portion to which access cannot be had by means of a key or keys in Landlord's possession, Landlord is authorized to gain access by such means as Landlord elects and the cost of repairing any damage occurring in doing so shall be borne by Tenant and paid to Landlord as Additional Rent upon demand.

**18. DEFAULT.**

18.1 Otherwise provided in Article 20, the following events shall be deemed to be Events of Default ("Events of Default") under this Lease:

18.1.1 Tenant shall fail to pay when due any sum of money becoming due to be paid to Landlord under this Lease, whether such sum be any installment of the rent reserved by this Lease, any other amount treated as Additional Rent under this Lease, or any other payment or reimbursement to Landlord required by this Lease, whether or not treated as Additional Rent under this Lease, and such failure shall continue for a period of five business days after written notice that such payment was not made when due, but if any such notice shall be given, for two or more times in a twelve (12) month period commencing with the date of such notice, the failure to pay within five business days after due any additional sum of money becoming due to be paid to Landlord under this Lease during the remainder of such period shall be an Event of Default, without notice.

18.1.2 Tenant shall fail to comply with any non-monetary term, provision or covenant of this Lease which is not provided for in another Section of this Article and shall not cure such failure within thirty (30) days after written notice of such failure to Tenant; provided, however, if such default cannot reasonably be cured within such thirty (30) day period, Tenant shall not be in default if Tenant promptly commences the cure of such default and diligently pursues such cure to completion within a reasonable time thereafter not to exceed one hundred twenty (120) days total.

18.1.3 Tenant shall become insolvent, admit in writing its inability to pay its debts generally as they become due, file a petition in bankruptcy or a petition to take advantage of any

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insolvency statute, make an assignment for the benefit of creditors, make a transfer in fraud of creditors, apply for or consent to the appointment of a receiver of itself or of the whole or any substantial part of its property, or file a petition or answer seeking reorganization or arrangement under the federal bankruptcy laws, as now in effect or hereafter amended, or any other applicable law or statute of the United States or any state thereof.

18.1.4 A court of competent jurisdiction shall enter an order, judgment or decree adjudicating Tenant bankrupt, or appointing a receiver of Tenant, or of the whole or any substantial part of its property, without the consent of Tenant, or approving a petition filed against Tenant seeking reorganization or arrangement of Tenant under the bankruptcy laws of the United States, as now in effect or hereafter amended, or any state thereof, and such order, judgment or decree shall not be vacated or set aside or stayed within thirty (30) days from the date of entry thereof.

18.1.5 Tenant fails to deliver any estoppel certificate requested by Landlord within the period described in Article 25, which failure continues for five (5) days after written notice of such failure from Landlord.

18.1.6 Tenant violates the restrictions on Transfer set forth in Article 9, which failure continues for thirty (30) days after written notice of such failure from Landlord.

## 19. REMEDIES.

19.1 Except as otherwise provided in Article 20, upon the occurrence of any of the Events of Default described or referred to in Article 18, Landlord shall have the option to pursue any one or more of the following remedies without any notice or demand whatsoever, concurrently or consecutively and not alternatively:

19.1.1 Landlord may, at its election, terminate this Lease or terminate Tenant's right to possession only, without terminating the Lease.

19.1.2 Upon any termination of this Lease, whether by lapse of time or otherwise, or upon any termination of Tenant's right to possession without termination of the Lease, Tenant shall surrender possession and vacate the Premises immediately, and deliver possession thereof to Landlord, and Tenant hereby grants to Landlord full and free license to enter into and upon the Premises in such event and to repossess Landlord of the Premises as of Landlord's former estate and to expel or remove Tenant and any others who may be occupying or be within the Premises and to remove Tenant's signs and other evidence of tenancy and all other property of Tenant therefrom without being deemed in any manner guilty of trespass, eviction or forcible entry or detainer, and without incurring any liability for any damage resulting therefrom, Tenant waiving any right to claim damages for such re-entry and expulsion, and without relinquishing Landlord's right to rent or any other right given to Landlord under this Lease or by operation of law.

19.1.3 Upon any termination of this Lease, whether by lapse of time or otherwise, Landlord shall be entitled to recover as damages, all Annual Rent, including any amounts treated as Additional Rent under this Lease, and other sums due and payable by Tenant on the date of



termination, plus as liquidated damages and not as a penalty, an amount equal to the sum of (a) then present value of the Annual Rent reserved in this Lease for the residue of the stated Term of this Lease including any amounts treated as Additional Rent under this Lease and all other sums provided in this Lease to be paid by Tenant, discounted to the present value thereof at a rate equal to the Prime Rate established from time to time by Chase Bank or any successor thereto minus the fair rental value of the Premises for such residue; and (b) the actual reasonable cost incurred by Landlord of performing any other covenants of Tenant hereunder which remained unperformed by Tenant as of the date of such termination.

19.1.4 Upon any termination of Tenant's right to possession only without termination of the Lease:

19.1.4.1 Neither such termination of Tenant's right to possession nor Landlord's taking and holding possession thereof as provided in Section 19.1.2 shall terminate the Lease or release Tenant, in whole or in part, from any obligation, including Tenant's obligation to pay the Annual Rent, including any amounts treated as Additional Rent, under this Lease for the full Term, and if Landlord so elects Tenant shall pay forthwith to Landlord the sum equal to the entire amount of the Annual Rent, including any amounts treated as Additional Rent under this Lease, for the remainder of the Term plus any other sums provided in this Lease to be paid by Tenant for the remainder of the Term.

19.1.4.2 Landlord may, but need not, relet the Premises or any part thereof for such rent and upon such terms as Landlord, in its reasonable discretion, shall determine (including the right to relet the premises for a greater or lesser term than that remaining under this Lease, the right to relet the Premises as a part of a larger area, and the right to change the character or use made of the Premises). In connection with or in preparation for any reletting, Landlord may, but shall not be required to, make repairs, alterations and additions in or to the Premises and redecorate the same to the extent Landlord reasonably deems necessary or desirable, and Tenant shall, upon demand, pay the cost thereof, together with Landlord's expenses of reletting, including, without limitation, any commission incurred by Landlord. Landlord shall use commercially reasonable efforts to mitigate its damages arising out such Event of Default by reletting the Premises in a commercially reasonable manner; provided, that Landlord and Tenant agree that nevertheless Landlord shall at most be required to use only the same efforts Landlord then uses to lease premises in the Building generally and that in any case that Landlord shall not be required to give any preference or priority to the showing or leasing of the Premises over any other space that Landlord may be leasing or have available and may place a suitable prospective tenant in any such other space regardless of when such other space becomes available. Landlord shall not be required to observe any instruction given by Tenant about any reletting or accept any tenant offered by Tenant unless such offered tenant has a credit-worthiness acceptable to Landlord and leases the entire Premises upon terms and conditions including a rate of rent (after giving effect to all expenditures by Landlord for tenant improvements, broker's commissions and other leasing costs) all no less favorable to Landlord than as called for in this Lease, nor shall Landlord be required to make or permit any assignment or sublease for more than the current term or which Landlord would not be required to permit under the provisions of Article 9.

19.1.4.3 Until such time as Landlord shall elect to terminate the Lease and shall thereupon be entitled to recover the amounts specified in such case in Section 19.1.3, Tenant shall pay to Landlord upon demand the full amount of all Annual Rent, including any amounts treated as Additional Rent under this Lease and other sums reserved in this Lease for the remaining Term, together with the costs of repairs, alterations, additions, redecorating and Landlord's expenses of reletting and the collection of the rent accruing therefrom (including attorney's fees and broker's commissions), as the same shall then be due or become due from time to time, less only such consideration as Landlord may have received from any reletting of the Premises; and Tenant agrees that Landlord may file suits from time to time to recover any sums falling due under this Article 19 as they become due. Any proceeds of reletting by Landlord in excess of the amount then owed by Tenant to Landlord from time to time shall be credited against Tenant's future obligations under this Lease but shall not otherwise be refunded to Tenant or inure to Tenant's benefit.

19.2 Landlord may, at Landlord's option, enter into and upon the Premises if Landlord determines in its sole discretion that Tenant is not acting within a commercially reasonable time to maintain, repair or replace anything for which Tenant is responsible under this Lease and correct the same, without being deemed in any manner guilty of trespass, eviction or forcible entry and detainer and without incurring any liability for any damage or interruption of Tenant's business resulting therefrom. If Tenant shall have vacated the Premises, Landlord may at Landlord's option re-enter the Premises at any time during the last six months of the then current Term of this Lease and make any and all such changes, alterations, revisions, additions and tenant and other improvements in or about the Premises as Landlord shall elect, all without any abatement of any of the Annual Rent and Additional Rent otherwise to be paid by Tenant under this Lease.

19.3 If, on account of any breach or default by Tenant in Tenant's obligations under the terms and conditions of this Lease, it shall become necessary or appropriate for Landlord to employ or consult with an attorney concerning or to enforce or defend any of Landlord's rights or remedies arising under this Lease, Tenant agrees to pay all Landlord's attorney's fees so incurred. Tenant expressly waives any right to: (a) trial by jury; and (b) service of any notice required by any present or future law or ordinance applicable to landlords or tenants but not required by the terms of this Lease.

19.4 Pursuit of any of the foregoing remedies shall not preclude pursuit of any of the other remedies provided in this Lease or any other remedies provided by law (all such remedies being cumulative), nor shall pursuit of any remedy provided in this Lease constitute a forfeiture or waiver of any rent due to Landlord under this Lease or of any damages accruing to Landlord by reason of the violation of any of the terms, provisions and covenants contained in this Lease.

19.5 No act or thing done by Landlord or its agents during the Term shall be deemed a termination of this Lease or an acceptance of the surrender of the Premises, and no agreement to terminate this Lease or accept a surrender of said Premises shall be valid, unless in writing signed by Landlord. No waiver by Landlord of any violation or breach of any of the terms, provisions and covenants contained in this Lease shall be deemed or construed to constitute a waiver of any other violation or breach of any of the terms, provisions and covenants contained in this Lease.

Landlord's acceptance of the payment of Annual Rent or Additional Rent or other payments after the occurrence of an Event of Default shall not be construed as a waiver of such Default, unless Landlord so notifies Tenant in writing. Forbearance by Landlord in enforcing one or more of the remedies provided in this Lease upon an Event of Default shall not be deemed or construed to constitute a waiver of such Default or of Landlord's right to enforce any such remedies with respect to such Default or any subsequent Default.

19.6 Any and all property which may be removed from the Premises by Landlord pursuant to the authority of this Lease or of law, to which Tenant is or may be entitled, may be handled, removed and/or stored, as the case may be, by or at the direction of Landlord but at the risk, cost and expense of Tenant, and Landlord shall in no event be responsible for the value, preservation or safekeeping thereof. Tenant shall pay to Landlord, upon demand, any and all expenses incurred in such removal and all storage charges against such property so long as the same shall be in Landlord's possession or under Landlord's control. Any such property of Tenant not retaken by Tenant from storage within sixty (60) days after removal from the Premises shall, at Landlord's option, be deemed conveyed by Tenant to Landlord under this Lease as by a bill of sale without further payment or credit by Landlord to Tenant.

19.7 Confession of Judgment for Possession of Real Property. Upon the occurrence of an Event of Default hereunder, or upon the expiration of the Term of this Lease, whether the ~~initial~~-stated term or the earlier termination or surrender hereof, as provided in this Lease, it shall be lawful for any attorney of any court of record to appear as attorney for Tenant as well as for all persons claiming through, by, or under Tenant, and to, by complaint or in ejectment of Tenant and all persons claiming through, by or under Tenant and for which a copy of the Lease, verified by affidavit, shall be sufficient warrant, whereupon, if Landlord so desires, a writ of possession or other appropriate writ under the rules of civil procedure then in effect may issue forthwith, without any prior writ or proceedings. Whether this Lease is terminated or not and possession of the Premises remains in, or is restored to Lessee, Landlord shall have the right for the same Event of Default and upon any subsequent Event(s) of Default, or upon the termination of this Lease, to bring one or more further actions to recover possession of the Premises and confess judgment for the recovery of possession of the Premises as provided in this Section 19.7.

19.7.1 Tenant's Acknowledgment and Understanding of Confession of Judgment. TENANT HEREBY ACKNOWLEDGES THAT TENANT HAS HAD THE OPPORTUNITY TO SEEK THE ASSISTANCE OF LEGAL COUNSEL IN THE REVIEW AND EXECUTION OF THIS LEASE AND IF COUNSEL WAS CONSULTED, TENANT FURTHER ACKNOWLEDGES THAT THE MEANING AND EFFECT OF THE FOREGOING PROVISIONS CONCERNING CONFESSION OF JUDGMENT HAVE BEEN FULLY EXPLAINED TO TENANT BY SUCH COUNSEL. TENANT UNDERSTANDS AND AGREES THAT THIS LEASE CONTAINS PROVISIONS BY WHICH LANDLORD MAY ENTER JUDGMENT BY CONFESSION AGAINST TENANT. TENANT UNDERSTANDS THAT, WITHOUT THESE PROVISIONS, TENANT WOULD RECEIVE PRIOR NOTICE IN ADDITION TO THE NOTICE SET FORTH HEREIN IN CONNECTION WITH AN EVENT OF DEFAULT AND A HEARING OF ANY CLAIMS BY LANDLORD BEFORE A JUDGMENT COULD BE ENTERED. HOWEVER, TENANT HEREBY FREELY,

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KNOWINGLY, INTELLIGENTLY WAIVES THESE RIGHTS AND CONSENTS TO LANDLORD'S ENTERING JUDGMENT AGAINST TENANT BY CONFESSION PURSUANT TO THE TERMS OF THE LEASE. TENANT ALSO UNDERSTANDS THAT UPON THE ENTRY OF JUDGMENT, LANDLORD MAY DIRECT THE SHERIFF TO PUT THE TENANT OUT OF POSSESSION OF THE PREMISES. TENANT, FREELY, KNOWINGLY AND INTELLIGENTLY WAIVES THE RIGHT TO NOTICE AND HEARING BEFORE LANDLORD MAY RETAKE POSSESSION OF THE PREMISES PURSUANT TO A CONFESSED JUDGMENT AND AGREES THAT LANDLORD MAY RETAKE POSSESSION OF THE PREMISES AND MAY DIRECT THE SHERIFF TO DO SO, IMMEDIATELY UPON ENTRY OF JUDGMENT. TENANT CERTIFIES THAT TENANT'S ANNUAL INCOME EXCEEDS \$10,000.00 AND THAT THIS IS A COMMERCIAL TRANSACTION.

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Tenant's Initials and Date

19.7.2 Landlord's Assignee's Right to Confess Judgment. The right to enter judgment against Tenant by confession and to enforce all of the other provisions of this Lease herein provided for may at the option of any assignee of this Lease, be exercised by any assignee of the Landlord's right, title and interest in this Lease in his, her or their own name, any statute, rule of court, custom, or practice to the contrary notwithstanding. In the event that this Lease is amended (including but not limited to an amendment extending the Term of this Lease and/or expanding the Premises), the right to enter judgment by confession against Tenant for monetary damages and in ejectment shall remain in full force and effect.

19.7.3 All remedies hereinbefore given to Landlord and all rights and remedies otherwise given to it by law and equity shall be cumulative and concurrent. No termination of this Lease or the taking or recovery of the Premises shall deprive Landlord of any of its remedies or actions against Tenant for Minimum Rent and Additional Rent, nor shall the bringing of any action for Minimum Rent and Additional Rent be construed as a waiver of the right to obtain possession of the Premises.

19.7.4 In any action for Rent or other charges payable hereunder, Landlord shall cause to be filed in such action an affidavit setting forth the facts necessary to authorize the entry of judgment and, if a true copy of this Lease (and of the truth of the copy such affidavit shall be sufficient proof) be filed in such action, it shall not be necessary to file the original as a warrant of attorney, any law, rule of court, custom or practice to the contrary notwithstanding. Tenant releases to Landlord, and to any and all attorneys who may appear for Tenant, all errors in any proceedings taken by Landlord, whether by virtue of the powers of attorney contained in this Lease or not, and all liability therefor. Tenant expressly waives the benefits of all laws, not or hereafter in force, exempting any goods within the Premises or elsewhere from restraint, levy or sale.

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**20. TENANT'S BANKRUPTCY OR INSOLVENCY.**

20.1 If at any time and for so long as Tenant shall be subjected to the provisions of the United States Bankruptcy Code or other law of the United States or any state thereof for the protection of debtors as in effect at such time (each a "Debtor's Law"):

20.1.1 Tenant, Tenant as debtor-in-possession, and any trustee or receiver of Tenant's assets (each a "Tenant's Representative") shall have no greater right to assume or assign this Lease or any interest in this Lease, or to sublease any of the Premises than accorded to Tenant in Article 9, except to the extent Landlord shall be required to permit such assumption, assignment or sublease by the provisions of such Debtor's Law. Without limitation of the generality of the foregoing, any right of any Tenant's Representative to assume or assign this Lease or to sublease any of the Premises shall be subject to the conditions that:

20.1.1.1 Such Debtor's Law shall provide to Tenant's Representative a right of assumption of this Lease which Tenant's Representative shall have timely exercised and Tenant's Representative shall have fully cured any default of Tenant under this Lease.

20.1.1.2 Tenant's Representative or the proposed assignee, as the case shall be, shall have deposited with Landlord as security for the timely payment of Annual Rent or Additional Rent an amount equal to the larger of: (a) three months' rent and other monetary charges accruing under this Lease; and (b) any sum specified in Article 5; and shall have provided Landlord with adequate other assurance of the future performance of the obligations of the Tenant under this Lease. Without limitation, such assurances shall include, at least, in the case of assumption of this Lease, demonstration to the satisfaction of the Landlord that Tenant's Representative has and will continue to have sufficient unencumbered assets after the payment of all secured obligations and administrative expenses to assure Landlord that Tenant's Representative will have sufficient funds to fulfill the obligations of Tenant under this Lease; and, in the case of assignment, submission of current financial statements of the proposed assignee, audited by an independent certified public accountant reasonably acceptable to Landlord and showing a net worth and working capital in amounts determined by Landlord to be sufficient to assure the future performance by such assignee of all of the Tenant's obligations under this Lease.

20.1.1.3 The assumption or any contemplated assignment of this Lease or subleasing any part of the Premises, as shall be the case, will not breach any provision in any other lease, mortgage, financing agreement or other agreement by which Landlord is bound.

20.1.1.4 Landlord shall have, or would have had absent the Debtor's Law, no right under Article 9 to refuse consent to the proposed assignment or sublease by reason of the identity or nature of the proposed assignee or sublessee or the proposed use of the Premises concerned

**21. QUIET ENJOYMENT.**

Landlord represents and warrants that it has full right and authority to enter into this Lease and that Tenant, while paying the Annual Rent and Additional Rent and performing its other covenants and agreements contained in this Lease, shall peaceably and quietly have, hold and

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enjoy the Premises for the Term without hindrance or molestation from Landlord subject to the terms and provisions of this Lease. Landlord shall not be liable for any interference or disturbance by other tenants or third persons, nor shall Tenant be released from any of the obligations of this Lease because of such interference or disturbance.

**22. DAMAGE BY FIRE, ETC.**

22.1 In the event the Premises or the Building are damaged by fire or other cause, Landlord shall notify Tenant in writing within thirty (30) days after the occurrence of such casualty whether, in Landlord's reasonable estimation, such damage can be materially restored within one hundred eighty (180) day from the receipt of insurance proceeds. If Landlord determines that such damages can be repaired within such 180 day period, Landlord shall forthwith repair the same and this Lease shall remain in full force and effect, except that Tenant shall be entitled to a proportionate abatement in Annual Rent and Additional Rent from the date of such damage. Such abatement of rent shall be made pro rata in accordance with the extent to which the damage and the making of such repairs shall interfere with the use and occupancy by Tenant of the Premises from time to time. For purposes of this Lease, the Building or Premises shall be deemed "materially restored" if they are in such condition as would not prevent or materially interfere with Tenant's use of the Premises for the purpose for which it was being used immediately before such damage.

22.2 If Tenant's notice provided within 30 days of the casualty pursuant to Section 22.1 above states that the applicable repairs cannot, in Landlord's reasonable estimation, be made within one hundred eighty (180) days from the receipt of insurance proceeds, or if the casualty occurs within the last twelve (12) months of the Term, Landlord and Tenant (unless an Event of Default is existing or if Tenant caused the applicable damage) shall each have the option of giving the other, at any time within thirty (30) days after such damage, notice terminating this Lease as of the date of such damage. In the event of the giving of such notice, this Lease shall expire and all interest of the Tenant in the Premises shall terminate as of the date of such damage as if such date had been originally fixed in this Lease for the expiration of the Term and all obligations of Tenant hereunder shall terminate. In the event that neither Landlord nor Tenant exercises its option to terminate this Lease, then provided that Landlord's mortgagee consents to such restoration or repair, Landlord shall repair or restore such damage, this Lease continuing in full force and effect, and the Annual Rent and Additional Rent hereunder shall be proportionately abated as provided in Section 22.1.

22.3 Landlord shall not be required to repair or replace any damage or loss by or from fire other cause to any panels, decorations, partitions, additions, railings, ceilings, floor coverings, office fixtures or any other personal property or improvements installed on the Premises or belonging to Tenant. Any insurance that may be carried by Landlord or Tenant against loss or damage to the Building or Premises shall be for the sole benefit of the party carrying such insurance and under its sole control.

22.4 In the event that the Landlord should fail to complete such repairs and material restoration within ninety (90) days after the date estimated by Landlord therefor as extended by this Section 22.4, Tenant (Tenant shall have no right of cancellation if an Event of Default exists

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and if Tenant caused the damage) may at its option and as its sole remedy terminate this Lease by delivering written notice to Landlord, within fifteen (15) days after the expiration of said period of time, whereupon the Lease shall end on the date of such notice or such later date fixed in such notice as if the date of such notice was the date originally fixed in this Lease for the expiration of the Term; provided, however, that if construction is delayed because of changes, deletions or additions in construction requested by Tenant, strikes, lockouts, casualties, Acts of God, war, material or labor shortages, government regulation or control or other causes beyond the reasonable control of Landlord, the period for restoration, repair or rebuilding shall be extended for the amount of time Landlord is so delayed; provided further, that no such delay shall be permitted on account of general economic conditions.

22.5 Notwithstanding anything to the contrary contained in this Article: (a) Landlord shall not have any obligation whatsoever to repair, reconstruct, or restore the Premises when the damages resulting from any casualty covered by the provisions of this Article 22 occur during the last twelve (12) months of the Term or any extension thereof, but if Landlord determines not to repair such damages Landlord shall notify Tenant and if such damages shall render any material portion of the Premises untenantable Tenant (Tenant shall have no right of cancellation if Tenant is in default of any of the provisions of this Lease beyond any applicable grace or cure period and if Tenant caused the damage) shall have the right to terminate this Lease by notice to Landlord within fifteen (15) days' after receipt of Landlord's notice; and (b) in the event the holder of any indebtedness secured by a mortgage or deed of trust covering the Premises or Building requires that any insurance proceeds be applied to such indebtedness, then Landlord shall have the right to terminate this Lease by delivering written notice of termination to Tenant within fifteen (15) days after such requirement' is' made by any such holder, whereupon this Lease shall end on the date of such damage as, if the date of such damage were the date originally fixed in this Lease for the expiration of the Term.

22.6 In the event of any damage or destruction to the Building or Premises by any peril covered by the provisions of this Article 22, it shall be Tenant's responsibility to properly secure the Premises and upon notice from Landlord to remove forthwith, at its sole cost and expense, such portion of all of the personal property belonging to Tenant or its licensees from such portion or all of the Building or Premises as Landlord shall request.

### **23. EMINENT DOMAIN.**

If all or any substantial part of the Premises shall be taken or appropriated by any public or quasi-public authority under the power of eminent domain, or conveyance in lieu of such appropriation, either party to this Lease shall have the right (Tenant shall have no right to terminate the Lease if Tenant is in default of any of the terms and conditions of this Lease beyond any applicable grace or cure period), at its option, of giving the other, at any time within thirty (30) days after such taking, notice terminating this Lease, except that Tenant may only terminate this Lease by reason of taking or appropriation, if such taking or appropriation shall be so substantial as to materially interfere with Tenant's use and occupancy of the Premises. If neither party to this Lease shall so elect to terminate this Lease, the Annual Rent and Additional Rent thereafter to be paid shall be adjusted on a fair and equitable basis under the circumstances. In addition to the rights

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of Landlord above, if any substantial part of the Building shall be taken or appropriated by any public or quasi-public authority under the power of eminent domain or conveyance in lieu thereof and such taking materially affects Tenant's use of or access to the Premises and the Building, and regardless of whether the Premises or any part thereof are so taken or appropriated, either party shall have the right, at its sole option, to terminate this Lease. Landlord shall be entitled to any and all income, rent, award, or any interest whatsoever in or upon any such sum, which may be paid or made in connection with any such public or quasi-public use or purpose, and Tenant hereby assigns to Landlord any interest it may have in or claim to all or any part of such sums, other than any separate award which may be made with respect to Tenant's trade fixtures and moving expenses; Tenant shall make no claim for the value of any unexpired Term.

**24. SALE BY LANDLORD.**

In event of a sale or conveyance by Landlord of the Building, the same shall operate to release Landlord from any future liability upon any of the covenants or conditions, expressed or implied, contained in this Lease in favor of Tenant, and in such event Tenant agrees to look solely to the responsibility of the successor in interest of Landlord in and to this Lease. Except as set forth in this Article 24, this Lease shall not be affected by any such sale and Tenant agrees to attorn to the purchaser or assignee. If any security has been given by Tenant to secure the faithful performance of any of the covenants of this Lease, Landlord may transfer or deliver said security, as such, to Landlord's successor in interest and thereupon Landlord shall be discharged from any further liability with regard to said security

**25. ESTOPPEL CERTIFICATES.**

Within twenty (20) days following any written request which Landlord may make from time to time, Tenant shall execute and deliver to Landlord or mortgagee or prospective mortgagee a sworn statement certifying: (a) the date of commencement of this Lease; (b) the fact that this Lease is unmodified and in full force and effect (or, if there have been modifications to this Lease, that this lease is in full force and effect, as modified, and stating the date and nature of such modifications); (c) the date to which the Annual Rent and Additional Rent and other sums payable under this Lease have been paid; (d) the fact that there are no current defaults under this Lease by either Landlord or Tenant except as specified in Tenant's statement; and (e) such other customary matters as may be requested by Landlord. Landlord and Tenant intend that any statement delivered pursuant to this Article 25 may be relied upon by any mortgagee, beneficiary or purchaser and Tenant shall be liable for all loss, cost or expense resulting from the failure of any sale or funding of any loan caused by any material misstatement contained in such estoppel certificate.

**26. SURRENDER OF PREMISES.**

26.1 Tenant shall, at least thirty (30) days before the expiration of the Term, arrange to meet Landlord for a joint inspection of the Premises. Within ten (10) days after such joint inspection, Landlord and Tenant in good faith will determine Tenant's responsibility for repairs and restoration, if any, necessary to return the Premises to the condition required by Section 26.2 below. In the event of Tenant's failure to arrange such joint inspection to be held prior to vacating

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the Premises, Landlord's inspection at or after Tenant's vacating the Premises shall be conclusively deemed correct for purposes of determining Tenant's responsibility for repairs and restoration.

26.2 At the end of the Term or any renewal of the Term or other sooner termination of this Lease, Tenant will peaceably deliver up to Landlord possession of the Premises, together with all improvements or additions upon or belonging to the same, by whomsoever made, in the same conditions received or first installed, broom clean and free of all debris, excepting only ordinary wear and tear and damage by fire or other casualty. Following the completion of the joint inspection described in Section 26.1 above, Tenant may, and at Landlord's request shall, at Tenant's sole cost, remove upon termination of this Lease, any and all furniture, furnishings, movable partitions of less than full height from floor to ceiling, trade fixtures and other property installed by Tenant, title to which shall not be in or pass automatically to Landlord upon such termination, repairing all damage caused by such removal. Property not so removed shall, unless requested to be removed, be deemed abandoned by the Tenant and title to the same shall thereupon pass to Landlord under this Lease as by a bill of sale. All other alterations, additions and improvements in, on or to the Premises shall be dealt with and disposed of as provided in Article 6 hereof.

26.3 All obligations of Tenant under this Lease not fully performed as of the expiration or earlier termination of the Term shall survive the expiration or earlier termination of the Term. In the event that Tenant's failure to perform prevents Landlord from releasing the Premises, Tenant shall continue to pay Annual Rent and Additional Rent pursuant to the provisions of Article 14 until such performance is complete. Upon the expiration or earlier termination of the Term, Tenant shall pay to Landlord as Additional Rent the amount, as agreed upon by Landlord and Tenant following the completion of the joint inspection described in Section 26.1 above, necessary to repair and restore the Premises as provided in this Lease and/or to discharge Tenant's obligation for unpaid amounts due or to become due to Landlord.

**27. NOTICES.**

Any notice or document required or permitted to be delivered under this Lease shall be addressed to the intended recipient, shall be transmitted personally, by fully prepaid registered or certified United States Mail return receipt requested, or by reputable independent contract delivery service furnishing a written record of attempted or actual delivery, and shall be deemed to be delivered when tendered for delivery to the addressee at its address set forth on the Reference Page, or at such other address as it has then last specified by written notice delivered in accordance with this Article 27, or if to Tenant at either its aforesaid address or its last known registered office or home of a general partner or individual owner, whether or not actually accepted or received by the addressee.

**28. TAXES PAYABLE BY TENANT.**

In addition to Annual Rent and Additional Rent and other charges to be paid by Tenant under this Lease, Tenant shall reimburse to Landlord as Additional Rent, upon demand, any and all taxes payable by Landlord (other than net income taxes) whether or not now customary or within the contemplation of the parties to this Lease: (a) upon or with respect to the possession,

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leasing, operation, management, maintenance, alteration, repair, use or occupancy of the Premises or any portion thereof, including any sales, use or service tax imposed as a result thereof; (b) upon Tenant's gross receipts or payroll or the value of Tenant's equipment, furniture, fixtures and other personal property of Tenant or leasehold improvements, alterations or additions located in the Premises; or (c) upon this transaction or any document to which Tenant is a party creating or transferring any interest of Tenant in this Lease or the Premises. In addition to the foregoing, Tenant agrees to pay as Additional Rent, before delinquency, any and all taxes levied or assessed against Tenant and which become payable during the term hereof upon Tenant's equipment furniture, fixtures and other personal property of Tenant located in the Premises.

**29. LANDLORD DEFAULT.**

If Landlord shall default in the performance of any of its obligations hereunder, or if Landlord shall fail to make any payment which Landlord agrees to make hereunder, then Tenant, without being obligated to and without waiving such default, shall have the following remedies which shall be cumulative and shall be in addition to those remedies which Tenant may have at law or in equity. If Tenant provides written notice to Landlord (and any mortgagee of which Tenant has been notified) of any default of Landlord hereunder, and Landlord (or such mortgagee) shall fail to cure such default within thirty (30) days following the receipt of such notice (or as soon as possible under all of the circumstances in the event of an emergency), Tenant may perform such obligation, or pay any sums due to any third party, as Landlord's agent; provided, however, if such default cannot reasonably be cured within such thirty (30) day period, Landlord shall not be in default if Landlord (or such mortgagee) promptly commences the cure of such default and diligently pursues such cure to completion within a reasonable time thereafter not to exceed one hundred twenty (120) days total. The full reasonable amount of the costs and expenses incurred by Tenant to perform such obligation or make such payment, together with reasonable attorney's fee incurred by Tenant, shall be paid by Landlord to Tenant within thirty (30) days after presentation of invoices therefor to Landlord; provided, if Landlord fails to pay such amount within such 30-day period, Tenant shall have the right to offset such unpaid amounts against the next installment(s) of Additional Rent due and payable hereunder.

**30. DEFINED TERMS AND HEADINGS.**

The Article headings shown in this Lease are for convenience of reference and shall in no way define, increase, limit or describe the scope or intent of any provision of this Lease. Any indemnification or insurance of Landlord shall apply to and inure to the benefit of all the following "Landlord Entities", being Landlord, Landlord's investment manager, and the trustees, boards of directors, officers, general partners beneficiaries, stockholders, employees and agents of each of them. Any option granted to Landlord shall also include or be exercisable by Landlord's trustee, beneficiary, agents and employees, as the case may be. In any case where this Lease is signed by more than one person the obligations under this Lease shall be joint and several. The terms "Tenant" and "Landlord" or any pronoun used in place thereof shall indicate and include the masculine or feminine, the singular or plural number, individuals, firms or corporations and each of their respective successors executors, administrators and permitted assigns, according to the context hereof. The term "rentable area" shall mean the rentable area of the Premises or the

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Building as calculated by the Landlord on the basis of the plans and specifications of the Building including a proportionate share of any common areas. Tenant hereby accepts and agrees to be bound by the figures for the rentable space footage of the Premises and Tenant's Proportionate Share shown on the Reference Page.

**31. TENANT'S AUTHORITY.**

If Tenant signs as a corporation each of the persons executing this Lease on behalf of Tenant represents and warrants that Tenant has been and is qualified to do business in the state in which the Building is located, that the corporation has full right and authority to enter into this Lease, and that all persons signing on behalf of the corporation were authorized to do so by appropriate corporate actions. If Tenant signs as a partnership, trust or other legal entity, each of the persons executing this Lease on behalf of Tenant represents and warrants that Tenant has complied with all applicable laws, rules and governmental regulations relative to its right to do business in the state and that such entity on behalf of the Tenant was authorized to do so by any and all appropriate partnership trust or other actions. Tenant agrees to furnish promptly upon request a corporate resolution proof of due authorization by partners or other appropriate documentation evidencing the due authorization of Tenant to enter into this Lease.

**32. COMMISSIONS.**

Each of the parties represents and warrants to the other that it has not dealt with any broker or finder in connection with this Lease except as described on the Reference Page. All commissions payable to the brokers identified on the Reference Page shall be paid by Landlord.

**33. TIME AND APPLICABLE LAW.**

Time is of the essence of this Lease and all of its provisions. This Lease shall in all respects be governed by the laws of the state in which the Building is located.

**34. SUCCESSORS AND ASSIGNS.**

Subject to the provisions of Article 9, the terms, covenants and conditions contained in this Lease shall be binding upon and inure to the benefit of the heirs, successors, executors, administrators and assigns of the parties to this Lease.

**35. ENTIRE AGREEMENT.**

This Lease, together with its Exhibits, contains all agreements of the parties to this Lease and supersedes any previous negotiations. There have been no representations made by the Landlord or understandings made between the parties other than those set forth in this Lease and its Exhibits. This Lease may not be modified except by a written instrument duly executed by the parties to this Lease.

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**36. EXAMINATION NOT OPTION.**

Submission of this Lease shall not be deemed to be a reservation of the Premises. Landlord shall not be bound by this Lease until it has received a copy of this Lease duly executed by Tenant and has delivered to Tenant a copy of this Lease duly executed by Landlord, and until such delivery Landlord reserves the right to exhibit and lease the Premises to other prospective tenants. Notwithstanding anything contained in this Lease to the contrary, Landlord may withhold delivery of possession of the Premises from Tenant until such time as Tenant has paid to Landlord any security deposit required by Article 5, the first month's rent as set forth in Article 3 and any sum owed pursuant to this Lease.

**37. RECORDATION.**

Tenant shall not record or register this Lease or a short form memorandum hereof without the prior written consent of Landlord, and then shall pay all charges and taxes incident such recording or registration.

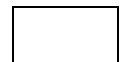
**38. LIMITATION OF LANDLORD'S LIABILITY.**

Redress for any claim against Landlord under this Lease shall be limited to and enforceable only against and to the extent of Landlord's interest in the Building. The obligations of Landlord under this Lease are not intended to and shall not be personally binding on, nor shall any resort be had to the private properties of, any of its trustees or board of directors and officers, as the case may be, its investment manager, the general partners thereof, or any beneficiaries, stockholders, employees, or agents of Landlord or the investment manager.

**39. COMPLIANCE WITH LAWS**

39.1 The Tenant shall keep the Premises in clean and orderly condition, promptly execute and materially comply with all statutes, ordinances, rules, orders, regulations and requirements ("Laws") of the Federal, Provincial and City governments and of any and all their departments, agencies and bureaus or any other governmental authorities (collectively, "Governmental Authorities") applicable to the Premises and with all notices for the correction, prevention and abatement of nuisances, violations or other grievances in, upon or connected with the Premises during the term of this Lease. Tenant shall also promptly materially comply with and execute all rules, orders and regulations relating to the Building of the Board of Fire Underwriters or similar or successor agency and all insurance companies writing policies pertaining to the Premises, for the prevention of fires (collectively "Fire Requirements"), at its sole cost and expense.

39.2 If the Tenant shall fail or neglect to timely comply with any of the aforesaid Laws and/or Fire Requirements or if the Tenant shall fail or neglect to make any necessary or required repairs then the Landlord or its agents, without notice in the case of an emergency and in all other cases if such default is not cured within ten (10) days from the date of the giving by Landlord to Tenant of notice of such intention, may, but shall in no event be obligated to, enter the Premises and make said repairs, comply with any or all of said Laws and/or Fire Requirements and perform any such obligation of the Tenant, all at the cost and expense of the Tenant.



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39.3 Tenant shall obtain all approvals, certificates or permits of every kind and nature required in connection with Tenant's use and occupancy of the Premises.

**40. PARKING.**

Subject to the requirements and limitations set forth in the in the Building's Rules and Regulations, and any other provision therein applicable to the parking of vehicles, Landlord shall provide Tenant, throughout the Term, with the non-exclusive use of up to four (4) surface parking spaces per 1,000 rentable square feet of the Premises, which parking spaces shall be located in the general parking area at the Property. (the "Parking Area"). Landlord hereby also acknowledges and agrees that, in addition to the foregoing non-reserved spaces, Tenant shall have a total of eight (8) reserved covered parking spaces within the Parking Area for Tenant's employees working at the Premises and the Expansion Premises.

**41. DRAFTING OF LEASE**

Notwithstanding anything contained to the contrary contained herein or presumed at law or otherwise, the parties and signatories hereto hereby agree and acknowledge that, for the purposes of the interpretation or construction of this Lease and its riders, etc., neither party/signatory shall be deemed or considered to be the drafter of the Lease, it riders, etc., it being the intention of the parties that any interpretation and/or construction of the same be made by a court of competent jurisdiction without regard to the history of the drafting, or to the drafter(s), of the same.

**42. [INTENTIONALLY DELETED]**

**43. BUILDING CONTAMINANTS.**

To prevent the contamination, growth, or deposit of any mold, mildew, bacillus, virus, pollen, or other micro-organism (collectively, "Biologicals") and the deposit, release or circulation of any indoor contaminants including emissions from paint, carpet and drapery treatments, cleaning, maintenance and construction materials and supplies, pesticides, pressed wood products, insulation, and other materials and products (collectively with Biologicals, "Contaminants") that could adversely affect the health, safety or welfare of any tenant, employee, or other occupant of the Building or their invitees (each, an "Occupant"), Tenant shall, at Tenant's sole cost and expense, at all times during the term hereof (1) operate the Premises in such a manner to reasonably prevent or minimize the accumulation of stagnant water and moisture in planters, kitchen appliances and vessels, carpeting, insulation, water coolers, and any other locations where stagnant water or moisture could accumulate, and (2) otherwise operate the Premises to prevent the generation, growth, deposit, release or circulation of any Contaminants.

**44. WI-FI ACCESS.**

44.1 Tenant shall have the right to install a wireless intranet, Internet, and communications network (also known as "Wi-Fi") within the Premises for the use of Tenant and

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its employees and [clients/customers] (the "Network") subject to this clause and all the other clauses of this Lease as are applicable.

44.2 Tenant shall not solicit, suffer, or permit other tenants or occupants of the Building to use the Network or any other communications service, including, without limitation, any wired or wireless Internet service that passes through, is transmitted through, or emanates from the Premises.

44.3 Subject to Landlord's approval, which shall not be unreasonably withheld, and subject to any necessary governmental approval, Tenant shall have the right to place communications dishes, antennae and related equipment (collectively the "Antenna Equipment") on the roof of the Building for its own use. Placement of the Antenna Equipment will comply with all applicable city, county, or other jurisdictional zoning ordinances. There shall be no charge to Tenant during the Lease Term for the placement of Antenna Equipment. The specific location of the Antenna Equipment, and the plans and specifications for such equipment and its installation, shall be subject to Landlord's prior written approval, which shall not be unreasonably withheld, conditioned, or delayed. Tenant shall have access to the Antenna Equipment pursuant to the Building's Rules and Regulations provided Tenant supplies Landlord with forty-eight (48) hours prior notice. Upon vacating the Premises, Tenant shall remove the Antenna Equipment installed pursuant to this Section and shall restore the roof to substantially its condition prior to installation of the Antenna Equipment described herein, reasonable wear and tear and casualty damage excepted. With Landlord's approval as to location and manner of installation, which shall not be unreasonably withheld, conditioned, or delayed, Tenant shall be entitled to install, connect, run, and maintain fiber optic conduits, telephone lines, and other wiring within the Building which shall be reasonably located so as not materially to interfere with other tenants. Tenant shall receive any condemnation award related to the Antenna Equipment installed by Tenant pursuant hereto. Tenant and Landlord operating communications dishes, antennae, or other telecommunications equipment shall (1) operate their equipment within the technical parameters specified by its manufacturer and/or as defined by the FCC, and (2) not use any portion of the Building in any way which causes radio frequency and/or electrical interference with any equipment of another tenant or licensee operated prior in time to the interfering equipment and in accordance with subsection (1) hereof. In the event of any such interference by Tenant, Tenant shall terminate the interference (as applicable). In the event the interference is caused by others, Landlord shall use commercially reasonable efforts to cause such interference be terminated.

44.4 Tenant agrees that Tenant's communications equipment, Antenna Equipment and the communications equipment of Tenant's service providers and contractors located in or about the Premises or installed in the Building to service the Premises including, without limitation, any antennas, switches, or other equipment (collectively, "Tenant's Communications Equipment") shall be of a type and, if applicable, a frequency that will not cause radio frequency, electromagnetic, or other interference to any other party or any equipment of any other party including, without limitation, Landlord, other tenants, or occupants of the Building or any other party. In the event that Tenant's Communications Equipment causes or is believed to cause any such interference, upon receipt of notice from Landlord of such interference, Tenant will take all steps necessary to correct and eliminate the interference. If the interference is not eliminated

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within 24 hours (or a shorter period if Landlord believes a shorter period to be appropriate) then, upon request from Landlord, Tenant shall shut down the Tenant's Communications Equipment pending resolution of the interference, with the exception of intermittent testing, upon prior notice to and with the approval of Landlord.

44.5 Tenant acknowledges that Landlord has granted and/or may grant lease rights, licenses, and other rights to various other tenants and occupants of the Building and to telecommunications service providers.

**45. ALLOWANCE – TENANT PERFORMING WORK.**

45.1 Tenant may construction improvements in the Premises after the Commencement Date ("Tenant's Work"), as conceptually depicted on Exhibit "E" attached hereto. Landlord shall provide Tenant with a construction allowance equal to \$25/RSF (i.e., \$183,150 based on 7,326 rentable square feet) (the "Landlord's Contribution"), to be used by Tenant towards the cost of Tenant's Work and the purchase and installation of furniture, fixtures and equipment (the "FF&E") in the Premises. Landlord shall make disburse the Landlord's Contribution to the Tenant in the accordance with the following:

45.1.1 Landlord shall make progress payments to Tenant of Landlord's Contribution on a monthly basis, as hereinafter provided. Each progress payment shall be equal to 90% of the cost of the Tenant Work incurred and/or the FF&E installed in the Premises (for which no prior requests for payment have been made) for the period for which payment is requested. Each progress payment shall be made to Tenant within thirty (30) days after Landlord's receipt of Tenant's requisition request, together with the required documentation described below, provided such request and documentation are delivered to Landlord by the tenth (10th) day of the month and further provided that all of the following conditions are met at the time each such payment is requested and due:

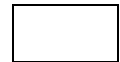
45.1.1.1 No Event of Default is continuing as of the applicable payment date; and

45.1.1.2 No mechanic's lien has been filed against Landlord, Tenant, the Premises, or the Building, which lien has not yet been discharged of; and

45.1.1.3 Tenant submits to Landlord all of the following documentation:

45.1.1.1.1 A requisition for payment, provided, however, that Tenant shall submit such requisition for payment no more often than once monthly (and subject to the time constraints set forth above), and each such requisition shall cover services performed and materials supplied (for which no prior requests for payment have been made) for the period(s) preceding the month in which such submission is made; and

45.1.1.1.2 A certification by the architect engaged by Tenant or general contractor for the Tenant's Work stating that the portion of the Work for which Tenant is applying for payment has been completed in accordance



with the Plans and Specifications approved by Landlord and, to the architect's knowledge or general contractor, all applicable laws (or, with respect to any FF&E, that such FF&E has been installed in the Premises); and

45.1.1.1.3 Itemized bills from Tenant's architects, consultants, contractors, engineers, and suppliers for services performed and materials supplied for those portions of the Tenant's Work or the FF&E for which Tenant seeks payment and for which Tenant has not previously submitted a requisition (and where Tenant elects to be reimbursed, such bills shall have been marked "paid" by the architect, consultant, contractor, engineer, or supplier); and

45.1.1.1.4 Executed and acknowledged releases of lien in form and substance reasonably satisfactory to Landlord evidencing payment for any prior work or services performed and materials supplied for which Tenant previously applied for payment.

45.1.2 The progress payments shall be made, at Tenant's option, either to:

45.1.2.1 Tenant's architects, consultants, contractors, engineers, and suppliers engaged in the performance of the Initial Alterations for whom Tenant requests payment; or

45.1.2.2 Tenant, as reimbursement for the amounts paid by Tenant for such services and/or supplies.

45.1.3 Tenant shall be responsible for all additional costs incurred by Tenant above Landlord's Contribution for Tenant's Work and the FF&E.

45.2 The plans and specifications for the Tenant's Work shown on Exhibit "E" are conceptual in nature and do not constitute final plans. Prior to the performance of the Tenant Work, Tenant shall submit to Landlord for Landlord's written approval detailed plans and specifications therefor ("Plans and Specifications"), including the list of all contractors and subcontractors, and Tenant shall not proceed with the Tenant's Work until it obtains Landlord's written approval, which approval shall not be unreasonably withheld, conditioned or delayed and provided to Tenant no later than fifteen (15) days after receipt of all of the applicable Plans and Specifications (Landlord's failure to provide such approval within such 15-day period being deemed to be an approval thereof). Tenant may subsequently modify the Plans and Specifications in connection with the performance of the Tenant's Work without Landlord's consent, unless such modifications (i) have an estimated cost more than \$20,000.00 in the aggregate or (ii) affect the structural integrity of the Building or the utility systems servicing the Building, in which case Tenant shall present such modifications to Landlord for its approval in the manner set forth above with respect to the initial Plans and Specifications. Tenant, in addition to the fees set forth below, shall reimburse Landlord for all actual reasonable costs and expenses, including all third party consultant costs, incurred by Landlord for the review and approval of the Plans and Specifications.



45.3 Tenant's Work shall be deemed to be "Substantially Completed" when the work shown on the approved Plans and Specifications has been completed except for minor or insubstantial details of construction, mechanical adjustments, or finishing touches like plastering or painting, which items shall not adversely affect Tenant's conduct of its ordinary business activities in the Premises; and Tenant has not commenced business operations within the Premises.

45.4 Tenant shall have the right, in its sole discretion, to select the level of Landlord's involvement in the bidding and performance of the Tenant's Work as provided in one of clauses 45.4.1-3 below. Following such selection, Tenant shall pay to Landlord, as Additional Rent, the applicable fee for the supervision of Tenant's Work set forth in one of clauses 45.1.1-3 below:

45.4.1 Three percent (3%) fee of the total cost of Tenant's Work if Landlord is responsible for the oversight of the bidding process, bid comparison, recommendations, selection of general contractors for bidding, oversight of the construction process and review of change orders and coordination with the project architect / engineer for the construction meetings on site and completion of the job.

45.4.2 Two percent (2%) fee of the total cost of Tenant's Work if Landlord is responsible for all of the items in the above scope other than the bidding process.

45.4.3 One percent (1%) fee of the total cost of the Tenant's Work if Landlord is responsible for all of the items in the above scope other than (1) the bidding process and (2) coordination with the project architect /engineer for the construction meetings on site and completion of the job.

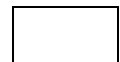
45.5 In addition to Landlord's Contribution set forth above, Landlord shall provide Tenant with an improvement allowance equal to \$6.50/RSF of the Expansion Premises (as defined below) (i.e., \$95,829.50 based on 14,743 square feet ("Landlord's Improvement Contribution")), to be used by Tenant towards the cost of improvement work and the purchase and installation of FF&E within the Premises and the Expansion Premises, in accordance with the following:

45.5.1 Landlord, upon request from Tenant from time to time, shall remit a portion of the Landlord's Improvement Contribution, in one or more installments up to an aggregate amount of \$62,657.75 (equal to \$4.25/RSF of the Expansion Premises) to Tenant if at the time each such payment is requested and due, provided that all of the following conditions are met at the time each such payment is requested and due:

45.5.1.1 No Event of Default is continuing; and

45.5.1.2 No mechanic's lien has been filed against Landlord, Tenant, the Leased Premises, or the Building, which lien has not yet been discharged of record or otherwise bonded in accordance with applicable law; and

45.5.1.3 Tenant submits to Landlord all of the following documentation:



45.5.1.3.1 A requisition for payment, provided, however, that Tenant shall submit such requisition for payment no more often than once monthly (and subject to the time constraints set forth above), and each such requisition shall cover services performed and materials supplied (for which no prior requests for payment have been made) for the period(s) preceding the month in which such submission is made; and

45.5.1.3.2 A certification by the architect engaged by Tenant or general contractor for the Initial Alterations stating that the portion of the work for which Tenant is applying for payment has been completed in accordance with the Plans and Specifications approved by Landlord and, to the architect's knowledge or general contractor, all applicable laws (or, with respect to any FF&E, that such FF&E has been installed in the Premises or the Expansion Premises, as applicable); and

45.5.1.3.3 Itemized bills from Tenant's architects, consultants, contractors, engineers, and suppliers for services performed and materials supplied for those portions of the work or the FF&E for which Tenant seeks payment and for which Tenant has not previously submitted a requisition (and where Tenant elects to be reimbursed, such bills shall have been marked "paid" by the architect, consultant, contractor, engineer, or supplier); and

45.5.1.3.4 Executed and acknowledged releases of lien in form and substance reasonably satisfactory to Landlord evidencing payment for any prior work or services performed and materials supplied for which Tenant previously applied for payment.

45.5.2 The progress payments shall be made, at Tenant's option, either to:

45.5.2.1 Tenant's architects, consultants, contractors, engineers, and suppliers engaged in the performance of the Initial Alterations for whom Tenant requests payment; or

45.5.2.2 Tenant, as reimbursement for the amounts paid by Tenant for such services and/or supplies.

45.5.3 The remainder of Landlord Contribution, equal to \$33,171.75 (equal to \$2.25/RSF of the Expansion Premises), shall be disbursed to Tenant upon September 1, 2019 so long as (i) no Event of Default is then existing and (ii) Tenant is occupying the Expansion Premises and the Premises.



**46. EXPANSION PREMISES**

46.1 Provided that no Event of Default is then existing, as of September 1, 2019 (the “Expansion Commencement Date”), the definition of “Premises”, as set forth on the Reference Page, shall be modified to add Suite 200 of the Building, as more particularly depicted in Exhibit “E”, consisting of approximately 14,743 rentable square feet of space (the “Expansion Premises”). Effective as of the Expansion Commencement Date, the Lease shall be modified as follows:

46.1.1 The “Premises” shall consist of approximately 22,069 rentable square feet of space located in Suites 200 and 250 of the Building;

46.1.2 The Tenant’s Proportionate Share shall be 33.53%; and

46.1.3 The Annual Rent and Monthly Installment of Rent shall be in accordance with the rent schedule set forth on Exhibit “D-2”.

46.2 All other terms and conditions of the Lease shall remain the same except for the above-described changes. Upon request by Tenant, Landlord shall enter into an amendment to the Lease further evidencing the above modifications; provided, that failure to enter into such amendment shall not negate the effect of such modification effective as of the Expansion Commencement Date. Notwithstanding the foregoing, effective as of the Premises Expansion Date the terms of the Office Lease dated March, 2012 between Landlord’s and Tenant’s respective predecessors-in-interest with respect to the Expansion Premises (the “Existing Expansion Premises Lease”) shall be automatically terminated and of no further force or effect except for such terms thereof as may survive the termination of such Expansion Premises Lease by their express terms. Until the Expansion Commencement Date, nothing set forth in this Lease shall affect the Existing Expansion Premises Lease and this Lease and the Existing Expansion Premises Leases shall constitute separate and independent legal obligations of Landlord and Tenant to each other until the Existing Expansion Premises Date.

**[SIGNATURES APPEAR ON THE FOLLOWING PAGE]**

Initials

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**LANDLORD:**

**NORTHBROOK TC EQUITIES LLC  
NORTHBROK 134 WEST 93 EQUITIES LLC  
NORTHBROOK LEMAD EQUITIES LLC  
NORTHBROOK CH EQUITIES LLC  
NORTHBROOK CLINTON EQUITIES LLC  
NORTHBROOK UK1 EQUITIES LLC  
NORTHBROOK LOKEN LLC  
NORTHBROOK HS DEVELOPMENT LLC  
NORTHBROOK HS RK LLC  
NORTHBROOK TEIDIF LLC  
AS TENANTS IN COMMON**

**TENANT:**

**STRONGBRIDGE U.S., INC.**

By: /s/ Robert Kanter

By: /s/ Robert Lutz

Print: \_\_\_\_\_

Print: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

Initials

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## **EXHIBIT "A"**

### **Premises**

Exhibit A is intended only to show the general layout of the Premises as of the beginning of the Term of this Lease. It does not in any way supersede any of Landlord's rights set forth in Section 17.2 with respect to arrangements and/or locations of public parts of the Building and changes in such arrangements and/or locations. It is not to be scaled; any measurements or distances shown should be taken as approximate.

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**EXHIBIT "B"**

**Initial Alterations/Tenant's Work**

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## **EXHIBIT "C"**

### **Rules and Regulations**

1. No sign, placard, picture, advertisement, name or notice shall be installed or displayed on any part of the outside or inside of the Building without the prior written consent of the Landlord. Landlord shall have the right to remove, at Tenant's expense and without notice, any sign installed or displayed in violation of this rule. All approved signs or lettering on doors and walls shall be printed, painted, affixed or inscribed at the expense of Tenant by a person or vendor chosen by Landlord. In addition, Landlord reserves the right to change from time to time the format of the signs or lettering and to require previously approved signs or lettering to be appropriately altered.
  2. If Landlord objects in writing to any curtains, blinds, shades or screens attached to or hung in or used in connection with any window or door of the Premises, Tenant shall immediately discontinue such use. No awning shall be permitted on any part of the Premises. Tenant shall not place anything or allow anything to be placed against or near any glass partitions or doors or windows which may appear unsightly, in the opinion of Landlord, from outside the Premises.
  3. Tenant shall not obstruct any sidewalks, halls, passages, exits, entrances, elevators, escalators or stairways of the Building. The halls, passages, exits, entrances, shopping malls, elevators, escalators and stairways are not for the general public, and Landlord shall in all cases retain the right to control and prevent access to the Building of all persons whose presence in the judgment of Landlord would be prejudicial to the safety, character, reputation and interests of the Building and its tenants provided that nothing contained in this rule shall be construed to prevent such access to persons with whom any tenant normally deals in the ordinary course of its business, unless such persons are engaged in illegal activities. No tenant and no employee or invitee of any tenant shall go upon the roof of the Building.
  4. The directory of the Building will be provided exclusively for the display of the name and location of tenants only and Landlord reserves the right to exclude any other names therefrom, but not the name of the Tenant.
  5. All cleaning and janitorial services for the Building and the Premises shall be provided exclusively through Landlord. Tenant shall not cause any unnecessary labor by carelessness or indifference to the good order and cleanliness of the Premises. Landlord shall not in any way be responsible to any Tenant for any loss of property on the Premises, however occurring, or for any damage to any Tenant's property by the janitor or any other employee or any other person. Landlord shall insure that any cleaning or janitorial service company shall have commercially reasonable insurance.
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6. Landlord will furnish Tenant free of charge with four keys to each door in the Premises. Landlord may make a reasonable charge for any additional keys, and Tenant shall not make or have made additional keys, and Tenant shall not alter any lock or install a new or additional lock or bolt on any door of its Premises. Tenant, upon the termination of its tenancy, shall deliver to Landlord the keys of all doors which have been furnished to Tenant, and in the event of loss of any keys so furnished, shall pay Landlord therefor.

7. If Tenant requires telegraphic, telephonic, burglar alarm or similar services, it shall first obtain, and comply with, Landlord's instructions in their installation.

8. No equipment, materials, furniture, packages, supplies, merchandise or other property will be received in the Building or carried in the elevators except between such hours and in such elevators as may be designated by Landlord.

9. Tenant shall not place a load upon any floor, which exceeds the load per square foot such floor was designed to carry and which is allowed by law. Landlord shall have the right to prescribe the weight, size and position to all equipment, materials, furniture or other property brought into the Building. Heavy objects shall, stand on such platforms as determined by Landlord to be necessary to properly distribute the weight. Business machines and mechanical equipment belonging to Tenant which cause noise or vibration that may be transmitted to the structure of the Building or to any space in the Building to such a degree as to be objectionable to Landlord or to any tenants shall be placed and maintained by Tenant, at Tenant's expense, on vibration eliminators or other devices sufficient to eliminate noise or vibration. The persons employed to move such equipment in or out of the Building must be acceptable to Landlord. Landlord will not be responsible for loss of, or damage to, any such equipment or other property from any cause, and all damage done to the Building by maintaining or moving such equipment or other property shall be repaired at the expense of Tenant.

10. Tenant shall not use any method of heating or air conditioning other than that supplied by Landlord. Tenant shall not waste electricity, water or air conditioning. Tenant shall keep corridor doors closed.

11. Landlord reserves the right to exclude from the Building between the hours of 6 p.m. and 7 a.m. the following day, or such other hours as may be established from time to time by Landlord, and on Sundays and legal holidays any person unless that person is an employee of Tenant or accompanied by an employee of Tenant, known to the person or employee in charge of the Building and has a pass or is properly identified. Tenant shall be responsible for all persons for whom it requests passes and shall be liable to Landlord for all acts of such persons. Landlord shall not be liable for damages for any error with regard to the admission to or exclusion from the Building of any person.

12. Tenant shall close and lock the doors of its Premises and entirely shut off all water faucets or other water apparatus and electricity, gas or air outlets before Tenant and its

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employees leave the Premises. Tenant shall be responsible for any damage or injuries sustained by other tenants or occupants of the Building or by Landlord for noncompliance with this rule.

13. The toilet rooms, toilets, urinals, wash bowls and other apparatus shall not be used for any purpose other than that for which they were constructed, no foreign substance of any kind whatsoever shall be thrown into any of them, and the expense of any breakage, stoppage or damage resulting from the violation of this rule shall be borne by the Tenant who, or whose employees or invitees, shall have caused it.

14. Tenant shall not install any radio or television antenna, satellite dish, loudspeaker or other device on the roof or exterior walls of the Building. Tenant shall not interfere with radio or television broadcasting or reception from or in the Building or elsewhere.

15. Except as approved by Landlord, Tenant shall not mark, drive nails, screw or drill into the partitions, woodwork or plaster or in any way deface the Premises. Tenant shall not cut or bore holes for wires. Tenant shall not affix any floor covering to the floor of the Premises in any manner except as approved by Landlord. Tenant shall repair any damage resulting from noncompliance with this rule.

16. Tenant shall not install, maintain or operate upon the Premises any vending machine.

17. Tenant shall store all its trash and garbage within its Premises. Tenant shall not place in any trash box or receptacle any material that cannot be disposed of in the ordinary and customary manner of trash and garbage disposal. All garbage and refuse disposal shall be made in accordance with directions issued from time to time by Landlord.

18. No cooking shall be done or permitted by any Tenant on the Premises, except by the Tenant of Underwriters' Laboratory approved microwave oven or equipment for brewing coffee, tea, hot chocolate and similar beverages shall be permitted provided that such equipment and use is in accordance with all applicable federal, state and city laws, codes, ordinances, rules and regulations.

19. Tenant shall not use in any space or in the public halls of the Building any hand trucks except those equipped with the rubber tires and side guards or such other material-handling equipment as Landlord may approve. Tenant shall not bring any other vehicles of any kind into the Building.

20. Tenant shall not use the name of the Building in connection with or in promoting or advertising the business of Tenant except as Tenant's address.

21. The requirements of Tenant will be attended to only upon appropriate application to the office of the Building by an authorized individual. Employees of Landlord shall not perform any work or do anything outside of their regular duties unless under special

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instruction from Landlord, and no employee of Landlord will admit any person (Tenant or otherwise) to any office without specific instructions from Landlord.

22. Landlord may waive any one or more of these Rules and Regulations for the benefit of any particular tenant or tenants, but no such waiver by Landlord shall be construed as a waiver of such Rules and Regulations in favor of any other tenant or tenants, nor prevent Landlord from thereafter enforcing any such Rules and Regulations against any or all of the tenants of the Building.

23. These Rules and Regulations are in addition to, and shall not be construed to in any way modify or amend, in whole or in part, the terms, covenants, agreements and conditions of any lease of premises in the Building.

24. Landlord reserves the right to make such other and reasonable rules and regulations as in its judgment may from time to time be needed for safety and security, for care and cleanliness of the Building and for the preservation of good order in and about the Building. Tenant agrees to abide by all such rules and regulations in this Exhibit "C" stated and any additional rules and regulations which are adopted.

25. Tenant shall be responsible for the observance of all of the foregoing rules by Tenant's employees, agents, clients, customers, invitees and guests.

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**EXHIBIT "D-1"**

**RENT SCHEDULE**

<b>Year</b>	<b>Annual Minimum Rent</b>	<b>Monthly Minimum Rent</b>
Year 1	\$150,183.00	\$12,515.25
Year 2	\$153,846.00	\$12,820.50
Year 3*	\$157,509.00	\$13,125.75
Year 4**	\$161,172.00	\$13,431.00
Year 5**	\$164,835.00	\$13,736.25

\* Amounts for Year 3 are only through Expansion Premises Commencement Date.

\*\* Amounts for Years 4 and 5 are only if Expansion Premises Commencement Date does not occur.

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**EXHIBIT "D-2"**

**RENT SCHEDULE AFTER THE EXPANSION PREMISES COMMENCEMENT DATE**

<b>Year</b>	<b>Annual Minimum Rent</b>	<b>Monthly Minimum Rent</b>
Year 4*	\$485,518.00	\$40,459.84
Year 5	\$496,552.50	\$41,397.38

\* Amount for Year 4 is from and after Expansion Premises Commencement Date.

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**EXHIBIT "E"**

**Expansion Premises**

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**STRONGBRIDGE BIOPHARMA plc****2017 INDUCEMENT PLAN****STOCK OPTION AWARD**

Strongbridge Biopharma plc (the “Company”) has granted you a Stock Option (the “Option”) under the 2017 Inducement Plan (the “Plan”). The terms of the grant are set forth in the Stock Option Award Agreement provided to you (the “Agreement”). The following provides a summary of the key terms of the grant; however, you should read the entire Agreement, along with the terms of the Plan, to fully understand the grant.

**SUMMARY OF STOCK OPTION AWARD**

<b>Grantee:</b>	[name]
<b>Date of Grant:</b>	[date]
<b>Vesting Schedule:</b>	25% of the Option vesting on the one-year anniversary of the Date of Grant; the remaining 75% of the Option vesting in 12 equal, quarterly installments after the one-year anniversary of the Date of Grant (provided employee is employed by the Company on each vesting date)
<b>Exercise Price Per Share:</b>	\$_[ ]
<b>Total Number Shares Subject to the Option:</b>	[ ]
<b>Term/Expiration Date:</b>	[date]

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**STRONGBRIDGE BIOPHARMA plc**

**2017 INDUCEMENT PLAN**

**STOCK OPTION AWARD AGREEMENT**

This **STOCK OPTION AWARD AGREEMENT** (the "Agreement"), dated as of [date] (the "Date of Grant"), is delivered by Strongbridge Biopharma plc (the "Company") to [name] (the "Grantee").

**RECITALS**

A. The 2017 Inducement Plan (the "Plan") provides for the grant of options to purchase shares of common stock of the Company ("Company Stock"). The Company has decided to make a stock option award as a material inducement to the Grantee to enter into employment with the Company (or its parent or subsidiary, as applicable) (the "Employer"). Capitalized terms that are used but not defined herein shall have the respective meanings accorded to such terms in the Plan.

B. The Plan is administered and interpreted by a committee (the "Committee") composed of at least two members designated by the Board of Directors of the Company (the "Board").

**NOW, THEREFORE**, the parties to this Agreement, intending to be legally bound hereby, agree as follows:

1. **Grant of Option.** Subject to the terms and conditions set forth in this Agreement and in the Plan, the Company hereby grants to the Grantee a Stock Option (the "Option") to purchase [ ] shares of Company Stock at an exercise price of \$[ ] per share.
2. **Vesting.** The Option shall become vested and exercisable, according to the following vesting schedule, if the Grantee continues to be employed by, or provide service to, the Employer from the Date of Grant until the applicable vesting date:

<b><u>Vesting Date</u></b>	<b><u>% of Option Vested</u></b>
25% of the Option vesting on the one-year anniversary of the Date of Grant (provided employee is employed by the Company on each vesting date)	25%
the remaining 75% of the Option vesting in 12 equal, quarterly installments after the one-year anniversary of the Date of Grant (provided employee is employed by the Company on each vesting date)	75%

The vesting of the Option shall be cumulative, but shall not exceed 100% of the shares subject to the Option granted above. If the foregoing schedule would produce fractional shares, the portion of the Option that vests shall be rounded down to the nearest whole share.

3. **Term of Option.**

(a) The Option shall have a term of ten (10) years from the Date of Grant and shall terminate at the expiration of that period, unless it is terminated at an earlier date pursuant to the provisions of this Agreement or the Plan.

(b) Unless a later termination date is provided for in a Company-sponsored plan, policy or arrangement, or any agreement to which the Employer is a party, the Option shall automatically terminate upon the happening of the first of the following events:

(i) The expiration of the ninety (90) day period after the Grantee ceases to be employed by, or provide service to, the Employer, if the termination is for any reason other than Disability (as defined in the Plan), death or Cause (as defined in the Plan).

(ii) The expiration of the one (1) year period after the Grantee ceases to be employed by, or provide service to, the Employer on account of the Grantee's Disability.

(iii) The expiration of the one (1) year period after the Grantee ceases to be employed by, or provide service to, the Employer, if the Grantee dies (x) while employed by, or providing service to, the Employer or (y) within ninety (90) days after the Grantee ceases to be so employed or provide such services on account of a termination described in subparagraph (i) above.

(iv) The date on which the Grantee ceases to be employed by, or provide service to, the Employer on account of a termination by the Employer for Cause. In addition, notwithstanding the prior provisions of this Paragraph 3, if the Committee determines that the Grantee has engaged in conduct that constitutes Cause at any time while the Grantee is employed by, or providing service to, the Employer or after the Grantee's termination of employment or service, any Option held by the Grantee shall immediately terminate, and the Grantee shall automatically forfeit all shares underlying any exercised portion of an Option for which the Company has not yet delivered the share certificates, upon refund by the Company of the Exercise Price paid by the Grantee for such shares.

Notwithstanding the foregoing, in no event may the Option be exercised after the date that is immediately before the tenth anniversary of the Date of Grant. Any portion of the Option that is not vested and exercisable at the time the Grantee ceases to be employed by, or provide service to, the Employer shall immediately terminate.

4. **Exercise Procedures**

(a) Subject to the provisions of Paragraphs 2 and 3 above, the Grantee may exercise part or all of the vested Option by delivering a written notice of exercise to the Company in the manner provided in this Agreement, specifying the number of shares of Company Stock as to which the Option is to be exercised. The Grantee shall pay the Exercise Price (i) in cash, (ii) by

delivering shares of Company Stock owned by the Grantee (including Company Stock acquired in connection with the exercise of an Option, subject to such restrictions as the Committee deems appropriate) and having a Fair Market Value (as defined in the Plan) on the date of exercise equal to the Exercise Price or by attestation (on a form prescribed by the Committee) to ownership of shares of Company Stock having a Fair Market Value on the date of exercise equal to the Exercise Price; (iii) by payment through a broker in accordance with procedures permitted by Regulation T of the Federal Reserve Board; or (iv) by such other method as the Committee may approve. In addition, the Grantee may elect to settle the Option on a "net basis" by taking delivery of the number of Company Stock equal to Fair Market Value of the shares subject to any Option less the exercise price, any tax (or governmental obligation) or other administration fees due. The Company may impose from time to time such limitations as it deems appropriate on the use of shares of Company Stock to exercise the Option.

(b) The obligation of the Company to deliver shares of Company Stock upon exercise of the Option shall be subject to all applicable laws, rules, and regulations and such approvals by governmental agencies as may be deemed appropriate by the Company, including such actions as Company counsel shall deem necessary or appropriate to comply with relevant securities laws and regulations. The Company may require that the Grantee (or other person exercising the Option after the Grantee's death) represent that the Grantee is purchasing shares of Company Stock for the Grantee's own account and not with a view to or for sale in connection with any distribution of the shares of Company Stock, or such other representation as the Company deems appropriate.

(c) All obligations of the Company under this Agreement shall be subject to the rights of the Company as set forth in the Plan to withhold amounts required to be withheld for any taxes, if applicable. The Grantee may elect to satisfy any tax withholding obligation of the Company with respect to the Option by having shares of Company Stock withheld up to an amount that does not exceed the minimum applicable withholding tax rate for federal (including FICA), state and local tax liabilities.

5. **Change of Control.** Upon a Change of Control (as defined in the Plan), the Option shall automatically accelerate and become fully vested and exercisable, provided that the Grantee is employed by, or providing service to, the Employer on the date of such Change of Control.

6. **Restrictions on Exercise.** Except as the Company may otherwise permit pursuant to the Plan, only the Grantee may exercise rights under the Option during the Grantee's lifetime and, after the Grantee's death, the Option shall be exercisable (subject to the limitations specified in the Plan) solely by the personal representative or other person entitled to succeed to the rights of the Grantee, or by the person who acquires the right to exercise the Option by will or by the laws of descent and distribution, or if permitted in any case by the Committee, pursuant to a domestic relations order or otherwise as permitted by the Committee, to the extent that the Option is vested and exercisable pursuant to this Agreement. Any such successor must furnish proof satisfactory to the Company of his or her right to receive the Option under the Grantee's will or under the applicable laws of descent and distribution.

7. **Adjustments.** The provisions of the Plan applicable to Adjustments (as described in Section 4 of the Plan) shall apply to the Option.

8. **Grant Subject to Plan Provisions.** This grant is made pursuant to the Plan, the terms of which are incorporated herein by reference, and in all respects shall be interpreted in accordance with the Plan. The grant and exercise of the Option are subject to interpretations, regulations and determinations concerning the Plan established from time to time by the Committee in accordance with the provisions of the Plan, including, but not limited to, provisions pertaining to (i) rights and obligations with respect to withholding taxes, (ii) the registration, qualification or listing of the shares of Company Stock, (iii) changes in capitalization of the Company and (iv) other requirements of applicable law. The Committee shall have the authority to interpret and construe the Option pursuant to the terms of the Plan, and its decisions shall be conclusive as to any questions arising hereunder.

9. **No Employment or Other Rights.** The grant of the Option shall not confer upon the Grantee any right to be retained by or in the employ or service of the Company and shall not interfere in any way with the right of the Company to terminate the Grantee's employment or service at any time. The right of the Company to terminate at will the Grantee's employment or service at any time for any reason is specifically reserved.

10. **No Shareholder Rights.** Neither the Grantee, nor any person entitled to exercise the Grantee's rights in the event of the Grantee's death, shall have any of the rights and privileges of a shareholder with respect to the shares of Company Stock subject to the Option, until certificates for shares of Company Stock have been issued upon the exercise of the Option.

11. **Assignment and Transfers.** Except as the Committee may otherwise permit pursuant to the Plan, the rights and interests of the Grantee under this Agreement may not be sold, assigned, encumbered or otherwise transferred except, in the event of the death of the Grantee, by will or by the laws of descent and distribution or if permitted in any specific case by the Committee, pursuant to a domestic relations order or otherwise as permitted by the Committee. In the event of any attempt by the Grantee to alienate, assign, pledge, hypothecate, or otherwise dispose of the Option or any right hereunder, except as provided for in this Agreement, or in the event of the levy or any attachment, execution or similar process upon the rights or interests hereby conferred, the Company may terminate the Option by notice to the Grantee, and the Option and all rights hereunder shall thereupon become null and void. The rights and protections of the Company hereunder shall extend to any successors or assigns of the Company and to the Company's parents, subsidiaries, and affiliates. This Agreement may be assigned by the Company without the Grantee's consent.

12. **Applicable Law.** The validity, construction, interpretation and effect of this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to the conflicts of laws provisions thereof.

13. **Notice.** Any notice to the Company provided for in this Agreement shall be addressed to the Company in care of the Committee, and any notice to the Grantee shall be addressed to such Grantee at the current address shown on the payroll of the Company, or to such other address as the Grantee may designate to the Company in writing.

**IN WITNESS WHEREOF**, the Company has caused its duly authorized officer to execute this Agreement, and the Grantee has executed this Agreement, effective as of the Date of Grant.

**Strongbridge Biopharma plc:**

By:  
Name: Matthew Pauls  
Title: Chief Executive Officer

I hereby accept the Option described in this Agreement, and I agree to be bound by the terms of the Plan and this Agreement. I hereby further agree that all the decisions and determinations of the Committee shall be final and binding.

**Grantee:**

-

Name: [name]

Date: \_

*(Signature Page to Stock Option Award Agreement)*

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**STRONGBRIDGE BIOPHARMA PLC**

**2017 INDUCEMENT PLAN**

**RESTRICTED STOCK UNIT AWARD**

Strongbridge Biopharma plc (the “Company”) has determined to grant to you an award of restricted stock units (the “RSUs”) under the 2017 Inducement Plan (the “Plan”). The terms of the grant are set forth in the attached Restricted Stock Unit Award Agreement (the “Agreement”). The following provides a summary of the key terms of the Agreement; however, you should read the entire Agreement along with the terms of the Plan, to fully understand the Agreement.

**SUMMARY OF RESTRICTED STOCK UNIT AWARD**

<b>Grantee:</b>	[NAME]
<b>Date of Grant:</b>	[DATE]
<b>Vesting Schedule:</b>	100% vest on 2-year anniversary of Date of Grant (provided employee is employed by the Company on such vesting date)
<b>Total Number of Restricted Stock Units Granted:</b>	[# UNITS]

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# STRONGBRIDGE BIOPHARMA PLC

## 2017 INDUCEMENT PLAN

### RESTRICTED STOCK UNIT AWARD AGREEMENT

This RESTRICTED STOCK UNIT AWARD AGREEMENT (the “Agreement”), dated as of [DATE] (the “Date of Grant”), is delivered by Strongbridge Biopharma plc (the “Company”) to [NAME] (the “Grantee”).

The Company has determined to provide the Grantee an award of restricted stock units under the 2017 Inducement Plan (the “Plan”) and in accordance with the terms and conditions set forth in this Agreement. Capitalized terms that are used but not defined herein shall have the respective meanings accorded to such terms in the Plan.

The Plan is administered and interpreted by a committee (the “Committee”) composed of at least two members designated by the Board of Directors of the Company (the “Board”).

The Company and Grantee, intending to be legally bound hereby, agree as follows:

**1. Grant of Restricted Stock Unit Award.** Subject to the terms and conditions set forth in this Agreement and the Plan, the Company hereby awards to the Grantee [# UNITS] Restricted Stock Units (the “RSUs”) under the Plan. The Grantee accepts the RSUs and agrees to be bound by the terms and conditions of this Agreement and the Plan with respect to the award. Each vested RSU entitles the Grantee to receive one share of Company Stock, as described in Paragraph 2 below.

**2. Vesting of Award/Payment of Shares.**

(a) The RSUs shall vest in full on the second anniversary of the Date of Grant (the “Vesting Date”), if the Grantee continues to be employed by, or provide service to, the Company (or its parent or subsidiary, as applicable) (the “Employer”) from the Date of Grant until the Vesting Date.

(b) If and when the RSUs vest, the Company will issue to the Grantee one share of Company Stock for each whole RSU that has vested, subject to satisfaction of the Grantee’s tax withholding obligations as described in Paragraph 5 below, in accordance with Section 7(c) of the Plan. The RSUs shall cease to be outstanding upon such issuance of shares.

(c) Unless otherwise provided in a Company-sponsored plan, policy or arrangement, or any agreement to which the Employer is a party, the Grantee shall forfeit the unvested RSUs in the event the Grantee ceases to be employed by, or provide service to, the Employer prior to the Vesting Date.

**3. No Stockholder Rights Prior to Settlement; Issuance of Certificates.** In accordance with Section 7(e) of the Plan, the Grantee shall have no rights as a stockholder with respect to any

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shares of Company Stock represented by the RSUs until the date of issuance of the shares of Company Stock (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), if applicable. Except as otherwise required by the Plan, no adjustment shall be made for dividends, distributions, or other rights for which the record date is prior to the date, if any, that shares of Company Stock are issued.

4. **Change of Control.** The provisions of the Plan applicable to a Change of Control (as described in Section 10 of the Plan) shall apply to the RSUs.

5. **Withholding.** The Grantee shall be required to pay to the Company, or make other arrangements satisfactory to the Company to provide for the payment of, any federal, state, local or other taxes that the Employer is required to withhold with respect to the grant or vesting of the RSUs, or the Employer may deduct from other wages paid by the Employer the amount of any withholding taxes due with respect to the RSUs. The Grantee may elect to satisfy any income tax withholding obligation of the Employer with respect to the RSUs by having shares of Company Stock withheld up to an amount that does not exceed the minimum applicable withholding tax rate for federal (including FICA), state, local and other tax liabilities. Unless the tax withholding obligations of the Company are satisfied, the Company shall have no obligation to deliver to the Grantee any Company Stock. In the event the Company's obligation to withhold arises prior to the delivery to the Grantee of shares of Company Stock or it is determined after the delivery of shares of Company Stock to the Grantee that the amount of the Company's withholding obligation was greater than the amount withheld by the Company, the Grantee agrees to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

6. **Adjustments.** The provisions of the Plan applicable to adjustments (as described in Section 4 of the Plan) shall apply to the RSUs.

7. **Assignment and Transfers.** Except as the Committee may otherwise permit pursuant to the Plan, the rights and interests of the Grantee under this Agreement may not be sold, assigned, encumbered or otherwise transferred except, in the event of the death of the Grantee, by will or by the laws of descent and distribution. In the event of any attempt by the Grantee to alienate, assign, pledge, hypothecate, or otherwise dispose of the RSUs or any right hereunder, or in the event of the levy or any attachment, execution or similar process upon the rights or interests hereby conferred, the Company may terminate the RSUs by notice to the Grantee, and the RSUs and all rights hereunder shall thereupon become null and void. The rights and protections of the Company hereunder shall extend to any successors or assigns of the Company and to the Company's parents, subsidiaries, and affiliates. This Agreement may be assigned by the Company without the Grantee's consent.

8. **Miscellaneous.**

(a) **No Right to Employment.** The grant of the RSUs shall not be construed as giving the Grantee the right to be retained by or in the employ of the Employer or any other employment right.

( b ) **Delivery Subject to Legal Requirements.** The obligation of the Company to deliver stock shall be subject to the condition that if at any time the Board shall determine in its discretion

that the listing, registration or qualification of the shares upon any securities exchange or under any state or federal law, or the consent or approval of any governmental regulatory body is necessary or desirable as a condition of, or in connection with, the issue of shares, the shares may not be issued in whole or in part unless such listing, registration, qualification, consent or approval shall have been effected or obtained free of any conditions not acceptable to the Board. The issuance of shares to the Grantee pursuant to this Agreement is subject to any applicable taxes and other laws or regulations of the United States or of any state having jurisdiction thereof.

(c) RSUs Subject to Plan. By entering into this Agreement the Grantee agrees and acknowledges that the Grantee has received and read a copy of the Plan. The RSUs are subject to the terms and provisions of the Plan, as they may be amended from time to time, and such terms and provisions of the Plan are hereby incorporated herein by reference. In the event of a conflict between any term or provision contained herein and a term or provision of the Plan, the applicable terms and provisions of the Plan will govern and prevail.

(d) Committee Authority. By entering into this Agreement the Grantee agrees and acknowledges that all decisions and determinations of the Committee shall be final and binding on the Grantee, his or her beneficiaries and any other person having or claiming an interest in the RSUs.

(e) Severability. If any provision of this Agreement is or becomes or is deemed to be invalid, illegal or unenforceable in any jurisdiction or would disqualify this Agreement or the RSUs under any applicable law, such provision shall be construed or deemed amended to conform to applicable law (or if such provision cannot be so construed or deemed amended without materially altering the purpose or intent of this Agreement and the grant of the RSUs hereunder, such provision shall be stricken as to such jurisdiction and the remainder of this Agreement and the award shall remain in full force and effect).

(d) Notices. Any notice to be given to the Company under the terms of this Agreement shall be addressed to the Company, at the attention of the Committee, at its principal place of business, and any notice to be given to Grantee may be sent to Grantee's address as it appears in the payroll records of the Company, or at such other addresses as either party may designate in writing to the other.

(e) Section 409A. This Agreement and the RSUs granted hereunder are intended to fit within the "short-term deferral" exemption from Section 409A of the Code, as set forth in Treasury Regulation Section 1.409A-1(b)(4) or any successor provision, or to comply with, or otherwise be exempt from, Section 409A of the Code. This Agreement and the RSUs shall be administered, interpreted and construed in a manner consistent with Section 409A of the Code.

( f ) Governing Law. The validity, construction, interpretation and effect of this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to the conflict of laws provisions thereof

(g) Interpretation. The Grantee accepts the RSUs subject to all the terms and provisions of this Agreement and the terms and conditions of the Plan.

( g ) Headings. Headings are given to the paragraphs and subparagraphs of this Agreement solely as a convenience to facilitate reference. Such headings shall not be deemed in any way material or relevant to the construction or interpretation of this Agreement or any provision thereof.

( h ) Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement. Facsimile or other electronic transmission of any signed original document or retransmission of any signed facsimile or other electronic transmission will be deemed the same as delivery of an original.

( i ) Complete Agreement. Except as otherwise provided for herein, this Agreement and those agreements and documents expressly referred to herein embody the complete agreement and understanding among the parties and supersede and preempt any prior understandings, agreements or representations by or among the parties, written or oral, which may have related to the subject matter hereof in any way. The terms of this Agreement shall be binding upon the executors, administrators, heirs, successors and assigns of the Grantee.

*[Signature Page Follows]*

**IN WITNESS WHEREOF**, the Company and Grantee have executed this Agreement as of the grant date shown above.

**Strongbridge Biopharma plc**

By: \_\_\_\_\_  
Name: Matthew Pauls  
Title: Chief Executive Officer

I hereby accept the RSUs described in this Agreement, and I agree to be bound by the terms of the Plan and this Agreement. I hereby further agree that all the decisions and determinations of the Committee shall be final and binding.

**GRANTEE:**

\_\_\_\_\_  
Name: [NAME]

Date: \_\_\_\_\_

(Signature Page to Restricted Stock Unit Award Agreement)

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LICENSE AND ASSIGNMENT AGREEMENT

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dated

**16 JANUARY 2018**

by

**AETERNA ZENTARIS GMBH**  
the Licensor

and

The

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### **Schedule 1**

CMO Contracts

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PIP Budget



## License and Assignment Agreement

This Agreement is dated 16 January 2018 (“**Effective Date**”)

### Between

, (the “”),; and

**Strongbridge Ireland Limited**, a corporation incorporated under the laws of Ireland, (the “”).

The Licensor and the Licensee sometimes being referred to in this Agreement as a “**Party**” or together the “**Parties**”.

### Recitals

- A. The Licensor owns or has the exclusive right to certain technology, intellectual property rights, regulatory files and confidential and/or proprietary information relating to the Product (as defined below).
- B. The Licensor is interested in assigning the ownership of the Product Registrations (as defined below) and granting an exclusive license under the intellectual property to the Licensee to carry out development, manufacturing, registration and commercialization of the Product in the Territory (as defined below).
- C. The Licensee, together with its Affiliates (as defined below), are engaged in the development, manufacturing and commercialization of pharmaceutical products in the Territory and possess the resources, skills and experience there necessary to perform their obligations under this Agreement.

The Parties now agree as follows:

#### 1. Definitions and interpretation

“**Adult Indication**” means assessing GHD in adults.

“**Affiliates**” means an entity that has a relationship directly or indirectly with another entity such that either entity is Controlled by, Controlling, has the power to Control, or under common Control with the other entity, or a third party Controls, or has the power to Control, both of the entities, where “**Control**” means possession, directly or indirectly, of the power to direct or cause the direction of the activities, management and policies of the relevant entity and in the case of a corporate entity shall include but not be limited to the holding of more than fifty percent (50%) of the share capital of the entity or the equivalent power or authority to elect more than fifty percent (50%) of the board of directors of such entity or the equivalent management body. The Parties acknowledge that in the case of certain entities organized under the Laws of certain countries outside of the EU, the maximum percentage ownership permitted by Law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity.

“**Agreement**” means this License and Assignment Agreement together with its attached Schedules.

“**Anti-Bribery Law**” means the US Foreign Corrupt Practices Act, UK Bribery Act 2010 and any other applicable Law, rule, regulation, or other legally binding measure of any jurisdiction that relates to bribery, corruption, or, for purposes of U.S. Law, transfers of value to licensed healthcare providers.

“**API**” means the active pharmaceutical ingredient macimorelin acetate, and any metabolite, salt, ester, hydrate, solvate, isomer, enantiomer, free acid form, free base form, crystalline form, co-crystalline form, amorphous form, pro-drug, racemate, polymorph, chelate, stereoisomer, tautomer, or optically active form of any of the foregoing.

“**Bankruptcy Event**” means, with respect to either Party:

- (a) a notice having been issued to convene any meeting for the purpose of passing a resolution or seeking a petition to wind up or liquidate that Party, or to seek bankruptcy or official administration, or such a resolution having been passed or such a petition having been issued, including a petition under title 11 of the United States Code or any similar statute, Law or regulation (except in relation to a solvent reconstruction or reorganization of that Party);
- (b) an involuntary petition in an insolvency proceeding or any proceeding seeking reorganization, arrangement composition, readjustment, liquidation or similar relief under any statute, Law or regulation, is filed against a Party and is not dismissed or stayed within ninety (90) days of the filing thereof or that Party admits or accepts;
- (c) a trustee in bankruptcy, receiver, administrative receiver, receiver and manager, court appointed receiver, interim receiver, custodian, sequestrator or similar officer is appointed in respect of that Party or over any part of that Party's assets or any third party takes steps to appoint such an officer in respect of that Party and is not dismissed, vacated or stayed within ninety (90) days of the appointment thereof and if stayed, is not dismissed or vacated within ninety (90) days of the such stay;
- (d) a Party takes any step, (including starting negotiations), with a view to readjustment, rescheduling or deferral of any part of that Party's indebtedness including a moratorium with creditors, or proposes or makes any general assignment, composition or arrangement with or for the benefit of all or some of that Party's creditors or makes or suspends or threatens to suspend making payments to all or some of that Party's creditors or the Party submits to any type of voluntary arrangement with creditors; or
- (e) a Party takes any step, (including starting negotiations), to file a petition or answer seeking for that Party any reorganization, arrangement, composition, conservatorship, winding up, readjustment, liquidation or similar relief under any statute, Law or regulation.

“**Business Day**” means between 9.00 am and 5.00 pm local time on a day other than a Saturday, Sunday, bank or other public holiday in Germany or any State in the USA.

“**Calendar Quarter**” means each period of three months ending on 31 March, 30 June, 30 September or 31 December.

“**Calendar Year**” means each successive period of twelve calendar (12) months commencing on 1 January.

“**Children**” means persons 18 years of age or younger including neonates, infants and adolescents.

“**Clinical Trial**” means the administration of the Product to humans for purposes of generating data on characteristics of the Product including, without limitation, any study carried out in order to obtain or maintain a Regulatory Approval in any country of the Territory.

“**CMO**” means a Person that conducts contract manufacture on behalf of another Person.

“**CMO Contracts**” means those contracts set out at Schedule 1.

“**Commercial Information**” means all information which is Controlled and relates to the pricing, reimbursement, marketing, promotion and selling of the Product including but not limited to (i) commercialization plans, strategic and implementation; and (ii) pharmaco-economic studies justifying pricing; and (iii) analysis of competitive products and environment including market research reports; and (iv) product positioning strategies (including unique selling proposition and understanding of competitors' positioning strategies) and promotional strategies (including Promotional Materials); and (v) Pricing Approval submissions and the content of bids for tenders; and (vi) virtual product and clinical support approaches and techniques via web page; and (vii) medical education strategies; and (viii) strategies used for building relationships with health insurance and managed care entities; and (ix) analysis of market sales and prescription data; (x) terms of contractual arrangements with purchasers; and (xi) customer lists.

“**Commercialize**” or “**Commercialization**” means any and all activities directed to commercialization, including marketing, promoting, detailing, importing, distributing, warehousing, offering for sale, having sold and/or selling a pharmaceutical product, including market research, pre-launch marketing and educational activities, and sampling.

“**Commercially Reasonable Efforts**” means, in respect of a Party, efforts and resources commonly used by a pharmaceutical company of a similar size to that Party, based on market capitalization, to Commercialize (or where the phrase 'Commercially Reasonable Efforts' is used in this Agreement in a context other than relating to Commercialization, to perform such other act as the operative language of this Agreement states) a product owned by such a company or to which it has rights, which product is at a similar stage in its development or product life and is of similar market potential to the Product, in each case taking into account issues of safety and efficacy, product profile, the proprietary position, the then-current competitive environment for such product and the likely timing of such product's entry into the market, the regulatory environment and status of such product, and other relevant scientific, technical and commercial factors, in each case as measured by the facts and circumstances at the time such efforts are due and in relation to the country or countries to which such efforts pertain.

“**Confidential Information**” means, subject to the relevant carve-outs set forth in Section 11:

- (a) the terms and conditions of this Agreement, for which each Party will be considered a Disclosing Party and a Recipient Party;
- (b) the Dossier, Know How and Commercial Information within the Licensor IPR Package for which the Licensor will be considered the Disclosing Party and the Licensee shall be the Recipient Party;
- (c) information within the Licensee IPR Package in relation to which the Licensee will be considered the Disclosing Party and the Licensor the Recipient Party; and
- (d) any other non-public information, whether or not patentable, disclosed or provided by one Party to the other Party in connection with this Agreement, including, without limitation, information regarding such Party's strategy, business plans, objectives, research, technology, products, business affairs or finances including any non-public data relating to Commercialization of any product and other information of the type that is customarily considered to be confidential information by parties engaged in activities that are substantially similar to the activities being engaged in by the Parties under this Agreement, for which the Party making such disclosure will be considered the Disclosing Party and the receiver will be the Recipient Party.

“**Control**” (including variations such as “**Controlled**” and except as used in the definition of 'Affiliates') means with respect to any intellectual property or other rights, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or grant a license, sub-license or other right to or under, such intellectual property or other rights without violating the terms of any agreement or other arrangement with any Third Party.

“**Cost of Manufacture**” means the amounts paid or payable by the relevant Party to the CMO in respect of relevant Products or Materials supplied.

“**CTD Format**” means the format of a common technical document recommended by ICH or adopted by any Governmental Authority in the Territory responsible for marketing authorization or monitoring the marketing of the Product that are formatting requirements or methods for the submission of other or supplemental information or data to such Government Authority and as may be updated from time to time.

“**CTM**” shall mean Product in a form suitable for administration to humans in a Clinical Trial manufactured in accordance with the specifications and GMP and as required by any IND appropriately packaged and labelled.

“**Data Room**” means the data room hosted and operated by Merrill for and on behalf of the Licensor, entitled 'Macrilen';

“**Development (and the corresponding verb “to Develop”)**” means all development and regulatory activities regarding the Product and the API in the Territory, including:

- (a) carrying out the PIP or any other pediatric study required to obtain Regulatory Approval for the Product for the Pediatric Indication in any country in the Territory; and
- (b) preparing, submitting, reviewing or developing data or information necessary for the purpose of submission to a Regulatory Authority to obtain or maintain and/or expand Regulatory Approval of the Product in the Territory including data management, statistical designs and studies, document preparation, and other related administrative costs.

“**Development Costs**” means the direct and indirect costs of the PIP currently anticipated to be five million to six million dollars (\$5,000,000 –\$6,000,000) as set forth in the PIP Budget, subject to any increases of such budget agreed by the Parties.

“**Development Plan**” means the plan for carrying out the PIP attached in Schedule 9, as such plan may be updated in accordance with Section 5, either in relation to the PIP or otherwise.

“**Disclosing Party**” means the Party which discloses Confidential Information to the other Party.

“**Disclosure Schedule**” means the disclosure schedule, in the form of Schedule 5.

“**Documents**” means analyses, books, CD-ROM, charts, comments, computations, designs, discs, diskettes, files, graphs, ledgers, notebooks, paper, photographs, plans, records, recordings, reports, research notes, tapes, web pages and websites, and any other graphic or written data or other media on which Know How is made available, communicated, or use whether permanently stored or available temporarily through other means, and advertising and Promotional Materials of any nature whatsoever including preparatory materials for the same.

“**Dossier**” means the information and data for the Product in a country in CTD Format (or otherwise) and as registered with a Regulatory Authority for the Regulatory Approval containing the administrative, safety, efficacy, quality, non-clinical and clinical data, chemistry and manufacturing control data and communications with the Regulatory Authority for the Product as it may change from time to time.

“**EMA**” means the European Medicines Agency.

“**Encumbrance**” means a mortgage, charge, pledge, lien, option, restriction, right of first refusal, right of pre-emption, third party right or interest, other encumbrance or security interest of any kind, or another type of preferential arrangement (including, without limitation, a title transfer or retention arrangement) having similar effect but for the purposes of this Agreement always excluding a license.

“**EU**” means the countries of the European Union from time to time which are currently Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and includes the United Kingdom regardless of future treaty or common relationships with the other countries in the EU or Europe.

“**Europe**” means that group of countries comprised of the EU plus (if they are not Member States) Iceland, Liechtenstein, Norway, Switzerland and UK.

“**Existing CMO Contracts**” has the meaning given to it in Section 6.1.

“**Existing Indications**” means the Adult Indication and the Pediatric Indication.

“**Exploitation Agreement**” means the exploitation agreement between (i) Aeterna Zentaris GmbH (formerly Zentaris GmbH); (ii) The Centre National De La Recherche Scientifique; (iii) The University of Montpellier 1; and (iv) The University of Montpellier 2, entered into in 2005.

“**FDA**” means the U.S. Food and Drug Administration.

“**Final Report**” means the clinical study report including attachments, quality assurance, monitoring reports, and raw data that record the performance or information generated from a Clinical Trial, whether or not compliant with ICH E3 or conducted under GCP, and that includes such personal health information or personal identifying information as may be necessary to assure the quality and integrity of the report.

“**First Commercial Sale Date**” means the date of the first commercial sale in an arm's length transaction to a Third Party of the Product for an Existing Indication in each country in the Territory by or on behalf of the Licensee, an Affiliate, Sub-licensee after obtaining Regulatory Approval and any Pricing Approvals for the Product necessary or desirable in such country. For clarity “**First Commercial Sale Date**” shall not be any date on which sale of Product for an Existing Indication occurs in the Territory for use on a compassionate use or named patient basis.

“**Formal Presentation**” means a presentation of the results of a Clinical Trial based on the data and conclusions set out in an Interim Report.

“**GCP**” means the then-current standards, practices and procedures for good clinical practices, including but not limited to those promulgated or endorsed by:

- (c) the European Commission Directive 20/2001/EC relating to good clinical practice in clinical trials on medicinal products for human use;

- (d) the ICH Harmonised Tripartite Guidelines for Good Clinical Practice (E6) and any other guidelines for good clinical practices for trials on medicinal products in the European Union;
- (e) the FDA as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA and the provisions of 21 C.F.R. Part 312; and
- (f) the equivalent applicable Law in any relevant country.

“**GHD**” means growth hormone deficiency.

“**GLP**” means the then-current standards, practices and procedures for good laboratory practices, including but not limited to those promulgated or endorsed by:

- (g) the European Commission Directives 2004/9/EC and 2004/10/EC relating to the application of the principles of good laboratory practices as well as "The rules governing medicinal products in the European Union," Volume 3, Scientific guidelines for medicinal products for human use (ex - OECD principles of GLP);
- (h) the then-current standards, practices and procedures promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58; and
- (i) the equivalent applicable Law in any relevant country.

“**GMP**” means the then-current standards, practices and procedures for good laboratory practices, including but not limited to those promulgated or endorsed by:

- (j) the European Commission Directives 2004/9/EC and 2004/10/EC relating to the application of the principles of good laboratory practices as well as "The rules governing medicinal products in the European Union," Volume 3, Scientific guidelines for medicinal products for human use (ex - OECD principles of GLP);
- (k) the then-current standards, practices and procedures promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58; and
- (l) the equivalent applicable Law in any relevant country;

“**Government Authority**” shall have the same meaning as Regulatory Authority.

“**ICH**” means the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

“**IND**” means an Investigational New Drug Application exemption or Clinical Trial Application filed with, acknowledged, or accepted by, Governmental Authorities prior to beginning clinical trials in humans in any country, or any comparable application to and acceptance by the Regulatory Authority of a country or group of countries prior to beginning clinical trials in humans in that country or in that group of countries.

“**Interim Report**” shall mean a written report that contains an initial analysis of the results of a Clinical Trial once that Clinical Trial has completed and the data from that Clinical Trial has been collated and analyzed and, in particular reporting, on the extent to which the endpoints of the Clinical Study have been met but which is not the Final Report, has not yet been subject to quality assurance and precedes the Final Report.

“**JSC**” means the joint steering committee established under Section 3.1.

**“Know How”** means technical and other information which is not in the public domain, including information and data comprising or relating to (i) non-clinical data including pharmacological, toxicological and metabolic data and results of all non-clinical studies relevant to the product; and (ii) clinical safety and efficacy data including data analyses, study reports and information contained in protocols, filings or other submissions to and responses from ethical committees and Regulatory Authorities; and (iii) safety (pharmacovigilance) data; and (iv) production facilities and processes including any drug master file, specifications, techniques, manufacturing line procedures, chemistry and manufacturing control data, standard operating procedures quality assurance and quality control processes and techniques, and all other documentation retained to comply with GMP procedures; and (v) information relating to contract manufacturers and the manufacturing supply chain of the Product, including API, fill finish, primary and secondary packaging (items (iv) and (v) together being **“Manufacturing Know How”**). Know How includes (a) Documents containing Know How; and (b) includes and covers any legal rights including trade secrets, copyright, database or design rights protecting such Know How. The fact that an item is known to the public shall not be taken to preclude the possibility that a compilation including the item, and/or a development relating to the item, is not known to the public.

**“Knowledge”** means a Party's and its Affiliates' understanding in good faith as possessed in the case of Licensor, by Michael Ward, Gilbert Mueller, Brian Garrison, Richard Sachse or Matthias Gerlach and in the case of Licensee, by Stephen Long, Matthew Pauls and A. Brian Davis, of the relevant facts and information after performing a reasonable investigation with respect to such facts and information.

**“Launch”** means the initial transfer of the Product billed or invoiced by Licensee (or an Affiliate or Sub-licensees) to a non-Sub-licensee Third Party in the Territory following the Effective Date.

**“Law”** or **“Laws”** means any federal, state, local, municipal, foreign, international, multinational, or other constitution, law, statute, treaty, rule, regulation, ordinance, code, binding case law or principle of common law, rule or regulation, promulgated or issued by an Governmental Authority, as well as any Judgments, decrees, injunctions or agreements of any entity in the course of dispute resolution that might have binding or precedential effect on the Parties, and also includes any industry standard, third party certification, any technical or scientific standard to which adherence is required by any Governmental Authority and any rules or policies of non-governmental accreditation, standards, certification, or oversight bodies and includes any obligations or responsibilities applicable to holders of Product Registrations including, without limitation, pharmacovigilance and required annual or expedited reporting needed to maintain such Product Registration.

**“Legal Requirement”** means any applicable Law of any Government Authority including any amendment, extension or replacement thereof which is from time to time in force.

**“License”** means the rights and license granted by Licensor to Licensee pursuant to the terms of Section 2.1.

**“Licensee CMO Contracts”** has the meaning given to it in Section 6.2.

**“Licensee IPR Package”** means the intellectual property and other rights at any time during the Term Controlled by the Licensee or its Affiliates relating to the Product pursuant to Section 10.3 including but not limited to:

- (a) Licensee Patent Rights;
- (b) Know How;

- (c) Dossiers;
- (d) Commercial Information; and
- (e) the Licensee Trademark.

“**Licensee Know-How**” means the Know-How Controlled by the Licensee at the date of termination of this Agreement solely to the extent related to the Product.

“**Licensee Materials**” means the Materials Controlled by the Licensee at the date of termination of this Agreement that are necessary to Manufacture the Product.

“**Licensee Patent Rights**” means all Patent Rights generated or developed by or on behalf of the Licensee and/or its Affiliates at any time during the Term of this Agreement containing claims covering the Product or the Manufacturing of the Product.

“**Licensee Trademarks**” means all Trademarks Controlled by the Licensee relating solely to the Product, but excludes the Licensor Trademark.

“**Licensor IPR Package**” means the intellectual property and other rights Controlled by the Licensor or its Affiliates relating to the Product (with the exception of the Licensor Materials, Controlled at any time during the Term) including but not limited to:

- (a) the Licensor Patent Rights;
- (b) Know How;
- (c) Dossiers;
- (d) the Commercial Information in relation to the Territory; and
- (e) the Licensor Trademark.

“**Licensor Materials**” means those Materials of the Licensor as set out in Schedule 4.

“**Licensor Patent Rights**” means the Patent Rights Controlled by the Licensor at any time during the Term of this Agreement in the countries of the Territory containing claims covering the Product and approved uses of the Product, which at the Effective Date are those set out in Schedule 7.

“**Licensor Supply Period**” has the meaning given to it in Section 6.4.

“**Licensor Trademark**” means the Macrilen trademark registered in the Territory and any accompanying logos, trade names, trade dress and/or other indicia relating to the Product Controlled by the Licensor.

“**Losses**” means any and all losses, damages, liabilities, costs and expenses (including, without limitation, reasonable attorneys' fees and expenses). In calculating “**Losses**”, the duty to mitigate on the part of the Party suffering the Losses shall be taken into account.

“**Manufacture**” or “**Manufacturing**” means to make, have made, produce, manufacture, process, fill, finish, package, label, perform quality control testing, perform quality assurance, release procedures, ship or store a compound or product or any component thereof. When used as a noun, “**Manufacture**” or “**Manufacturing**” means any and all activities involved in Manufacturing a compound or product or any component thereof.

“**Material**” means any quantities of raw materials (including, without limitation, active pharmaceutical ingredients, drug substance, precursors, intermediates, drug product and



excipients), labels, packaging materials, dedicated physical components, and dedicated equipment, reference standards or reagents, needed for the Manufacturing of the Product.

“**NDA**” means the new drug application filed with and approved by the FDA for the Product having NDA number 205598.

“**NDA Product**” means the Product that is the subject of the NDA.

“**Net Sales**” means:

- (m) the gross amount invoiced by the Licensee, its Affiliates, Sub-licensees or Sub-distributors for sale of Products to third parties, less the following deductions relating to sales of the Products in each case as required by applicable GAAP:
  - (i) normal and customary trade, cash and quantity discounts accrued or actually given, credits, price adjustments or allowances for damaged products, returns or rejections of products;
  - (ii) chargeback payments and rebates (or the equivalent thereof) for the Product granted to group purchasing organizations, managed health care organizations or to federal, state/provincial, local and other governments, including their agencies, or to trade customers;
  - (iii) reasonable and customary freight, shipping insurance and other transportation expenses directly related to the sale of the Product (if actually borne by the Licensee, its Affiliates, or Sub-licensees without reimbursement from any Third Party);
  - (iv) required distribution commissions/fees payable to any Third Party providing distribution services to the Licensee; and
- (n) sales, value-added, excise taxes, tariffs and duties, and other taxes and government charges directly related to the sale, to the extent that such items are included in the gross invoice price of the Product and actually borne by the Licensee, its Affiliates, or Sub-licensees without reimbursement from any Third Party (but not including taxes assessed against the income derived from such sale).

For these purposes sale of Products shall include the Product as Developed by the Licensee from time to time.

Nothing herein shall prevent Licensee or any of its Affiliates or Sub-licensees from making selling, distributing or invoicing Product at a discounted price for shipments to Third Parties in connection with clinical studies, sampling, compassionate sales, or an indigent program or similar *bona fide* arrangements in which such party agrees to forego a normal profit margin for good faith business reasons and notwithstanding anything herein to the contrary, to the extent such distribution is made without charge it shall not be deemed a sale for purposes of determining Net Sales. Sales or other commercial dispositions of Products (1) between Licensee and its Affiliates and/or its Sub-licensees (except where such Affiliates or Sub-licensees are an end user of the Product), or (2) provided to Third Parties without charge, in connection with research and development, Clinical Trials, compassionate use, humanitarian and charitable donations, or indigent programs or for use, in reasonable and customary quantities, as samples, shall in each case, be excluded from the computation of Net Sales, and no payments will be payable on such sales or such other commercial dispositions.

“**New Indication**” means an indication for the treatment of any disease or condition other than the Existing Indications.

**“Outstanding CMO Contracts”** has the meaning given to it in Section 6.1.

**“Pediatric Indication”** means assessing GHD in Children.

**“Patent Rights”** means:

- (a) all national, regional and international patents and patent applications, including provisional patent applications; and
- (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications; and
- (c) any and all patents that have issued or in the future issue from the foregoing patent applications in paragraphs (a) and (b) above, including author certificates, inventor certificates, utility models, petty patents and design patents and certificates of invention; and
- (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications in paragraphs (a) to (c) above inclusive, and
- (e) any similar rights, including so-called pipeline protection (where the subject matter previously disclosed was not previously patentable in a particular jurisdiction but subsequently becomes patentable subject matter in such jurisdiction), or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent applications and patents.

**“Person”** means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

**“PIP”** means the pediatric investigation plan, pediatric study plan, the pediatric study, pediatric drug development and/or any other clinical or pharmacological data collection as submitted to and agreed by EMA (April 11 2017) and which will support authorization of PGHD for the Product by EMA and as further requested by FDA in FDA’s Pediatric Written Request (PWR) under the Best Pharmaceuticals for Children Act (BPCA) which PWR stipulates that the PIP as submitted and agreed to by EMA will meet the requirements to obtain a period of pediatric exclusivity in the U.S..

**“PIP Budget”** means the budget attached hereto as Schedule 10, which budget relates to the PIP and sets out the direct and indirect costs of the PIP anticipated by the Parties as at the Effective Date as such budget may be updated from time to time in accordance with Section 5.5.

**“Pricing Approval”** means:

- (a) such approval, agreement, determination or governmental decision establishing prices for the Product that can be charged and will be reimbursed by Government Authorities in countries in the Territory where Government Authorities or Government Authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise; and

(b) a price established in a supply contract with a Government Authority following a tender process.

**“Product”** means any pharmaceutical product containing the API, including the product developed by the Licensor for the Existing Indications and approved by the FDA for marketing in the United States under the NDA.

**“Product Registrations”** means all applications (including any IND, and the NDA), orphan designations, new drug applications, abbreviated new drug applications, new drug submissions, and any comparable applications and submissions, together with any and all supplements or modifications or amendments thereto, whether existing, pending, withdrawn or in draft form, together with all correspondence to or from any Governmental or Regulatory Authority with respect thereto, prepared and submitted to any Governmental or Regulatory Authority in the Territory with respect to the Product including the NDA and any supplemental drug applications filed with and approved by the FDA or other Regulatory Authorities for the Product whether relating to the Pediatric Indication, a New Indication and/or other dosages of the Product.

**“Promotional Materials”** means all sales representative training materials and all written, printed, graphic, electronic, audio or video matter, including journal advertisements, sales visual aids, leave-behind items, reprints, direct mail, internet postings and sites and broadcast advertisements intended for use or used by or on behalf of Licensee or its Affiliates in connection with any promotion of a Product.

**“Recipient Party”** means the Party which receives Confidential Information from the other Party.

**“Regulatory Approval”** means any approval required from a Regulatory Authority to market and sell a pharmaceutical product in any country of the Territory including the NDA, but excluding any Pricing Approval required or commercially desirable.

**“Regulatory Authority”** means any supranational, national or local parliament, regional, state, county, city, town, village, municipal, district, commission, department or agency including FDA, EMA, or any competent authority in the EU, Europe or the United Kingdom or other country in which the Product holds marketing authorization, authority (including a listing authority in relation to a stock exchange), inspectorate, minister, ministry official, or other public or statutory Person (whether autonomous or not), multinational organization or any other body exercising, or entitled to exercise, any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power of any nature over the Parties.

**“Regulatory Submissions”** means any submission by a Person to a Regulatory Authority in connection with the Product.

**“Royalty Term”** means, Existing Indication by Existing Indication, and country by country of the Territory, the period that is from the First Commercial Sale Date until the later of either:

- (a) the expiry of all Valid Claims of the Licensor Patent Rights in such country;
- (b) the expiration of any regulatory marketing exclusivity period or other statutory designation that provides similar exclusivity for the Commercialization of the Product in such country; and
- (c) ten (10) full Calendar Years following such First Commercial Sale Date.

Where “expiry” in relation to a Valid Claim for purposes of royalty calculations means the cessation of a claim to meet the definition of Valid Claim.

“**Sub-licensee**” means a Third Party to whom the Licensee or its Affiliates grants a sublicense in accordance with Section 2.

“**Supply Chain**” has the meaning given to it in Section 6.1.

“**Taxes**” means all taxes of any kind, and all charges, fees, customs, levies, duties, imposts, required deposits or other assessments, including all federal, state, local or foreign net income, capital gains, gross income, gross receipt, property, franchise, sales, use, excise, withholding, payroll, employment, social security, workers' compensation, unemployment, occupation, capital stock, ad valorem, value added, transfer, gains, windfall profits, net worth, asset, transaction, and other taxes, and any interest, penalties or additions to tax with respect thereto, imposed upon any individual or entity by any taxing authority or other governmental authority under the Laws of the applicable country in the Territory.

“**Term**” means the period commencing on the Effective Date and, unless earlier terminated in accordance with this Agreement, expiring country by country of the Territory at the end of the Royalty Term in such country.

“**Term Loan Agreement**” means the Term Loan Agreement, dated as of July 14, 2017, among Strongbridge U.S. Inc., a Delaware corporation, Strongbridge Biopharma Public Limited Company, a public limited company incorporated under the laws of Ireland, the Licensee, Cortendo Cayman Ltd., an exempted company incorporated in the Cayman Islands, Cortendo AB (Publ), a public limited liability company incorporated under the laws of Sweden, the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto and CRG Servicing LLC, a Delaware limited liability company, as amended, supplemented or otherwise modified from time to time.

“**Territory**” means the United States of America and Canada.

“**Third Party**” means a party other than either of the Parties or any of their respective Affiliates.

“**Trademarks**” means registered trademarks and applications thereof, unregistered trade or service marks, get up, logos, trade dress and company names in each case with any and all associated goodwill and all rights or forms of protection of a similar or analogous nature including rights which protect goodwill.

“**Valid Claim**” means either:

- (a) a claim of an issued and unexpired patent included within Patent Rights, which has not been held revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or un-appealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or
- (b) a claim of a pending patent application included within Patent Rights which claim was filed and is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal or refiling of the application, provided that no more than seven (7) years have passed since the earliest priority date for such application.

“**Year**” means each complete Calendar Year following the First Commercial Sale Date.

1.2 In this Agreement:

- (a) the table of contents and headings are inserted for ease of reference only and shall not affect the interpretation of any provision of this Agreement;

- (b) all references to a particular Section, paragraph or Schedule shall be a reference to that Section, paragraph or Schedule, in or to this Agreement as it may be amended from time to time pursuant to this Agreement;
- (c) words in one gender include any other gender, words importing individuals import companies and vice versa, words in the singular include the plural and vice versa, and words importing the whole shall be treated as including a reference to any part thereof;
- (d) references to a company shall include any company, corporation or other body corporate wherever and however incorporated or established;
- (e) reference to the words “include” or “including” (or any similar term) are not to be construed as implying any limitation and general words introduced by the word “other” (or any similar term) shall not be given a restrictive meaning by reason of the fact that they are preceded by words indicating a particular class of acts, matters or things;
- (f) references to “writing” or “written” includes any method of reproducing words or text in a legible and non-transitory form and, for the avoidance of doubt, shall include text transmitted by e-mail;
- (g) references to “indemnify” and to “indemnifying” any person against any Losses by reference to any matter includes indemnifying and keeping that person indemnified against all Losses from time to time made, suffered or incurred as a direct or indirect consequence of or which would not have arisen but for that matter;
- (h) when calculating the period of time before which, within which or following which any act is to be done or step taken pursuant to this Agreement, the date that is the reference date in calculating that period shall be excluded. If the last day of that period is not a Business Day, the period in question shall end on the next Business Day; and
- (i) reference to any statute or regulation includes any modification, amendment or re-enactment that statute or regulation.

## **2. Grant of rights / license**

2.1 The Licensor, subject to the terms of this Agreement, grants to the Licensee the exclusive, non-assignable (except in conjunction with an assignment of this Agreement under Section 15) right and license to use the Licensor IPR Package:

- (a) to Commercialize the Product in the Territory;
- (b) to Manufacture in any country the quantities of Product required for Commercialization in the Territory; and
- (c) to Develop the Product for Commercialization in the Territory.

2.2 Subject to Section 15.2 and Section 2.3, the Licensee shall have the right to sublicense its rights under the License to an Affiliate or Third Party Sub-licensees without the consent of the Licensor, except in the case of a Third Party where in one transaction or a series of related transactions Licensee sublicenses substantially all of its rights under the License to such Third Party.

2.3 The Parties agree that:

- (a) prior to the grant of a sub-license pursuant to Section 2.2, the Licensee shall serve written notice on the Licensor and such notice shall contain the following information:
    - (i) the identity of the proposed Sub-licensee; and
    - (ii) the reasons why the Licensee believes such Sub-licensee will be able to perform its obligation;
  - (b) where the proposed sub-license is to a Third Party where in one transaction or a series of related transactions Licensee seeks to sub-license substantially all of its rights under the License to such Third Party and the Licensor has a veto right under Section 2.2 above, then the notice to be provided to the Licensor pursuant to Section 2.3(a) must be provided at least six (6) weeks prior to entry into the proposed sub-license with such Third Party; and
  - (c) the Licensee (in its capacity as sub-licensor) shall remain responsible for all of its obligations hereunder and if the acts or omissions of any such Sub-licensee cause the Licensee to be in breach of this Agreement the Licensee shall be responsible therefor (with all the express consequences provided for under this Agreement and any implied consequences) regardless of any remedy which the Licensee may have against the Sub-licensee. In particular but without limitation, the Licensee shall perform its financial obligations under this Agreement regardless of a breach by any Sub-Licensee.
- 2.4 During such time as either Party owes Royalties to the other Party under this Agreement, each Party shall not, and shall procure that its Affiliates and Sub-licensees shall not, directly or indirectly, Develop, Manufacture or Commercialize in the Territory any product for assessing GHD in adults or Children other than the Product.
- 2.5 During the Term the Licensee, its Affiliates and Sub-Licensees shall refrain from:
- (a) seeking or accepting any actual or potential orders for the Product that are known or are reasonably suspected to be for use outside the Territory and the Licensee shall refer to the Licensor all inquiries that the Licensee receives for the Product for sale or ultimate delivery outside the Territory; or
  - (b) establishing any branch or maintaining any distribution depot for the Product outside the Territory.
- 2.6 During the Term:
- (a) the Licensor, its Affiliates and licensees (other than Licensee) shall refrain from seeking or accepting any actual or potential orders for the Product that are known or are reasonably suspected to be for use inside the Territory; and
  - (b) the Licensor shall refer to the Licensee all inquiries that the Licensor receives for the Product for sale or ultimate delivery inside the Territory.
- 2.7 For clarity, nothing in this Section 2 shall limit or restrict the Licensor, its Affiliates, or any Third Party licensee of the Licensor, from using the Licensor IPR Package in connection with the development or Commercialization of the Product outside of the Territory or in connection with the Manufacture of the Product outside of the Territory or inside the Territory for development or Commercialization outside the Territory.

### 3. Governance

3.1 With effect from the Effective Date the Parties shall establish and run a Joint Steering Committee (“JSC”).

3.2 The JSC shall be organized as follows:

- (a) the JSC shall comprise four (4) persons (“JSC Members”) and the Licensor and the Licensee respectively shall be entitled to appoint two (2) JSC Members, including one person whose primary responsibility shall relate to Development, to remove any JSC Member appointed by it and to appoint any person to fill a vacancy arising from the removal or retirement of such JSC Member appointed by it. JSC Members must be appropriate for the primary function of the JSC in terms of their seniority, availability, function in their respective organization, training and experience. There will be a chairperson (“JSC Chairperson”) who will be one of the Licensee JSC Members;
- (b) the Licensee and the Licensor respectively shall each notify the other of any change in the identities of their JSC Members. Both sides shall use reasonable efforts to keep an appropriate level of continuity in representation. JSC Members may be represented at any meeting by another person designated in writing by the absent JSC Member;
- (c) JSC shall hold meetings in person as frequently as the members of the JSC may agree shall be necessary, and otherwise by teleconference or a video-conference, but no less frequently than four (4) times each Calendar Year in total. Dates of meetings shall be agreed by the Parties not less than thirty (30) days beforehand. Each Party shall submit the agenda items and associated materials that it wishes to be considered no later than seven (7) days prior to the meeting and it is agreed that Licensor JSC Members shall only be entitled to submit agenda items for inclusion which relate to matters that have or could potentially have a material impact on the Product, payments to be made pursuant to this Agreement or the Licensor more generally. The first meeting of the JSC will take place as soon as reasonably practicable after the Effective Date, but in no event later than ninety (90) days after the Effective Date, at such location as the members of the JSC may agree or, failing such agreement, Dublin, Ireland. Special meetings of the JSC may be called by any JSC Member upon reasonable written notice to the then current chairman of the JSC not more than twice in any Calendar Year absent a material matter requiring JSC attention that cannot reasonably be delayed until the next scheduled JSC meeting;
- (d) if not held by teleconference or videoconference, the venue for meetings of the JSC shall be held at such location as the members of the JSC may agree or, failing such agreement, Dublin, Ireland. Each Party shall be responsible for its own expenses including travel and accommodation costs incurred in connection with JSC meetings; and
- (e) the JSC Chairperson or its designee shall be responsible for preparing the minutes of any JSC meeting as soon as reasonably practicable thereafter, seeking unanimous approval of those minutes from the JSC Members, signing and dating the approved minutes and distributing a copy of the signed minutes to each Party.

3.3 The JSC shall have the following purposes:

- (a) as regards Commercialization:
  - (i) to: (A) provide the Licensor with visibility into the Commercialization of the Product in the Territory by the Licensee via reports prepared in the ordinary course for the Licensee's internal purposes, provided that such internal reports

at a minimum provide the Licensor with the information set out in Section 7.2 at least quarterly, failing which the Licensee shall deliver such information in accordance with Section 7.2 irrespective of whether it is prepared in the ordinary course or not; (B) procure that the Licensor has reasonable access to Commercial Information of the Licensee relating solely to the Product; (C) ensure that the Licensor is informed regarding acceptance of the Product and Product quality complaints; and (D) provide a means for the Licensor to provide input for any activities relating to Commercialization; and

- (ii) (to the extent materially relevant to the sale of the Product in the Territory, to provide the Licensee with visibility into the Commercialization of the Product outside the Territory by the Licensor, to include reasonable information in relation to overall sales volume, market messaging, branding, product positioning strategies, and the information to be provided to the Licensee as specified in Section 7,

and otherwise to act as a forum for general liaison and communication between the Parties in relation to Commercialization of the Product by the Licensee. It is agreed that neither Party shall be required to provide copies of term sheets or commercial agreements relating to grants to Third Parties of rights related to the Product, by Licensee in the Territory, or by the Licensor outside the Territory;

- (b) provide each Party with visibility into the other Party's Development activities with respect to the Product other than in relation to the PIP, and to provide a forum for discussion of such Development activities;
- (c) oversee and guide the Licensor's activities in carrying out the PIP, to consider reports from the Licensor in respect of the PIP, to provide a means for the Licensee to provide input and, where so provided hereunder, approval for any activities relating to the PIP and for general liaison and communication between the Parties in relation to the PIP;
- (d) review and approve with respect to the PIP (including any amendments to any of the following):
  - (i) the investigational medicinal Product Dossier;
  - (ii) locations of Clinical Trial sites;
  - (iii) the identity of principal investigators for the Clinical Trial sites;
  - (iv) the investigator brochure;
  - (v) informed consent documentation;
  - (vi) proposed amendments by the Parties to the PIP Budget (it being noted that pursuant to Sections 3.5 and 5.5, the JSC may not increase the PIP Budget without the written consent of both Parties);
  - (vii) where a contract is to be entered into with a CRO in relation to the Product after the Effective Date, the identity of and the proposed contract with such CRO;
  - (viii) the identity and contracts with major vendors (e.g. site monitors); and
  - (ix) protocols prepared by the Licensor for the PIP;
- (e) coordinate with respect to:



- (i) the finalization of the each Party's supply chain for the Product for its respective Territory;
- (ii) the transition of responsibility for the Manufacture of the Product for the Territory from the Licensor to the Licensee; and
- (iii) the general improvement of the supply chain of the Product, both inside and outside the Territory,

and for general liaison and communication between the Parties in relation to the Manufacture of the Product; and

- (f) shall perform such other functions and responsibilities as are given to it under the express provisions of this Agreement but shall have no authority to amend any commercial terms of this Agreement or any matter that would cause any payments stated in this Agreement to be other than the amount of those terms as stated herein.

3.4 Each Party shall give reasonable consideration to input provided by the other Party to the JSC on all matters set forth in Section 3.3, provided however that the JSC shall have authority to make decisions solely with respect to the PIP. Such decisions shall be made by unanimous agreement of the JSC Members wherever possible with the Licensee JSC Members together having one vote on behalf of the Licensee and the Licensor JSC Members together having one vote on behalf of the Licensor. Both Parties will use their reasonable efforts to build consensus. All decisions of the JSC shall be minuted by or on behalf of the JSC Chairperson who shall seek unanimous approval of those minutes from the JSC Members, sign and date the approved minutes and promptly send a copy of the minutes of each JSC meeting to both Parties. The JSC shall exercise this authority in good faith and in accordance with the terms of this Agreement, and any decision by the JSC on such matters made in accordance with this Section 3.4 shall be binding upon the Parties. Subject to Section 3.5 below:

- (a) in the event that agreement on a PIP-related decision cannot be reached within thirty (30) days, the matter shall be referred for resolution by negotiation between a representative appointed by Licensor, and for Licensee, the President and CEO of Strongbridge Biopharmaceuticals plc or his/her designee, and if the executives cannot reach agreement on the issues under consideration within ten (10) Business Days, then the matter shall be referred to a Third-Party pharmaceutical executive mutually and reasonably agreeable to the Parties and having no less than ten (10) years' experience directing biopharmaceutical product development programs as set forth in Section 3.4(b);
- (b) Expedited Expert Referral.
  - (i) the Parties shall agree to the identify of such Third-Party pharmaceutical executive as promptly as practicable and in no event later than ten (10) days following the expiration of the ten (10) day period set forth in Section 3.4(a);
  - (ii) not later than ten (10) days following the expiration of the ten (10) day period set forth in Section 3.4(b)(i), each Party shall submit to the Third-Party pharmaceutical executive (with a copy to the other Party) a position paper setting forth the desired decision on the applicable matter and the rationale for such desired decision, including any supporting documentation provided to the JSC in relation to the matter under consideration thereto, such position paper not to exceed 5000 words (not including supporting documentation);
  - (iii) the Parties shall request the Third-Party pharmaceutical executive to render, not later than ten (10) days following the expiration of the ten (10) day period

set forth in Section 3.4(b)(ii) (or such other time to which the Parties and such executive may all agree), a decision in good faith and based solely on the arguments set forth in such position papers (and for the avoidance of doubt, neither Party shall be permitted to contact the Third-Party pharmaceutical executive to provide additional information or arguments), and such decision shall be restricted to the one of the desired outcomes set forth in the respective position papers of the Parties, and shall render such decision without providing more than the identity of the Party whose desired outcome constitutes such decision;

- (iv) such decision by the Third-Party pharmaceutical executive shall be final and binding on the Parties; and
- (v) the Party whose desired outcome is not adopted by the Third-Party pharmaceutical executive shall be responsible for payment of the fee owed to the Third-Party pharmaceutical executive .

3.5 The Parties agree that in no event shall the JSC or any dispute resolution process have the authority to increase the PIP Budget without the express written consent of both Parties in accordance with Section 5.5.

#### 4. **Technology transfer and technical / regulatory assistance<sup>1</sup>**

The Licensor shall:

- (a) maintain the Data Room until the first anniversary of the Effective Date (the “**Closure Date**”) and shall give nominated representatives of the Licensee access to such Data Room;
- (b) as soon as reasonably practicable following the Closure Date, the Licensor shall provide to the Licensee two identical CD-ROM discs on which are contained copies of all Documents contained, on the Closure Date, within the Data Room;
- (c) in accordance with the timing set forth in Schedule 2, to the extent not already in the Data Room, make available to the Licensee the Know How Controlled by it, the Dossier filed in respect of the NDA and the Commercial Information Controlled by it and details about the Licensor Trademarks and Licensor Patent Rights, including those items set forth on Schedule 2. Licensor shall provide those materials as soon as reasonably practicable after the Effective Date, and in no event later than any time specified on Schedule 2 for any particular item set out thereon; and
- (d) immediately following execution of this Agreement, and before transfer of the Product Registrations (NDA, IND, ODD), provide the Licensee with a CD-ROM disc or discs containing all FDA correspondence related to these applications and the complete electronic copy of the NDA, IND and ODD in the exact format and active file links as submitted to the FDA in respect of the NDA and IND and as pdf files in respect of the ODD. This should include the FDA submission acknowledgements if filed electronically.
- (e) provide not later than six months after the Effective Date the transfer of a copy of the electronic Trial Master File(s) for the NDA supporting studies.

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<sup>1</sup> **Note to draft:** Parties to discuss and determine how to handle the preservation of and access of Licensee to any clinical samples held by Licensor.

## 5. Development

### Development Plan

- 5.1 In each Calendar Year that Development regarding the PIP is occurring, each Party shall at its own cost and expense (subject to Section 5.4) use Commercially Reasonable Efforts to carry out the activities specified in the Development Plan in relation to the PIP as the responsibility of such Party so as to meet the timelines set out in them.
- 5.2 During the period of Development regarding the PIP by the Licensor, it shall update the Development Plan on or before November 1<sup>st</sup> in each year and shall submit the same to the JSC for review and approval.

### PIP

- 5.3 The Licensor shall:
- (a) be responsible for the conduct of the PIP, subject to and in accordance with the timelines set out in the Development Plan and subject to the direction of the JSC;
  - (b) conduct all activities in relation to the PIP in compliance with all Legal Requirements, ethics committee, informed consent or similar approvals in relation thereto, and in compliance with GCP;
  - (c) provide periodic updates regarding the PIP to the JSC as reasonably requested by the JSC;
  - (d) permit Licensee (at its own cost) and upon reasonable notice to audit, during normal business hours, the trial master file and shall cooperate with any such audit; and
  - (e) promptly provide to the JSC the results of the PIP in the form of a copy of any Interim Report, a Formal Presentation and a copy of the Final Report as these occur, even if between JSC scheduled meetings.
- 5.4 The Licensee shall reimburse the Licensor for seventy per cent (70%) of the ongoing documented Development Costs reasonably incurred by the Licensor in accordance with the Development Plan and the PIP Budget. The Licensee shall reimburse its proportion of the Development Costs not later than sixty (60) days following receipt of the Licensor's invoices and supporting evidence of such Development Costs having been incurred in connection with the conduct of the PIP, which the Licensor shall submit as and when such Development Costs arise but no more frequently than on a quarterly basis, save where an invoice is for an amount equal to or greater than \$100,000 whereupon the Licensor shall be permitted to invoice on a monthly basis. Payment shall be made by the Licensee within thirty (30) Business Days of the date of receipt of the Licensor's invoice, into such bank account as the Licensor shall specify from time to time. For the avoidance of doubt, the Licensor shall be responsible for the remaining thirty per cent (30%) of such Development Costs in connection with the conduct of the PIP.
- 5.5 During the period in which the PIP is ongoing, the Parties may, from time to time, together agree in writing to update the PIP Budget and where this occurs the proposed changes will be submitted to the JSC for review and discussion. Once agreed by the Parties in writing, the revised PIP Budget shall be the 'PIP Budget' for the purposes of this Agreement.
- 5.6 Upon a Bankruptcy Event of Licensor, Licensee shall have the right, but not the obligation, to assume full control of the PIP upon written notice to Licensor. Following any such notice, Licensor shall, to the extent permitted by Law, use its reasonable endeavors to promptly assign to Licensee or its designee all contracts associated with the PIP and shall cooperate

with Licensee to ensure a smooth transition of control of the PIP to Licensee, including by executing such documents requested by Licensee as are necessary to enable such transition. Licensee shall thereafter carry out the PIP as set forth in the Development Plan on behalf of itself with respect to the Territory and on behalf of Licensor outside the Territory. Licensee shall pay Licensor's thirty percent (30%) share of the cost and expenses of the PIP as set forth in the PIP Budget and shall be entitled to deduct all such costs and expenses from any amounts of royalties or milestones owed to Licensor hereunder prior to making any payments to Licensor.

#### **Development other than the PIP**

- 5.7 Except as expressly set forth above in relation to the PIP and subject to Section 5.7 below, each Party shall:
- (a) be responsible for the conduct and all associated costs and expenses of the Development activities for the Product in its own territory and for the avoidance of doubt 'territory' shall mean the USA and Canada for the Licensee and the rest of the world for the Licensor;
  - (b) conduct all such Development activities in compliance with all Legal Requirements, ethics committee, informed consent or similar approvals in relation thereto, and in compliance with GCP;
  - (c) provide the JSC with a summary and update in reasonable detail of such Development activities at each meeting of the JSC; and
  - (d) provide the other Party with a copy of a near-final draft of each Clinical Trial protocol or update to a protocol for the Product at least forty-five (45) days prior to the date on which such protocols or updates are provided to any Regulatory Authority or Clinical Trial site, in order to permit such other Party to comment on such protocol or update, and shall reasonably consider in good faith any comments thereon provided by such other Party within thirty (30) days following such other Party's receipt of such copy of such protocol or update.
- 5.8 The Parties agree that where any Development activity of the Licensee is, in the Licensor's reasonable opinion, going to have a material adverse impact on the Development, Manufacture or Commercialization of the Product outside of the Territory for the Existing Indications, then the prior written consent of the of the Licensor will be required, such consent not to be unreasonably withheld, delayed or conditioned.
- 5.9 If Licensee wishes to Develop Product in the Territory for a New Indication, Licensee shall have the right to do so on the following conditions:
- (a) the Licensee shall be solely responsible for the costs and expenses of the Development activities;
  - (b) the Licensee shall supply the Licensor with all material Know How, Dossiers and other Licensee IPR Package relating thereto, including a copy of each Final Report promptly following its preparation;
  - (c) subject to paragraph 5.9(d), the Licensee hereby grants to the Licensor a perpetual, irrevocable, exclusive, sub-licensable, right and license to use the Licensee IPR Package for the Product for such New Indication to Develop, manufacture and Commercialize the Product outside the Territory; and
  - (d) Licensor shall pay royalties to Licensee under such license on the same payment terms as, and at a rate equal to two percent (2%) less than the rate owed by, Licensee

to Licensor for sales of Products hereunder, with all applicable definitions and provisions having the Parties reversed, *mutatis mutandis*.

## **Regulatory Approvals**

### **5.10 Assignment of the NDA and Domain Names.**

- (a) Subject to the terms and conditions set out in this Agreement, Licensor hereby sells, conveys, and transfers to Licensee, and Licensee hereby purchases and accepts the sale, conveyance and transfer of all of Licensor's right, title and interest in the Product Registrations (including the NDA and the IND and orphan designation with respect thereto, and all copyrights, data and information contained therein), and the domain names set forth on Schedule 6, in the Territory on the Effective Date, subject to Licensor's express right to return of the Product Registrations and domain names upon certain terminations of the Agreement as set forth in Section 14.
- (b) Promptly after the Effective Date, each Party shall file with the FDA letters and applications in compliance with 21 CFR § 314.72 in the forms set forth on Schedule 3 in order to record with the FDA the change in ownership of the NDA from Licensor to Licensee.
- (c) Promptly following the first Marketing approval for a Product outside the Territory, to the extent permitted by applicable Law, Licensee shall ensure that any internet users from outside the Territory who access the domain names listed on Schedule 6 (or any variants of these that are now or in the future become owned by the Licensee or an Affiliate or agent of the Licensee), are redirected to Licensor's website or another website designated by Licensor covering the Licensor Product outside the Territory, provided that Licensor shall provide a link on such website with reasonably prominent instructions so that visitors to its site from inside the Territory or otherwise with an interest in the Product in the Territory are directed to jump to Licensor's website or another website designated by Licensor covering the Licensor Product inside the Territory.

### **5.11 The Licensee shall:**

- (a) subject to Section 5.11(b) below, at its sole cost and expense (subject to Section 5.3 with respect to costs of the PIP), use Commercially Reasonable Efforts to obtain any further Regulatory Approvals for the Product and any Pricing Approval required or commercially desirable in each country of the Territory, and such Regulatory Approvals shall, in all instances, be obtained by the Licensee in its own name and the Licensor shall provide its reasonable assistance to the Licensee to enable the Licensee to obtain the Regulatory Approvals in the Licensee's name; and
- (b) use Commercially Reasonable Efforts following the Effective Date to obtain Regulatory Approval for the Product in Canada for the Adult Indication.

### **5.12 The Licensee shall:**

- (a) conduct all Development activities (other than the PIP which is the responsibility of the Licensor) in the Territory in compliance with all Legal Requirements;
- (b) be responsible for the preparation of all submissions for the grant of a Regulatory Approval in the Territory; and
- (c) as soon as reasonably practicable following its receipt of the final study report for the last necessary clinical trial for the PIP, prepare and make all submissions for the grant

of Regulatory Approval in each country in the Territory for the Product for the Pediatric Indication using Commercially Reasonable Efforts.

- 5.13 The Licensee shall be responsible for all filings and submissions in respect of Regulatory Approvals for the Product in the Territory as well as attending all meetings with Government Authorities and Regulatory Authorities in respect thereof and:
- (a) shall provide, at the request of the Licensor, copies of all material proposed filings, in advance of the filing or submission thereof, for review and comment by the Licensor. The Licensee shall consider in good faith in its revision of the filing or submission, any comments made by Licensor; and
  - (b) shall inform the Licensor in advance of all meetings or conference calls with the Regulatory Authorities with respect to Products including on Pricing Approval issues and one Licensor representative shall have the right to attend solely as a non-participating observer in the meeting, to the extent permitted by such Regulatory Authorities.
- 5.14 The Licensee shall, from the Effective Date, use Commercially Reasonable Efforts to maintain the orphan status of the NDA Product.

## **6. Supply**

### **CMO Contracts**

- 6.1 An illustration of the Licensor's proposed supply chain for the Product for the USA is set out in Schedule 8 of this Agreement (the “**Supply Chain**”). Certain of the CMO Contracts that comprise the Supply Chain have been entered into by the Licensor or its Affiliates as of the Effective Date (the “**Existing CMO Contracts**”) while others have not been concluded as at the Effective Date (the “**Outstanding CMO Contracts**”). The Licensee shall use Commercially Reasonable Efforts to procure a full supply chain of the Product for the USA to enable the launch of the Product as soon as reasonably practicable after the Effective Date and the Licensee shall provide such reasonable assistance as the Licensor may reasonably request, subject to the provisions of Section 6.3(f).
- 6.2 The Parties agree that the Licensor shall not be required to assign, transfer or novate any of the Existing CMO Contracts to the Licensee but the Parties shall have a joint option (meaning, for the avoidance of doubt, that both Parties must consent to the assignment, transfer or novation) to do so, which is jointly exercisable at any time within 90 days of the Effective Date. The Licensee shall:
- (a) in respect of the Outstanding CMO Contracts, be entitled to enter into negotiations with the relevant CMOs in respect of such contracts, in place of the Licensor, and conclude such contracts in its own name or that of an Affiliate; and
  - (b) in respect of the Existing CMO Contracts, negotiate in good faith with the Licensor's CMOs or with alternative Third Party manufacturers with the intention of concluding its own direct terms with such CMOs or Third Party manufacturers,
- and the contracts which the Licensee enters into pursuant to Sections 6.2(a) and (b) are together the “**Licensee CMO Contracts**”.
- 6.3 The Parties agree that:
- (a) the Licensor shall provide to the Licensee such reasonable assistance as the Licensee shall reasonably request to help the Licensee to enter into the Licensee CMO Contracts;

- (b) they shall work together in good faith following the Effective Date to ensure that, where they both use common CMOs in their respective supply chains, that they leverage volume discounts from such common CMOs when ordering Materials;
- (c) each Party shall use reasonable efforts to ensure that they do not enter into any contract with a shared contracting party that disadvantages the other Party in such other Party's dealing with such contracting party;
- (d) each Party's contracts with shared suppliers shall provide that in the event of a shortage or other restriction on the supply of a commonly purchased material from such suppliers, the supplier, as between the Parties, shall allocate available supply *pro rata* to the Parties based upon each Parties forecasts for such material in place prior to any knowledge of a potential or actual shortage thereof;
- (e) if the Licensor and Licensee together choose to exercise the joint option (meaning, for the avoidance of doubt, that both Parties must consent to exercise of the option) referred to in Section 6.2 then the Parties shall, through the JSC, work together to assign, transfer or novate the Existing CMO Contracts to the Licensee whereupon such Existing CMO Contracts shall become Licensee CMO Contracts; and
- (f) the Licensee shall reimburse the Licensor for all reasonable costs and expenses (including employee costs which shall be charged on an hourly basis) associated with assistance requested by Licensee from and provided by the Licensor (or its Affiliates or any of their respective employees or consultants) pursuant to this Section 6.

#### **Interim Licensor Supply Arrangements**

6.4 The Parties will co-operate and work in good faith during the transition period following the Effective Date, as regards supply arrangements. More particularly, and subject to Sections 6.5 and 6.6 below, insofar as the Licensee requires Materials for the Manufacture of the Product under any Existing CMO Contract then, for the period from the Effective Date until the date upon which the Licensee enters into the relevant Licensee CMO Contract ("**Licensor Supply Period**"):

- (a) the Licensor shall procure that the relevant CMO supplies Materials to the Licensee or one of its Affiliates or CMOs, subject to the terms and conditions of such Existing CMO Contract, for the purposes of Manufacture by the Licensee or one of its Affiliates or CMOs of the Product for the Territory;
- (b) the Licensor shall procure that the Licensor Materials set forth on Schedule 4 to be delivered to the Licensor, are instead delivered to such location as the Licensee notifies to the Licensor in writing prior to that date, and the Licensee shall within 10 Business Days of receipt of any such Licensor Material, pay to the Licensor an amount equal to the amount set forth on Schedule 4 for the corresponding Licensor Material so received by Licensee;
- (c) the Licensor shall not, during the Licensor Supply Period, terminate the relevant Existing CMO Contract or amend it in a manner which would be adverse to the interests of the Licensee; and
- (d) the Licensor shall, at Licensee's cost and expense, take such actions in respect of such Existing CMO Contract as the Licensee may reasonably request, including where a CMO is in breach of the terms of an Existing CMO Contract, to enforce its rights against such CMO for and on behalf of the Licensee.

6.5 The Parties agree that:

- (a) the liability of the Licensor to the Licensee pursuant to Section 6.4(a), shall be limited, in all instances other than a liability arising from the negligence or willful misconduct of the Licensor in connection with the performance of its obligations under Section 6.4(a), to the amount actually recovered by the Licensee from the relevant CMO;
- (b) Licensor, promptly upon receipt thereof, shall send by electronic means copies of all invoices in respect of Materials supplied by the Licensor pursuant to Section 6.4(a) of this Agreement, which invoices Licensee shall pay on behalf of Licensor in accordance with the payment terms thereof, provided that if Licensee fails to make any such payment of a timely sent invoice copy for amounts not in dispute by Licensee (including invoices or portions of invoices previously but no longer in dispute), Licensor shall be entitled to pay such invoice (including any penalty or interest owed as a result of late payment thereof ) and to invoice Licensee for such payment, which Licensee shall pay to Licensor promptly. Licensee shall indemnify the Licensor and its Affiliates in respect of any claim made by a CMO against the Licensor as a result of the Licensee's failure to make any payments due to a CMO (including any disputed amounts that the Licensee incorrectly disputes); and
- (c) the Licensor shall not be required to comply with its obligations pursuant to Section 6.4 to the extent that this would breach any applicable Laws and/or which would put it in breach of its obligations under any Existing CMO Contract.

6.6 The Parties agree that:

- (a) the Licensee shall use Commercially Reasonable Efforts to take full responsibility for and management of supply of Products in the Territory as soon as reasonably practicable following the Effective Date; and
- (b) to the extent that the Licensee does not take responsibility for and management of supply of Products by the date which is twelve (12) months from the Effective Date, then:
  - (i) the Parties shall enter into a supply agreement to govern such supply arrangements between the Parties (the "**Supply Agreement**"); and
  - (ii) subject to the terms of the Supply Agreement, the Licensor shall have no further obligations under Sections 6.4 - 6.9 of this Agreement (which relate to the interim supply arrangements); and
- (c) with effect from the end of the Licensor Supply Period (or, if earlier, the date which is 9 months from the Effective Date), the Licensee shall either itself or through the Supply Agreement be responsible for supply, and shall manage the Manufacturing of all Materials and Product for sale in the Territory.

For the avoidance of doubt, the Licensor shall be responsible for and shall manage the Manufacturing of all Materials and Product for sale in countries outside of the Territories.

6.7 During the Licensor Supply Period, the Licensor will provide letters of access allowing access for the Licensee to the extent possible to the production sites of its CMOs, in each case where Materials have been manufactured for the Licensee pursuant to Section 6.4, in order to enable the Licensee to visit such sites and to review the Manufacturing and any documentation relating to the Materials or its Manufacturing maintained at such site to the extent necessary or required by applicable Law or the requirements of any Regulatory Authority or to prepare for any investigation or inspection that may be carried out by any Regulatory Authority.



- 6.8 The Parties shall cooperate and discuss in good faith with a view to agreeing a plan (including timeline and a detailed description of all documentation containing Manufacturing Know-How that will need to be provided to the Licensee) for the successful transfer of the Manufacturing Know-How Controlled by the Licensor to the Licensee during the Licensor Supply Period and on an ongoing basis thereafter in order to assist the Licensee in Manufacturing or having Manufactured the Product. Licensor agrees to make a technical transfer of any Manufacturing Know-How existing as of the Effective Date or created at any point during the Term which it Controls to the Licensee in accordance with the timelines agreed in any technical transfer plan (with respect to Manufacturing Know-How in existence as of the Effective Date and Controlled by Licensor) and within such time as is reasonably practicable after creation of such Manufacturing Know-How or upon the Licensor becoming aware of the existence of such Manufacturing Know-How (with respect to Manufacturing Know-How created or discovered during the Term). The Licensee agrees to make a technical transfer of any Licensee Manufacturing Know-How which it Controls created at any point during the Term to the Licensor within such time as is reasonably practicable after creation of such Licensee Manufacturing Know-How or upon the Licensee becoming aware of the existence of such Licensee Manufacturing Know-How. Except as set forth in Section 6.9, the costs of the transfer of Manufacturing Know-How shall be shared equally by the Parties.
- 6.9 For any change in a Manufacturing process or Material used for the Product (including the Product, itself) that are made as a result of a requirement of at least one Regulatory Authority in the Territory and at least one Regulatory Authority outside the Territory, the parties agree to split all costs and expenses related to developing and implementing such change (but not the cost of any Material used in the Product) with Licensee bearing seventy percent (70%) of such costs and expenses and Licensor bearing thirty percent (30%) of such costs and expenses

#### **Licensee Supply of Materials**

- 6.10 Where the Licensor seeks to obtain Product or Materials for the Manufacture of the Product for outside the Territories from the Licensee, then the Parties shall negotiate in good faith to enter into a supply agreement for such Product and/or Material on commercially reasonable terms.

#### **PIP**

- 6.11 Notwithstanding any other provision of this agreement, where the PIP is fully or partially conducted in the Territory, the Licensor shall be entitled to supply to the relevant Third Parties assisting with the PIP such amount of CTM as is necessary for the PIP.

#### **7. Commercialization.**

- 7.1 Licensee shall either itself or through its Affiliates, and Sub-licensees Commercialize the Product in the Territory using Commercially Reasonable Efforts and 'Commercially Reasonable Efforts' for these purposes shall include, but not be limited to the Licensee:
- (a) as soon as reasonably practicable following the Effective Date hiring, at a minimum, 15 field specialists whose role shall solely relate to the Product and maintaining such minimum number of field specialists for at least the 12 month period following the first Launch; and
  - (b) ensuring, that notwithstanding the resources required by the Licensee for the preparation for and the launch of another product by the Licensee (or its Affiliates), it continues to provide an appropriate level of resources dedicated to the Commercialization of the Product.

### **Information Sharing**

- 7.2 The Licensee shall provide Licensor through the JSC with reports and other commercialization planning documents for the Product as are generated in the ordinary course for the Licensee's internal purposes. To the extent that such ordinary course reports and planning documents do not provide the Licensor with the following information on a quarterly basis, the Licensee shall be required to provide such information to the Licensor upon a quarterly basis: current sales forecasts and actual volume of sales of the Product in the Territory, the number of specialist sales staff dedicated wholly or partially to the Commercialization of the Product, any material decrease in either from time to time and the reasons therefor and the nature and scale of promotional activities in the Territory.

### **Pricing**

- 7.3 Licensee will use Commercially Reasonable Efforts to secure required Pricing Approval for the Product in the Territory for each Existing Indication. The Licensee will have sole authority for determining and establishing the price and terms of sale (including any rebates or discounts) of Product in the Territory. Each Party shall provide the other Party with copies of any material Documents or other material pertaining to Pricing Approvals in such providing Party's respective territory.

### **Promotional Materials**

- 7.4 The Licensee or its Affiliates or Sub-licensees will be responsible for the creation, preparation, production and reproduction of all Promotional Materials and for filing, as required by Legal Requirements, all Promotional Materials with Regulatory Authorities in the Territory. Subject to Section 9, the Licensee shall use its own corporate name and/or logo or those of an Affiliate on Promotional Materials in connection with Commercialization of Product in the Territory, unless otherwise mutually agreed by the Parties.

### **Promotional claims/compliance**

- 7.5 The Licensee shall not promote the Product for intended uses or indications other than those in the labelling as approved by the Regulatory Authority in the Territory from time to time nor shall the Licensee make any medical or promotional claims for any Product other than as permitted by Legal Requirements (which for the avoidance of doubt shall include the False Claims Act). When distributing information related to any Product or its use for the Existing Indications in the Territory (including information contained in scientific articles, reference publications and publicly available healthcare economic information), the Licensee must comply with all Legal Requirements (which for the avoidance of doubt shall include the False Claims Act) in the applicable country.

### **International Congresses / Symposia**

- 7.6 For international congresses or symposia:
- (a) where Licensee wishes to have a presence in a symposium or congress outside the Territory regarding the Product, Licensee shall notify Licensor in advance of Licensee's proposed presence, providing reasonable detail regarding such planned presence and seeking Licensor's consent (such consent not to be unreasonably withheld, delayed or conditioned) for such presence. Licensor, as soon as reasonably practicable, but in no event later than ten (10) days after receiving such notice, shall notify Licensee of Licensor either withholding consent (with the reasons therefor) or providing consent to such presence;

- (b) where Licensor wishes to have a presence in a symposium or congress inside the Territory regarding the Product, Licensor shall notify Licensee in advance of Licensor's proposed presence, providing reasonable detail regarding such planned presence and seeking Licensee's consent (such consent not to be unreasonably withheld, delayed or conditioned) for such presence. Licensee, as soon as reasonably practicable, but in no event later than ten (10) days after receiving such notice, shall notify Licensor of Licensee either withholding consent (with the reasons therefor) or providing consent to such presence; and
- (c) The Parties shall, to the extent reasonable and practicable, coordinate attendance at such conference or symposium (including displaying brand names, trademarks and logos for the Product, to the extent permitted by Law).

#### **Product Complaints**

- 7.7 The Licensee will be responsible for responding to product complaints regarding Product in the Territory and the Licensor for responding to product complaints regarding Product outside the Territory. If the Licensor receives complaints about Product for a country in the Territory, it will refer such complaints to the Licensee (and vice versa), and the Licensee will be responsible for responding thereto (and vice versa). Each Party shall, in all instances, keep the other fully apprised of matters in relation to such product complaints including by providing copies of all correspondence with the complainant.

#### **Medical and consumer inquiries**

- 7.8 The Licensee will be responsible for responding to medical questions or inquiries from members of the medical and paramedical professions and consumers regarding Product in the Territory in accordance with Laws. If the Licensor receives questions about Product for a country in the Territory, it will refer such questions to the Licensee, and the Licensee will be responsible for responding thereto. Each Party shall, in all instances, keep the other Party reasonably apprised of matters in relation to any such questions or inquiries that are material and/or frequently asked, including by providing copies of correspondence with the relevant members of the medical or paramedical professions or consumers.

#### **Compliance with Laws**

- 7.9 Each Party will perform its obligations under this Agreement in accordance with all Laws. Each Party shall obtain from the requisite Government Authorities any consents, licenses, permits, waivers, approvals, authorizations, clearances, registrations or orders required to be obtained or made by such Party in connection with the authorization, execution and delivery by such Party of this Agreement and its performance of its obligations under this Agreement including but not limited to the importation, exportation, sale and distribution of the Product.

#### **Regulatory affairs**

- 7.10 Post-Approval Regulatory Submissions.
- (a) Subject to Section 7.10(b) below, as between the Parties, Licensee shall have sole responsibility, at its own expense, for preparing, filing and maintaining all Regulatory Submissions for Product in the Territory after the Effective Date, including Regulatory Submissions in connection with Development activities hereunder (collectively, "**Post-Approval Regulatory Submissions**"). Licensee shall use Commercially Reasonable Efforts to compile, submit and prosecute all Post-Approval Regulatory Submissions, in a format acceptable to the applicable Regulatory Authorities in the Territory. All Post-Approval Regulatory Submissions for Product in the Territory shall be filed in the name of Licensee. Licensee shall be responsible for

all communications and other dealings with the Regulatory Authorities relating to the Post-Approval Regulatory Submissions and Licensee shall be the legal and beneficial owner of all Post-Approval Regulatory Submissions.

- (b) Prior to submitting a Post-Approval Regulatory Submission regarding a material matter (such as a supplemental change to the NDA), Licensee shall provide a draft (which may be wholly or partly in electronic form) to the Licensor for review and comment.

#### 7.11 Adverse Event Reporting.

- (a) Licensor shall be responsible for complying with all Legal Requirements governing adverse events both inside and outside the Territory that occur prior to the transfer of NDA to Licensee, and Licensor's responsibilities shall thereafter continue outside the Territory. Licensor shall submit copies of reports of adverse events to Licensee simultaneously with submission to the applicable Regulatory Authorities, and, following, transfer of the NDA to Licensee, Licensee shall submit copies of adverse events to Licensor simultaneously with submission to the applicable Regulatory Authorities in the Territory. Licensee shall be responsible for complying with all Legal Requirements governing adverse events in the Territory that occur after the transfer of the NDA to Licensee. Each Party shall notify the other in a timely manner and in any event within forty eight (48) hours of receiving any notice from a Regulatory Authority, independent review committee, data safety monitoring board or another similar Clinical Trial or post-marketing monitoring body alleging concern regarding a patient safety issue or other material information relevant to the safety or efficacy of Product.
- (b) As will be more fully set forth in the Safety Agreement and agreed to pursuant to Section 7.11(d), Licensor shall be responsible at its own cost for establishing and maintaining a global safety database for the Product based on procedures and guidelines so agreed by the Parties for the operation of such database.
- (c) If during the Product's Development or Commercialization, the Product becomes subject to adverse effects or information of the type referred to in the last sentence of Section 7.11(a) is received, in each case which Licensee, in good faith, reasonably believes would seriously impact the long-term viability of Product in the Territory, Licensee shall determine whether or not there exists such serious impact on the long-term viability of such Product and, what if anything, the Parties should do to address the matter. If Licensee, upon consideration of the relevant facts and in its sole discretion, determines that the Parties are unable to successfully address and resolve the safety issue, Licensee shall provide written notice to Licensor of such determination, which notice shall set forth the reasons therefor, and Licensee may terminate its rights and obligations under this Agreement upon written notice.
- (d) As promptly as practicable following the Effective Date, but in no event later than one hundred eighty (180) days thereafter, Licensee and Licensor will develop and agree upon safety data exchange procedures in a separate and detailed safety agreement (the "**Safety Agreement**"). Such agreement will describe the coordination of collection, investigation, reporting, and exchange of information concerning adverse events or any other safety problem of any significance, and product quality and product complaints involving adverse events, sufficient to permit each Party, its Affiliates, licensees or sublicensees to comply with its legal obligations. The safety data exchange procedures will be promptly updated if required by changes in Legal Requirements. In the event of any conflict or inconsistency between this Agreement

and the Safety Agreement with respect to: (i) safety-related matters, the Safety Agreement shall prevail; and (ii) any other matter, this Agreement shall prevail.

#### 7.12 Regulatory Correspondence.

- (a) Notification to Other Parties of Regulatory Correspondence. Each Party shall promptly (and in any event, within two (2) Business Days of the date of receipt of notice) notify the other Party in writing of, and shall provide the other Party with copies of, any correspondence and other documentation received or prepared by such Party in connection with any of the following events:
  - (i) receipt of a material regulatory letter, warning letter, Form 483, or similar item, from any Regulatory Authority directed to the Manufacture, packaging, and/or storage of Product, any Licensee facility or any contract Manufacturing facility associated with Licensee's supply of Product;
  - (ii) any recall or correction of any batch of Product; and
  - (iii) any regulatory comments relating to Product requiring a response or action by a Party.
- (b) Regulatory Correspondence requiring a Licensor response. In the event that Licensor receives any material regulatory letter or comments from any Regulatory Authority directed to its development or Manufacture of Product requiring a response or action by Licensor, including, but not limited to, receipt of a Form 483 or a warning letter, Licensee (as applicable) will promptly provide Licensor with any data or information in Licensee's possession that is required by Licensor in preparing any response relating to Licensor's development of such Product, and will cooperate with Licensor's reasonable requests related to Licensor preparing such response.
- (c) Regulatory Correspondence requiring a Licensee response. In the event that Licensee receives any material regulatory letter or comments from any Regulatory Authority relating to the development or Manufacture of Product, Licensor (as applicable) will promptly provide Licensee with any data or information required by Licensee in preparing any response relating to Licensor's development or Manufacture of Product, and will cooperate fully with Licensee in preparing such response. To the extent reasonably practicable (subject to the time a response is mandated), Licensee shall provide Licensor with a copy of each such response for Licensor's review and comment at least two (2) Business Days prior to Licensee's submission of the response.

7.13 Regulatory updates. During the Term, each Party will keep the other Party generally apprised of the status of any Regulatory Submissions related to Product inside and outside the Territory. Licensee shall immediately notify Licensor in writing upon receipt by Licensee of any Regulatory Approval to market Product in the Territory. Licensor shall immediately notify Licensee in writing upon receipt by Licensor of any Regulatory Approvals to market Product outside the Territory.

## 8. Financial Provisions

### Upfront fee

8.1 The Licensee will pay to the Licensor an upfront fee of twenty four million USD (US\$24,000,000) within five (5) days of the Effective Date.

### **Regulatory Milestone Payment**

8.2 The Licensee will pay to the Licensor a milestone payment of five million USD (US\$5,000,000) within thirty (30) days of the grant of Regulatory Approval in the USA for the Product for the Pediatric Indication.

### **Commercial Milestone Payments**

8.3 The following one-time payments shall be paid by the Licensee to the Licensor in USD sixty (60) days following first achievement of the following Commercialization milestone events:

- (a) cumulative Net Sales of Product in a Calendar Year reaching twenty five million dollars: Commercialization payment of four million dollars (US\$4,000,000);
- (b) cumulative Net Sales of Product in a Calendar Year reaching fifty million dollars: Commercialization payment of ten million dollars (US\$10,000,000);
- (c) cumulative Net Sales of Product in a Calendar Year reaching one hundred million dollars: Commercialization payment of twenty million dollars (US\$20,000,000);
- (d) cumulative Net Sales of Product in a Calendar Year reaching two hundred million dollars: Commercialization payment of forty million dollars (US\$40,000,000); and
- (e) cumulative Net Sales of Product in a Calendar Year reaching five hundred million dollars: Commercialization payment of one hundred million dollars (US\$100,000,000).

8.4 Each of the milestone payments subject to Sections 8.2 and 8.3, shall only be payable by the Licensee upon the first occurrence of the applicable event whenever it occurs. Upon the occurrence of the applicable event the milestone payment shall be payable even if more than one occurs in a Calendar Year. Such milestone payments are non-refundable in any circumstances whatsoever and are not creditable against the royalties due under Section 8.6.

8.5 The Licensee shall report the occurrence of each milestone event under Sections 8.2 and 8.3 to the Licensor within forty-five (45) days of its occurrence and at the same time shall make the milestone payment to the Licensor for which Sections 8.2 and/or 8.3 provides.

### **Royalties; Taxes**

8.6 The Licensee will pay to the Licensor royalties during the Royalty Term as set forth below:

Royalty = **A** + **B** where:

**A** equals fifteen per cent (15%) of that portion of Net Sales of Product in the Territory, which, during the Calendar Year in question, is less than or equal to seventy five million USD (US\$75,000,000); and

**B** equals eighteen per cent (18%) of that portion of Net Sales of Product in the Territory, which, during the Calendar Year in question, is greater than seventy five million USD (US\$75,000,000).

If, in the United States, if data exclusivity remains following expiry of the last Valid Claim in a United States patent or patent application, then the royalty rate calculated above shall be reduced to (A +B)/2 (and the remaining royalty payments shall be payable as a royalty on Know-How). In any country in the Territory where, during the Royalty Term, there are no Valid Claims of Licensor Patent Rights or data exclusivity protection for the Product for a particular Existing Indication, the royalty rate shall be reduced to five percent (5%) (and the

remaining royalty payments shall be payable as a royalty on Know-How) irrespective of the amount of Net Sales of Product.

- 8.7 To the extent that a New Indication is Developed and Commercialized by or on behalf of Licensee following the Effective Date then royalties will be payable upon the Net Sales of Product for such New Indication in accordance with Section 8.6. For these purposes:
- (a) the time periods referred to in the definitions of 'Term' and 'Royalty Term' shall relate to the New Indication(s) and not the Existing Indication (and related definitions, including that of 'First Commercial Sale Date' shall be read accordingly);
  - (b) the provisions of Section 8.6 shall otherwise apply mutatis mutandis to Net Sales derived from such New Indication; and
  - (c) Net Sales of the Product for such New Indication shall be included in the calculation of the 'Commercialization Milestone Payments'.
- 8.8 For the avoidance of doubt, any royalties or other payments owed by Licensor under any agreement to which Licensor or any Affiliate of Licensor is a party, including the Exploitation Agreement, shall be the sole responsibility of Licensor.
- 8.9 All royalties due to the Licensor under this Agreement shall be calculated and payable on a Calendar Quarter basis, and shall be paid by the Licensee to the Licensor in USD within sixty (60) days following the end of each of 31 March, 30 June, 30 September and 31 December in each year (“**60 day Period**” and “**Quarter End**” respectively). Within sixty (60) days of each Quarter End the Licensee shall send to the Licensor a written report setting out (i) Product by Product and country by country the amount of Net Sales in such country during such quarter expressed in the local currency of that country and a breakdown of whether these relate to the Adult Indication, Pediatric Indication or New Indication; and (ii) the amount of the royalties due to the Licensor in relation to such Quarter. Any sales in a country other than the U.S., for purposes of determining the Net Sales amount shall be calculated using the average rate of exchange of the currency of such country for the applicable calendar month, as published in *The Wall Street Journal*, New York edition.
- 8.10 **Taxes.**
- (a) Licensor shall be liable for all income and other Taxes (including interest) imposed upon any payments made by Licensee to Licensor under this Agreement (“**Agreement Payments**”). If applicable Laws, rules or regulations require the withholding of Taxes, Licensee shall make such withholding payments and shall subtract the amount thereof from the Agreement Payments. Licensee shall submit to Licensor appropriate proof of payment of the withheld Taxes as well as the official receipts within a reasonable period of time. Licensee shall provide Licensor reasonable assistance in order to allow Licensor to obtain the benefit of any present or future treaty against double taxation which may apply to the Agreement Payments.
  - (b) Licensee shall bear and be responsible for and pay all applicable Taxes related to:
    - (i) the transfer to Licensee of the Product Registrations and the license rights granted under this Agreement; and
    - (ii) the Development and Commercialization by Licensee of the Product in the Territory other than for the PIP.
- 8.11 Each Party and its Affiliates shall use all reasonable efforts to maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the amount to be reimbursed with respect to Development Costs, or other amounts to be paid,

reimbursed, credited, offset or shared hereunder incurred or generated (as applicable) by such Party's or Affiliate's achievement of sales milestones, royalty payments and other compensation or reimbursement payable under this Agreement. Upon reasonable prior notice, such records shall be open during regular business hours for a period of three (3) years from the creation of individual records for examination at the auditing Party's expense, and not more often than once each Calendar Year, by an independent certified public accountant selected by the auditing Party and reasonably acceptable to the audited Party or Affiliate for the sole purpose of verifying for the auditing Party the accuracy of the financial statements or reports or sales milestone notices furnished by the audited Party or Affiliate pursuant to this Agreement or of any payments made, or required to be made, by or to the audited Party or Affiliate to the other pursuant to this Agreement. Any such auditor shall not disclose the audited Party's or Affiliate's confidential information to the auditing Party, but shall, instead, report that there was or was not a discrepancy uncovered by the audit and if such a discrepancy was uncovered, the amount and direction of it. Any amounts shown to be owed but unpaid, or overpaid and in need of reimbursement, shall be paid or refunded (as the case may be) within thirty (30) days after the accountant's report, plus interest (as set forth in Section 8.13) from the original due date (unless challenged in good faith by the audited Party, in which case any undisputed portion shall be paid in accordance with the foregoing timetable, any dispute with respect to such challenge shall be resolved in accordance with Section 16, any remaining disputed portion shall be paid within thirty (30) days after resolution of the dispute, and interest shall accrue (as set forth in Section 8.13) with respect to the disputed portion from the original due date). The auditing Party shall bear the full cost of such audit unless such audit reveals an overpayment to, or an underpayment by, the audited Party or Affiliate that resulted from a discrepancy in a report that the audited Party or Affiliate provided to the other Party during the applicable audit period, which underpayment or overpayment was more than ten percent (10%) of the amount set forth in such report, in which case the audited Party or Affiliate shall bear the full cost of such audit. Each Party, at the request of the other Party, shall make available to the other Party the results of any audit performed by the non-requesting Party on such non-requesting Party's Sub-licensees hereunder.

- 8.12 All payments made to either Party under this Agreement shall be made by wire transfer to the account of such Party.
- 8.13 If a Party fails to make any payment due to the other Party hereunder on the due date for payment and the payment is not in dispute between the Parties, without prejudice to the other right or remedy available to the other Party, the Party owed such Payment shall be entitled to charge the Licensee interest (both before and after judgment) on the amount unpaid at the annual rate of LIBOR plus two per cent (2%) calculated on a daily basis until payment in full is made without prejudice to the Licensor's right to receive payment on the due date.

## **9. Trademarks**

- 9.1 The Licensee shall have the option to use the Licensor Trademark in relation to the Commercialization of Product in the Territory. The use by the Licensee of the Licensor Trademark shall not constitute or imply any assignment or transfer of the Licensor Trademark or any goodwill associated with it. Any goodwill accrued in connection with the use of the Licensor Trademark shall accrue solely to the benefit of the Licensor. The Licensee shall ensure that each reference to and use of the Licensor Trade Mark by the Licensee in Promotional Materials is acceptable to the Licensor and is accompanied by an acknowledgement that the Licensor Trade Mark is owned by the Licensor and used by the Licensee under license.



- 9.2 The Licensee shall not challenge the validity of the Licensor Trademark and shall not aid or assist third parties to do so. Whatever use the Licensee makes of the Licensor Trademark shall inure to the sole and exclusive benefit of the Product in accordance with this Agreement.
- 9.3 Except as required by applicable Law, neither Party shall use the other Party's corporate name, or use any Trademarks of the other Party (other than the Licensor Trademark) in connection with any Promotional Materials or publication without the other Party's prior written consent which shall not be unreasonably withheld. The above restriction will not apply to representations that the Licensee is the exclusive licensee of the Licensor for the Product in the Territory.
- 9.4 In the case of infringement or misuse of the Licensor Trademark, if the Licensor fails to initiate proceedings within three (3) months of the Licensee's notification thereof, the Licensee may give the Licensor notice requesting the Licensor to take such proceedings within thirty (30) days of the date of this second notice. If the Licensor fails to initiate such proceedings within such period, the Licensee shall be entitled to do so at its own cost and expense in which case it shall have sole conduct of any claim or proceedings. The Licensor shall, and shall procure that its Affiliates shall, reasonably assist and cooperate with the Licensee in any such claim, provided that the Licensee shall reimburse the Licensor for all reasonable out-of-pocket costs and expenses, if any, relating to such assistance and cooperation. Such reasonable assistance and cooperation of the Licensor and its Affiliates shall include but not be limited to the execution of such documents and the performance of such other acts, including being joined as a party to any proceedings, as may be reasonably required to facilitate such claim, including but not limited to such documents and acts that may, upon the Licensee's request, be required for the registration of the Licensee as exclusive licensee of the Licensor Trademark in the Territory at the trademark office in the relevant countries of the Territory. The Licensee shall have sole right to settle such proceedings provided such settlement does not directly or indirectly adversely affect the Licensor's rights and interests outside of the Territory, and shall be entitled to retain any financial payment awarded in such proceedings or agreed in any such settlement for its own account.

#### **10. Intellectual Property (except Trademarks)**

- 10.1 For the purposes of this Section 10, the "Licensor IPR Package" shall exclude the Licensor Trademark and the "Licensee IPR Package" shall exclude Trademarks.
- 10.2 Except as expressly set forth in this Agreement, nothing in this Agreement transfers ownership of the Licensor IPR Package to the Licensee.
- 10.3 The Licensee shall own all the Licensee IPR Package. The Licensee shall use Commercially Reasonable Efforts to procure that, under the terms of any appointment of a Sub-licensee, all Materials, Know How and Commercial Information generated or developed by or upon their behalf shall be Controlled by the Licensee.
- 10.4 The Licensee grants to the Licensor a perpetual, exclusive, sub-licensable, fully paid-up royalty free right and license to use the Licensee IPR Package outside the Territory for Development, Manufacture and Commercialization of the Product outside the Territory other than for a New Indication, which license rights are covered solely by the license set forth in Section 5.9.
- 10.5 The Licensor shall be solely responsible at its own cost and expense for the filing, prosecution, maintenance and/or defense of the Licensor Patent Rights in the Territory using reasonable efforts to prosecute all patent applications forming part of the Licensor Patent Rights to grant in the USA, including conducting any necessary or desirable claims or proceedings (including but not limited to any interference, reissue or re-examination or opposition or revocation proceedings). The Licensor shall keep the Licensee reasonably

informed of all filings made for the Licensor Patent Rights in the Territory including sending the Licensee a copy of any such filing and otherwise shall keep the Licensee informed of all material developments in relation to such Licensor Patent Rights and shall, upon the Licensee's request, provide the Licensee with copies of relevant Documents related to the filing, prosecution and maintenance of such Licensor Patent Rights. The Licensor shall give full consideration of, and absent a compelling reason to the contrary shall adopt any reasonable representation made by the Licensee in relation to the prosecution of the Licensor Patent Rights in the Territory when making any submission to a patent office (including the scope of foreign filings) and in the conduct of any proceedings in relation to such Licensor Patent Rights.

- 10.6 In the event that the Licensor declines to file or, having filed, declines to further prosecute, maintain and/or defend any pending Licensor Patent Rights in any country of the Territory, the Licensor shall provide the Licensee with written notice thereof. In the case where the Licensor has filed but is declining to further prosecute or maintain the Licensor Patent Rights, such notice shall be given at least thirty (30) days prior to the expiration of any official substantive deadline relating to such activities. In any of such circumstances the Licensee shall have the right to decide that the Licensee should file, continue to file, prosecute and maintain such Licensor Patent Rights and in such case the Licensee shall give written notice to the Licensor. The Licensor shall upon receipt of any such notice from the Licensee transfer to the Licensor all its files relating to the relevant Licensor Patent Rights and at the Licensee's cost and expense execute any documents to otherwise transfer control of such filing, prosecution and maintenance to the Licensor and thereafter the Licensee shall be responsible for the cost and expense of prosecuting and maintaining such Licensor Patent Rights. In addition the Licensor shall assign such Licensor Patent Rights to the Licensee for zero or nominal consideration, whereupon they shall not be part of any license rights granted to or through Licensor hereunder.
- 10.7 The Licensee shall be responsible at its own cost and expense and in its sole discretion for the filing, prosecution, maintenance and/or defense of Patent Rights in respect of inventions within Know How developed by the Licensee, its Affiliates or Sub-licensees relating to or potentially covering Product (the "**Licensee Patents Rights**"). The Licensee shall keep the Licensor informed of all material developments in relation to the Licensee Patent Rights and shall, upon the Licensor's request, provide the Licensor with copies of relevant documents related to the filing, prosecution and maintenance of the Licensee Patent Rights. The Licensee shall consider in good faith any reasonable representation made by the Licensor in relation to the prosecution of Patent Rights within the Licensee Patent Rights when making any submission to a patent office and in the conduct of any proceedings in relation to such Licensee Patent Rights in Europe.
- 10.8 In the event that the Licensee declines to file or, having filed, declines to further prosecute, maintain and/or defend any pending Licensee Patent Rights in any country of the Territory or Europe, the Licensee shall provide the Licensor with written notice thereof. In the case where the Licensee has filed but is declining to further prosecute or maintain such Licensee Patent Rights, such notice shall be given at least thirty (30) days prior to the expiration of any official substantive deadline relating to such activities. In any of such circumstances the Licensor shall have the right to decide that the Licensor should file, continue to file or prosecute such Licensee Patent Rights and in such case the Licensor shall give written notice to the Licensee. The Licensee shall upon receipt of any such notice from the Licensor transfer to the Licensor all its files relating to such Licensee Patent Rights and execute any documents necessary to transfer control of such filing, prosecution and maintenance to the Licensor. In addition the Licensee shall assign such Licensee Patent Rights to the Licensor for zero or nominal consideration, whereupon they shall not be part of any license rights granted to or through Licensee hereunder.

- 10.9 If either Party becomes aware of any actual, threatened or suspected infringement or misuse by a Third Party of any of the Licensor IPR Package relating to the Product in the Territory, it shall promptly inform the other Party in writing of all available evidence and details available to it concerning said infringement (the “**Infringement Notice**”). With respect to any actual, threatened or suspected infringement, the Licensee shall have the right, but not an obligation, at its own cost and expense to bring, defend or maintain any suit or action, in which case it shall have sole conduct of any claim or proceedings including any counterclaim for invalidity or unenforceability or any declaratory judgment action. The Licensor shall provide all necessary assistance to the Licensee in relation to such proceedings (including being joined as a party to any such proceedings) and the Licensee shall on demand by the Licensor indemnify the Licensor against reasonable costs of such activity that were approved by Licensee in advance in writing, provided that if the Licensor elects to be separately represented (which shall be at the Licensor's discretion), such separate representation shall be at the Licensor's sole cost and expense. The Licensee shall retain any award of costs and damages made or settlement sum paid, after recovery by the Licensor of its actual out-of-pocket costs and expenses. The Licensee will not (i) enter into any settlement of or make admission or stipulation in any such proceedings that admits any liability of Licensor or materially negatively impacts Licensor's rights hereunder or in the Licensor IPR Package without the Licensor's prior written consent, not to be unreasonably withheld or delayed.
- 10.10 If under Section 10.9, the Licensee fails to take any such proceedings within 90 days of any Infringement Notice, then the Licensor shall have the right, but not the obligation, upon 20 days prior notice to the Licensee at the Licensor's expense to bring, defend or maintain any suit or action or to control the conduct thereof against any actual, threatened or suspected infringement. The Licensee shall provide all necessary assistance to the Licensor in relation to such proceedings (including being joined as a party to any such proceedings). In any such action brought by the Licensor, the Licensor shall retain any award of costs and damages made or settlement sum paid, after recovery by the Licensee of its actual out-of-pocket costs and expenses. The Licensor will not enter into any settlement of or make admission or stipulation in any such proceedings that admits any liability of Licensee or materially negatively impacts Licensee's rights hereunder or in the Licensor IPR Package without the Licensee's prior written consent, not to be unreasonably withheld or delayed.
- 10.11 If either Party or its Affiliates receives formal notice from a Third Party that the Development, Manufacture or Commercialization of Product in the Territory under this Agreement infringes or otherwise violates the intellectual property rights of such Third Party in the Territory, then such Party must promptly notify the other Party in writing of this allegation. As soon as reasonably practicable after the receipt of such notice and at all times thereafter, the Parties will meet and consider the appropriate course of action with respect to such allegation of infringement. In any such instance, each Party will at its own cost, expense and liability, have the right to defend any action naming it; however, the Parties will at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use good faith efforts mutually to agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning a potential defense and/or settlement of any such claim. The rights and obligations in this Section 10.11 will apply even if only one Party defends any such claimed infringement action commenced by a Third Party. Neither Party will enter into any settlement of or make admission or stipulation in any such proceedings that admits any liability of the other Party or materially negatively impacts such other Party's rights hereunder or in the Licensor IPR Package without such other Party's prior written consent, not to be unreasonably withheld or delayed.
- 10.12 The Parties agree to cooperate in an effort to avoid loss of any of the Patent Rights forming part of the Licensor IPR Package or Licensee IPR Package including by executing any

documents as may be reasonably required. In particular, the Parties shall cooperate with each other in obtaining patent term extension or restoration or supplemental protection certificate (“**Patent Term Extensions**”) or their equivalents in any country of the Territory. Licensee shall have the sole right and shall use Commercially Reasonable Efforts to seek any available Patent Term Extensions in the Territory.

## 11. Confidentiality

- 11.1 Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, during the Term and for seven (7) years thereafter, it shall, and shall cause its Affiliates, to keep confidential and not publish or otherwise disclose to any Third Party, and not use for any purpose other than as provided for in this Agreement, any Confidential Information of the other Party or any of its Affiliates, provided that each Party and its Affiliates may disclose the Confidential Information of the other Party or its Affiliates to the receiving Party's and its Affiliates' officers, directors, employees, agents and advisors who in each case are bound by commercially reasonable obligations of confidentiality with respect to the use and disclosure of such Confidential Information. Notwithstanding the foregoing, Confidential Information of a Party or its Affiliate shall exclude that portion of such information or materials that the receiving Party (or the receiving Party's Affiliate) can demonstrate by competent written proof:
- (a) was generally available in the public domain at the time it was disclosed to the receiving party or subsequently came into the public domain through no fault of the receiving party; or
  - (b) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party or is subsequently disclosed to the receiving Party or its Affiliate by a Third Party without obligations of confidentiality with respect thereto.
  - (c) is independently discovered or developed by the receiving Party or its Affiliate without the aid, application, or use of Confidential Information.
- 11.2 For clarity, specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Recipient Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Recipient Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Recipient Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Recipient Party unless the combination is in the public domain or in the possession of the Recipient Party.
- 11.3 Notwithstanding the above obligations of confidentiality and non-use a Recipient Party may disclose Confidential Information:
- (a) In responding to a valid order of a court of competent jurisdiction or other competent authority; provided that the receiving Party shall, to the extent reasonably practicable under the circumstances, first have given to the disclosing Party notice and a reasonable opportunity to quash the order or obtain a protective order requiring that the Confidential Information be held in confidence or used only for the purpose for which the order was issued; and provided further that if such order is not quashed or a protective order is not obtained, the Confidential Information disclosed shall be limited to the information that is legally required to be disclosed;

- (b) to a Regulatory Authority as reasonably necessary to obtain Regulatory Approval in a particular jurisdiction to the extent consistent with the licenses granted under terms of this Agreement; and
  - (c) In complying with Applicable Law, provided that to the extent such disclosure is required to comply with a Legal Requirement, including to the extent such disclosure is required in publicly filed financial statements or other public statements under rules governing a stock exchange; provided, to the extent possible bearing in mind such Legal Requirements and subject to the next subsequent sentence of this Section (c), such Party shall provide the other Party with a copy of the proposed text of such statements or disclosure five (5) days in advance of the date on which the disclosure is to be made to enable the other Party to review and provide comments, unless a shorter review time is agreed. [If the compliance with a Legal Requirement requires filing of this Agreement, the filing Party shall to the extent possible seek confidential treatment of portions of this Agreement from the relevant Government Authority and shall provide the other Party with a copy of the proposed filings at least five (5) days prior to filing for the other Party to review any such proposed filing.]<sup>2</sup> Each Party agrees that it will obtain its own legal advice with regard to its compliance with Legal Requirements and will not rely on any statements made by the other Party relating to such Legal Requirements;
  - (d) (i) to its actual or potential investment bankers; (ii) to existing and potential investors in connection with an offering or placement of securities for purposes of obtaining financing for its business and to actual and prospective lenders for the purpose of obtaining financing for its business; and (iii) to a bona fide potential acquirer or merger partner for the purposes of evaluating entering into a merger or acquisition, provided, however, any such persons must be obligated to substantially the same extent as set forth in Section 11 to hold in confidence and not make use of such Confidential Information for any purpose other than those permitted by this Agreement; and
  - (e) to its legal advisers for the purpose of seeking advice.
- 11.4 Nothing in this Section 11 restricts either Party from using or disclosing any of its own Confidential Information for any purpose whatsoever, subject always to the rights granted in this Agreement and provided always that the Licensee shall not under any circumstances publish the results of any clinical studies on Product without the prior written approval of the Licensor.
- 11.5 Following execution of this Agreement, each Party shall release a separate press release regarding this transaction and the wording of each press release shall be pre-agreed by the other Party. Other than such press releases, save as permitted in Section 11.3 neither Party shall make any public announcement or statement to the public containing Confidential Information without the prior written consent of the other. No such public announcements or statements shall be made without the prior review and consent of the appropriate individual designated for the purpose by the other Party

### **Publicity**

- 11.6 Licensor, along with trial investigators, has submitted for publication a draft publication regarding the pivotal trial for the NDA Product. Promptly upon Licensor's receipt thereof, Licensor agrees to provide a copy to Licensee a of all correspondence and editorial feedback regarding such publication for Licensee's review and comment, which comments Licensor

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<sup>2</sup> Note to draft: Parties to discuss whether or not the agreement will be afforded confidential treatment.

shall accept and incorporate into such publication prior to any resubmission or finalization thereof.

- 11.7 Subject to Section 7.6, other than with respect to the publication regarding the pivotal trial, the Parties shall each provide the other Party with copies of any publications or meeting abstracts relating to a Product for such other Party's review and comment at least thirty (30) days prior to submitting such publication to any journal or submitting or presenting it or an abstract thereof at any congress, conference or other public meeting, and each Party agrees to take reasonably into account any comments received from the other Party thereon.
- 11.8 Following final submission of the publication for the pivotal trial, (a) Licensor and its Affiliates and Sub-licensees shall refrain from engaging any study investigator, practitioners, opinion leaders, patient advocates and payers in the Territory regarding the Product for any reason, including scientific discourse, without the prior consent of Licensee (such consent not to be unreasonably withheld, delayed or conditioned); and (b) Licensee and its Affiliates and Sub-licensees shall refrain from engaging any study investigator, practitioners, opinion leaders, patient advocates and payers outside the Territory regarding the Product for any reason, including scientific discourse, without the prior consent of the Licensor (such consent not to be unreasonably withheld, delayed or conditioned).

## **12. Representations, warranties and covenants**

- 12.1 Mutual Representations and Warranties. Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as of the Effective Date as follows:
- (a) Corporate Existence and Power. It is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant or receive, as the case may be, the licenses granted and received hereunder.
- (b) Authority and Binding Agreement. It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.
- ( c ) No Conflict. It is not a party to and will not enter into any agreement that would prevent it from granting the rights or exclusivity granted or intended to be granted to the other Party under this Agreement or performing its obligations under this Agreement.
- (d) No Debarment. Such Party is not debarred, has not been convicted, and is not subject to debarment or conviction pursuant to Section 306 of the Federal Food, Drug and Cosmetics Act. To such Party's Knowledge, in the course of the Development of the API or Products, such Party has not used prior to the Effective Date and shall not use, during the Term, any employee, agent or independent contractor who has been debarred by any Regulatory Authority, or, to the best of such Party's Knowledge, is the subject of debarment proceedings by a Regulatory Authority or has been convicted pursuant to Section 306 of the FD&C Act.
- (e) Anti-Corruption. Such Party, its Affiliates and their respective directors, officers, employees, agents or other persons or entities acting on its behalf (all the foregoing collectively "**Representatives**") have conducted and will conduct their businesses as

they relate to this Agreement, in compliance with Anti-Bribery Laws. Without limiting the generality of the foregoing, such Party represents and warrants that it has and will have necessary procedures in place to prevent bribery and corrupt conduct by it and its Representatives in connection with the Development, Manufacture and Commercialization of the Product.

12.2 Representations, Warranties and Covenants by Licensor. Licensor hereby represents, warrants and covenants to Licensee, as of the Effective Date, as follows, except as set forth otherwise in the Disclosure Schedule:

- (a) Licensor owns or has a valid right to grant the licenses hereunder to the Licensor IPR Package existing as of the Effective Date, including the NDA and Licensor Patent Rights, and Licensor has the right to make the assignments and grant the licenses to Licensee as purported to be granted pursuant to this Agreement. Neither Licensor nor any of its Affiliates has entered into any agreement granting any right, interest or claim in or to, any Licensor Patent Rights or Licensor Know-How to any Third Party (other than pursuant to the CMO Contracts included in the Data Room) that would conflict with the licenses to Licensee as purported to be granted pursuant to this Agreement.
- (b) All Licensor Patent Rights are listed in Schedule 7. All Licensor Patent Rights are subsisting and are not invalid or unenforceable, in whole or in part, are being prosecuted in the patent offices indicated in Schedule 7 in accordance with Applicable Law, and all applicable fees have been paid on or before the Effective Date. The Licensor Patent Rights represent all Patent Rights within Licensor' or its Affiliates' ownership or Control that Licensor reasonably believes include claims covering the making, using, and composition of matter of the API or the Products, or the Development, Manufacture or Commercialization thereof, as of the Effective Date. Licensor has properly recorded in the relevant U.S. and Canadian patent offices the assignments, or other necessary documents, supporting its legal title to the Licensor Patent Rights. To the Licensor' Knowledge, Licensor and its Affiliates have presented, or will present prior to the pertinent patent office deadlines, all relevant references, documents, or information of which it and the inventors are aware to the relevant patent examiner at the pertinent patent office, in connection with the prosecution of the pending patent applications included in the Licensor Patent Rights.
- (c) There are no claims, judgments, or settlements against, or amounts with respect thereto, owed by Licensor or any of its Affiliates relating to the Product Registrations, the Licensor Patent Rights, or the Licensor Know-How. No claim or litigation has been brought or threatened in writing by any Person against Licensor alleging, and Licensor has no Knowledge of any reasonable basis for any such claim or allegation, whether or not asserted, that (i) the Licensor Patent Rights or the Licensor Know-How are invalid or unenforceable, or (ii) the Product Registrations, the Licensor Patent Rights, or the Licensor Know-How, or the disclosing, copying, making, assigning, or licensing of the Product Registrations, the Licensor Patent Rights, or the Licensor Know-How, or the Development, Manufacture, Commercialization or other exploitation of the API or Products as contemplated herein, does or will violate, infringe, misappropriate or otherwise conflict or interfere with, any Patent or other intellectual property or proprietary right of any Third Party.
- (d) To Licensor's Knowledge, no Person is infringing or threatening to infringe or misappropriating or threatening to misappropriate the Licensor Patent Rights, the Licensor Know-How, or the Product Registrations. To Licensor' Knowledge, there are no activities by Third Parties that would constitute infringement or misappropriation of the Licensor Technology (in the case of pending claims, evaluating them as if issued).

- (e) Each Person who, to Licensor's Knowledge, has or has had any rights in or to any Licensor Patent Rights or any Licensor Know-How, has assigned and has executed an agreement assigning its entire right, title, and interest in and to such Licensor Patent Rights and Licensor Know-How to Licensor. To Licensor's Knowledge, no current officer, employee, agent, or consultant of Licensor or any of its Affiliates is in violation of any term of any assignment or other agreement regarding the protection of Patents or other intellectual property or proprietary information of Licensor or such Affiliate or of any employment contract relating to the relationship of any such Person with Licensor.
- (f) None of the intellectual property rights licensed hereunder by Licensor to Licensee and existing as of the Effective Date are owned or Controlled in whole or in part by any Third Party other than the rights under the CMO Contracts included in the Data Room.
- (g) With respect to those portions of the Licensor Know-How the confidentiality of which is material to the Commercialization of Products, such portions of the Licensor Know-How have been kept confidential or have been disclosed to Third Parties only under terms of confidentiality. To Licensor's Knowledge, no breach of such confidentiality has been committed by any Third Party.
- (h) There are no pending, and to Licensor's Knowledge there are no threatened, actions, claims, demands, suits, proceedings, arbitrations, grievances, citations, summonses, subpoenas, inquiries or investigations of any nature, civil, criminal, regulatory or otherwise, in law or in equity, against Licensor or any of its Affiliates or, to the Knowledge of Licensor, pending or threatened against any Third Party, in each case, relating to the transactions contemplated by this Agreement.
- (i) Other than the Exploitation Agreement, Licensor has not entered into any agreement with a Third Party pursuant to which Licensor may be obligated to pay a royalty or other consideration with respect to sales of a Product, nor is there any agreement that the Licensor is a party to which conflicts with or restricts in any material manner, the rights assigned or licensed by Licensor to Licensee hereunder.
- (j) Licensor is not, and to Licensor's Knowledge no other party to such agreement is, in breach of any obligations owed under the Exploitation Agreement.
- (k) Licensor has provided or made available to Licensee, prior to the Effective Date, true, complete, and correct copies of all material adverse information with respect to the safety and efficacy of the API and Product which is known to Licensor.
- (l) To Licensor's Knowledge, Licensor and its Affiliates and licensees have generated, prepared, maintained, and retained all Product Registrations that are required to be maintained or retained pursuant to and in accordance with applicable Law, and all such information is true, complete and correct and what it purports to be.
- (m) Licensor and its Affiliates have conducted, and to Licensor's Knowledge, their respective contractors licensees and consultants have conducted, all Development of the API or the Products that they have conducted prior to the Effective Date in accordance with applicable Law. To Licensor's Knowledge, Licensor has conducted, and has caused its licensees, contractors and consultants to conduct, any and all pre-clinical and clinical studies related to the API and Products in accordance with Applicable Law. To Licensor's Knowledge, Licensor and its Affiliates and licensees have employed (and, with respect to such tests and studies that Licensor will perform, will employ) Persons with appropriate education, knowledge and experience to conduct and to oversee the conduct of the PIP.



- (n) To Licensor's Knowledge, neither Licensor nor any of its Affiliates or licensees, nor any of its or their respective officers, employees, or agents has made an untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to the Development of the API or the Products, failed to disclose a material fact required to be disclosed to the FDA or any other Regulatory Authority with respect to the Development of the API or the Products, or committed an act, made a statement, or failed to make a statement with respect to the Development of the API or the Products that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous Laws or policies in the Territory.
- (o) The inventions claimed in the Licensor Patent Rights (i) were not conceived or made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof, (ii) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(f), and (iii) are not otherwise subject to the provisions of the Bayh-Dole Act.

12.3 Each Party undertakes to inform the other as soon as it becomes aware that any of the following events are reasonably likely to occur:

- (a) cessation of conducting its business or trading;
- (b) sale of all or any material portion of its assets or business;
- (c) entry of a judgment against such Party in an amount that exceeds US\$100,000 or the entry of any declaratory, injunctive or other equitable remedy or court order that would materially impair such Party's ability to continue to conduct its business or to perform its obligations under this Agreement;
- (d) any attachment (including prejudgment attachment) of any material assets;
- (e) failure to pay any wages to such Party's employees when due (except to the extent subject to a bona fide dispute);
- (f) a financial institution which lends money to such Party declaring an event of default by the company under any bank loan or other debt instrument;
- (g) entry by the Party into any restructuring or workout agreement, or similar agreement, relating to any material indebtedness (being debt exceeding US\$100,000); or
- (h) loss of any permits, licenses or governmental authorizations that are reasonably necessary in order for the Party to continue to engage in its current business.

12.4 Except as expressly set forth herein, each Party expressly disclaims and excludes any and all representations and warranties, express, implied, statutory or otherwise, including without limitation the warranties of merchantability and fitness for a particular purpose.

12.5 EXCEPT WITH RESPECT TO (1) AMOUNTS OWED TO A THIRD PARTY WHICH AMOUNTS FALL WITHIN THE INDEMNIFICATION OBLIGATIONS OF A PARTY UNDER SECTIONS 13.1 AND 13.2, (2) DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS HEREUNDER, OR (3) DAMAGES AVAILABLE IN THE CASE OF A PARTY'S FRAUD, GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY

BREACH OF THIS AGREEMENT OR ANY TORT CLAIMS ARISING HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

12.6 Nothing in this Agreement shall be taken to exclude or limit either Party's liability to the extent that such liability cannot be excluded or limited in Law, including for death or personal injury, fraud or fraudulent misrepresentation.

12.7 The Parties agree that:

- (a) Licensor shall use all reasonable efforts to negotiate and execute, as soon as reasonably practicable after the Effective Date, an amendment to the Exploitation Agreement which provides that upon the termination of the Exploitation Agreement The Centre National De La Recherche Scientifique will be obligated to enter into an agreement with the Licensee, in respect of the Territory, on substantially the same terms as those provided to the Licensor under the Exploitation Agreement including in respect of royalty payments; and
- (b) the Licensee shall use all reasonable efforts to assist the Licensor in respect of its obligation at Section 12.7(a) above,

and it is agreed that the Licensor shall not be obligated pursuant to this Section 12.7 to agree to any increase in the royalties payable under the Exploitation Agreement.

### **13. Indemnity and insurance cover**

13.1 Indemnification by Licensee. Subject to Sections 13.3 and 13.4, Licensee shall indemnify, defend and hold Licensor, its Affiliates, and their respective directors, officers, employees consultants, contractors, sub-licensees and agents (collectively, the "**Licensor Indemnitees**") harmless from and against any and all claims, suits, proceedings or causes of action ("**Claims**") brought against such Licensor Indemnitee, including any damages or other amounts payable with respect to such Claims, as well as any reasonable attorneys' fees and costs of litigation incurred as to any such Claim until the indemnifying Party has acknowledged that it will provide indemnification hereunder with respect to such Claim as provided below (collectively, "**Damages**"), in each case to the extent resulting from or based on:

- (a) any development work done by Licensee for a Product, or any sale, use, importation, storage, handling, distribution or offer for sale or sale of Product by Licensee or any of its Affiliates or sub-licensees;
- (b) Licensee's breach of this Agreement or any representation or warranty made by Licensee herein;
- (c) the willful misconduct of, or violation of applicable Law by, Licensee, its Affiliates or Sub-licensees, or their respective employees, contractors or agents in the performance of this Agreement; and/or (d) breach of a contractual or fiduciary obligation owed by Licensee (including without limitation misappropriation of trade secrets).
- (d) infringement or misappropriation with respect to the Development, Manufacture, or Commercialization of the Product in the Territory under the Licensee IPR Package or Licensee Trademarks.

and the foregoing indemnity obligation shall not apply to the extent such Claims or Damages result from any matter for which Licensor is required to indemnify Licensee.

13.2 Indemnification by Licensor. Subject to Sections 13.3 and 13.4, Licensor shall indemnify, defend and hold Licensee, its Affiliates, and their respective directors, officers, employees

consultants, contractors, sub-licensees and agents (collectively, the “**Licensee Indemnitees**”) harmless from and against any and all Third Party Claims brought against such Licensee Indemnitee, including any Damages resulting therefrom, in each case to the extent resulting from or based on:

- (a) any development work done by Licensor for a Product, or any sale, use, importation, storage, handling, distribution or offer for sale or sale of Product by Licensor or any of its Affiliates or sub-licensees;
- (b) Licensor's breach of this Agreement or any representation or warranty made by Licensor therein;
- (c) the willful misconduct of, or violation of applicable Law by, Licensor, its Affiliates or sub-licensees, or their respective employees, contractors or agents in the performance of this Agreement;
- (d) breach of a contractual or fiduciary obligation owed by Licensor (including without limitation misappropriation of trade secrets); or
- (e) infringement or misappropriation with respect to the Development, Manufacture, or Commercialization of the NDA Product under the Licensor IPR Package or Licensor Trademarks.

and the foregoing indemnity obligation shall not apply to any Damages to the extent such Damages result from any matter for which Licensee is required to indemnify Licensor pursuant to Section 13.1(b), (c), or (d).

13.3 Indemnification of Product Liability Claims. Notwithstanding any other provision of this Agreement, this Section 13.3 shall govern the allocation of liability with respect to claims of property injury, bodily injury or death related to Product in the Territory.

- (a) Subject to Section 13.4, Licensor shall indemnify and hold the Licensee Indemnitees harmless from and against any and all Damages which a Licensee Indemnitee may incur or suffer arising out of any Third Party claim of property damage, bodily injury or death (including negligence, tort, strict liability or otherwise) to the extent caused by (i) any Licensor Design Defect or (ii) any sale, use, importation, storage, handling, distribution, offer for sale or sale of Product, or development of a Product conducted by Licensor. A “**Licensor Design Defect**” shall be a defect in the design or formulation of the NDA Product as such NDA Product is designed and formulated as set forth in the NDA on the Effective Date.
- (b) Subject to Section 13.4 and except to the extent provided in subsection (a) above, Licensee shall defend, indemnify and hold the Licensor Indemnitees harmless from and against any and all Damages arising out of any Third Party claims of property damage, bodily injury or death (including negligence, tort, strict liability or otherwise) to the extent caused by (i) any sale, use, importation, storage, handling, distribution, offer for sale or sale of Product, or development of such Product conducted by, Licensee; or (ii) any Licensee Design Defect. A “**Licensee Design Defect**” shall be a defect in the design or formulation of the Product designed or formulated by Licensee that differs from the design or formulation of the NDA Product as of the Effective Date.

13.4 Indemnification Procedures. A Party seeking indemnification under Section 13.1, 13.2 or 13.3 hereof (the “**Indemnitee**”) shall promptly notify the other Party (the “**Indemnitor**”) in writing of any claim, lawsuit or other action in respect of which the Indemnitee, its Affiliates, or any of their respective directors, officers, employees and agents intend to claim such

indemnification. The Indemnitee shall permit, and shall cause its Affiliates and their respective directors, officers, employees and agents to permit the Indemnitor to have complete control of such defense (except as set forth below) so long as it promptly assumes the defense and prosecutes the defense with appropriate diligence and care. Notwithstanding the foregoing, such Indemnitor shall not have the right to defend or direct the defense of any such claim, lawsuit or other action that (x) is asserted directly by or on behalf of a Third Party that is a supplier or direct customer of the Indemnitee, or (y) seeks an injunction or other equitable relief against the Indemnitee. The Party controlling the defense hereunder (the “**Defending Party**”) shall have the authority, at its discretion, to settle any such claim, lawsuit or other action only with the prior written consent of the Party who is not controlling the defense (the “**Non-Defending Party**”), provided, however, that such consent shall not be unreasonably withheld or delayed so long as such settlement does not adversely affect the Non-Defending Party's rights hereunder or impose any obligations on the Non-Defending Party in addition to those set forth herein. The Defending Party and the Non-Defending Party, and their respective Affiliates, and their respective directors, officers, employees and agents shall cooperate fully with each other and their respective legal representatives in the investigation and defense of any claim, lawsuit or other action covered by this indemnification. The Defending Party shall keep the Non-Defending Party reasonably informed of the progress of the action and shall consider the comments and observations of the Non-Defending Party timely given in the course of the proceedings. If the Indemnitor is the Defending Party, the Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and expense. Notwithstanding the foregoing, the Indemnitee may be represented by separate counsel at the expense of the Indemnitor if a conflict of interest exists between the interests of the Indemnitor and Indemnitee so that a single counsel representing Indemnitor cannot adequately defend the rights of the Indemnitee.

- 13.5 Survival of Indemnification Obligations. The provisions of Sections 12.7 shall survive the termination or expiration of this Agreement.
- 13.6 Each Party shall maintain, at its own cost, the insurance coverages set forth in this Section 13.6; provided, however, the Licensee has the right, in its sole discretion, to self-insure in part or in whole for any such coverages:
- (a) commencing as of the Effective Date, and thereafter for the period of time required under Section 13.7, each Party shall obtain and maintain on an ongoing basis, commercial general liability insurance, including contractual liability, in the minimum amount of ten million dollars (\$10,000,000) per occurrence, combined single limit for bodily injury and property damage liability, and
  - (b) commencing as of the Effective Date, and thereafter for the period of time required under Section 13.7, each Party shall obtain and maintain on an ongoing basis, products liability insurance, including contractual liability, in the minimum amount of ten million dollars (\$10,000,000) per occurrence, combined single limit for bodily injury and property damage liability.
- 13.7 Except to the extent that the Licensee self-insures as authorized under Section 13.6, the following provisions apply:
- (a) All insurance coverages shall be primary insurance with respect to each Party's own participation under this Agreement, and shall be maintained with an insurance for the Licensee or companies having an A.M. Best's rating (or its equivalent) of A-XII or better.
  - (b) Each Party shall be provided additional insured status under the other party's commercial general liability and products liability insurance policies.

- (c) The insurance policies shall be under an occurrence form, but if only a claims-made form is available to a Party, then in such a case, such Party shall maintain the insurance coverage for at least five (5) years following such Party's completing performance of its obligations under this Agreement.
- (d) Each Party's aggregate deductibles under its commercial general liability and products liability and other insurance policies shall be reasonably satisfactory to the other Party, taking into account the deductibles that are prudent and customary with respect to the activities in which it is engaged under this Agreement.
- (e) Each Party's insurance coverage shall include an option to purchase tail coverage for claims arising during a period covered by such insurance (the policy period) but for which claims are not brought during the policy period, which tail period shall have a duration of at least five (5) years following the end of the policy period. The tail coverage will be purchased if the insurance coverage in place is cancelled or non-renewed.
- (f) Each Party shall provide to the other Party its respective certificates of insurance evidencing the insurance coverages set forth in Section 13.6 Each Party shall provide to the other Party at least thirty (30) days prior written notice of any cancellation, non-renewal or material change in any of the insurance coverages. Each Party shall, upon receipt of written request from the other Party, provide renewal certificates to the other Party for as long as such Party is required to maintain insurance coverages hereunder.

#### **14. Duration and termination of the agreement**

- 14.1 The Agreement shall enter into force and effect on the Effective Date and shall remain in full force and effect country by country of the Territory for the duration of the Term, subject to earlier termination as provided in this Agreement. At the expiry of the Royalty Term in each country of the Territory the licenses granted by the Parties hereunder shall become perpetual, irrevocable, fully paid up and royalty free in such country.
- 14.2 The Licensee shall be entitled to terminate the Agreement:
  - (a) effective immediately upon prior written notice to the Licensor pursuant to Section 7.11(d), if the Licensee can demonstrate that there are reasonable good faith grounds to believe there is a safety concern related to the Product, or
  - (b) effective immediately upon prior written notice to the Licensor in case of withdrawal of the Regulatory Approval for the Product in the United States for whatever reason which the Licensee reasonably believes will be permanent;
  - (c) effective upon two hundred and seventy (270) days' prior written notice to the Licensor, for any reason or no reason; or
  - (d) pursuant to Section 14.4 below, which relates to a material breach of the Agreement by the Licensor.
- 14.3 The Licensor shall be entitled to terminate this Agreement pursuant to Section 14.4 below, which relates to a material breach of the Agreement by the Licensee.
- 14.4 Either Party (the non-breaching Party) shall have the right to terminate this Agreement upon giving ninety (90) days written notice to the other Party on the occurrence of a material breach by such other Party (the breaching Party) which material breach is incapable of remedy or which, in the case of a breach capable of remedy, shall not have been remedied

within such ninety (90) day notice period, provided that the non-breaching Party shall have identified in its notice the breach in reasonable detail. If the breach relates to:

- (a) Canada then the Licensor shall only have the right to terminate this Agreement in relation Canada; or
- (b) the USA then the Licensor shall have the right to terminate this Agreement in its entirety.

If the breaching Party in good faith disputes such material breach or disputes the failure to cure or remedy such material breach and provides written notice of that dispute to the non-breaching Party within the above notice period, then the matter will be addressed under the dispute resolution provisions in Section 16 and the non-breaching Party may not terminate this Agreement until it has been determined under Section 16 that the breaching Party is in material breach of this Agreement, and the breaching Party further fails to cure such breach within sixty (60) days after the conclusion of that dispute resolution procedure.

14.5 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by either Party are, and shall otherwise be deemed to be, for purposes of section 365(n) of the U.S. Bankruptcy Code, licenses of right to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that each Party, as licensee of certain rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the occurrence of a Bankruptcy Event in respect of a Party (such Party, the “**Debtor**”) under the U.S. Bankruptcy Code, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensed to such other Party and all embodiments of such intellectual property, which, if not already in such other Party's possession, shall be promptly delivered to it:

- (a) upon any such commencement of a bankruptcy proceeding upon such other Party's written request therefor, unless the Debtor elects to continue to perform all of its obligations under this Agreement; or
- (b) if not delivered following the rejection of this Agreement by the Debtor upon written request therefor by the other Party.

14.6 Expiration of, or termination of this Agreement by Licensee pursuant to Section 14.4, shall result in the following:

- (a) All rights granted by the Licensor to the Licensee in the Licensor IPR Package and Licensor Trademarks under the Agreement shall become fully-paid-up, royalty-free and perpetual.
- (b) The rights and obligations of the Parties set forth in Section 10 shall continue until the date that is six (6) years after the last to expire Valid claim of a Patent Right Controlled by either Party shall have expired.
- (c) The obligations with respect to monitoring and exchange of safety information set forth in Section 7.11 shall continue for as long as both Parties are Developing or Commercializing a Product anywhere in the World, with each Party bearing its own costs and expenses with respect thereto.

14.7 Termination of this Agreement by Licensee other than pursuant to Section 14.4, or by Licensor pursuant to Section 14.2(b), shall result in the following, which, if the termination is in relation to a country, shall only apply in such country:

- (a) Termination of all rights granted by the Licensor to the Licensee under the Agreement and reversion to the Licensor of such rights. The Licensee shall immediately cease all use of the Licensor IPR Package and shall cease all Development, manufacturing and Commercialization activity. All Sub-licenses agreements and arrangements shall terminate simultaneously.
- (b) The Licensee hereby grants to the Licensor a non-exclusive, perpetual, sub-licensable, fully paid-up royalty free right and license to use the Licensee IPR Package inside such Country for the Development and Commercialization of the Product in such country and for the Manufacture of Products in the Territory. Termination shall have no impact upon the Licensor's rights to use the Licensee IPR Package outside the Territory.
- (c) The Licensee shall promptly transfer to the Licensor the Licensee Materials, Licensee Know How, Product Registrations and Commercial Information and Documents containing the same (including any of the same in the possession of a Sub-licensee).
- (d) Commensurate with Legal Requirements, to the extent held by the Licensee, it shall as soon as reasonably practicable after termination transfer to the Licensor or its nominee all right, title and interest in all relevant Product Registrations held by the Licensee for the relevant Product(s), and the Licensee shall execute all necessary and appropriate letters to the FDA and other Regulatory Authorities in the Territory (if any) to ensure that ownership of the Product Registrations are transferred to the Licensor (i) for United States Product Registrations, within 15 days of termination, and for Canadian Product Registrations, within 70 days of termination. The date upon which a Product Registration is registered in the Licensor's name shall be known as the “**Transfer Date**”. In the event that such a transfer is not possible under Legal Requirements, the Licensee shall use reasonable efforts at Licensor's sole cost and expense to ensure that the Licensor has the benefit of the relevant Product Registrations and, to this end, consents to any Regulatory Authority in the Territory cross-referencing to the data and information on file with any Regulatory Authority as may be necessary to facilitate the granting of second Product Registrations to the Licensor in the terminated countries. In such circumstance as soon as the second Product Registrations are given to the Licensor, the Licensor will, so far as possible under Legal Requirements, cancel the corresponding first Product Registration. Further from the date of submission of the appropriate letters to the Regulatory Authorities in the Territory (if any) necessary to ensure that ownership of the Product Registrations is given to the Licensor until the Product Registrations are actually transferred to the Licensor or second Product Registrations are issued by such Regulatory Authorities, the Licensee shall, at Licensor's sole cost and expense:
  - (i) submit all necessary filings, correspondence and reports, attend all necessary meetings and otherwise conduct such other activities as are necessary to maintain the Product Registrations;
  - (ii) as soon as practicably possible submit to the Licensor copies of all filings and correspondence that are submitted to any Regulatory Authority to the extent they relate to all relevant Product(s) in the Territory; and
  - (iii) provide the Licensor with advance written notice of any meetings or telephone calls with any Regulatory Authority in the Territory relating to Product Registrations and allow the Licensor to participate in all such meetings or telephone calls.

- (e) The Licensee shall as soon as reasonably practicable notify the Licensor of the amount of stocks of Product owned by it (title not having passed to a customer) and the precise location of such stocks with corresponding stock numbers, and the amount of such stocks subject to customer orders but not yet delivered. The Licensor shall have the option (exercisable by written notice to the Licensee to be given not more than one (1) month termination), either (i) to inspect and purchase from the Licensee a price equal to Cost of Manufacture all of or any part of stocks of the Product held by the Licensee which are not subject to orders from customers and are in good and saleable condition or (ii) permit the Licensee to sell all or some of such stocks of Products for a period up to and no later than the Licensee holds its own Regulatory Approval for Product in the relevant country. All other stocks of Products shall be destroyed by the Licensee.
- (f) The Licensee shall inform the Licensor of the details of all stocks including batch numbers sold by the Licensee, its Affiliates, or Sub-licensees in the previous six (6) months to distributors or wholesalers and the names and other details of such distributors or wholesalers.
- (g) The Licensee shall be entitled to invoice and collect and retain payment for Products sold by Licensee prior to termination, and shall be responsible for any payments, rebates, administrative fees or chargebacks (“**Commercial Payments**”) due to customers (including those payments due under managed care agreements and agreements with health maintenance organization) for Products sold by the Licensee, its Affiliates and Sub-Licensees prior to the termination date and the Licensor shall be responsible for Commercial Payments to customers for Products sold or dispensed thereafter. In the event that, with respect to Products sold or dispensed during the Calendar Quarter in which the termination date occurs, the Parties cannot determine the date on which such Products were sold, then the Party that has made a Commercial Payment for such Product shall be entitled to obtain reimbursement from the other party on a pro rata basis for such Commercial Payment (with the Licensee's pro rata share constituting the proportion of days in the Calendar Quarter up to and including the termination date, and the Licensor's pro rata share constituting the proportion of days in such Quarter following the termination date). Either Party that has made a Commercial Payment, all or a portion of which is the responsibility of the other Party, shall submit a payment request to the other Party, with supporting documentation, and such other Party shall reimburse the requesting Party for the Commercial Payment (or portion thereof) for which it is responsible within thirty (30) days of receipt of such request.
- (h) The Licensee shall be responsible for any rebates due to a governmental entity (“**Government Rebates**”) applicable to Product sold by the Licensee, its Affiliates, or Sub-licensees prior to the termination date. The Parties acknowledge that the request for such payments is submitted to the National Drug Code holder (or its equivalent outside the USA) of the Product and, as such, the Licensee will receive, process and pay Government Rebates on all Product bearing Licensee National Drug Code and shall within 30 days of payment, submit to the Licensor an invoice for the amounts of any Government Rebates made in relation to Product sold after the termination date. In the event that, with respect to Product sold or dispensed during the Calendar Quarter in which the termination date occurs, the Parties cannot determine the date on which such Product was sold or dispensed, then the Party that has made a Government Rebate for such Product shall be entitled to obtain reimbursement from the other Party on a pro rata basis for such Government Rebate (with the Licensee's pro rata share constituting the proportion of days in the Calendar Quarter up to and including the termination date, and the Licensor's pro rata share constituting the



proportion of days in such Calendar Quarter following the termination date). Either Party that has made a Government Rebate, all or a portion of which is the responsibility of the other Party, shall submit a payment request to the other Party, with supporting documentation, and such other Party shall reimburse the requesting Party for the Government Rebate (or portion thereof) for which it is responsible within thirty (30) days of receipt of such request.

- (i) The Licensee shall be responsible for returns from any customer in respect of all Product sold by the Licensee, its Affiliates, or Sub-licensees prior to the termination date and the Licensor shall be responsible for returns in respect of all Product sold or dispensed after the termination date, regardless of when such return occurs. Neither Party shall seek to encourage Product returns or accept Product returns other than in the ordinary course of business save, in each case, with the written consent of the other Party. The Licensee shall process all Product returns received by it and shall destroy the returned Product. The Licensee shall reimburse the Licensor (within ten (10) days of request therefor) with respect to any returns of Product sold on or prior to the termination date for all costs and expenses relating to the return, including the actual cost of destruction and related administrative costs and expenses.
- (j) The Licensee will transfer to the Licensor the domain name for the internet website established by the Licensee.
- (k) To the extent permitted by applicable Law, for a period not to exceed ninety (90) days, Licensee will reasonably cooperate at Licensor's sole cost and expense as reasonably requested by Licensor, in assisting with the smooth transition of the Commercialization of the Product in the Territory from Licensee to Licensor

14.8 Termination of the Agreement shall be without prejudice to any rights that shall have accrued to the benefit of either party before such termination, including the right of either party to receive or recover: (i) damages sustained by reason of the breach of the Agreement by the other party, or (ii) any payments for Products which may then be owing under the terms of the Agreement (including any invoice). In addition, the following provisions of this Agreement shall survive termination of this Agreement:

- (a) Section 11 (*Confidentiality*);
- (b) this Section 14 (*Duration and termination of the agreement*);
- (c) Section 16 (*Governing law and disputes*); and
- (d) any provision of this Agreement necessary for its interpretation or enforcement.

14.9 If:

- (a) a Court pursuant to Section 16.2 **Error! Reference source not found.** finds that Licensee is obligated to transfer the Product Registrations pursuant to Section 14.7(d) has not done so in a timely manner; or
- (b) if Licensee agrees in any settlement or otherwise that it is obliged to transfer the Product Registrations pursuant to Section 14.7(d),

then the Licensor shall be entitled to equitable relief pursuant to Section 16.2 including specific performance of such obligation, without a need to post bond or other surety.

## 15. Assignment/succession

15.1 Subject to Section 15.2, this Agreement shall not be assignable nor shall the rights licensed hereunder or the ownership of the NDA (other than pursuant to Section 5.10) be transferable

in any way by either Party except by prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed; provided, however, that:

- (a) other than with respect to assignment of the ownership of the NDA, which assignment shall require the consent of the other Party, not to be unreasonably withheld, conditioned or delayed, either Party may assign this Agreement in whole or in part to a corporate Affiliate on reasonable prior written notice to the other Party of such assignment on the condition that the assigning Party shall remain liable hereunder for the prompt payment and performance of all obligations of the assignee;
- (b) this Agreement may be assigned by a Party to a Third Party in connection with a sale or transfer of all or substantially all of such Party's business or assets to which this Agreement relates or in connection with a merger or consolidation transaction involving such Third Party provided always that such Third Party gives a written deed of undertaking to the non-affected Party agreeing to abide by all the obligations under this Agreement of the assigning Party; and
- (c) Licensee may pledge, grant a security interest, lien or charge in, or other encumbrance upon, any of Licensee's rights or interests in this Agreement (and may assign this Agreement or the rights hereunder, in whole or in part in connection with any of the foregoing), including without limitation pursuant to the terms of the Term Loan Agreement (and any amendment, restatement, replacement or refinancing thereof) and any related documents.

15.2 If a Bankruptcy Event occurs with respect to the Licensee, then:

- (a) the Licensee shall not be permitted to assign this Agreement or transfer its rights hereunder; and
- (b) except as specified in Section 15.1(c), the Licensor shall not be deemed to have consented to: (i) any assignment by the Licensee of this Agreement; or (ii) the transfer of any of the Licensee rights contained in this Agreement.

15.3 This Agreement shall be binding upon, and shall inure to the benefit of, all permitted assigns.

## **16. Governing law and disputes**

16.1 This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, United States without regard to its conflicts of laws principles.

16.2 The Parties consent to the exclusive jurisdiction of the Federal courts and the State courts of the State of New York, in each case, located in the borough of Manhattan, City of New York (the "**New York Courts**") in any dispute, suit or action (each, a "**Proceeding**") arising out of or relating to this Agreement or the transactions contemplated hereby, and hereby irrevocably and unconditionally (i) agrees not to commence any such Proceeding except in such New York Courts, (ii) agrees that any claim in respect of any such Proceeding may be heard and determined in the New York Courts, (iii) waives, to the fullest extent it may legally and effectively do so, any objection which it may now or hereafter have to the laying of venue of any such Proceeding in any such New York Court, and (iv) waives, to the fullest extent permitted by Law, the defense of an inconvenient forum to the maintenance of such Proceeding in any such New York Court. Each of the parties agrees that a final judgment in any such Proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by Law. **THE PARTIES HEREBY IRREVOCABLY WAIVE, AND AGREE TO CAUSE THEIR RESPECTIVE AFFILIATES TO WAIVE, THE RIGHT TO TRIAL BY JURY IN SUCH PROCEEDINGS.**

**17. Miscellaneous**

17.1 Force Majeure

Neither Party shall be responsible for any delay or failure to perform its obligations under the Agreement or shall be liable to the other for loss or damages for any default or delay caused by conditions beyond its reasonable control, including but not limited to acts of God, governmental restrictions, declared or not declared wars or insurrections, strikes, terrorism, floods or work stoppages. If either of the Parties is so affected it shall give prompt written notice of such cause to the other Party. The Party giving such notice shall thereupon be excused from such of its obligations under the Agreement as it is thereby disabled from performing for so long as it is so disabled.

17.2 Notices

- (a) Any notice (which term shall in this Section 17.2 include any other formal written communication) required to be given under this Agreement or in connection with the matters contemplated by it shall, except where otherwise specifically provided, be in writing in the English language.
- (b) Any such notice shall be addressed as provided in Section 17.2(a) and may be:
  - (i) delivered by hand (which shall include by courier), in which case it shall be deemed to have been given upon delivery at the relevant address if it is delivered not later than 17.00 hours on a Business Day, or, if it is delivered later than 17.00 hours on a Business Day or at any time on a day which is not a Business Day, at 08.00 hours on the next Business Day; or
  - (ii) sent by electronic mail, in which case it shall be deemed to be given when the E-mail leaves the E-mail gateway of the sender where it leaves such gateway before 17.00 hours on any Business Day or in any other case at 08.00 hours on the next Business Day after it leaves such gateway and the onus shall be on the sender to prove the time that the E-mail left its gateway.
- (c) The addresses and other details of the Parties for notices are, subject to Section 17.2(d):

If to the Licensor, addressed to:

Attention: Michael Ward (President & Chief Executive Officer)

Address:

Æterna Zentaris, 315 Sigma Drive, Charleston, SC 29486

E-mail address: mward@aezsinc.com

If to the Licensee, addressed to:

Attention: Chief Legal Officer

Address: 10 Earlsfort Terrace, Dublin 2, D02 T380

E-mail address: s.long@strongbridgebio.com

- (d) Any Party to this Agreement may notify the other Party of any change to the address or any of the other details specified in Section 17.2(c), provided that such notification

shall only be effective on the date specified in such notice or two Business Days after the notice is given, whichever is later.

17.3 In proving service of any notice in accordance with Section 17.2, it shall be sufficient to prove that the envelope containing the notice was properly addressed and delivered by hand to the relevant address or that the e-mail was sent to the correct e-mail address, as the case may be.

17.4 No Other Rights

Except as otherwise expressly provided in the Agreement, no other right, express or implied, is granted by the Agreement.

17.5 Further Actions

Each party agrees to execute, acknowledge and deliver such further instruments, and to do all such other reasonable acts, as may be necessary or appropriate in order to carry out the purposes and intent of the Agreement.

17.6 Amendment

No amendment, modification or supplement of any provision of the Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer or director of each party.

17.7 Waiver

No provision of the Agreement shall be waived by any act, omission or knowledge of any party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer or director of the waiving party. The waiver by either Party of a breach or a default of any provision of this Agreement by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision, nor shall any delay or omission on the part of either Party to exercise or avail itself of any right, power or privilege that it has or may have hereunder operate as a waiver of any right, power or privilege by such Party.

17.8 Counterparts

The Agreement may be executed in any number of counterparts, each of which need not contain the signature of more than one party but all such counterparts taken together shall constitute one and the same agreement. A signed Agreement received by a party hereto via facsimile will be deemed an original, and binding upon the party who signed it. Facsimile signatures or signatures sent by email attachment or telecopy shall be valid and binding to the same extent as original signatures. This agreement shall not be effective until each party has executed at least one counterpart.

17.9 Severability

Whenever possible, each provision of the Agreement shall be interpreted in such manner as to be effective and valid under applicable Law, but if any provision of the Agreement is held to be prohibited by or invalid under applicable Law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of the Agreement.

17.10 Independent Contractors

The relationship between the Licensor and the Licensee created by the Agreement is one of independent contractors and neither party shall have the power or authority to bind or obligate

the other. There is no employee-employer relationship or partnership relationship between the Licensor and the Licensee or any of its representatives.

17.11 Local Law Requirements

Except as otherwise specifically provided herein, each party shall at their own expense in their respective countries, take such steps as may be required to satisfy any Laws or requirements with respect to declaring, filing, recording or otherwise rendering the Agreement valid.

17.12 Expenses

Each party shall bear its own expenses and costs incurred in the negotiations leading up to and in preparation of the Agreement and of matters incidental to the Agreement.

17.13 Entire Agreement of the Parties

The Agreement (including the Schedules) shall constitute and contain the complete, final and exclusive understanding and agreement of the parties and cancels and supersedes any and all prior negotiations, correspondence, understanding and agreements, whether oral or written, between the Licensor and the Licensee respecting the subject matter thereof.

17.14 Exclusion

The Parties exclude the application of any international statutes on the sales of goods, including the United Nations Convention on International Contracts for the Sales of Goods.

17.15 Language

The English version of the Agreement shall be deemed the official and governing instrument, notwithstanding any translations thereof.

*[Signature Page Follows]*

**Execution**

Intending to be legally bound, the parties have caused the Agreement to be executed by their duly authorized officers or directors as of the Effective Date.

**Aeterna Zentaris GmbH**

By: \_\_\_\_\_  
Name: Michael Ward \_\_\_\_\_  
Title: \_\_\_\_\_  
Its: CEO \_\_\_\_\_

**Strongbridge Ireland Limited**

By: \_\_\_\_\_  
Name: A. Brian Davis \_\_\_\_\_  
Title: \_\_\_\_\_  
Its: Director \_\_\_\_\_

**Schedule 1**

**CMO Contracts**

<b>Objective / Purpose</b>	<b>CMO</b>	<b>Address</b>	<b>Contract</b>	<b>Execution Date</b>
Manufacturing of Boc-AEZS-130, packaging, quality control, batch release, stability testing and distribution	Flamma SpA	Via Bedeschi 22, 24040 Chignolo d'Isola, Italy	QA	2017-09-12
			SA	n.a.
Manufacturing of AEZS-130 drug substance, packaging, labelling, quality control, batch release and stability testing	PolyPeptide Laboratories France SAS	7 rue de Boulogne, 67100 Strasbourg, France	QA	2017-10-06*
			SA	2013-08-21*
Manufacturing drug product, primary packaging, quality control, stability testing and batch release	Allphamed Pharbil Arzneimittel GmbH	Hildebrandstrasse 12, 37081 Goettingen, Germany	QA	2017-09-27
			SA	2013-08-08*
Labeling, secondary packaging, batch release and distribution	Corden Pharma GmbH	Otto-Hahn-Strasse, 68723 Plankstadt, Germany	QA	2017-11-21
			SA	In preparation, draft status
Storage of drug product stability samples	Pharbil Pharma GmbH	Reichenberger Strasse 43, 33605 Bielefeld, Germany	n.a.	Internally regulated within NextPharma subsidiaries
Batch certification for export from EU and final batch release to US market	Aeterna Zentaris GmbH	Weismuellerstrasse 50, 60314 Frankfurt am Main, Germany	n.a.	Internally regulated within Aeterna Zentaris
Storage and distribution (3PL services)	ICS AmerisourceBergen	3101 Gaylord Parkway, Frisco, TX 75034, USA	Statements of Work	In preparation, draft status

SA: Supply Agreement, QA: Quality Agreement

\* Update in progress

**Schedule 2**

**Technology Transfer Critical Materials and Timing**

To the extent not already in the Data Room:

<i>Materials</i>	<i>Timing for transfer</i>
Copy of a customer facing slide deck for MCO purposes.	As soon as possible on or after the Effective Date
Copies of any additional draft/final promotional documents.	As soon as possible on or after the Effective Date
Any medical affairs planning documents generated, including any physician lists, conference planning documents, speaker training materials, etc.	As soon as possible on or after the Effective Date
Drafts of any presentations or product-related manuscripts in preparation at the time of deal closing	As soon as possible on or after the Effective Date
Information pertaining to any requests in the last 12 months for supply of drug product or funding to support clinical research or expanded access to drug in the Territory	As soon as possible on or after the Effective Date
Copies of batch records and certificates of analysis for any Licensor Materials to be transferred to Licensee. This should include the batch records and certificates of analysis of the input materials used to make each batch of Licensor Materials (drug product, AEZS-130 drug substance, and Boc-AEZS-130 intermediate).	Prior to or upon transfer of the applicable Licensor Material
Copies of all pricing, access and reimbursement related material. Including requests for proposals, analysis and contracts.	As soon as possible on or after the Effective Date



**Schedule 3**

**FDA Letters**

**FDA NDA TRANSFER LETTER**

Month Date, Year

Jean-Marc Guettier, MD  
Director  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Metabolism and Endocrinology Products  
5901-B Amundson Road  
Beltsville, MD 20705-1266

**Re: NDA #205598 Macimorelin (AEZS-130, formally ARD-07) Granules for oral solution  
GENERAL CORRESPONDENCE-Transfer of NDA Ownership**

Dear Dr. Guettier,

Reference is made to the NDA 205598 Macimorelin (AEZS-130, formally ARD-07) Granules for oral solution. Aeterna Zentaris Inc., hereby submits a General Correspondence-Transfer of NDA ownership to notify that we have transferred ownership of this application from Aeterna Zentaris Inc., to the new owner:

Strongbridge Ireland Limited,  
10 Earlsfort Terrace, Dublin 2, D02 T380  
900 Northbrook Drive, Suite 200, Trevoise, PA 19053  
Attn: Susan Thornton, Vice President, Regulatory Affairs  
e-mail: s.thornton@strongbridgebio.com  
Phone: 484-589-0395

Effective Month Date, Year, all rights and responsibilities regarding NDA 205598 are transferred to Strongbridge Ireland Limited ("Strongbridge"). Strongbridge will concurrently notify the Agency of its acceptance of ownership of the designation under separate cover. A complete copy of the NDA 205598, including IND #73,196 and Orphan Drug Designation #06-2255, has been provided to Strongbridge for their files.

If there are any questions, or if additional information is required, please contact me at XXX-XXX-XXXX.

Sincerely,

{Name}  
{Title}

**FDA NDA ACCEPTANCE LETTER**

Month Date, Year

Jean-Marc Guettier, MD  
Director  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Metabolism and Endocrinology Products  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

**Re: NDA #205598 Macimorelin (AEZS-130, formally ARD-07) Granules for oral solution  
GENERAL CORRESPONDENCE-Transfer of NDA Ownership**

Dear Dr. Guettier,

Pursuant to 21 CFR §314.72, Strongbridge Ireland Limited, hereby notifies the FDA of a change in ownership of NDA 205598 Macimorelin. As indicated in correspondence dated XXXX, from Aeterna Zentaris Inc. (copy enclosed), all rights to NDA 205598 Macimorelin have been transferred from Aeterna Zentaris Inc. to Strongbridge Ireland Limited, effective Month Date, Year with the following associated address:

Strongbridge Ireland Limited,  
10 Earlsfort Terrace, Dublin 2, D02 T380  
Attn: Susan Thornton, Vice President, Regulatory Affairs  
e-mail: s.thornton@strongbridgebio.com  
Phone: 484-589-0395  
Fax: 215-355-7389

Strongbridge Ireland Limited, ("Strongbridge") has made arrangements with Aeterna Zentaris Inc. to obtain a complete copy of the NDA 205598, including supplements, and records that are required to be kept under 21 CFR 314.81. In addition, Strongbridge reserves the right to request a copy of the application from FDA's files under the fee schedule in 20.45 of FDA's public information regulations. Strongbridge hereby commits to the agreements, promises, and conditions made by the former owner and contained in the application.

Provided herein is a new form FDA 356h signed by the Strongbridge agent of record.

If there are any questions, or if additional information is required, please contact me at 484-589-0395.

Sincerely,

Susan Thornton  
Vice President, Regulatory Affairs  
Strongbridge Biopharma (parent company of Strongbridge Ireland Limited)  
900 Northbrook Drive, Suite 200  
Trevose, PA 19053 USA  
Office: 484-589-0395  
Mobile: 215-518-2620  
s.thornton@strongbridgebio.com  
CC: Meghna Jairath, Regulatory Project Manager

**FDA IND TRANSFER LETTER**

Month Date, Year

Jean-Marc Guettier, MD  
Director  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Metabolism and Endocrinology Products  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

**RE: IND # 73,196 Macimorelin (AEZS-130, Formerly ARD-07) Granules for Oral Solution**  
**GENERAL CORRESPONDENCE-Transfer of IND Ownership**

Dear Dr. Guettier,

Reference is made to IND #73,196 originally submitted on February 7, 2007 for Macimorelin (AEZS-130, Formerly ARD-07) Granules for Oral Solution, as a diagnostic for growth hormone deficiency [GHD]. Aeterna Zentaris Inc., hereby submits a General Correspondence-Transfer of IND ownership to notify that we have transferred ownership of this application from Aeterna Zentaris Inc., to a new sponsor:

Strongbridge Ireland Limited,  
10 Earlsfort Terrace, Dublin 2, D02 T380  
Attn: Susan Thornton, Vice President, Regulatory Affairs  
e-mail: s.thornton@strongbridgebio.com  
Phone: 484-589-0395  
Fax: 215-355-7389

Effective Month Date, Year, all rights and responsibilities regarding IND #73,196 are transferred to Strongbridge Ireland Limited (“Strongbridge”). Strongbridge will concurrently notify the Agency of its acceptance of ownership of the designation under separate cover. A complete copy of the IND #73,196 has been provided to Strongbridge for their files.

If there are any questions, or if additional information is required, please contact me at XXX-XXX-XXXX.

Sincerely,

{Name}  
{Title}

**FDA IND ACCEPTANCE LETTER**

Month Date, Year

Jean-Marc Guettier, MD  
Director  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Metabolism and Endocrinology Products  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

**Re: IND # 73,196 Macimorelin (AEZS-130, Formerly ARD-07) Granules for Oral Solution  
Transfer of IND Ownership**

Dear Dr. Guettier,

Reference is made to IND #73,196 originally submitted on February 7, 2007 for Macimorelin (AEZS-130, Formerly ARD-07) Granules for Oral Solution, as a diagnostic for growth hormone deficiency [GHD].

Pursuant to 21 CFR §312, Strongbridge Ireland Limited, hereby notifies the FDA of a change in ownership of IND #73,196 for Macimorelin. As indicated in correspondence dated XXXX, from Aeterna Zentaris Inc., (copy enclosed), all rights to IND #73,196 for Macimorelin have been transferred from Aeterna Zentaris Inc. to Strongbridge Ireland Limited, effective Month Date, Year with the following associated address:

Strongbridge Ireland Limited,  
10 Earlsfort Terrace, Dublin 2, D02 T380  
Attn: Susan Thornton, Vice President, Regulatory Affairs  
e-mail: s.thornton@strongbridgebio.com  
Phone: 484-589-0395  
Fax: 215-355-7389

Provided herein is a new form FDA 1571 signed by the Strongbridge U.S. Agent of record.

Strongbridge has made arrangements with Aeterna Zentaris Inc. to obtain a complete copy of the IND #73,196, including amendments, and records. Strongbridge hereby commits to the agreements, promises, and conditions made by the former owner and contained in the application.

If there are any questions, or if additional information is required, please contact me at 484-589-0395.

Sincerely,

Susan Thornton  
Vice President, Regulatory Affairs  
Strongbridge Biopharma (parent company of Strongbridge Ireland Limited)  
900 Northbrook Drive, Suite 200  
Trevose, PA 19053 USA  
Office: 484-589-0395  
Mobile: 215-518-2620  
s.thornton@strongbridgebio.com  
CC: Meghna Jairath, Regulatory Project Manager

**FDA ORPHAN DESIGNATION TRANSFER LETTER**

Month Date, Year

Gayatri R. Rao, MD., JD.  
Director, Office of Orphan Products Development  
Food and Drug Administration  
WO32-5271  
10903 New Hampshire Avenue  
Silver Spring, MD 200993-002

**RE: Designation #06-2255, Macimorelin Acetate as a Diagnosis of Growth Hormone Deficiency  
Transfer of Orphan Drug Designation Ownership**

Dear Dr. Rao,

Reference is made to Orphan Drug Designation (ODD) #06-2255, originally approved on May 14, 2007, for Macimorelin acetate as a Diagnosis of Growth Hormone. Aeterna Zentaris Inc., hereby submits a Transfer of Orphan Drug Designation ownership to notify that we have transferred ownership of this application from Aeterna Zentaris Inc., to a new sponsor:

Strongbridge Ireland Limited,  
10 Earlsfort Terrace, Dublin 2, D02 T380  
Attn: Susan Thornton, Vice President, Regulatory Affairs  
e-mail: s.thornton@strongbridgebio.com  
Phone: 484-589-0395  
Fax: 215-355-7389

Effective Month Date, Year, all rights and responsibilities regarding ODD #06-2255 are transferred to Strongbridge Ireland Limited. Strongbridge Ireland Limited will concurrently notify the Agency of its acceptance of ownership of the designation under separate cover. A complete copy of the ODD #06-2255 has been provided to Strongbridge Ireland Limited for their files.

If there are any questions, or if additional information is required, please contact me at XXX-XXX-XXXX.

Sincerely,

{Name}  
{Title}

**FDA ORPHAN DESIGNATION ACCEPTANCE LETTER**

Month Date, Year  
Gayatri R. Rao, MD., JD.  
Director, Office of Orphan Products Development  
Food and Drug Administration  
WO32-5271  
10903 New Hampshire Avenue  
Silver Spring, MD 200993-002

**RE: Designation #06-2255, Macimorelin Acetate as a Diagnosis of Growth Hormone Deficiency  
Transfer of Orphan Drug Designation Ownership**

Dear Dr. Rao,

Reference is made to Orphan Drug Designation (ODD) #06-2255 originally approved on May 14, 2007 for Macimorelin acetate as a Diagnosis of Growth Hormone.

Pursuant to 21 CFR §316.27, Strongbridge Ireland Limited hereby notifies the FDA of a change in ownership of IND #73,196 for Macimorelin. As indicated in correspondence dated XXXX, from Aeterna Zentaris Inc., (copy enclosed), all rights to IND #73,196 for Macimorelin have been transferred from Aeterna Zentaris Inc. to Strongbridge Ireland Limited (Strongbridge), effective Month Date, Year with the following associated address:

Strongbridge Ireland Limited,  
10 Earlsfort Terrace, Dublin 2, D02 T380  
Attn: Susan Thornton, Vice President, Regulatory Affairs  
e-mail: s.thornton@strongbridgebio.com  
Phone: 484-589-0395  
Fax: 215-355-7389

Provided herein is a new form FDA 1571 signed by the Strongbridge agent of record.

Strongbridge has made arrangements with Aeterna Zentaris Inc. to obtain a complete copy of the ODD #06-2255, including amendments, and records. Strongbridge hereby commits to the agreements, promises, and conditions made by the former owner and contained in the application.

If there are any questions, or if additional information is required, please contact me at 484-589-0395.

Sincerely,

Susan Thornton  
Vice President, Regulatory Affairs  
Strongbridge Biopharma (parent company of Strongbridge Ireland Limited)  
900 Northbrook Drive, Suite 200  
Trevose, PA 19053 USA  
Office: 484-589-0395  
Mobile: 215-518-2620  
s.thornton@strongbridgebio.com  
CC: Meghna Jairath, Regulatory Project Manager

**Schedule 4**

**Licensor Materials to be Transferred to Licensee**

**API/ Drug substance**

<b>Batch</b>	<b>Units</b>	<b>QC-release ** till</b>	<b>Shipment from</b>	<b>Shipment to</b>	<b>3PL***</b>	<b>Delivery date</b>	<b>Costs</b>	<b>Total Cost</b>
Batch T*	937g	05/2018	Polypeptide SaS 7 rue de Boulogne 67100 Strasbourg France	Allpharmed PHARBIL GmbH (NextPharma) Hildebrandstr. 12 37081 Goettingen Germany	World Courier (AmerisourceBergen)	Jun/ 2017	360,000 Euro	<b>360,000€</b>
Batch U****	~1kg	Planned QC-testing in Feb/2018	Polypeptide SaS 7 rue de Boulogne 67100 Strasbourg France	Allpharmed PHARBIL GmbH (NextPharma) Hildebrandstr. 12 37081 Goettingen Germany	World Courier (AmerisourceBergen)	Mar/ 2018	~370,000 Euro	<b>370,000€</b>

\*: relevant for the first DP-batch in scale (9,000-9,500 sachets)

\*\* : QC-testing against the current Drug substance release specification (D-87575\RS\_0830)

\*\*\*: AeternaZentaris was responsible for the Shipment (Incoterms2010 EXW)

\*\*\*\*: relevant for the second DP-batch in scale (9,000-9,500 sachets)

**Drug product/ finished product**

Batch	Units	Expiry date*	Shipment from	Shipment to	3PL**	Delivery date	Costs	Total Cost
A1710002A	1197	09/2021	CordenPharma GmbH Otto-Hahn Strasse 68723 Plankstadt, Germany	ICS Brooks 420 International Blvd, Suite 500 KY 40109 US	Schenker MHG (CordenPharma) is responsible for the shipment; DDP acc. Incoterms2010)	Feb 7th, 2018	44,5 Euro/unit + 6,500 Euro validation fee/batch	<b>59,766.50€</b>
A1710003A	1127	09/2021	CordenPharma GmbH Otto-Hahn Strasse 68723 Plankstadt, Germany	ICS Brooks 420 International Blvd, Suite 500 KY 40109 US	Schenker MHG (CordenPharma) is responsible for the shipment; DDP acc. Incoterms2010)	Feb 7th, 2018	44,5 Euro/unit + 6,500 Euro validation fee/batch	<b>56,651.50€</b>
n/a	9,000-9,500***	n/a	CordenPharma GmbH Otto-Hahn Strasse 68723 Plankstadt, Germany	ICS Brooks 420 International Blvd, Suite 500 KY 40109 US	Schenker MHG (CordenPharma) is responsible for the shipment; DDP acc. Incoterms2010)	Apr/ 2018	8,9 Euro/unit + 6,500 Euro validation fee/batch	<b>86,600€-91,050€</b>
n/a	9,000-9,500****	n/a	CordenPharma GmbH Otto-Hahn Strasse 68723 Plankstadt, Germany	ICS Brooks 420 International Blvd, Suite 500 KY 40109 US	Schenker MHG (CordenPharma) is responsible for the shipment; DDP acc. Incoterms2010)	Q3/ 2018	8,9 Euro/unit + 6,500 Euro validation fee/batch	<b>86,600€-91,050€</b>

\*: QC-testing against the current DrugProduct release specification (D-87575\RS\_0974\_02) and Finished Product specification (D-87575\PS\_1072\_01)

\*\* : Document: "Process description for handling and flow of CordenPharma Airfreight shipments"

\*\*\*: manufacturing of the first validation batch has been started on Jan 12<sup>th</sup>, 2018; API-batch T is applied

\*\*\*\*: manufacturing of the second validation batch is planned in Q3/2018; API-batch U will be applied



## Schedule 5

### Disclosure Schedule

This Disclosure Schedule (this “**Disclosure Schedule**”) is furnished in connection with that certain Licence and Assignment Agreement (the “**Agreement**”), dated on or around 16 January 2018, by and among Aeterna Zentaris GmbH, a corporation incorporated under the laws of Germany (the “**Licensor**”) and Strongbridge Ireland Limited, a corporation incorporated under the laws of Ireland (the “**Licensee**”).

Capitalized terms used but not defined in this Disclosure Schedule have the meanings set forth for them in the Agreement. The information in this Disclosure Schedule represents exceptions to and qualifications of the representations and warranties set forth in the corresponding numbered sections of the Agreement, and is arranged to correspond to the numbered and lettered sections of the Agreement.

If there is any inconsistency between the statements in the body of the Agreement and those in the Disclosure Schedule (other than specific exceptions set forth as such with respect to representations or warranties stated in the Agreement), the statements in the body of the Agreement will control. The mention of any matter or event in this Disclosure Schedule is not an admission or acknowledgement, in and of itself, that such information is material either individually or in combination with other matters or events disclosed herein, or has resulted in or would result in a material adverse effect, or is outside the ordinary course of business. The information contained in the Disclosure Schedule is disclosed solely for purposes of the Agreement, and no information contained herein shall be deemed an admission to any third party of any matter whatsoever, including violation of any law or breach of any agreement.

*[Remainder of page intentionally left blank]*

**Schedule 12.2(b) and (c)  
Licensor Patent Rights**

The following papers identified by Licensee:

(1) EPI572: A novel peptide-mimetic GH secretagogue with potent and selective GH-releasing activity in man by Broglio et al

*J. Endocrinol. Invest.* 25: RC26-RC28 2002

RAPID COMMUNICATION

**EPI572: A novel peptido-mimetic GH secretagogue with potent and selective GH-releasing activity in man**

F. Broglio\*, F. Boutignon\*\*, A. Benso\*, C. Gottero\*, F. Prodani\*, E. Arvat\*, C. Ghè\*\*\*, F. Catapano\*\*\*, A. Torzella\*\*\*\*, V. Loconsole\*\*\*\*, C. Muscietti\*\*\*\*, D. Bazzoli\*\*\*\*\*, V. Guarise\*\*\*\*\*, L.A. Fabbretti\*\*\*\*\*

(2)

Targeting the Ghrelin Receptor

Orally Active GHS and Cortistatin Analogs

Romano Deghenghi et al, *Endocrine*, vol. 22, no. 1, 13–18, October 2003

(3) GH-releasing hormone and GH-releasing peptide-6 for diagnostic testing in GH-deficient adults

by Vera Popovic et al; *Lancet* 2000; 356: 1137.42

## Schedule 6

### Domain Names

1. macrilen.com
2. macrilen.org

Schedule 7

Licensors Patent Rights

**Title:** *"Growth Hormone Secretagogues"*

**Owner:** Aeterna Zentaris GmbH

**Internal No.:** 99/25 PH

Internal No	Country	Application No	Application Date	Patent No	Granted Date	Expiry Date
US 99/25 PH/2	USA	09/880,498	13.06.2001	US 6,861,409 B2	01.03.2005	01.08.2022
US 99/25 PH/3	USA	10/837,620	04.05.2004	US 7,297,681 B2	20.11.2007	01.08.2022
CA-PCT 99/25 PH	Canada	2,407,659	13.06.2001	2,407,659	09.11.2010	13.06.2021

**Title:** *"Methods and kits to diagnose Growth Hormone Deficiency"*

**Owner:** Aeterna Zentaris GmbH

**Internal No.:** 06/05 Z

Internal No	Country	Application No	Application Date	Patent No	Granted Date	Expiry Date
US-PCT 06/05 Z	USA	12/279,805	19.02.2007	US 8,192,719 B2	05.06.2012	12.10.2027

*"Method of Assessing Growth Hormone Deficiency Comprising Oral Administration Of a Macimorelin Containing Composition and Collecting One or Two Post-administration Samples"*

**Titel:**

**Owner:** Aeterna Zentaris GmbH

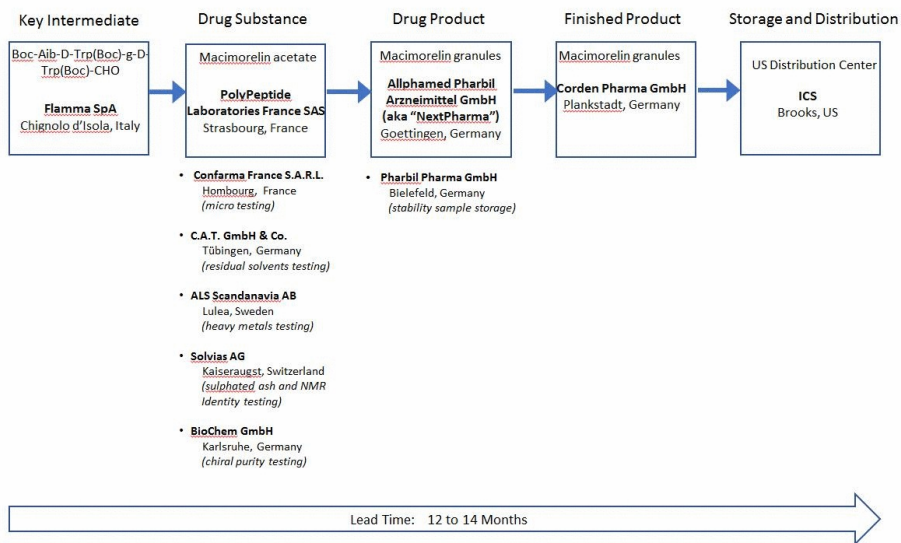
**Internal No.:** 17/01 Z

Prio-Anmeldung	Country	Application No	Application Date	Patent No	Granted Date	Expiry Date
US-Prio 17/01 Z	US	62/609,059	21.12.2017			

Schedule 8

Supply Chain

Macrilen® US-Supply Chain Map



## Schedule 9

### Development Plan

- 1. Pediatric development plan,  
based on the Pediatric Investigation Plan as agreed with the EMA:**
  - o Pediatric development plan to be discussed with FDA
  - o Study 1: Ascending single oral doses of macimorelin in at least 24 stratified pediatric patients from 2 to less than 18 years of age with suspected GDH
  - o Study 2: Diagnostic efficacy and safety of macimorelin acetate in at least 50 stratified pediatric patients from 2 to less than 18 years of age with suspected GDH.
  - o Estimated approx. costs 3 – 3.5 Mio EUR
  - o Estimated approx. 4 years
  
- 2. Phase IV study:**
  - o Collect data to support label change to two blood draws at 45 and 60 min to diagnose AGHD
  - o A US patent application directed to a Macrilen test with two blood draws was filed 21-Dec-17
  - o Estimated clinical duration approx. 6 months
  - o Estimated costs approx. 500 TEUR

## **Schedule 10**

### **PIP Budget**

The proposal has been approved by EMA, but must be discussed with FDA and adapted if necessary.

#### **Study AEZS-130-P01**

Open label, single dose trial to investigate the pharmacokinetics, pharmacodynamics, safety and tolerability of macimorelin acetate after ascending single oral doses of macimorelin in paediatric patients from two to less than 18 years of age with suspected GHD.

Date of completion: by July 2020

Patient number: at least 24 subjects

#### **Study AEZS-130-P02**

Open label, single dose trial to determine the diagnostic efficacy and safety of macimorelin acetate in paediatric patients from two to less than 18 years of age with suspected GHD.

Date of completion: July 2022

Patient number: at least 50 subjects

**Budget proposal total: US\$5,000,000 – 6,000,000**

CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.

EXECUTION VERSION

## AMENDMENT 1 TO TERM LOAN AGREEMENT

THIS AMENDMENT 1 TO TERM LOAN AGREEMENT, dated as of January 16, 2018 (this "*Amendment*" and the date hereof, the "*Amendment No. 1 Effective Date*") is made among STRONGBRIDGE U.S. INC., a Delaware corporation ("*Lead Borrower*"), STRONGBRIDGE BIOPHARMA PUBLIC LIMITED COMPANY, a public limited company incorporated under the laws of Ireland ("*Parent*"), CORTENDO CAYMAN LTD., an exempted company incorporated in the Cayman Islands ("*Cayman Borrower*"), STRONGBRIDGE IRELAND LIMITED, a private limited company incorporated under the laws of Ireland ("*Irish Borrower*"), CORTENDO AB (PUBL), a public limited liability company incorporated under the laws of Sweden with registration number 556537-6554 ("*Swedish Borrower*") and, together with the Lead Borrower, Parent, Cayman Borrower and Irish Borrower, each, a "*Borrower*" and collectively, "*Borrowers*"), CRG Servicing LLC, as administrative agent and collateral agent (in such capacity, "*Administrative Agent*") and the lenders listed on the signature pages hereof under the heading "LENDERS" (each a "*Lender*" and collectively, the "*Lenders*"), with respect to the Loan Agreement described below.

## RECITALS

WHEREAS, Borrowers, the Administrative Agent and the Lenders are parties to the Term Loan Agreement, dated as of July 14, 2017, with the Subsidiary Guarantors from time to time party thereto (the "*Loan Agreement*").

WHEREAS, the parties hereto desire to amend the Term Loan Agreement on the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual agreements, provisions and covenants contained herein, the parties agree as follows:

**SECTION 1. Definitions; Interpretation.**

(a) **Terms Defined in Loan Agreement.** All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement.

(b) **Interpretation.** The rules of interpretation set forth in **Section 1.03** of the Loan Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**SECTION 2. Amendments to Term Loan Agreement.** Subject to **Section 3** of this Amendment, the Loan Agreement is, effective as of the Amendment No. 1 Effective Date, hereby amended to delete the stricken text (indicated textually in the same manner as the following example: ~~stricken text~~) and to add the underlined text (indicated textually in the same manner as the following example: underlined text) as set forth in the pages of the Loan Agreement attached hereto as Exhibit A hereto, together with all Schedules and Exhibits A, C-1, C-2, C-3, C-4, D and I thereto (the Loan Agreement, as amended by this Amendment, being referred to as the “*Amended Loan Agreement*”).

**SECTION 3. Conditions of Effectiveness.** The effectiveness of **Section 2** of this Amendment shall be subject to the following conditions precedent being satisfied or waived by the Administrative Agent:

(a) Borrowers and all of the Lenders shall have duly executed and delivered this Amendment pursuant to **Section 13.04** of the Loan Agreement; provided, however, that this Amendment shall have no binding force or effect unless all conditions set forth in this **Section 3** have been satisfied;

(b) Borrowers and the Administrative Agent shall have duly executed and delivered the Amended Fee Letter;

(c) The Irish Borrower shall have duly executed and delivered or provided the following documents:

(i) Co-Borrower Assumption Agreement, pursuant to which the Irish Borrower agrees to become a “Borrower” for all purposes of the Loan Agreement;

(ii) Joinder Agreement, pursuant to which the Irish Borrower agrees to become a “Grantor” for all purposes of the Security Agreement;

(iii) Certified copies of the constitutive documents of the Irish Borrower and of resolutions of the Board of Directors (and/or shareholders, if applicable) or other applicable governing body of the Obligor authorizing the making and performance by it of the Loan Documents to which it is a party; and

(iv) A certificate of the Irish Borrower as to the authority, incumbency and specimen signatures of the persons who have executed the Loan Documents and any other documents in connection herewith on behalf of the Irish Borrower;

(d) The Irish Borrower shall have provided to Administrative Agent true and correct copies of that certain License and Assignment Agreement, dated as of the date hereof, between the Irish Borrower and Aeterna Zentaris GmbH, a corporation incorporated under the laws of

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Germany (“AZ”), together with all schedules and exhibits thereto, and all other material documents relating to the transactions contemplated thereby (collectively, the “*Macrilen License Agreement*”);

(e) The Macrilen License Agreement (i) shall have been duly executed and delivered by the Irish Borrower and AZ, (ii) shall be in the form provided to the Administrative Agent, and (iii) shall provide for the acquisition of North American marketing rights of Macrilen under terms reasonably satisfactory to the Administrative Agent and the Lenders, including terms that are intended to mitigate insolvency risks to the Lenders applicable in the event of an insolvency of the licensor or the Irish Borrower and permitting the collateral assignment of, and grant to the Administrative Agent a senior perfected security interest in, both the license rights and the proceeds relating thereto;

(f) No Default or Event of Default under the Loan Agreement shall have occurred and be continuing or would result from the transactions contemplated by the Macrilen License Agreement; and

(g) Borrowers shall have paid or reimbursed Administrative Agent and the Lenders for all of their reasonable out of pocket costs and expenses (including the reasonable fees and expenses of counsel to Administrative Agent and the Lenders, and any sales, goods and services or other similar Taxes applicable thereto, and printing, reproduction, document delivery and travel costs), pursuant to **Section 13.03(a)(i)(z)** of the Loan Agreement.

**SECTION 4. Representations and Warranties; Reaffirmation.**

(a) Each Borrower hereby represents and warrants to each Lender as follows:

(i) Borrowers have full power, authority and legal right to make and perform this Amendment. This Amendment is within each Borrower’s corporate or equivalent powers and have been duly authorized by all necessary corporate or equivalent action and, if required, by all necessary shareholder action. This Amendment has been duly executed and delivered by Borrowers and constitutes a legal, valid and binding obligation of Borrowers, enforceable against Borrowers in accordance with its terms, except as such enforceability may be limited by (a) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors’ rights and (b) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law). This Amendment (w) does not require any consent or approval of, registration or filing with, or any other action by, any Governmental Authority or any third party, except for such as have been obtained or made and are in full force and effect, (x) will not violate any order of any Governmental Authority, (y) will not violate any applicable law or regulation or the charter, bylaws, constitutional or other organizational documents of Parent and its Subsidiaries and (z)

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will not violate or result in a default under any indenture, agreement or other instrument binding upon Parent and its Subsidiaries or assets, or give rise to a right thereunder to require any payment to be made by any such Person.

(ii) No Default has occurred and is continuing or will result after giving effect to this Amendment.

(iii) The representations and warranties made by or with respect to Borrowers in **Section 7** of the Loan Agreement are true and correct on and as of the date hereof, and immediately after giving effect to this Amendment, with the same force and effect as if made on and as of such date (except that the representation regarding representations and warranties that refer to a specific earlier date is that they were true and correct on such earlier date), in each case taking into account any changes made to schedules updated in accordance with **Section 7.21** of the Loan Agreement or attached hereto.

(iv) There has been no Material Adverse Effect since the date of the Loan Agreement.

(b) Each Obligor hereby ratifies, confirms, reaffirms, and acknowledges its obligations under the Loan Documents to which it is a party and agrees that the Loan Documents remain in full force and effect, undiminished by this Amendment, except as expressly provided herein. By executing this Amendment, each Borrower acknowledges that it has read, consulted with its attorneys regarding, and understands, this Amendment.

(c) Borrowers and Lenders hereby acknowledge and agree that upon an event of an acceleration or other mandatory prepayment event, the "Redemption Date" for purposes of calculating the Prepayment Premium due and payable upon such acceleration or other mandatory prepayment will be date of such acceleration or such obligation to mandatorily prepay arose.

**SECTION 5. GOVERNING LAW; SUBMISSION TO JURISDICTION; WAIVER OF JURY TRIAL.**

(a) **Governing Law.** This Amendment and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction; *provided that* Section 5-1401 of the New York General Obligations Law shall apply.

(b) **Submission to Jurisdiction.** Borrowers agree that any suit, action or proceeding with respect to this Amendment or any other Loan Document to which it is a party or any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in Houston, Texas or in the courts of its own corporate domicile and irrevocably submits to the non-exclusive jurisdiction of each such court for the purpose of any such suit, action,

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proceeding or judgment. This **Section 5** is for the benefit of the Lenders only and, as a result, no Lender shall be prevented from taking proceedings in any other courts with jurisdiction. To the extent allowed by applicable Laws, the Lenders may take concurrent proceedings in any number of jurisdictions.

(c) **Waiver of Jury Trial.** BORROWERS, THE ADMINISTRATIVE AGENT, AND EACH LENDER HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AMENDMENT, THE OTHER LOAN DOCUMENTS OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

**SECTION 6. Miscellaneous.**

(a) **No Novation; No Waiver.** This Amendment shall not constitute a novation of the Loan Agreement or any of the Loan Documents. Except as expressly stated herein, nothing contained herein shall be deemed to constitute a waiver of compliance with any term or condition contained in the Loan Agreement or any of the other Loan Documents or constitute a course of conduct or dealing among the parties. Except as expressly stated herein, the Lenders reserve all rights, privileges and remedies under the Loan Documents. Except as amended hereby, the Loan Agreement and other Loan Documents remain unmodified and in full force and effect. All references in the Loan Documents to the Loan Agreement shall be deemed to be references to the Loan Agreement as amended hereby.

(b) **Severability.** In case any provision of or obligation under this Amendment shall be invalid, illegal or unenforceable in any jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

(c) **Headings.** Headings and captions used in this Amendment (including the Exhibits, Schedules and Annexes hereto, if any) are included for convenience of reference only and shall not be given any substantive effect.

(d) **Integration.** This Amendment constitutes a Loan Document and, together with the other Loan Documents, incorporates all negotiations of the parties hereto with respect to the subject matter hereof and is the final expression and agreement of the parties hereto with respect to the subject matter hereof.

(e) **Counterparts.** This Amendment may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Amendment by signing any such counterpart.  
Executed

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counterparts delivered by facsimile or other electronic transmission (e.g., “PDF” or “TIF”) shall be effective as delivery of a manually executed counterpart.

(f) **Controlling Provisions.** In the event of any inconsistencies between the provisions of this Amendment and the provisions of any other Loan Document, the provisions of this Amendment shall govern and prevail. Except as expressly modified by this Amendment, the Loan Documents shall not be modified and shall remain in full force and effect.

(g) **Notices.** The Administrative Agent and Lenders hereby designate that all notices, requests, instructions, directions and other communications provided for herein shall be provided in accordance with **Section 13.02** of the Loan Agreement to the address specified on the signature pages hereto.

[Remainder of page intentionally left blank]

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IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWERS:

**STRONGBRIDGE U.S. INC.**

By /s/ Stephen J. Long  
Name: Stephen J. Long  
Title: Chief Legal Officer

Address for Notices:  
900 Northbrook Drive  
Suite 200  
Trevose, PA 19053  
Attn: Chief Legal Officer  
Tel.: 610-254-9225  
Fax: 215-355-7389  
Email: s.long@strongbridgebio.com

**STRONGBRIDGE BIOPHARMA PLC**

By /s/ Stephen J. Long  
Name: Stephen J. Long  
Title: Chief Legal Officer

Address for Notices:  
900 Northbrook Drive  
Suite 200  
Trevose, PA 19053  
Attn: Chief Legal Officer  
Tel.: 610-254-9225  
Fax: 215-355-7389  
Email: s.long@strongbridgebio.com

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**CORTENDO AB (PUBL)**

By /s/ Stephen J. Long  
Name: Stephen J. Long  
Title: Authorized Signatory

Address for Notices:  
900 Northbrook Drive  
Suite 200  
Trevose, PA 19053  
Attn: Chief Legal Officer  
Tel.: 610-254-9225  
Fax: 215-355-7389  
Email: s.long@strongbridgebio.com

**CORTENDO CAYMAN LTD.**

By /s/ A. Brian Davis  
Name: A. Brian Davis  
Title: Director

Address for Notices:  
900 Northbrook Drive  
Suite 200  
Trevose, PA 19053  
Attn: Chief Legal Officer  
Tel.: 610-254-9225  
Fax: 215-355-7389  
Email: s.long@strongbridgebio.com

**STRONGBRIDGE IRELAND LIMITED**

By /s/ Stephen J. Long  
Name: Stephen J. Long  
Title: Secretary

Address for Notices:  
900 Northbrook Drive  
Suite 200  
Trevose, PA 19053

---

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SEPARATELY WITH THE COMMISSION. THE OMITTED  
MATERIAL HAS BEEN FILED SEPARATELY WITH THE  
COMMISSION.**

Attn: Chief Legal Officer  
Tel.: 610-254-9225  
Fax: 215-355-7389  
Email: [s.long@strongbridgebio.com](mailto:s.long@strongbridgebio.com)

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ADMINISTRATIVE AGENT:

**CRG SERVICING LLC**

By /s/ Nathan Hukill

Name: Nathan Hukill

Title: Authorized Signatory

Address for Notices:

1000 Main Street, Suite 2500

Houston, TX 77002

Attn: Portfolio Reporting

Tel.: 713.209.7350

Fax: 713.209.7351

Email: notices@crglp.com

---

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LENDERS:

**CRG PARTNERS III L.P.**

By CRG PARTNERS III GP L.P., its General Partner  
By CRG PARTNERS III GP LLC, its General Partner

By /s/ Nathan Hukill \_\_\_\_\_

Name: Nathan Hukill  
Title: Authorized Signatory

Address for Notices:  
1000 Main Street, Suite 2500  
Houston, TX 77002  
Attn: Portfolio Reporting  
Tel.: 713.209.7350  
Fax: 713.209.7351  
Email: notices@crglp.com

**CRG PARTNERS III – PARALLEL FUND “A” L.P.**

By CRG PARTNERS III – PARALLEL FUND “A” GP L.P., its  
General Partner  
By CRG PARTNERS III – PARALLEL FUND “A” GP LLC,  
its General Partner

By /s/ Nathan Hukill \_\_\_\_\_

Name: Nathan Hukill  
Title: Authorized Signatory

Address for Notices:  
1000 Main Street, Suite 2500  
Houston, TX 77002  
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**CRG PARTNERS III (CAYMAN) LEV AIV I L.P.**

By CRG PARTNERS III (CAYMAN) GP L.P., its General Partner  
By CRG PARTNERS III (CAYMAN) GP LLC, its General Partner

By /s/ Nathan Hukill  
Name: Nathan Hukill  
Title: Authorized Signatory

Witness: /s/ Nicole Nesson

Name: Nicole Nesson

Address for Notices:  
1000 Main Street, Suite 2500  
Houston, TX 77002  
Attn: Portfolio Reporting  
Tel.: 713.209.7350  
Fax: 713.209.7351  
Email: notices@crglp.com

**CRG PARTNERS III (CAYMAN) UNLEV AIV I L.P.**

By CRG PARTNERS III (CAYMAN) GP L.P., its General Partner  
By CRG PARTNERS III (CAYMAN) GP LLC, its General Partner

By /s/ Nathan Hukill  
Name: Nathan Hukill  
Title: Authorized Signatory

Witness: /s/ Nicole Nesson

Name: Nicole Nesson

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Address for Notices:  
1000 Main Street, Suite 2500  
Houston, TX 77002  
Attn: Portfolio Reporting  
Tel.: 713.209.7350  
Fax: 713.209.7351  
Email: notices@crglp.com

**CRG PARTNERS III - PARALLEL FUND "B" (CAYMAN) L.P.**  
By CRG PARTNERS III (CAYMAN) GP L.P., its General Partner  
By CRG PARTNERS III (CAYMAN) GP LLC, its General Partner

By /s/ Nathan Hukill  
Name: Nathan Hukill  
Title: Authorized Signatory

Witness: /s/ Nicole Nesson

Name: Nicole Nesson

Address for Notices:  
1000 Main Street, Suite 2500  
Houston, TX 77002  
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VCOC LENDER:

**CRG PARTNERS III L.P.**

By CRG PARTNERS III GP L.P., its General Partner  
By CRG PARTNERS III GP LLC, its General Partner

By /s/ Nathan Hukill

Name: Nathan Hukill  
Title: Authorized Signatory

Address for Notices:  
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Houston, TX 77002  
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**Exhibit A  
to Amendment**

AMENDED LOAN AGREEMENT

[See attached.]

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EXHIBIT A TO AMENDMENT NO. 1  
MARKED VERSION REFLECTING CHANGES  
PURSUANT TO AMENDMENT NO. 1  
ADDED TEXT SHOWN UNDERSCORED  
DELETED TEXT SHOWN ~~STRIKETHROUGH~~

---

**TERM LOAN AGREEMENT,**

**dated as of**

**July 14, 2017,**

**as amended by Amendment 1 to Term Loan Agreement, dated as of January 16, 2018**

**among**

**STRONGBRIDGE U.S. INC,  
STRONGBRIDGE BIOPHARMA PLC,  
CORTENDO AB (PUBL),  
CORTENDO CAYMAN LTD.,  
STRONGBRIDGE IRELAND LIMITED,  
as Borrowers,**

**The Subsidiary Guarantors from Time to Time Party Hereto,**

**The Lenders from Time to Time Party Hereto,**

**and**

**CRG SERVICING LLC,  
as Administrative Agent and Collateral Agent**

**U.S. \$100,000,000**

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**SCHEDULES AND EXHIBITS**

- Schedule 1 - Commitments
  - Schedule 6.01 - Foreign Security Documents
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  - Schedule 9.05 - Existing Investments
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  - Exhibit A - Form of Assumption Agreement
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  - Exhibit F - Form of Landlord Consent
  - Exhibit G - Form of Subordination Agreement
  - Exhibit H - Form of Intercreditor Agreement (Permitted Priority Debt)
  - Exhibit I - Form of Warrant
-

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TERM LOAN AGREEMENT, dated as of July 14, 2017 and amended by Amendment 1 to Term Loan Agreement, dated as of January 16, 2018 (this "**Agreement**"), among STRONGBRIDGE U.S. INC., a Delaware corporation ("**Lead Borrower**"), STRONGBRIDGE BIOPHARMA PUBLIC LIMITED COMPANY, a public limited company incorporated under the laws of Ireland ("**Parent**"), STRONGBRIDGE IRELAND LIMITED, a private limited company incorporated under the laws of Ireland ("**Irish Borrower**"), CORTENDO CAYMAN LTD., an exempted company incorporated in the Cayman Islands ("**Cayman Borrower**"), CORTENDO AB (PUBL), a public limited liability company incorporated under the laws of Sweden with registration number 556537-6554 ("**Swedish Borrower**") and together with the Lead Borrower, Parent, Irish Borrower, Cayman Borrower, and each other Person that becomes, or is required to become, a "Borrower" after the date hereof pursuant to **Section 8.12(a)** or **(b)**, each a "**Borrower**" and collectively, "**Borrowers**"), the Subsidiary Guarantors from time to time party hereto, the Lenders from time to time party hereto and CRG SERVICING LLC, a Delaware limited liability company ("**CRG Servicing**"), as administrative agent and collateral agent for the Lenders (in such capacities, together with its successors and assigns, "**Administrative Agent**").

WITNESSETH:

Borrowers have requested the Lenders to make term loans to Borrowers, and the Lenders are prepared to make such loans on and subject to the terms and conditions hereof. Accordingly, the parties agree as follows:

#### SECTION 1 DEFINITIONS

**1.01 Certain Defined Terms.** As used herein, the following terms have the following respective meanings:

"**Accounting Change Notice**" has the meaning set forth in **Section 1.04(a)**.

"**Act**" has the meaning set forth in **Section 13.17**.

"**Acquisition**" means any transaction, or any series of related transactions, by which any Person directly or indirectly, by means of a take-over bid, tender offer, amalgamation, merger, purchase or license of assets, or similar transaction having the same effect as any of the foregoing, (a) acquires any business or product, or any division, product or line of business or all or substantially all of the assets of any Person engaged in any business or any division, product or line of business, (b) acquires control of securities of a Person engaged in a business representing more than 50% of the ordinary voting power for the election of directors or other governing body if the business affairs of such Person are managed by a board of directors or other governing body, or (c) acquires control of more than 50% of the ownership interest in any

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Person engaged in any business that is not managed by a board of directors or other governing body.

“*Administrative Agent*” has the meaning set forth in the introduction hereto.

“*Affected Lender*” has the meaning set forth in **Section 2.06(a)**.

“*Affiliate*” means, with respect to a specified Person, another Person that directly, or indirectly through one or more intermediaries, Controls or is Controlled by or is under common Control with the Person specified.

“*Agreement*” has the meaning set forth in the introduction hereto.

“*Amended Fee Letter*” means the amended and restated fee letter agreement dated as of the Amendment No. 1 Effective Date among Borrowers and Administrative Agent.

“*Amended Perfection Certificate*” means that certain perfection certificate dated as of the Amendment No. 1 Effective Date delivered by each Borrower to Administrative Agent.

“*Amendment No. 1*” means Amendment 1 to Term Loan Agreement, dated as of January 16, 2018, by and among the Borrowers, the Administrative Agent and the Lenders party thereto.

“*Amendment No. 1 Effective Date*” has the meaning specified in Amendment No. 1.

“*Anti-Corruption Laws*” means all laws, rules, and regulations of any jurisdiction applicable to any Obligor, its Subsidiaries or Affiliates from time to time concerning or relating to bribery or corruption, including the United States Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder.

“*Anti-Money Laundering Laws*” means any and all laws, statutes, regulations or obligatory government orders, decrees, ordinances or rules applicable to an Obligor, its Subsidiaries or Affiliates related to terrorism financing or money laundering, including any applicable provision of the Act and The Currency and Foreign Transaction Reporting Act (also known as the “Bank Secrecy Act,” 31 U.S.C. §§5311-5330 and 12 U.S.C. §§ 1818(s), 1820(b) and 1951-1959).

“*Asset Sale*” has the meaning set forth in **Section 9.09**.

“*Asset Sale Net Proceeds*” means the aggregate amount of the cash proceeds received from any Asset Sale, net of any bona fide costs incurred in connection with such Asset Sale, plus, with respect to any non-cash proceeds of an Asset Sale, the fair market value of such non cash proceeds as determined by the Majority Lenders, acting reasonably.



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“*Assignment and Assumption*” means an assignment and assumption entered into by a Lender and an assignee of such Lender.

“*Assumption Agreement*” means a Guarantee or Borrower Assumption Agreement substantially in the form of **Exhibit A** by an entity that, pursuant to **Section 8.12(a)**, is required to become a “Subsidiary Guarantor” or “Borrower” hereunder.

“*Bankruptcy Code*” means Title 11 of the United States Code entitled “Bankruptcy.”

“*Beneficiary*” has the meaning set forth in **Section 1.05**.

“*Benefit Plan*” means any employee benefit plan as defined in Section 3(3) of ERISA (whether governed by the laws of the United States or otherwise) to which any Obligor or Subsidiary thereof incurs or otherwise has any obligation or liability, contingent or otherwise.

“*Borrower*” and “*Borrowers*” have the meanings set forth in the introduction hereto.

“*Borrower Facility*” means the premises located at 900 Northbrook Drive, Suite 200, Trevose, PA 19053, which are leased by Borrower pursuant to the Borrower Lease.

“*Borrower Landlord*” means Insight Pharmaceuticals LLC, a Delaware limited liability company.

“*Borrower Lease*” means the Sublease Agreement dated March 31, 2015 by and between Borrower and Borrower Landlord.

“*Borrower Party*” has the meaning set forth in **Section 13.03(b)**.

“*Borrowing*” means a borrowing consisting of Loans made on the same day by the Lenders according to their respective Commitments (including a borrowing of a PIK Loan).

“*Borrowing Date*” means the date of a Borrowing.

“*Borrowing Notice Date*” means, (a) in the case of the first Borrowing, a date that is at least three (3) Business Days prior to the Borrowing Date of such Borrowing, (b) in the case of the second Borrowing, a date that is at least one Business Day prior to the Borrowing Date of such Borrowing and, (c) in the case of a subsequent Borrowing (that is not the first Borrowing or the second Borrowing), a date that is at least twelve (12) Business Days prior to the Borrowing Date of such Borrowing.

“*Business Day*” means a day (other than a Saturday or Sunday) on which commercial banks are not authorized or required to close in New York City.

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“*Capital Lease Obligations*” means, as to any Person, the obligations of such Person to pay rent or other amounts under a lease of (or other agreement conveying the right to use) real and/or personal Property which obligations are required to be classified and accounted for as a capital lease on a balance sheet of such Person under GAAP and, for purposes of this Agreement, the amount of such obligations shall be the capitalized amount thereof, determined in accordance with GAAP.

“*Cayman Borrower*” has the meaning set forth in the introduction hereto.

“*Change of Control*” means (a) the acquisition of ownership, directly or indirectly, beneficially or of record, by any Person or group of Persons acting jointly or otherwise in concert of capital stock representing more than 30% of the aggregate ordinary voting power represented by the issued and outstanding capital stock of Parent, (b) during any period of twelve (12) consecutive calendar months, the occupation of a majority of the seats (other than vacant seats) on the board of directors of Parent by Persons who were neither (i) nominated by the board of directors of Parent, nor (ii) appointed by directors so nominated, (c) the acquisition of direct or indirect Control of Parent by any Person or group of Persons acting jointly or otherwise in concert; in each case whether as a result of a tender or exchange offer, open market purchases, privately negotiated purchases or otherwise, or (d) Lead Borrower ceases to be a wholly owned direct or indirect subsidiary of Parent.

“*Claims*” means any claims, demands, complaints, grievances, actions, applications, suits, causes of action, orders, charges, indictments, prosecutions, informations (brought by a public prosecutor without grand jury indictment) or other similar processes, assessments or reassessments.

“*Closing Date*” means July 14, 2017.

“*Code*” means the Internal Revenue Code of 1986, as amended from time to time, and the rules and regulations promulgated thereunder from time to time.

“*Collateral*” means any Property in which a Lien is purported to be granted under any of the Security Documents (or all such Property, as the context may require).

“*Commitment*” means, with respect to each Lender, the obligation of such Lender to make Loans to Borrower in accordance with the terms and conditions of this Agreement, which commitment is in the amount set forth opposite such Lender’s name on **Schedule 1** under the caption “Commitment”, as such Schedule may be amended from time to time. The aggregate Commitments on the Amendment No. 1 Effective Date equal \$100,000,000. For purposes of clarification, the amount of any PIK Loans shall not reduce the amount of the available Commitment.

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“*Commitment Period*” means the period from and including the first date on which all of the conditions precedent set forth in **Section 6.01** have been satisfied (or waived by the Lenders) and through and including March 19, 2019.

“*Commodity Account*” has the meaning set forth in the Security Agreement.

“*Compliance Certificate*” has the meaning given to such term in **Section 8.01(d)**.

“*Connection Income Taxes*” means Other Connection Taxes that are imposed on or measured by net income (however denominated) or that are franchise Taxes or branch profits Taxes.

“*Contracts*” means contracts, licenses, leases, agreements, obligations, promises, undertakings, understandings, arrangements, documents, commitments, entitlements or engagements under which a Person has, or will have, any liability or contingent liability (in each case, whether written or oral, express or implied).

“*Control*” means, in respect of a particular Person, the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of such Person, whether through the ability to exercise voting power, by contract or otherwise. “Controlling” and “Controlled” have meanings correlative thereto.

“*Controlled Foreign Corporation*” means a “controlled foreign corporation” as defined in Section 957(a) of the Code.

“*Copyright*” has the meaning set forth in the Security Agreement.

“*CRG Servicing*” has the meaning set forth in the introduction hereto.

“*Cure Amount*” has the meaning set forth in **Section 10.03(a)**.

“*Cure Right*” has the meaning set forth in **Section 10.03(a)**.

“*Default*” means any Event of Default and any event that, upon the giving of notice, the lapse of time or both, would constitute an Event of Default.

“*Default Rate*” has the meaning set forth in **Section 3.02(b)**.

“*Defaulting Lender*” means, subject to **Section 2.05**, any Lender that (a) has failed to perform any of its funding obligations hereunder, including in respect of its Loans, within three (3) Business Days of the date required to be funded by it hereunder, (b) has notified Lead Borrower or any Lender that it does not intend to comply with its funding obligations or has

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made a public statement to that effect with respect to its funding obligations hereunder or under other agreements in which it commits to extend credit, (c) has failed, within three Business Days after written request by the Administrative Agent or the Lead Borrower, to confirm in writing to the Administrative Agent and the Lead Borrower that it will comply with its prospective funding obligations hereunder (*provided* that such Lender shall cease to be a Defaulting Lender pursuant to this clause (c) upon receipt of such written confirmation by the Administrative Agent and the Lead Borrower), or (d) has, or has a direct or indirect parent company that has, (i) become the subject of an Insolvency Proceeding, (ii) had a receiver, conservator, trustee, administrator, assignee for the benefit of creditors or similar Person charged with reorganization or liquidation of its business or a custodian appointed for it, or (iii) taken any action in furtherance of, or indicated its consent to, approval of or acquiescence in any such proceeding or appointment; *provided* that a Lender shall not be a Defaulting Lender solely by virtue of the ownership or acquisition of any equity interest in that Lender or any direct or indirect parent company thereof by a Governmental Authority so long as such ownership interest does not result in or provide such Lender with immunity from the jurisdiction of courts within the United States or from the enforcement of judgments or writs of attachment on its assets or permit such Lender (or such Governmental Authority) to reject, repudiate, disavow or disaffirm any contracts or agreements made with such Lender. Any determination by the Administrative Agent that a Lender is a Defaulting Lender under any one or more of clauses (a) through (d) above shall be conclusive and binding absent manifest error, and such Lender shall be deemed to be a Defaulting Lender (subject to Section 2.05(b)) upon delivery of written notice of such determination to the Lead Borrower and each Lender.

*“Deposit Account”* has the meaning set forth in the Security Agreement.

*“Dollars”* and *“\$”* means lawful money of the United States of America.

*“Eligible Transferee”* means and includes a commercial bank, an insurance company, a finance company, a financial institution, any investment fund that invests in loans or any other “accredited investor” (as defined in Regulation D of the Securities Act) that is principally in the business of managing investments or holding assets for investment purposes.

*“Environmental Law”* means any federal, state, provincial or local governmental law, rule, regulation, order, writ, judgment, injunction or decree relating to pollution or protection of the environment or the treatment, storage, disposal, release, threatened release or handling of hazardous materials, and all local laws and regulations related to environmental matters and any specific agreements entered into with any competent authorities which include commitments related to environmental matters.

*“Equity Cure Right”* has the meaning set forth in **Section 10.03(a)**.

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“*Equity Interest*” means, with respect to any Person, any and all shares, interests, participations or other equivalents, including membership interests (however designated, whether voting or nonvoting), of equity of such Person, including, if such Person is a partnership, partnership interests (whether general or limited) and any other interest or participation that confers on a Person the right to receive a share of the profits and losses of, or distributions of property of, such partnership, but excluding debt securities convertible or exchangeable into such equity.

“*Equivalent Amount*” means, with respect to an amount denominated in one currency, the amount in another currency that could be purchased by the amount in the first currency determined by reference to the Exchange Rate at the time of determination.

“*ERISA*” means the United States Employee Retirement Income Security Act of 1974, as amended.

“*ERISA Affiliate*” means, collectively, any Obligor, Subsidiary thereof, and any Person under common control, or treated as a single employer, with any Obligor or Subsidiary thereof, within the meaning of Section 414(b), (c), (m) or (o) of the Code.

“*ERISA Event*” means (a) a reportable event as defined in Section 4043 of ERISA with respect to a Title IV Plan, excluding, however, such events as to which the PBGC by regulation has waived the requirement of Section 4043(a) of ERISA that it be notified within 30 days of the occurrence of such event; (b) the applicability of the requirements of Section 4043(b) of ERISA with respect to a contributing sponsor, as defined in Section 4001(a)(13) of ERISA, to any Title IV Plan where an event described in paragraph (9), (10), (11), (12) or (13) of Section 4043(c) of ERISA is reasonably expected to occur with respect to such plan within the following 30 days; (c) a withdrawal by any Obligor or any ERISA Affiliate thereof from a Title IV Plan or the termination of any Title IV Plan resulting in liability under Sections 4063 or 4064 of ERISA; (d) the withdrawal of any Obligor or any ERISA Affiliate thereof in a complete or partial withdrawal (within the meaning of Section 4203 and 4205 of ERISA) from any Multiemployer Plan if there is any potential liability therefore, or the receipt by any Obligor or any ERISA Affiliate thereof of notice from any Multiemployer Plan that it is in reorganization or insolvency pursuant to Section 4241 or 4245 of ERISA; (e) the filing of a notice of intent to terminate, the treatment of a plan amendment as a termination under Section 4041 or 4041A of ERISA, or the commencement of proceedings by the PBGC to terminate a Title IV Plan or Multiemployer Plan; (f) the imposition of liability on any Obligor or any ERISA Affiliate thereof pursuant to Sections 4062(e) or 4069 of ERISA or by reason of the application of Section 4212(c) of ERISA; (g) the failure by any Obligor or any ERISA Affiliate thereof to make any required contribution to a Plan, or the failure to meet the minimum funding standard of Section 412 of the Code with respect to any Title IV Plan (whether or not waived in accordance with Section 412(c) of the Code) or the failure to make by its due date a required installment under Section 430 of the Code

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with respect to any Title IV Plan or the failure to make any required contribution to a Multiemployer Plan; (h) the determination that any Title IV Plan is considered an at-risk plan or a plan in endangered to critical status within the meaning of Sections 430, 431 and 432 of the Code or Sections 303, 304 and 305 of ERISA; (i) an event or condition which might reasonably be expected to constitute grounds under Section 4042 of ERISA for the termination of, or the appointment of a trustee to administer, any Title IV Plan or Multiemployer Plan; (j) the imposition of any liability under Title I or Title IV of ERISA, other than PBGC premiums due but not delinquent under Section 4007 of ERISA, upon any Obligor or any ERISA Affiliate thereof; (k) an application for a funding waiver under Section 303 of ERISA or an extension of any amortization period pursuant to Section 412 of the Code with respect to any Title IV Plan; (l) the occurrence of a non-exempt prohibited transaction under Sections 406 or 407 of ERISA for which any Obligor or any Subsidiary thereof may be directly or indirectly liable; (m) the assertion of a material claim (other than routine claims for benefits) against any Plan or the assets thereof, or against any Obligor or any Subsidiary thereof in connection with any such plan; (n) receipt from the IRS of notice of the failure of any Qualified Plan to qualify under Section 401(a) of the Code, or the failure of any trust forming part of any Qualified Plan to fail to qualify for exemption from taxation under Section 501(a) of the Code; (o) the imposition of any lien (or the fulfillment of the conditions for the imposition of any lien) on any of the rights, properties or assets of any Obligor or any ERISA Affiliate thereof, in either case pursuant to Title I or IV, including Section 302(f) or 303(k) of ERISA or to Section 401(a)(29) or 430(k) of the Code; or (p) the establishment or amendment by any Obligor or any Subsidiary thereof of any "welfare plan", as such term is defined in Section 3(1) of ERISA, that provides post-employment welfare benefits in a manner that would increase the liability of any Obligor.

**"ERISA Funding Rules"** means the rules regarding minimum required contributions (including any installment payment thereof) to Title IV Plans, as set forth in Sections 412, 430, 431, 432 and 436 of the Code and Sections 302, 303, 304 and 305 of ERISA.

**"Event of Default"** has the meaning set forth in **Section 11.01**.

**"Exchange Rate"** means the rate at which any currency (the **"Pre-Exchange Currency"**) may be exchanged into another currency (the **"Post-Exchange Currency"**), as set forth on such date on the relevant Reuters screen at or about 11:00 a.m. (Central time) on such date. In the event that such rate does not appear on the Reuters screen, the "Exchange Rate" with respect to exchanging such Pre-Exchange Currency into such Post-Exchange Currency shall be determined by reference to such other publicly available service for displaying exchange rates as may be agreed upon by Lead Borrower and Administrative Agent or, in the absence of such agreement, such Exchange Rate shall instead be determined by Administrative Agent by any reasonable method as they deem applicable to determine such rate, and such determination shall be conclusive absent manifest error.

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“*Excluded Foreign Subsidiary*” means any Foreign Subsidiary that is (i) a Controlled Foreign Corporation or (ii) a Foreign Subsidiary owned by a Subsidiary described in clause (i).

“*Excluded Taxes*” means any of the following Taxes imposed on or with respect to a Recipient or required to be withheld or deducted from a payment to a Recipient: (a) Taxes imposed on or measured by net income (however denominated), franchise Taxes and branch profits Taxes, in each case (i) imposed as a result of such Recipient being organized under the laws of, or having its principal office or, in the case of any Lender, its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof), or (ii) that are Other Connection Taxes, (b) U.S. Federal withholding Taxes that are imposed on amounts payable to a Lender to the extent that the obligation to withhold amounts existed on the date that such Lender became a “Lender” under this Agreement (other than pursuant to an assignment request by Lead Borrower under **Section 5.03(g)**), or (ii) such Lender changes its applicable lending office, except in each case to the extent such Lender is a direct or indirect assignee of any other Lender that was entitled, at the time the assignment of such other Lender became effective or to such Lender immediately before it changed its applicable lending office, to receive additional amounts under **Section 5.03**, (c) any U.S. Federal withholding Taxes imposed under FATCA, and (d) Taxes attributable to such Recipient’s failure to comply with **Section 5.03(e)**.

“*Expense Cap*” has the meaning set forth in the Amended Fee Letter.

“*FATCA*” means Sections 1471 through 1474 of the Code, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not more onerous to comply with), any regulations or official interpretations thereof and any agreements entered into pursuant to Section 1471(b)(1) of the Code.

“*Federal Funds Effective Rate*” means, for any day, the weighted average of the rates on overnight federal funds transactions with members of the Federal Reserve System arranged by federal funds brokers, as published on the next succeeding Business Day by the Federal Reserve Bank of New York, or, if such rate is not so published for any day that is a Business Day, the average of the quotations for the day of such transactions received by Administrative Agent from three federal funds brokers of recognized standing selected by it.

“*First-Tier Foreign Subsidiary*” means an Excluded Foreign Subsidiary that is a direct Subsidiary of an Obligor.

“*Foreign Lender*” means a Lender that is not a U.S. Person.

“*Foreign Subsidiary*” means a Subsidiary of any Borrower that is not a U.S. Person.

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“**Fully-Diluted Basis**” means the Parent’s outstanding capital stock, measured as of the applicable Borrowing Date, including (a) all ordinary shares, (b) all preferred shares on an as-converted to ordinary share basis and (c) all shares of capital stock issuable upon the exercise of all outstanding warrants, options and other rights to purchase or acquire capital stock (inclusive of the warrants granted on such Borrowing Date) and the conversion or exchange of any securities convertible into or exchangeable for capital stock of the Parent.

“**GAAP**” means generally accepted accounting principles in the United States of America, as in effect from time to time, set forth in the opinions and pronouncements of the Accounting Principles Board and the American Institute of Certified Public Accountants, in the statements and pronouncements of the Financial Accounting Standards Board and in such other statements by such other entity as may be in general use by significant segments of the accounting profession that are applicable to the circumstances as of the date of determination. Subject to **Section 1.02**, all references to “GAAP” shall be to GAAP applied consistently with the principles used in the preparation of the financial statements described in **Section 7.04(a)**.

“**Governmental Approval**” means any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

“**Governmental Authority**” means any nation, government, branch of power (whether executive, legislative or judicial), state, province or municipality or other political subdivision thereof and any entity exercising executive, legislative, judicial, monetary, regulatory or administrative functions of or pertaining to government, including regulatory authorities, governmental departments, agencies, commissions, bureaus, officials, ministers, courts, bodies, boards, tribunals and dispute settlement panels, and other law-, rule- or regulation-making organizations or entities of any State, territory, county, city or other political subdivision of the United States.

“**Guarantee**” of or by any Person (the “**guarantor**”) means any obligation, contingent or otherwise, of the guarantor guaranteeing or having the economic effect of guaranteeing any Indebtedness or other obligation of any other Person (the “**primary obligor**”) in any manner, whether directly or indirectly, and including any obligation of the guarantor, direct or indirect, (a) to purchase or pay (or advance or supply funds for the purchase or payment of) such Indebtedness or other obligation or to purchase (or to advance or supply funds for the purchase of) any security for the payment thereof, (b) to purchase or lease property, securities or services for the purpose of assuring the owner of such Indebtedness or other obligation of the payment thereof, (c) to maintain working capital, equity capital or any other financial statement condition or liquidity of the primary obligor so as to enable the primary obligor to pay such Indebtedness or other obligation or (d) as an account party in respect of any letter of credit or letter of guaranty



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issued to support such Indebtedness or obligation; *provided* that the term Guarantee shall not include endorsements for collection or deposit in the ordinary course of business.

**“Guaranteed Obligations”** has the meaning set forth in **Section 14.01**.

**“Hazardous Material”** means any substance, element, chemical, compound, product, solid, gas, liquid, waste, by-product, pollutant, contaminant or material which is hazardous or toxic, and includes (a) asbestos, polychlorinated biphenyls and petroleum (including crude oil or any fraction thereof) and (b) any material classified or regulated as “hazardous” or “toxic” or words of like import pursuant to an Environmental Law.

**“Hedging Agreement”** means any interest rate exchange agreement, foreign currency exchange agreement, commodity price protection agreement or other interest or currency exchange rate or commodity price hedging arrangement.

**“Indebtedness”** of any Person means, without duplication, (a) (i) all obligations of such Person for borrowed money or (ii) obligations of such Person with respect to deposits or advances of any kind by third parties (other than an Obligor), (b) all obligations of such Person evidenced by bonds, debentures, notes or similar instruments, (c) all obligations of such Person upon which interest charges are customarily paid, (d) all obligations of such Person under conditional sale or other title retention agreements relating to property acquired by such Person, (e) all obligations of such Person in respect of the deferred purchase price of property or services (excluding current accounts payable incurred in the ordinary course of business), (f) all Indebtedness of others secured by (or for which the holder of such Indebtedness has an existing right, contingent or otherwise, to be secured by) any Lien on property owned or acquired by such Person, whether or not the Indebtedness secured thereby has been assumed, (g) all Guarantees by such Person of Indebtedness or other obligations of others, (h) all Capital Lease Obligations of such Person, (i) all obligations, contingent or otherwise, of such Person as an account party in respect of letters of credit and letters of guaranty, (j) obligations under any Hedging Agreement currency swaps, forwards, futures or derivatives transactions, (k) all obligations, contingent or otherwise, of such Person in respect of bankers’ acceptances, (l) all obligations of such Person under license or other agreements containing a guaranteed minimum payment or purchase by such Person, and (m) all Equity Interests of such Person subject to repurchase or redemption rights or obligations (excluding repurchases or redemptions at the sole option of such Person). The Indebtedness of any Person shall include the Indebtedness of any other entity (including any partnership in which such Person is a general partner) to the extent such Person is liable therefor as a result of such Person’s ownership interest in or other relationship with such entity, except to the extent the terms of such Indebtedness provide that such Person is not liable therefor.

**“Indemnified Party”** has the meaning set forth in **Section 13.03(b)**.

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**“Indemnified Taxes”** means (a) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any Obligation and (b) to the extent not otherwise described in clause (a), Other Taxes.

**“Insolvency Proceeding”** means (a) any case, action or proceeding before any court or other Governmental Authority relating to bankruptcy, reorganization, insolvency, liquidation, receivership, dissolution, winding-up or relief of debtors, or (b) any general assignment for the benefit of creditors, composition, marshaling of assets for creditors, or other, similar arrangement in respect of any Person’s creditors generally or any substantial portion of such Person’s creditors, in each case undertaken under U.S. Federal, state or foreign law, including the Bankruptcy Code.

**“Intellectual Property”** means all Patents, Trademarks, Copyrights, and Technical Information, whether registered or not, domestic and foreign. Intellectual Property shall include all:

- (a) applications or registrations relating to such Intellectual Property;
- (b) rights and privileges arising under applicable Laws with respect to such Intellectual Property;
- (c) rights to sue for past, present or future infringements of such Intellectual Property; and
- (d) rights of the same or similar effect or nature in any jurisdiction corresponding to such Intellectual Property throughout the world.

**“Interest-Only Period”** means the period from and including the first Borrowing Date and through and including (i) if Borrowers have not achieved the Recorlev Approval Milestone, the fourteenth (14<sup>th</sup>) Payment Date following the first Borrowing Date and (ii) if Borrowers have achieved the Recorlev Approval Milestone and so long as no Default or Event of Default has occurred and is continuing, the twenty-third (23<sup>rd</sup>) Payment Date following the first Borrowing Date.

**“Interest Period”** means, with respect to each Borrowing, (a) initially, the period commencing on and including the Borrowing Date thereof and ending on and excluding the next Payment Date, and, (b) thereafter, each period beginning on and including the last day of the immediately preceding Interest Period and ending on and excluding the next succeeding Payment Date.

**“Invention”** means any novel, inventive and useful art, apparatus, method, process, machine (including article or device), manufacture or composition of matter, or any novel,

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inventive and useful improvement in any art, method, process, machine (including article or device), manufacture or composition of matter.

**“Investment”** means, for any Person: (a) the acquisition (whether for cash, property, services or securities or otherwise) of capital stock, bonds, notes, debentures, partnership or other ownership interests or other securities of any other Person or any agreement to make any such acquisition (including any “short sale” or any sale of any securities at a time when such securities are not owned by the Person entering into such sale); (b) the making of any deposit with, or advance, loan or other extension of credit to, any other Person (including the purchase of property from another Person subject to an understanding or agreement, contingent or otherwise, to resell such property to such Person), but excluding any such advance, loan or extension of credit having a term not exceeding 90 days arising in connection with the sale of inventory or supplies by such Person in the ordinary course of business; (c) the entering into of any Guarantee of, or other contingent obligation with respect to, Indebtedness or other liability of any other Person and (without duplication) any amount committed to be advanced, lent or extended to such Person; or (d) the entering into of any Hedging Agreement.

**“Irish Borrower”** has the meaning set forth in the introduction hereto.

**“Irish Companies Act”** means the Companies Act 2014 of Ireland.

**“IRS”** means the U.S. Internal Revenue Service or any successor agency, and to the extent relevant, the U.S. Department of the Treasury.

**“Knowledge”** means, with respect to any Person, the actual knowledge of any Responsible Officer of such Person and, in the case of Lead Borrower, so long as he or she is employed by Parent or its Subsidiaries, the actual knowledge of Matthew Pauls, so long as such Person is an officer of Lead Borrower.

**“Landlord Consent”** means a Landlord Consent substantially in the form of **Exhibit F** or such other form as reasonably acceptable to the Administrative Agent.

**“Laws”** means, collectively, all international, foreign, federal, state, provincial, territorial, municipal and local statutes, treaties, rules, guidelines, regulations, ordinances, codes and administrative or judicial precedents or authorities, including the interpretation or administration thereof by any Governmental Authority charged with the enforcement, interpretation or administration thereof, and all applicable administrative orders, directed duties, requests, licenses, authorizations and permits of, and agreements with, any Governmental Authority, in each case whether or not having the force of law.

**“Lead Borrower”** has the meaning set forth in the introduction hereto.

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“**Lender**” means each Person listed as a “Lender” on a signature page hereto, together with its successors, and each assignee of a Lender pursuant to **Section 13.05(b)**.

“**Lien**” means any mortgage, lien, pledge, charge or other security interest, or any lease, title retention agreement, mortgage, restriction, easement, right-of-way or other encumbrance of any kind or character whatsoever or any preferential arrangement that has the practical effect of creating a security interest.

“**Liquidity**” means the balance of unencumbered (other than by Liens described in **Sections 9.02(a), 9.02(c)** (provided that there is no default under the documentation governing the Permitted Priority Debt) and **9.02(j)**) cash and Permitted Cash Equivalent Investments (which for greater certainty shall not include any undrawn credit lines), in each case, to the extent held in an account over which the Secured Parties have a perfected security interest.

“**Loan**” means (a) each loan advanced by a Lender pursuant to **Section 2.01** and (b) each PIK Loan deemed to have been advanced by a Lender pursuant to **Section 3.02(d)**. For purposes of clarification, except as otherwise expressly provided in this Agreement, any calculation of the aggregate outstanding principal amount of Loans on any date of determination shall include both the aggregate principal amount of loans advanced pursuant to **Section 2.01** and not yet repaid, and all PIK Loans deemed to have been advanced and not yet repaid, on or prior to such date of determination.

“**Loan Documents**” means, collectively, this Agreement, Amendment No. 1, the Amended Fee Letter, the Security Documents, each Warrant, the Original Perfection Certificate, the Amended Perfection Certificate, any subordination agreement or any intercreditor agreement entered into by Administrative Agent (on behalf of the Lenders) with any other creditors of Obligors or any agent acting on behalf of such creditors, and any other present or future document, instrument, agreement or certificate executed by Obligors and delivered to Administrative Agent or any Secured Party in connection with or pursuant to this Agreement or any of the other Loan Documents, all as amended, amended and restated, supplemented or otherwise modified.

“**Loss**” means judgments, debts, liabilities, expenses, costs, damages or losses, contingent or otherwise, whether liquidated or unliquidated, matured or unmatured, disputed or undisputed, contractual, legal or equitable, including loss of value, professional fees, including fees and disbursements of legal counsel on a full indemnity basis, and all costs incurred in investigating or pursuing any Claim or any proceeding relating to any Claim.

“**Macrilen License Agreement**” means that certain License and Assignment Agreement, dated as of the Amendment No. 1 Effective Date, between the Irish Borrower and Aetema

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Zentaris GmbH, a corporation incorporated under the laws of Germany, together with all schedules and exhibits thereto.

“**Macrilen Acquisition**” means the acquisition by the Irish Borrower of the exclusive North American marketing rights to Macrilen (macimorelin) pursuant to the Macrilen License Agreement.

“**Majority Lenders**” means, at any time, Lenders having at such time in excess of 50% of the aggregate Commitments (or, if such Commitments are terminated, the outstanding principal amount of the Loans) then in effect, ignoring, in such calculation, the Commitments of and outstanding Loans owing to any Defaulting Lender.

“**Margin Stock**” means “margin stock” within the meaning of Regulations U and X.

“**Market Capitalization**” means, as of any date of determination, the product of (a) the number of shares of Parent’s ordinary shares outstanding (other than treasury stock), as of such date of determination and (b) the closing sale price for the regular trading session of Parent’s ordinary shares on NASDAQ (or other principal exchange on which the Parent’s ordinary shares are traded) on such date of determination.

“**Material Adverse Change**” and “**Material Adverse Effect**” mean a material adverse change in or effect on (a) the business, condition (financial or otherwise), operations, performance or Property of Parent and its Subsidiaries taken as a whole, (b) the ability of any Obligor to perform its obligations under the Loan Documents, or (c) the legality, validity, binding effect or enforceability of the Loan Documents or the rights and remedies of Administrative Agent or any Lender under any of the Loan Documents.

“**Material Agreements**” means (a) the agreements which are listed in **Schedule 7.14** (as updated by Lead Borrower from time to time in accordance with **Section 7.21** to list all such agreements that meet the description set forth in clauses (b) and (c) of this definition), (b) material inbound and outbound license agreements (including, without limitation, the Macrilen License Agreement) and (c) all other agreements held by the Obligors from time to time, the absence or termination of any of which would reasonably be expected to result in a Material Adverse Effect; *provided, however*, that “Material Agreements” exclude all: (i) licenses implied by the sale of a product; and (ii) paid-up licenses for commonly available software programs under which an Obligor is the licensee. “Material Agreement” means any one such agreement.

“**Material Indebtedness**” means, at any time, any Indebtedness of any Obligor, the outstanding principal amount of which, individually or in the aggregate, exceeds \$300,000 (or the Equivalent Amount in other currencies).

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“*Material Intellectual Property*” means, the Obligor Intellectual Property described in **Schedule 7.05(c)** and any other Obligor Intellectual Property acquired after the Closing Date the loss of which would reasonably be expected to have a Material Adverse Effect.

“*Maturity Date*” means the earlier to occur of (a) the Stated Maturity Date, and (b) the date on which the Loans are accelerated pursuant to **Section 11.02**.

“*Maximum Rate*” has the meaning set forth in **Section 13.18**.

“*Minimum Required Revenue*” has the meaning set forth in **Section in 10.02**.

“*Multiemployer Plan*” means any multiemployer plan, as defined in Section 4001(a)(3) of ERISA, to which any ERISA Affiliate incurs or otherwise has any obligation or liability, contingent or otherwise.

“*Non-Consenting Lender*” has the meaning set forth in **Section 2.06(a)**.

“*Non-Disclosure Agreement*” has the meaning set forth in **Section 13.16**.

“*Notice of Borrowing*” has the meaning set forth in **Section 2.02**.

“*Obligations*” means, with respect to any Obligor, all amounts, obligations, liabilities, covenants and duties of every type and description owing by such Obligor to Administrative Agent, any Lender or any other indemnitee hereunder, arising out of, under, or in connection with, any Loan Document (other than the Warrant), whether direct or indirect (regardless of whether acquired by assignment), absolute or contingent, due or to become due, whether liquidated or not, now existing or hereafter arising and however acquired, and whether or not evidenced by any instrument or for the payment of money, including, without duplication, (a) if such Obligor is a Borrower, all Loans, (b) all interest, whether or not accruing after the filing of any petition in bankruptcy or after the commencement of any insolvency, reorganization or similar proceeding, and whether or not a claim for post-filing or post-petition interest is allowed in any such proceeding, and (c) all other fees, expenses (including fees, charges and disbursement of counsel), interest, commissions, charges, costs, disbursements, indemnities and reimbursement of amounts paid and other sums chargeable to such Obligor under any Loan Document (other than the Warrant).

“*Obligor Intellectual Property*” means Intellectual Property owned by or licensed to any of the Obligors.

“*Obligors*” means, collectively, each Borrower and the Subsidiary Guarantors and their respective successors and permitted assigns.

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“*OFAC*” means the Office of Foreign Assets Control of the United States Department of the Treasury.

“*Original Fee Letter*” means the fee letter agreement dated as of the Closing Date among Borrowers and Administrative Agent.

“*Original Perfection Certificate*” means that certain perfection certificate dated as of the Closing Date delivered by each Borrower party thereto to Administrative Agent.

“*Other Connection Taxes*” means, with respect to any Recipient, Taxes imposed as a result of a present or former connection between such Recipient and the jurisdiction imposing such Tax (other than connections arising from such Recipient having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Loan or Loan Document).

“*Other Taxes*” means all present or future stamp, court or documentary, intangible, recording, filing or similar Taxes that arise from any payment made under, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment (other than an assignment made pursuant to **Section 5.03(g)**).

“*Parent*” has the meaning set forth in the introduction hereto.

“*Participant*” has the meaning set forth in **Section 13.05(e)**.

“*Participant Register*” has the meaning set forth in **Section 13.05(f)**.

“*Patents*” has the meaning set forth in the Security Agreement.

“*Payment Date*” means each March 31, June 30, September 30, December 31 and the Maturity Date, commencing on the first such date to occur following the first Borrowing Date; *provided* that, if any such date shall occur on a day that is not a Business Day, the applicable Payment Date shall be the immediately preceding Business Day.

“*PBGC*” means the United States Pension Benefit Guaranty Corporation referred to and defined in ERISA and any successor entity performing similar functions.

“*Permitted Acquisition*” means any acquisition by any Obligor, whether by purchase, merger, license or otherwise, of all or substantially all of the assets of, all of the Equity Interests of, or a business line or unit or a division or a product of, any Person; *provided* that:

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(a) immediately prior to, and after giving effect thereto, no Default or Event of Default shall have occurred and be continuing or would result therefrom;

(b) all transactions in connection therewith shall be consummated, in all material respects, in accordance with all applicable Laws and in conformity in all material respects with all applicable Governmental Approvals;

(c) in the case of the acquisition of all of the Equity Interests of such Person, all of the Equity Interests (except for any such securities in the nature of directors' qualifying shares required pursuant to applicable Law) acquired, or otherwise issued by such Person or any newly formed Subsidiary of Parent in connection with such acquisition, shall be owned 100% by an Obligor or any other Subsidiary, and Parent shall have taken, or caused to be taken, each of the actions set forth in **Section 8.12**, if applicable;

(d) Parent and its Subsidiaries shall be in compliance with the financial covenants set forth in **Section 10.01** and **Section 10.02** on a *pro forma* basis after giving effect to such acquisition;

(e) such Person (in the case of an acquisition of Equity Interests) or assets (in the case of an acquisition of assets or a division) (i) shall be engaged or used, as the case may be, in the same business or lines of business in which Parent and/or its Subsidiaries are engaged or (ii) shall have a similar customer base as Parent and/or its Subsidiaries; and

(f) concurrent with the earlier of the execution of the applicable acquisition agreement or the consummation of such acquisition, Lead Borrower shall have provided Administrative Agent copies of the acquisition agreement and other material documents relative to the proposed acquisition.

**"Permitted Cash Equivalent Investments"** means (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than two (2) years from the date of acquisition thereof, (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc., and (c) Investments permitted by Parent's investment policy in effect on the Closing Date, as amended from time to time, provided that such amendment thereto has been approved in writing by the Administrative Agent.

**"Permitted Cure Debt"** means Indebtedness incurred in connection with the exercise of the Subordinated Debt Cure Right and (a) that is governed by documentation containing



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representations, warranties, covenants and events of default no more burdensome or restrictive than those contained in the Loan Documents, (b) that has a maturity date later than the Stated Maturity Date, (c) in respect of which no cash payments of principal or interest are required prior to the Stated Maturity Date, and (d) in respect of which the holders have agreed in favor of Borrowers, Administrative Agent and Lenders (i) that prior to the date on which the Commitments have expired or been terminated and all Obligations have been paid in full indefeasibly in cash, such holders will not exercise any remedies available to them in respect of such Indebtedness, (ii) that such Indebtedness is unsecured, and (iii) to terms of subordination in substantially the form attached hereto as **Exhibit G** or otherwise satisfactory to Administrative Agent.

**“Permitted Indebtedness”** means any Indebtedness permitted under **Section 9.01**.

**“Permitted Liens”** means any Liens permitted under **Section 9.02**.

**“Permitted Priority Debt”** means Indebtedness of Lead Borrower under one working capital revolving credit facility, in an amount not to exceed at any time 80% of the face amount at such time of Lead Borrower’s eligible accounts receivable; *provided* that (a) such Indebtedness, if secured, is secured solely by Lead Borrower’s accounts receivable, inventory and cash (other than proceeds of (i) Loans, (ii) Intellectual Property, (iii) Collateral that does not secure such Permitted Priority Debt, and (iv) the exercise of any Cure Right), but otherwise is not secured by any other property (including any Intellectual Property or proceeds thereof, or proceeds of Loans, or of Collateral that does not secure such Permitted Priority Debt, or of the exercise of any Cure Right), (b) the holders or lenders thereof have executed and delivered to Administrative Agent an intercreditor agreement in substantially the form of **Exhibit H** and with such changes (if any) as are reasonably satisfactory to Administrative Agent, or such other form as reasonably acceptable to the Administrative Agent and (c) the Obligors shall have achieved Revenue from the sale of the Product of at least \$30,000,000 during any consecutive twelve (12) month period ended on or prior to the effective date of such revolving credit facility.

**“Permitted Priority Liens”** means (a) Liens permitted under **Section 9.02(c), (d), (e), (f), (g), and (j)**, and (b) Liens permitted under **Section 9.02(b)**; *provided* that such Liens are also of the type described in **Section 9.02(c), (d), (e), (f), (g), and (j)**.

**“Permitted Refinancing”** means, with respect to any Indebtedness, any extensions, renewals and replacements of such Indebtedness; *provided* that such extension, renewal or replacement (a) shall not increase the outstanding principal amount of such Indebtedness, (b) contains terms relating to outstanding principal amount, amortization, maturity, collateral (if any) and subordination (if any), and other material terms taken as a whole no less favorable in any material respect to Parent and its Subsidiaries or the Secured Parties than the terms of any agreement or instrument governing such existing Indebtedness, (c) shall have an applicable

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interest rate which does not exceed the rate of interest of the Indebtedness being replaced, and (d) shall not contain any new requirement to grant any lien or security or to give any guarantee that was not an existing requirement of such Indebtedness.

**“Permitted Restructuring”** means a transaction or series of related transactions consummated for the purpose of achieving a group restructuring, which may include transfers or sales of assets among Obligor, service agreements or similar contractual arrangements between the Swedish Borrower and any other Obligor, intercompany loans and other extensions of credit between Obligor, the making of Investments by any Obligor in another Obligor, Restricted Payments to Obligor and mergers, consolidations, amalgamations, liquidations, winding up and dissolutions with or into Obligor; provided that, (1) no assets are transferred to the Swedish Borrower (except for (x) the ultimate purpose of a dividend, distribution or other Restricted Payment, or a sale or transfer thereof, to another Borrower, and (y) cash payments in connection with any service agreement or similar contractual arrangement between the Swedish Borrower and any other Obligor to the extent permitted by the proviso in clause (4) below), (2) assets are transferred only among Obligor or entities that become Obligor and, in the case of new Obligor, that will, concurrently with such transfer, pledge substantially all of their assets to secure the obligations under the Loan Documents, (3) an Obligor will be released from its obligations only by virtue of their merger, dissolution or liquidation into another Obligor (subject to **Section 12.11** in the case of the Swedish Borrower), (4) collateral would only be released to the extent necessary to permit the transfer thereof from one Obligor to another Obligor, provided that such collateral will upon such transfer, be pledged by the transferee Obligor (other than the Swedish Borrower to the extent assets are transferred or sold through it, in connection with the Permitted Restructuring; provided that no Default or Event of Default shall have occurred and be continuing and such assets consist of (i) assets held by the Swedish Borrower on the Closing Date, (ii) assets received from the Cayman Borrower (x) in exchange for assets of the Swedish Borrower of reasonably equivalent value or (y) in connection with, or as a result of, the merger, dissolution or liquidation of the Cayman Borrower, (iii) note receivables (subordinated to the Obligations in accordance with **Section 15**) owing from another Obligor to the Swedish Borrower in connection with the transfer of assets of reasonably equivalent value to such note receivables from the Swedish Borrower to such Obligor, and/or (iv) any service agreement or similar contractual arrangement between the Swedish Borrower and any other Obligor and any cash payments received by the Swedish Borrower pursuant thereto, provided that (A) the aggregate amount of such cash shall not exceed \$100,000 and (B) the aggregate amount of cash held at the Swedish Borrower shall not exceed \$100,000 at any time), (5) no withholding Tax shall become payable in respect of payments hereunder as a result of any such transaction, (6) any Obligor that acquires assets in the Permitted Restructuring or into which any other Obligor or Subsidiary is merged, liquidated or dissolved, shall be organized under the laws of Ireland, the Cayman Islands or other jurisdiction that permits the guarantee of the Obligations on a full and unconditional basis or recognizes the joint and severally liability of the Borrowers for the Obligations, and permits the grant of a security interest in substantially all of its assets and that is

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reasonably acceptable to the Administrative Agent, (7) the Lead Borrower shall not be dissolved or liquidated and shall be the surviving entity in any merger, consolidation or amalgamation with another Obligor, (8) any intercompany services agreements or arrangements with the Swedish Borrower shall be on terms no less favorable to the other Obligors than those that could be obtained on an arm's length basis, and (9) limitations specified in the last sentence of **Section 8.12(c)** shall not apply to any actions required to be taken so as to ensure any assets transferred in a Permitted Restructuring remain or become subject to security interests and Liens in favor, or for the benefit, of the Secured Parties.

**"Permitted Subordinated Debt"** means Indebtedness (a) that is governed by documentation containing representations, warranties, covenants and events of default no more burdensome or restrictive than those contained in the Loan Documents, (b) that has a maturity date later than the Stated Maturity Date, (c) in respect of which no cash payments of principal or interest are required prior to the Stated Maturity Date, (d) that converts into equity immediately upon the occurrence of an Event of Default, and (e) in respect of which the holders have agreed in favor of Borrowers and Secured Parties (i) that prior to the date on which the Commitments have expired or been terminated and all Obligations have been paid in full indefeasibly in cash, such holders will not exercise any remedies available to them in respect of such Indebtedness, (ii) that such Indebtedness is and shall remain unsecured, and (iii) to terms of subordination in substantially the form attached hereto as **Exhibit G** and with such changes (if any) as are reasonably satisfactory to Administrative Agent, or such other form as reasonably acceptable to the Majority Lenders.

**"Person"** means any individual, corporation, company, voluntary association, partnership, limited liability company, joint venture, trust, unincorporated organization or Governmental Authority or other entity of whatever nature.

**"PIK Loan"** has the meaning set forth in **Section 3.02(d)**.

**"PIK Period"** means the period beginning on the first Borrowing Date through and including (a) if Borrowers have not achieved the Recorlev Approval Milestone, the earlier to occur of (i) the fourteenth (14<sup>th</sup>) Payment Date after the first Borrowing Date and (ii) the date on which any Default shall have occurred (*provided* that if such Default shall have been cured or waived, the PIK Period shall resume until the earlier to occur of the next Default and the fourteenth (14<sup>th</sup>) Payment Date after the first Borrowing Date) and (b) if Borrowers have achieved the Recorlev Approval Milestone, the earlier to occur of (i) the twenty-third (23<sup>rd</sup>) Payment Date after the first Borrowing Date and (ii) the date on which any Default shall have occurred (*provided* that if such Default shall have been cured or waived, the PIK Period shall resume until the earlier to occur of the next Default and the twenty-third (23<sup>rd</sup>) Payment Date after the first Borrowing Date).

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“**Plan**” means any employee pension benefit plan (other than a Multiemployer Plan) subject to the provisions of Title IV of ERISA or Section 412 of the Code or Section 302 of ERISA, and in respect of which Parent or any ERISA Affiliate is (or, if such plan were terminated, would under Section 4069 of ERISA be deemed to be) an “employer” as defined in Section 3(5) of ERISA.

“**Prepayment Premium**” has the meaning set forth in **Section 3.03(a)**.

“**Product**” means KEVEYIS®, Recorlev, Veldoreotide, Macrilen and such other products as may be acquired or in-licensed by any Obligor, and each of their respective successors.

“**Property**” of any Person means any property or assets, or interest therein, of such Person.

“**Proportionate Share**” means, with respect to any Lender, the percentage obtained by dividing (a) the Commitment (or, if the Commitments are terminated, the outstanding principal amount of the Loans) of such Lender then in effect by (b) the sum of the Commitments (or, if the Commitments are terminated, the outstanding principal amount of the Loans) of all Lenders then in effect.

“**Qualified Plan**” means an employee benefit plan (as defined in Section 3(3) of ERISA) other than a Multiemployer Plan (a) that is or was at any time maintained or sponsored by any Obligor or any ERISA Affiliate thereof or to which any Obligor or any ERISA Affiliate thereof has ever made, or was ever obligated to make, contributions, and (b) that is intended to be tax qualified under Section 401(a) of the Code.

“**Real Property Security Documents**” means the Landlord Consent and any mortgage or deed of trust or any other real property security document executed or required hereunder to be executed by any Obligor and granting a security interest in real Property owned or leased (as tenant) by any Obligor in favor of the Secured Parties.

“**Recipient**” means Administrative Agent, any Lender or any other recipient of any payment to be made by or on account of any Obligation.

“**Recorlev Approval Milestone**” means (a) Borrowers obtain approval for the marketing and sale of Recorlev for the treatment of Endogenous Cushing’s syndrome from the United States Food and Drug Administration on or prior to December 31, 2020 and (b) Parent achieves an average Market Capitalization of at least \$150,000,000 for the thirty (30) consecutive days beginning on the date the approval referenced in clause (a) is obtained.

“**Redemption Date**” has the meaning set forth in **Section 3.03(a)**.

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“*Redemption Price*” has the meaning set forth in **Section 3.03(a)**.

“*Register*” has the meaning set forth in **Section 13.05(d)**.

“*Regulation T*” means Regulation T of the Board of Governors of the Federal Reserve System, as amended.

“*Regulation U*” means Regulation U of the Board of Governors of the Federal Reserve System, as amended.

“*Regulation X*” means Regulation X of the Board of Governors of the Federal Reserve System, as amended.

“*Regulatory Approvals*” means any registrations, licenses, authorizations, permits or approvals issued by any Governmental Authority and applications or submissions related to any of the foregoing.

“*Related Person*” means, with respect to any Person, such Person’s Affiliates and the partners, directors, officers, employees, agents, trustees, administrators, managers, advisors and representatives of such Person and of such Person’s Affiliates.

“*Requirement of Law*” means, as to any Person, any statute, law, treaty, rule or regulation or determination, order, injunction or judgment of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its Properties or revenues.

“*Responsible Officer*” of any Person means each of the president, chief business officer, chief financial officer, chief executive officer, chief legal officer, and chief medical officer or controller of such Person.

“*Restricted Payment*” means any dividend or other distribution (whether in cash, securities or other property) with respect to any Equity Interest of Parent or any of its Subsidiaries, or any payment (whether in cash, securities or other property), including any sinking fund or similar deposit, on account of the purchase, redemption, retirement, acquisition, cancellation or termination of any such shares of capital stock, share capital or other Equity Interest of Parent or any of its Subsidiaries or any option, warrant or other right to acquire any such shares of capital stock, share capital or other Equity Interest of Parent or any of its Subsidiaries.

“*Restrictive Agreement*” has the meaning set forth in **Section 7.15**.

“*Restructured Debt Securities*” has the meaning set forth in **Section 15.01**.

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“*Revenue*” of a Person means all revenue properly recognized under GAAP, consistently applied, less all rebates, discounts and other price allowances.

“*Sanctions*” means any international economic sanction administered or enforced by the United States (including OFAC), the United Nations Security Council, the European Union, Her Majesty’s Treasury or other relevant sanctions authority.

“*Sanctioned Jurisdiction*” means any country or territory to the extent that such country or territory is the subject of any Sanction.

“*Sanctioned Person*” means, at any time, (a) any Person listed in any Sanctions-related list of designated Persons maintained by OFAC, the U.S. Department of State, the United Nations Security Council, the European Union, Her Majesty’s Treasury, or other relevant sanctions authority, (b) any Person operating, organized or resident in a Sanctioned Jurisdiction or (c) any Person owned or Controlled by any such person or Persons described in clauses (a) and (b).

“*SEC*” means the Securities and Exchange Commission, or any other Governmental Authority succeeding to any of its principal functions.

“*Secured Parties*” means the Lenders, Administrative Agent, each other Indemnified Party and any other holder of any Obligation.

“*Securities Purchase Agreement*” means the Securities Purchase Agreement, dated as of the Closing Date, among Parent and the Lenders.

“*Security Agreement*” means the Security Agreement, dated as of the Closing Date, among the Obligors and Administrative Agent, granting a security interest in the Obligors’ personal Property in favor of the Secured Parties.

“*Security Documents*” means, collectively, the Security Agreement, each Short-Form IP Security Agreement, each Real Property Security Document, the Swedish Security Documents and each other foreign security document listed on **Schedule 6.01** and each other security document, control agreement or financing statement required or recommended to perfect Liens in favor of the Secured Parties.

“*Securities Account*” has the meaning set forth in the Security Agreement.

“*Senior Indebtedness*” has the meaning set forth in **Section 15.01**.

“*Short-Form IP Security Agreements*” means short-form copyright, patent or trademark (as the case may be) security agreements, dated as of the Closing Date, entered into by one or

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more Obligors in favor of Administrative Agent, for the benefit of the Secured Parties, each in form and substance reasonably satisfactory to Administrative Agent (and as amended, modified or replaced from time to time).

“*Solvent*” means, with respect to any Person at any time, that (a) the present fair saleable value of the Property of such Person is greater than the total amount of liabilities (including contingent liabilities) of such Person, (b) the present fair saleable value of the Property of such Person is not less than the amount that will be required to pay the probable liability of such Person on its debts as they become absolute and matured, (c) such Person has not incurred and does not intend to, and does not believe that it will, incur debts or liabilities beyond such Person’s ability to pay as such debts and liabilities mature and (d) such Person would not be unable to obtain a letter from its auditors that did not contain a going concern qualification.

“*Specified Financial Covenants*” has the meaning set forth in **Section 10.03(a)**.

“*Stated Maturity Date*” means the twenty-fourth (24<sup>th</sup>) Payment Date following the first Borrowing Date.

“*Subordinated Debt Cure Right*” has the meaning set forth in **Section 10.03(a)**.

“*Subordinated Intercompany Indebtedness*” has the meaning set for in **Section 15.01**.

“*Subsidiary*” means, with respect to any Person (the “*parent*”) at any date, any corporation, limited liability company, partnership, association or other entity the accounts of which would be consolidated with those of the parent in the parent’s consolidated financial statements if such financial statements were prepared in accordance with GAAP as of such date, as well as any other corporation, limited liability company, partnership, association or other entity (a) of which securities or other ownership interests representing more than 50% of the equity or more than 50% of the ordinary voting power or, in the case of a partnership, more than 50% of the general partnership interests are, as of such date, owned, controlled or held by the parent or one or more subsidiaries of the parent or by the parent and one or more subsidiaries of the parent or (b) that is, as of such date, otherwise Controlled by the parent or one or more subsidiaries of the parent or by the parent and one or more subsidiaries of the parent. Unless the context requires otherwise, “Subsidiary” refers to a Subsidiary of Parent.

“*Subsidiary Guarantors*” means each Subsidiary of Parent that becomes, or is required to become, a “Subsidiary Guarantor” after the Closing Date pursuant to **Section 8.12(a)** or **(b)**.

“*Substitute Lender*” has the meaning set forth in **Section 2.06(a)**.

“*Swedish Borrower*” has the meaning set forth in the introduction hereto.

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“*Swedish Obligated Party*” has the meaning set forth in **Section 1.05**.

“*Swedish Obligor*” means an Obligor incorporated under the laws of Sweden.

“*Swedish Security Documents*” means the Swedish share pledge agreement and Swedish IP Pledge Agreement described on **Schedule 6.01**.

“*Tax Affiliate*” means (a) Parent and its Subsidiaries, (b) each other Obligor and (c) any Affiliate of an Obligor with which such Obligor files or is eligible to file consolidated, combined or unitary Tax returns.

“*Tax Returns*” has the meaning set forth in **Section 7.08**.

“*Taxes*” means all present or future taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other charges imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

“*Technical Information*” means all trade secrets and other proprietary or confidential information, public information, non-proprietary know-how, any information of a scientific, technical, or business nature in any form or medium, standards and specifications, conceptions, ideas, innovations, discoveries, Invention disclosures, all documented research, developmental, demonstration or engineering work and all other information, data, plans, specifications, reports, summaries, experimental data, manuals, models, samples, know-how, technical information, systems, methodologies, computer programs, information technology and any other information.

“*Title IV Plan*” means an employee benefit plan (as defined in Section 3(3) of ERISA) other than a Multiemployer Plan (i) that is or was at any time maintained or sponsored by any Obligor or any ERISA Affiliate thereof or to which any Obligor or any ERISA Affiliate thereof has ever made, or was obligated to make, contributions, and (ii) that is or was subject to Section 412 of the Code, Section 302 of ERISA or Title IV of ERISA.

“*Trademarks*” is defined in the Security Agreement.

“*Transactions*” means the execution, delivery and performance by each Obligor of this Agreement and the other Loan Documents to which such Obligor is intended to be a party and the Borrowings (and the use of the proceeds of the Loans).

“*U.S. Person*” means a “United States Person” within the meaning of Section 7701(a)(30) of the Code.

“*U.S. Tax Compliance Certificate*” has the meaning set forth in **Section 5.03(e)(ii)(B)(3)**.



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“*VCOC Lender*” means CRG Partners III, L.P. and each other lender that is a “venture capital operating company” for purposes of ERISA and that is assigned any of the Loans.

“*Warrant*” means each warrant to purchase Equity Interests of Parent, issued by Parent to the Lenders in connection with the Transactions substantially in the form of **Exhibit I**.

“*Withdrawal Liability*” means, at any time, any liability incurred (whether or not assessed) by any ERISA Affiliate and not yet satisfied or paid in full at such time with respect to any Multiemployer Plan pursuant to Section 4201 of ERISA.

“*Withholding Agent*” means any Obligor and Administrative Agent.

**1.02 Accounting Terms and Principles.** All accounting determinations required to be made pursuant hereto shall, unless expressly otherwise provided herein, be made in accordance with GAAP. All components of financial calculations made to determine compliance with this Agreement, including **Section 10**, shall be adjusted to include or exclude, as the case may be, without duplication, such components of such calculations attributable to any Acquisition consummated after the first day of the applicable period of determination and prior to the end of such period, as determined in good faith by Parent based on assumptions expressed therein and that were reasonable based on the information available to Parent at the time of preparation of the Compliance Certificate setting forth such calculations.

**1.03 Interpretation.** For all purposes of this Agreement, except as otherwise expressly provided herein or unless the context otherwise requires, (a) the terms defined in this Agreement include the plural as well as the singular and vice versa; (b) words importing gender include all genders; (c) any reference to a Section, Annex, Schedule or Exhibit refers to a Section of, or Annex, Schedule or Exhibit to, this Agreement; (d) any reference to “this Agreement” refers to this Agreement, including all Annexes, Schedules and Exhibits hereto, and the words herein, hereof, hereto and hereunder and words of similar import refer to this Agreement and its Annexes, Schedules and Exhibits as a whole and not to any particular Section, Annex, Schedule, Exhibit or any other subdivision; (e) references to days, months and years refer to calendar days, months and years, respectively; (f) all references herein to “include” or “including” shall be deemed to be followed by the words “without limitation”; (g) the word “from” when used in connection with a period of time means “from and including” and the word “until” means “to but not including”; and (h) accounting terms not specifically defined herein shall be construed in accordance with GAAP (except for the term “property”, which shall be interpreted as broadly as possible, including, in any case, cash, securities, other assets, rights under contractual obligations and permits and any right or interest in any property, except where otherwise noted); and (i) all references to an “examiner” shall be deemed to mean an examiner appointed under Section 509 of the Irish Companies Act and “examinership” shall be construed accordingly. Unless otherwise expressly provided herein, references to organizational documents, agreements

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(including the Loan Documents) and other contractual instruments shall be deemed to include all permitted subsequent amendments, restatements, extensions, supplements and other modifications thereto.

**1.04 Changes to GAAP.** If, after the Closing Date, any change occurs in GAAP or in the application thereof and such change would cause any amount required to be determined for the purposes of the covenants to be maintained or calculated pursuant to **Section 8, 9 or 10** to be materially different than the amount that would be determined prior to such change, then:

(a) Parent will provide a detailed notice of such change (an “*Accounting Change Notice*”) to Administrative Agent within 30 days of such change;

(b) either Parent or the Majority Lenders may indicate within 90 days following the date of the Accounting Change Notice that they wish to revise the method of calculating such financial covenants or amend any such amount, in which case the parties will in good faith attempt to agree upon a revised method for calculating the financial covenants;

(c) until Parent and the Majority Lenders have reached agreement on such revisions, (i) such financial covenants or amounts will be determined without giving effect to such change and (ii) all financial statements, Compliance Certificates and similar documents provided hereunder shall be provided together with a reconciliation between the calculations and amounts set forth therein before and after giving effect to such change in GAAP;

(d) if no party elects to revise the method of calculating the financial covenants or amounts, then the financial covenants or amounts will not be revised and will be determined in accordance with GAAP without giving effect to such change; and

(e) any Event of Default arising as a result of such change which is cured by operation of this **Section 1.04** shall be deemed to be of no effect *ab initio*.

**1.05 Swedish Trust Provision.** If any Obligor incorporated under the laws of Sweden (the “*Swedish Obligated Party*”) is required to hold an amount on trust on behalf of any other party (the “*Beneficiary*”), the Swedish Obligated Party shall hold such money as agent for the Beneficiary in a separate account and shall promptly pay or transfer the same to the Beneficiary or as the Beneficiary may direct.

**1.06 Swedish Limitations.** Notwithstanding the other provisions of this Agreement, the obligations and liabilities of a Swedish Obligor under **Section 15** shall be limited if (and only if) required by the provisions of the Swedish Companies Act (Sw. aktiebolagslagen (2005:551)) regulating distribution of assets (Chapter 17, Sections 1 – 4 (or their equivalents from time to time)), and it is understood that the obligations and liabilities of such Swedish Obligor under

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Section 15 shall only apply to the extent permitted by the above mentioned provisions of the Swedish Companies Act.

## SECTION 2 THE COMMITMENT

**2.01 Commitments.** Each Lender agrees severally, on and subject to the terms and conditions of this Agreement (including **Section 6**), to make up to four term loans (*provided* that PIK Loans shall be deemed not to constitute “term loans” for purposes of this **Section 2.01**) to Borrowers, each on a Business Day during the Commitment Period in Dollars in an aggregate principal amount for such Lender not to exceed such Lender’s unfunded Commitment; *provided, however*, that no Lender shall be obligated to make a Loan in excess of such Lender’s Proportionate Share of the applicable amount of any Borrowing set forth in **Section 6** (if any) other than PIK Loans. Amounts of Loans repaid may not be reborrowed.

**2.02 Borrowing Procedures.** Subject to the terms and conditions of this Agreement (including **Section 6**), each Borrowing (other than a Borrowing of PIK Loans) shall be made on written notice in the form of **Exhibit B** given by Lead Borrower to Administrative Agent not later than 11:00 a.m. (Central time) on the Borrowing Notice Date (a “*Notice of Borrowing*”). Each Borrowing shall be made by the Lead Borrower.

**2.03 Fees.** The Borrowers shall pay to Administrative Agent and/or the Lenders, as applicable, such fees as described in the Amended Fee Letter.

**2.04 Use of Proceeds.** Each Borrower shall use the proceeds of the Loans for repayment of all outstanding Indebtedness and obligations under the Borrowers’ existing debt facility on the Closing Date, general working capital purposes of the Obligor and corporate purposes of the Obligor, to pay fees, costs and expenses incurred in connection with the Transactions and to pay fees (including upfront fees), costs and expenses and make milestone payments in connection with the Macrilen Acquisition; *provided* that the Lenders shall have no responsibility as to the use of any proceeds of Loans.

**2.05 Defaulting Lenders.**

(a) **Adjustments.** Notwithstanding anything to the contrary contained in this Agreement, if any Lender becomes a Defaulting Lender, then, until such time as that Lender is no longer a Defaulting Lender, to the extent permitted by applicable law:

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(i) **Waivers and Amendments.** Such Defaulting Lender's right to approve or disapprove any amendment, waiver or consent with respect to this Agreement shall be restricted as set forth in the definition of "Majority Lenders" and **Section 13.04**.

(ii) **Reallocation of Payments.** Any payment of principal, interest, fees or other amounts received by the Lenders for the account of such Defaulting Lender (whether voluntary or mandatory, at maturity, pursuant to **Section 11**, **Section 4.04** or otherwise), shall be applied at such time or times as follows: first, as Lead Borrower may request (so long as no Default exists), to the funding of any Loan in respect of which such Defaulting Lender has failed to fund its portion thereof as required by this Agreement; second, if so determined by the Majority Lenders and Lead Borrower, to be held in a non-interest bearing deposit account and released in order to satisfy obligations of such Defaulting Lender to fund Loans under this Agreement; third, to the payment of any amounts owing to the Lenders as a result of any judgment of a court of competent jurisdiction obtained by any Lender against such Defaulting Lender as a result of such Defaulting Lender's breach of its obligations under this Agreement; fourth, so long as no Default exists, to the payment of any amounts owing to Borrowers as a result of any judgment of a court of competent jurisdiction obtained by Borrowers against such Defaulting Lender as a result of such Defaulting Lender's breach of its obligations under this Agreement; and fifth, to such Defaulting Lender or as otherwise directed by a court of competent jurisdiction; *provided* that if (A) such payment is a payment of the principal amount of any Loans in respect of which such Defaulting Lender has not fully funded its appropriate share and (B) such Loans were made at a time when the conditions set forth in **Section 6** were satisfied or waived, such payment shall be applied solely to pay the Loans of all non-Defaulting Lenders on a *pro rata* basis prior to being applied to the payment of any Loans of such Defaulting Lender. Any payments, prepayments or other amounts paid or payable to a Defaulting Lender that are applied (or held) to pay amounts owed by a Defaulting Lender pursuant to this **Section 2.05(a)(ii)** shall be deemed paid to and redirected by such Defaulting Lender, and each Lender irrevocably consents hereto.

(b) **Defaulting Lender Cure.** If Lead Borrower and the Majority Lenders agree in writing in their sole discretion that a Defaulting Lender should no longer be deemed to be a Defaulting Lender, that Lender will, to the extent applicable, purchase that portion of outstanding Loans of the other Lenders or take such other actions as necessary to cause the Loans to be held on a *pro rata* basis by the Lenders in accordance with their Proportionate Share, whereupon that Lender will cease to be a Defaulting Lender; *provided* that no adjustments will be made retroactively with respect to fees accrued or payments made by or on behalf of Borrowers while that Lender was a Defaulting Lender; and *provided further* that, except to the extent otherwise expressly agreed by the affected parties, no change hereunder from Defaulting Lender to Lender will constitute a waiver or release of any claim of any party hereunder arising from that Lender's having been a Defaulting Lender.

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**2.06 Substitution of Lenders.**

(a) **Substitution Right.** If any Lender (an “*Affected Lender*”), (i) becomes a Defaulting Lender or (ii) does not consent to any amendment, waiver or consent to any Loan Document for which the consent of the Majority Lenders is obtained but that requires the consent of other Lenders (a “*Non-Consenting Lender*”), then (x) Borrowers may elect to pay in full such Affected Lender with respect to all Obligations due to such Affected Lender or (y) either Lead Borrower or Administrative Agent shall identify any willing Lender or Affiliate of any Lender or Eligible Transferee (in each case, a “*Substitute Lender*”) to substitute for such Affected Lender; *provided* that any substitution of a Non-Consenting Lender shall occur only with the consent of Administrative Agent.

(b) **Procedure.** To substitute such Affected Lender or pay in full all Obligations owed to such Affected Lender, Lead Borrower shall deliver a notice to such Affected Lender. The effectiveness of such payment or substitution shall be subject to the delivery by Lead Borrower (or, as may be applicable in the case of a substitution, by the Substitute Lender) of (i) payment for the account of such Affected Lender, of, to the extent accrued through, and outstanding on, the effective date for such payment or substitution, all Obligations owing to such Affected Lender (which for the avoidance of doubt, shall not include any Prepayment Premium) and (ii) in the case of a substitution, an Assignment and Assumption executed by the Substitute Lender, which shall thereunder, among other things, agree to be bound by the terms of the Loan Documents.

(c) **Effectiveness.** Upon satisfaction of the conditions set forth in **Sections 2.06(a)** and **(b)**, Administrative Agent shall record such substitution or payment in the Register, whereupon (i) in the case of any payment in full of an Affected Lender, such Affected Lender’s Commitments shall be terminated and (ii) in the case of any substitution of an Affected Lender, (A) such Affected Lender shall sell and be relieved of, and the Substitute Lender shall purchase and assume, all rights and claims of such Affected Lender under the Loan Documents, except that the Affected Lender shall retain such rights under the Loan Documents that expressly provide that they survive the repayment of the Obligations and the termination of the Commitments, (B) such Affected Lender shall no longer constitute a “Lender” hereunder and such Substitute Lender shall become a “Lender” hereunder and (C) such Affected Lender shall execute and deliver an Assignment and Assumption to evidence such substitution; *provided, however*, that the failure of any Affected Lender to execute any such Assignment and Assumption shall not render such sale and purchase (or the corresponding assignment) invalid.

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**SECTION 3  
PAYMENTS OF PRINCIPAL AND INTEREST**

**3.01 Repayment.**

(a) **Repayment.** During the Interest-Only Period, no scheduled payments of principal of the Loans shall be due. Each Borrower agrees to repay to the Lenders the outstanding principal amount of the Loans, on each Payment Date occurring after the Interest-Only Period, in equal installments. The amounts of such installments shall be calculated by dividing (i) the sum of the aggregate principal amount of the Loans outstanding on the first day following the end of the Interest-Only Period, by (ii) the number of Payment Dates remaining prior to and including the Stated Maturity Date.

(b) **Application.** Any optional or mandatory prepayment of the Loans shall be applied to the installments thereof under **Section 3.01(a)** in the inverse order of maturity. To the extent not previously paid, the principal amount of the Loans, together with all other outstanding Obligations, shall be due and payable on the Maturity Date.

**3.02 Interest.**

(a) **Interest Generally.** Subject to **Section 3.02(d)**, each Borrower agrees to pay to the Lenders interest on the unpaid principal amount of the Loans and the amount of all other outstanding Obligations, in the case of the Loans, for the period from the applicable Borrowing Date and, in the case of any other Obligation, from the date such other Obligation is due and payable, in each case, until paid in full, at a rate *per annum* equal to 12.50%.

(b) **Default Interest.** Notwithstanding the foregoing, upon the occurrence and during the continuance of any Event of Default, the interest payable pursuant to **Section 3.02(a)** shall increase automatically by 4.00% *per annum* (such aggregate increased rate, the “*Default Rate*”). Notwithstanding any other provision herein (including **Section 3.02(d)**), if interest is required to be paid at the Default Rate, it shall be paid entirely in cash.

(c) **Interest Payment Dates.** Subject to **Section 3.02(d)**, accrued interest on the Loans shall be payable in arrears on each Payment Date with respect to the most recently completed Interest Period in cash, and upon the payment or prepayment of the Loans (on the principal amount being so paid or prepaid); *provided* that interest payable at the Default Rate shall be payable from time to time on demand.

(d) **Paid In-Kind Interest.** Notwithstanding **Section 3.02(a)**, at any time during the PIK Period, Lead Borrower, on behalf of Borrowers, may elect to pay the interest on the outstanding principal amount of the Loans payable pursuant to **Section 3.01** as follows: (i) only 8.50% of the 12.50% *per annum* interest in cash and (ii) 4.00% of the 12.50% *per annum* interest

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as compounded interest, added to the aggregate principal amount of the Loans (the amount of any such compounded interest being a “*PIK Loan*”). The principal amount of each PIK Loan shall accrue interest in accordance with the provisions of this Agreement applicable to the Loans.

### 3.03 Prepayments.

(a) **Optional Prepayments.** Upon prior written notice to Administrative Agent delivered pursuant to **Section 4.03**, each Borrower shall have the right at any time to optionally prepay in whole or in part the outstanding principal amount of the Loans (a “*Redemption Date*”) for an amount equal to the aggregate principal amount of the Loans being prepaid plus the Prepayment Premium plus any accrued but unpaid interest and any fees then due and owing (such aggregate amount, the “*Redemption Price*”). The applicable “*Prepayment Premium*” shall be an amount calculated pursuant to **Section 3.03(a)(i)**.

(i) If the Redemption Date occurs:

(A) on or prior to the fourth (4th) Payment Date, the Prepayment Premium shall be an amount equal to 12.00% of the aggregate outstanding principal amount of the Loans being prepaid on such Redemption Date;

(B) after the fourth (4th) Payment Date, and on or prior to the eighth (8th) Payment Date, the Prepayment Premium shall be an amount equal to 6.00% of the aggregate outstanding principal amount of the Loans being prepaid on such Redemption Date;

(C) after the eighth (8th) Payment Date, and on or prior to the twelfth (12th) Payment Date, the Prepayment Premium shall be an amount equal to 3.00% of the aggregate outstanding principal amount of the Loans being prepaid on such Redemption Date;

(D) after the twelfth (12th) Payment Date, and on or prior to the sixteenth (16th) Payment Date, the Prepayment Premium shall be an amount equal to 2.00% of the aggregate outstanding principal amount of the Loans being prepaid on such Redemption Date;

(E) after the sixteenth (16th) Payment Date, and on or prior to the twentieth (20th) Payment Date, the Prepayment Premium shall be an amount equal to 1.00% of the aggregate outstanding principal amount of the Loans being prepaid on such Redemption Date;

(F) after the twentieth (20th) Payment Date, the Prepayment Premium shall be an amount equal to 0.00% of the aggregate outstanding principal amount of the Loans being prepaid on such Redemption Date.

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(ii) To determine the aggregate outstanding principal amount of the Loans, and how many Payment Dates have occurred, as of any Redemption Date for purposes of **Section 3.03(a)**:

(A) if, as of such Redemption Date, Borrowers shall have made only one Borrowing, the number of Payment Dates shall be deemed to be the number of Payment Dates that shall have occurred following the first Borrowing Date;

(B) if, as of such Redemption Date, Borrowers shall have made more than one Borrowing, then the Redemption Price shall equal the sum of multiple Redemption Prices calculated with respect to the Loans of each Borrowing, each of which Redemption Prices shall be calculated based on solely the aggregate outstanding principal amount of the Loans borrowed in such Borrowing (and PIK Loans subsequently borrowed in respect of interest payments thereon), as though the applicable number of Payment Dates equals the number of Payment Dates that shall have occurred following the applicable Borrowing Date. In the case of any partial prepayment, the amount of such prepayment shall be allocated to Loans made in the various Borrowings (and PIK Loans in respect thereof) in the order in which such Borrowings were made;

(iii) No partial prepayment shall be made under this **Section 3.03(a)** in connection with any event described in **Section 3.03(b)**.

The Prepayment Premium payable upon any prepayment shall be in addition to any payments required pursuant to the Amended Fee Letter.

**(b) Mandatory Prepayments.**

(i) **Asset Sales.** In the event of any contemplated Asset Sale or series of Asset Sales (other than any Asset Sale permitted under **Section 9.09(a), (b), (c)** (other than by the Swedish Borrower to the extent cash proceeds are received by it and held for a period of longer than five (5) Business Days), **(d), or (h)**) yielding Asset Sale Net Proceeds in excess of \$1,000,000 in the aggregate, Lead Borrower shall provide ten (10) days' prior written notice of such Asset Sale to Administrative Agent and, if within such notice period Majority Lenders or Administrative Agent advise Lead Borrower that the Majority Lenders require a prepayment pursuant to this **Section 3.03(b)(i)**, Borrowers shall: (x) if the assets sold represent substantially all of the assets or Revenues from the sale of the Products, or represent any specific line of business which either on its own or together with other lines of business sold over the term of this Agreement account for Revenue from the sale of the Products generated by such lines of business exceeding 10% of the Revenue from the sale of the Products in the immediately preceding year, prepay the aggregate outstanding principal amount of the Loans in an amount equal to the Redemption Price applicable on the date of such Asset Sale in accordance with



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**Section 3.03(a)**, and (y) in the case of all other Asset Sales not described in the foregoing **clause (x)**, prepay the Loans in an amount equal to the entire amount of the Asset Sale Net Proceeds of such Asset Sale, plus any accrued but unpaid interest and any fees (including any fees payable pursuant to the Amended Fee Letter) then due and owing, credited in the following order:

- (A) first, in reduction of Borrowers' obligation to pay any unpaid interest and any fees then due and owing;
- (B) second, in reduction of Borrowers' obligation to pay any Claims or Losses referred to in **Section 13.03** then due and owing;
- (C) third, in reduction of Borrowers' obligation to pay any amounts due and owing on account of the unpaid principal amount of the Loans;
- (D) fourth, in reduction of any other Obligation then due and owing; and
- (E) fifth, to Borrowers or such other Persons as may lawfully be entitled to or directed by Borrowers to receive the remainder.

(ii) **Change of Control.** In the event of a Change of Control, Lead Borrower shall immediately provide notice of such Change of Control to Administrative Agent and, if within ten (10) Business Days of receipt of such notice Majority Lenders or Administrative Agent advise Lead Borrower in writing that the Majority Lenders require a prepayment pursuant to this **Section 3.03(b)(ii)**, Borrowers shall prepay within three (3) Business Days after such written notice the aggregate outstanding principal amount of the Loans in an amount equal to the Redemption Price applicable on the date of such Change of Control in accordance with **Section 3.03(a)** and pay any fees payable pursuant to the Amended Fee Letter.

(c) **Required AHYDO Payment.** Notwithstanding anything herein to the contrary, if, at any Payment Date on or after September 30, 2022, the aggregate amount of accrued and unpaid original issue discount (as defined in Section 1273(a)(1) of the Code) on any Loan would, but for this Section 3.03(c), exceed an amount equal to the product of the issue price of such Loan multiplied by the yield to maturity (as defined in Treasury Regulations Section 1.12721(b)(1)(i)) of such Loan, the Borrowers shall prepay at each such applicable Payment Date, the minimum amount of principal plus accrued interest on such Loan necessary to prevent any of the accrued and unpaid interest and original issue discount on such Loan from being disallowed or deferred as a deduction under Section 163(e)(5) of the Code to the Borrowers; *provided* that such payment shall be accompanied by any fees payable under the Amended Fee Letter. Notwithstanding the foregoing, the Back-End Facility Fee (as defined in the Amended Fee Letter) shall be payable pursuant to its terms and shall not be accelerated. No partial

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prepayment of any Loan pursuant to any other provision of this Agreement shall alter the obligation of the Borrowers to make prepayments provided for in this Section 3.03(c). Any payment made pursuant to this **Section 3.03(c)** shall be applied in accordance with **Section 4.01(b)**.

#### **SECTION 4 PAYMENTS, ETC.**

##### **4.01 Payments.**

(a) **Payments Generally.** Each payment of principal, interest and other amounts to be made by the Obligor under this Agreement or any other Loan Document shall be made in Dollars, in immediately available funds, without deduction, set off or counterclaim, to an account to be designated by Administrative Agent by notice to Lead Borrower, not later than 4:00 p.m. (Central time) on the date on which such payment shall become due (each such payment made after such time on such due date to be deemed to have been made on the next succeeding Business Day).

(b) **Application of Payments.** Unless otherwise expressly provided in this Agreement, each Obligor shall, at the time of making each payment under this Agreement or any other Loan Document, specify to Administrative Agent the amounts payable by such Obligor hereunder to which such payment is to be applied (and in the event that Obligor fail to so specify, or if an Event of Default has occurred and is continuing, the Lenders may apply such payment in the manner they determine to be appropriate).

(c) **Non-Business Days.** If the due date of any payment under this Agreement (other than of principal of or interest on the Loans) would otherwise fall on a day that is not a Business Day, unless otherwise provided under the terms of this Agreement, such date shall be extended to the next succeeding Business Day, and, in the case of any payment accruing interest, interest thereon shall be payable for the period of such extension. If the due date of any payment under this Agreement of principal of or interest on the Loans would otherwise fall on a day that is not a Business Day, such payment shall be made in accordance with the definition of "Payment Date."

**4.02 Computations.** All computations of interest and fees hereunder shall be computed on the basis of a year of 360 days and actual days elapsed during the period for which payable.

**4.03 Notices.** Each notice of optional prepayment shall be effective only if received by Administrative Agent not later than 4:00 p.m. (Central time) on the date three (3) Business Days (or such shorter period as may be agreed to in Administrative Agent's sole discretion) prior to the date of prepayment. Each notice of optional prepayment shall specify the amount to be prepaid and the date of prepayment. Any notice of optional prepayment may state that such

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notice is conditioned upon the effectiveness of other credit facilities or the closing of another transaction, the proceeds of which will be used to prepay any outstanding Loans, in which case such prepayment may be conditional upon the effectiveness of such other credit facilities or the closing of such other transaction.

**4.04 Set-Off.**

(a) **Set-Off Generally.** Upon the occurrence and during the continuance of any Event of Default, each of Administrative Agent, each Lender and each of their Affiliates is hereby authorized at any time and from time to time, to the fullest extent permitted by law, to set off and apply any and all deposits (general or special, time or demand, provisional or final) at any time held and other indebtedness at any time owing by Administrative Agent, any Lender and any of their Affiliates to or for the credit or the account of any Obligor against any and all of the Obligations, whether or not such Person shall have made any demand and although such obligations may be unmaturing; *provided* that in the event that any Defaulting Lender shall exercise any such right of setoff, (x) all amounts so set off shall be paid over immediately to the Administrative Agent for further application in accordance with the provisions of **Section 2.05** and, pending such payment, shall be segregated by such Defaulting Lender from its other funds and deemed held in trust for the benefit of the Administrative Agent and the Lenders, and (y) the Defaulting Lender shall provide promptly to the Administrative Agent a statement describing in reasonable detail the Obligations owing to such Defaulting Lender as to which it exercised such right of setoff. Administrative Agent and each Lender agree promptly to notify Borrowers after any such set-off and application; *provided* that the failure to give such notice shall not affect the validity of such set-off and application. The rights of Administrative Agent, each Lender and each of their Affiliates under this **Section 4.04** are in addition to other rights and remedies (including other rights of set-off) that such Persons may have.

(b) **Exercise of Rights Not Required.** Nothing contained herein shall require Administrative Agent, any Lender or any of their respective Affiliates to exercise any such right or shall affect the right of such Person to exercise, and retain the benefits of exercising, any such right with respect to any other indebtedness or obligation of any Obligor.

**4.05 Pro Rata Treatment.**

(a) Unless Administrative Agent shall have been notified in writing by any Lender prior to the proposed date of any Borrowing that such Lender will not make the amount that would constitute its share of such Borrowing available to Administrative Agent, Administrative Agent may assume that such Lender has made such amount available to Administrative Agent on such date in accordance with **Section 2**, and Administrative Agent may, in reliance upon such assumption, make available to Borrowers a corresponding amount. If such amount is not in fact made available to Administrative Agent by the required time on the applicable Borrowing Date

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therefor, such Lender and Borrowers severally agree to pay to Administrative Agent forthwith, on demand, such corresponding amount with interest thereon, for each day from and including the date on which such amount is made available to Borrowers but excluding the date of payment to Administrative Agent, at a rate equal to the greater of (A) the Federal Funds Effective Rate and (B) a rate reasonably determined by Administrative Agent in accordance with banking industry rules on interbank compensation. If Borrowers and such Lender shall pay such interest to Administrative Agent for the same or an overlapping period, Administrative Agent shall promptly remit to Borrowers the amount of such interest paid by Borrowers for such period. If such Lender pays its share of the applicable borrowing to Administrative Agent, then the amount so paid shall constitute such Lender's Loan included in such borrowing. Any payment by Borrowers shall be without prejudice to any claim Borrowers may have against a Lender that shall have failed to make such payment to Administrative Agent.

(b) Unless Administrative Agent shall have received notice from Borrowers prior to the date on which any payment is due to Administrative Agent for the account of the Lenders hereunder that Borrowers will not make such payment, Administrative Agent may assume that Borrowers have made such payment on such date in accordance herewith and may, in reliance upon such assumption, distribute to the Lenders the amount due. In such event, if Borrowers have not in fact made such payment, then each of the Lenders severally agrees to repay to Administrative Agent forthwith on demand the amount so distributed to such Lender, with interest thereon, for each day from and including the date such amount is distributed to it to but excluding the date of payment to Administrative Agent, at the greater of the Federal Funds Effective Rate and a rate determined by Administrative Agent in accordance with banking industry rules on interbank compensation. Nothing herein shall be deemed to limit the rights of Administrative Agent or any Lender against any Obligor.

(c) If any Lender shall obtain any payment (whether voluntary, involuntary, through the exercise of any right of set-off, or otherwise) on account of the principal of or interest on any Loan made by it or other obligations hereunder, as applicable (other than pursuant to a provision hereof providing for non-pro rata treatment), in excess of its Proportionate Share, of such payment on account of the Loans, such Lender shall (i) notify Administrative Agent of the receipt of such payment, and (ii) within five (5) Business Days of such receipt purchase (for cash at face value) from the other Lenders, as applicable (directly or through Administrative Agent), without recourse, such participations in the Loans made by them or make such other adjustments as shall be equitable, as shall be necessary to cause such purchasing Lender to share the excess payment ratably with each of the other Lenders in accordance with their respective Proportionate Shares, as applicable; *provided, however*, that (A) if any such participations are purchased and all or any portion of the payment giving rise thereto is recovered, such participations shall be rescinded and the purchase price restored to the extent of such recovery, without interest and (B) the provisions of this paragraph shall not be construed to apply to (x) any payment made by any Borrower pursuant to and in accordance with the express terms of this Agreement (including the

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application of funds arising from the existence of a Defaulting Lender) or (y) any payment obtained by a Lender as consideration for the assignment or sale of a participation in any of its Loans to any assignee or participant, other than to a Borrower or any of its Affiliates (as to which the provisions of this paragraph shall apply). Each Borrower agrees that any Lender so purchasing a participation from another Lender pursuant to this **Section 4.05(c)** may exercise all its rights of payment (including the right of set-off) with respect to such participation as fully as if such Lender were the direct creditor of such Borrower in the amount of such participation. No documentation other than notices and the like referred to in this **Section 4.05(c)** shall be required to implement the terms of this **Section 4.05(c)**. Administrative Agent shall keep records (which shall be conclusive and binding in the absence of manifest error) of participations purchased pursuant to this **Section 4.05(c)** and shall in each case notify the Lenders following any such purchase. Each Borrower consents on behalf of itself and each other Obligor to the foregoing and agrees, to the extent it may effectively do so under applicable law, that any Lender acquiring a participation pursuant to the foregoing arrangements may exercise against each Obligor rights of setoff and counterclaim with respect to such participation as fully as if such Lender were a direct creditor of each Obligor in the amount of such participation.

## **SECTION 5 YIELD PROTECTION, ETC.**

### **5.01 Additional Costs.**

(a) **Change in Requirements of Law Generally.** If, on or after the Closing Date, the adoption of any Requirement of Law, or any change in any Requirement of Law, or any change in the interpretation or administration thereof by any court or other Governmental Authority charged with the interpretation or administration thereof, or compliance by any of the Lenders (or its lending office) with any request or directive (whether or not having the force of law) of any such Governmental Authority, shall impose, modify or deem applicable any reserve (including any such requirement imposed by the Board of Governors of the Federal Reserve System), special deposit, contribution, insurance assessment or similar requirement, in each case that becomes effective after the Closing Date, against assets of, deposits with or for the account of, or credit extended by, a Lender (or its lending office) or shall impose on a Lender (or its lending office) any other condition affecting the Loans or the Commitment, and the result of any of the foregoing is to increase the cost to such Lender of making or maintaining the Loans, or to reduce the amount of any sum received or receivable by such Lender under this Agreement or any other Loan Document, by an amount deemed by such Lender to be material (other than (i) Indemnified Taxes, (ii) Taxes described in **clauses (b) through (d)** of the definition of "Excluded Taxes" and (iii) Connection Income Taxes), then each Borrower shall pay to such Lender on demand such additional amount or amounts as will compensate such Lender for such increased cost or reduction.

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(b) **Change in Capital Requirements.** If a Lender shall have determined that, on or after the Closing Date, the adoption of any Requirement of Law regarding capital adequacy, or any change therein, or any change in the interpretation or administration thereof by any Governmental Authority charged with the interpretation or administration thereof, or any request or directive regarding capital adequacy (whether or not having the force of law) of any such Governmental Authority, in each case that becomes effective after the Closing Date, has or would have the effect of reducing the rate of return on capital of a Lender (or its parent) as a consequence of a Lender's obligations hereunder or the Loans to a level below that which a Lender (or its parent) could have achieved but for such adoption, change, request or directive by an amount reasonably deemed by it to be material, then each Borrower shall pay to such Lender on demand such additional amount or amounts as will compensate such Lender (or its parent) for such reduction.

(c) **Notification by Lender.** Each Lender (directly or through Administrative Agent) will promptly notify the Lead Borrower of any event of which it has knowledge, occurring after the Closing Date, which will entitle such Lender to compensation pursuant to this **Section 5.01**. Before giving any such notice pursuant to this **Section 5.01(c)** such Lender shall designate a different lending office if such designation (x) will, in the reasonable judgment of such Lender, avoid the need for, or reduce the amount of, such compensation and (y) will not, in the reasonable judgment of such Lender, be materially disadvantageous to such Lender. A certificate of the Lender claiming compensation under this **Section 5.01**, setting forth the additional amount or amounts to be paid to it hereunder, shall be conclusive and binding on Borrowers in the absence of manifest error.

(d) Notwithstanding anything herein to the contrary, (x) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (y) all requests, rules, guidelines or directives promulgated by the Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall in each case be deemed to constitute a change in Requirements of Law for all purposes of this **Section 5.01**, regardless of the date enacted, adopted or issued.

**5.02 Illegality.** Notwithstanding any other provision of this Agreement, in the event that on or after the Closing Date the adoption of or any change in any Requirement of Law or in the interpretation or application thereof by any competent Governmental Authority shall make it unlawful for a Lender or its lending office to make or maintain the Loans (and, in the reasonable opinion of such Lender, the designation of a different lending office would either not avoid such unlawfulness or would be materially disadvantageous to such Lender), then such Lender shall promptly notify the Lead Borrower thereof following which (a) the Lender's Commitment shall be suspended until such time as such Lender may again make and maintain the Loans hereunder and (b) if such Requirement of Law shall so mandate, the Loans shall be prepaid by Borrowers

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on or before such date as shall be mandated by such Requirement of Law in an amount equal to the Redemption Price applicable on the date of such prepayment in accordance with **Section 3.03(a)**.

**5.03 Taxes.**

(a) **Payments Free of Taxes.** Any and all payments by or on account of any Obligation shall be made without deduction or withholding for any Taxes, except as required by applicable law. If any applicable law requires the deduction or withholding of any Tax from any such payment by a Withholding Agent, then the applicable Withholding Agent shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld to the relevant Governmental Authority in accordance with applicable law and, if such Tax is an Indemnified Tax, then the sum payable by the applicable Obligor shall be increased as necessary so that after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this **Section 5**) the applicable Recipient receives an amount equal to the sum it would have received had no such deduction or withholding been made.

(b) **Payment of Other Taxes by the Obligors.** The Obligors shall timely pay to the relevant Governmental Authority in accordance with applicable law, or at the option of each Lender, timely reimburse it for, Other Taxes.

(c) **Evidence of Payments.** As soon as practicable after any payment of Taxes by any Obligor to a Governmental Authority pursuant to this **Section 5**, such Obligor shall deliver to Administrative Agent the original or a certified copy of a receipt issued by such Governmental Authority evidencing such payment.

(d) **Indemnification.** The Obligors shall jointly and severally reimburse and indemnify each Recipient, within 10 days after demand therefor, for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under this **Section 5**) payable or paid by such Recipient or required to be withheld or deducted from a payment to such Recipient and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to Lead Borrower by a Lender shall be conclusive absent manifest error.

(e) **Status of Lenders.**

(i) Any Lender that is entitled to an exemption from, or reduction of withholding Tax with respect to payments made under any Loan Document shall make available

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to each Borrower (directly or through Administrative Agent) such properly completed and executed documentation reasonably requested by such Borrower or Administrative Agent as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, any Lender shall make available (directly or through Administrative Agent) such other documentation prescribed by applicable law as reasonably requested by such Borrower or Administrative Agent as will enable Borrowers or Administrative Agent to determine whether or not such Lender is subject to backup withholding or information reporting requirements. Notwithstanding anything to the contrary in the preceding two sentences, the completion, execution and submission of such documentation (other than such documentation set forth in **Section 5.03(e)(ii)(A), (B) or (D)**) shall not be required if in the Lender's reasonable judgment such completion, execution or submission would subject such Lender to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of such Lender.

(ii) Without limiting the generality of the foregoing, in the event that Borrower is a U.S. Person:

(A) any Lender that is a U.S. Person shall make available to such Borrower (directly or through Administrative Agent) on or prior to the date on which such Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of such Borrower), executed originals of IRS Form W-9 (or successor form) certifying that such Lender is exempt from U.S. Federal backup withholding tax;

(B) any Foreign Lender shall, to the extent it is legally entitled to do so, make available to such Borrower (directly or through Administrative Agent and in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of such Borrower), whichever of the following is applicable:

(1) in the case of a Foreign Lender claiming the benefits of an income tax treaty to which the United States is a party (x) with respect to payments of interest under any Loan Document, executed originals of IRS Form W-8BEN or IRS Form W-8BEN-E, as applicable (or successor form) establishing an exemption from, or reduction of, U.S. Federal withholding Tax pursuant to the "interest" article of such tax treaty and (y) with respect to any other applicable payments under any Loan Document, IRS Form W-8BEN or IRS Form W-8BEN-E, as applicable (or successor form) establishing an exemption from, or reduction of, U.S. Federal withholding Tax pursuant to the "business profits" or "other income" article of such tax treaty;

(2) executed originals of IRS Form W-8ECI (or successor form);



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(3) in the case of a Foreign Lender claiming the benefits of the exemption for portfolio interest under Section 881(c) of the Code, (x) a certificate substantially in the form of **Exhibit C-1** to the effect that such Foreign Lender is not a “bank” within the meaning of Section 881(c)(3)(A) of the Code, a “10 percent shareholder” of the applicable Borrower within the meaning of Section 881(c)(3)(B) of the Code, or a “controlled foreign corporation” described in Section 881(c)(3)(C) of the Code (a “**U.S. Tax Compliance Certificate**”) and (y) executed originals of IRS Form W-8BEN or IRS Form W-8BEN-E, as applicable (or successor form); or

(4) to the extent a Foreign Lender is not the beneficial owner, executed originals of IRS Form W-8IMY (or successor form), accompanied by IRS Form W-8ECI (or successor form), IRS Form W-8BEN or IRS Form W-8BEN-E, as applicable (or successor form), a U.S. Tax Compliance Certificate substantially in the form of **Exhibit C-2** or **Exhibit C-3**, IRS Form W-9 (or successor form), and/or other certification documents from each beneficial owner, as applicable; *provided* that if the Foreign Lender is a partnership and one or more direct or indirect partners of such Foreign Lender are claiming the portfolio interest exemption, such Foreign Lender may provide a U.S. Tax Compliance Certificate substantially in the form of **Exhibit C-4** on behalf of each such direct and indirect partner.

(C) any Foreign Lender shall, to the extent it is legally entitled to do so, make available to such Borrower (directly or through Administrative Agent and in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of such Borrower), executed originals of any other form prescribed by applicable law as a basis for claiming exemption from or a reduction in U.S. Federal withholding Tax, duly completed, together with such supplementary documentation as may be prescribed by applicable law to permit such Borrower to determine the withholding or deduction required to be made; and

(D) if a payment made to a Lender under any Loan Document would be subject to U.S. Federal withholding Tax imposed by FATCA if such Lender were to fail to comply with the applicable reporting requirements of FATCA (including those contained in Section 1471(b) or 1472(b) of the Code, as applicable), such Lender shall make available to such Borrower (directly or through Administrative Agent) at the time or times prescribed by law as reasonably requested by such Borrower or Administrative Agent any necessary forms and information reasonably requested by such Borrower or Administrative Agent to establish that such Lender is not subject to withholding tax under FATCA or as may be necessary for the Borrowers and the Administrative Agent to comply with their obligations under FATCA and to determine that such Lender has complied with such Lender’s obligations under FATCA or to determine the amount to deduct and withhold from such payment. Solely for purposes of this

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clause (D), "FATCA" shall include any amendments made to FATCA after the date of this Agreement.

(iii) Each Lender agrees that if any form or certification it previously made available expires or becomes obsolete or inaccurate in any respect, such Lender shall update such form or certification or promptly notify Lead Borrower in writing of its legal inability to do so.

(f) **Treatment of Certain Refunds.** If any party determines, in its sole discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to this **Section 5** (including by the payment of additional amounts pursuant to this **Section 5**), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnity payments made under this **Section 5** with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of such indemnified party and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this paragraph (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) in the event that such indemnified party is required to repay such refund to such Governmental Authority. Notwithstanding anything to the contrary in this **Section 5.03(f)**, in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this **Section 5.03(f)** the payment of which would place the indemnified party in a less favorable net after-Tax position than the indemnified party would have been in if the indemnification payments or additional amounts giving rise to such refund had never been paid. This **Section 5.03(f)** shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

(i) **Mitigation Obligations.** If any Borrower is required to pay any Indemnified Taxes or additional amounts to any Lender or to any Governmental Authority for the account of any Lender pursuant to **Section 5.01** or this **Section 5.03**, then, except as otherwise provided in **Section 5.01(c)**, such Lender shall (at the request of the Lead Borrower) use commercially reasonable efforts to designate a different lending office for funding or booking its Loans hereunder or to assign and delegate its rights and obligations hereunder to another of its offices, branches or Affiliates if, in the sole reasonable judgment of such Lender, such designation or assignment and delegation would (i) eliminate or reduce amounts payable pursuant to **Section 5.01** or this **Section 5.03**, as the case may be, in the future, (ii) not subject such Lender to any unreimbursed cost or expense and (iii) not otherwise be disadvantageous to such Lender. Each Borrower hereby agrees to pay all reasonable costs and expenses incurred by any Lender in connection with any such designation or assignment and delegation.

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**SECTION 6  
CONDITIONS PRECEDENT**

**6.01 Conditions to the First Borrowing.** The first Borrowing occurred on the Closing Date and was subject to the following conditions precedent, which were satisfied or waived in writing by the Lenders on or prior to the Closing Date:

- (a) **Borrowing Date.** Such Borrowing shall be made on the Closing Date.
- (b) **Amount of First Borrowing.** The amount of such Borrowing shall equal \$40,000,000.
- (c) **Terms of Material Agreements, Etc.** Lenders shall be reasonably satisfied with the terms and conditions of all of the Obligors' Material Agreements.
- (d) **No Law Restraining Transactions.** No applicable law or regulation shall restrain, prevent or, in the reasonable judgment of the Lenders, impose materially adverse conditions upon the Transactions.
- (e) **Payment of Fees.** Lenders shall be satisfied with the arrangements to deduct the fees set forth in the Original Fee Letter (including the financing fee required pursuant to the Original Fee Letter) from the proceeds advanced.
- (f) **Lien Searches.** Lenders shall be satisfied with reasonable and customary Lien searches regarding each Borrower and their Subsidiaries made prior to such Borrowing.
- (g) **Documentary Deliveries.** The Lenders shall have received the following documents, each of which shall be in form and substance reasonably satisfactory to the Lenders:
  - (i) **Agreement.** This Agreement duly executed and delivered by Borrowers and each of the other parties hereto.
  - (ii) **Security Documents.**
    - (A) The Security Agreement, duly executed and delivered by each of the Obligors.
    - (B) [Reserved].
    - (C) Each of the Short-Form IP Security Agreements, duly executed and delivered by the applicable Obligor.

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(D) Original share certificates or other documents or evidence of title with regard to all Equity Interests owned by the Obligors (to the extent that such Equity Interests are certificated), together with, to the extent customary under the laws of the jurisdiction of organization of the issuer of such Equity Interests, share transfer documents, undated and duly executed in blank, letters of authority, irrevocable proxies and dividend mandates (as applicable).

(E) [Reserved].

(F) Evidence of filing of UCC-1 financing statements against each Obligor in its jurisdiction of formation or incorporation, as the case may be.

(G) [Reserved].

(H) [Reserved].

(I) Completed Form C1 templates in agreed form for each Security Document to which Parent is a party, prepared by Lenders' solicitors and approved and verified such by Parent's solicitors;

(J) Each foreign Security Documents listed on **Schedule 6.01**, duly executed and delivered by each of the Obligors party thereto.

(K) Without limitation, all other documents and instruments reasonably required to perfect (to the extent it is possible to do so in the relevant jurisdiction) the Secured Parties' Lien on, and security interest in, the Collateral, and a copy of all other notices, acknowledgements and documents required to be sent or delivered according to the terms of the Security Documents, required to be delivered on or prior to such Borrowing Date shall have been duly executed and delivered and be in proper form for filing, and shall create in favor of the Secured Parties, a perfected (to the extent it is possible to do so in the relevant jurisdiction) Lien on, and security interest in, the Collateral, subject to no Liens other than Permitted Liens.

(iii) **Original Fee Letter.** The Original Fee Letter duly executed and delivered by Borrowers and Administrative Agent.

(iv) **Warrants.** For the Lenders, *pro rata* in accordance with their Proportionate Shares, the Warrants, duly executed by Parent, for 0.80% of the ordinary shares of the Parent on a Fully-Diluted Basis as of the first Borrowing Date (inclusive of the Warrants granted on such date) at an exercise price equal to 110% of the closing price of Parent's ordinary shares on the date immediately prior to the first Borrowing Date.

(v) **Original Perfection Certificate.** The Original Perfection Certificate duly executed and delivered by the Obligors party thereto.

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(vi) **Approvals.** Certified copies of any material licenses, consents, authorizations and approvals of, and notices to and filings and registrations with, any Governmental Authority (including all foreign exchange approvals), and of all third-party consents and approvals, necessary in connection with the making and performance by the Obligors of the Loan Documents and the Transactions.

(vii) **Corporate Documents.** Certified copies of the constitutive documents of each Obligor (if publicly available in such Obligor's jurisdiction of formation or incorporation) and of resolutions of the Board of Directors (and/or shareholders, if applicable) or other applicable governing body of each Obligor authorizing the making and performance by it of the Loan Documents to which it is a party.

(viii) **Incumbency Certificate.** A certificate of each Obligor as to the authority, incumbency and specimen signatures of the persons who have executed the Loan Documents and any other documents in connection herewith on behalf of the Obligors.

(ix) **[Reserved].**

(x) **Opinions of Counsel.** A favorable opinion, dated such Borrowing Date, of counsels to the Obligors and/or the Lenders, as applicable, in each case in form reasonably acceptable to the Lenders and their counsel.

(xi) **Insurance.** Certificates and endorsements of insurance evidencing the existence of all insurance required to be maintained by the Obligors pursuant to **Section 8.05** and the designation of Administrative Agent as the lender's loss payees or additional named insured, as the case may be, thereunder.

(xii) **Payoff Letter.** A duly executed and delivered payoff letter with respect to Borrowers' existing debt facility with Oxford Finance LLC and Horizon Technology Finance Corporation, together with such documentation required to terminate and release all security interests in connection therewith, each in form and substance reasonably satisfactory to Administrative Agent.

(xiii) **Irish Obligors Certificate.** With respect to Parent, a certificate of Parent (signed by a director) confirming that it and each other Obligor are members of a group of companies consisting of Parent as holding company, and each other Obligor, as a subsidiary within the meaning of Sections 7 and 8 of the Irish Companies Act and for the purposes of section 243 of the Irish Companies Act.

(xiv) **Landlord Consent.** A Landlord Consent executed by the Borrower Landlord.

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(xv) **Bailee Waiver.** A bailee waiver executed by Cardinal Health.

(h) **Securities Purchase.** The transactions contemplated by the Securities Purchase Agreement shall have been consummated concurrently with funding of the first Borrowing.

**6.02 Conditions to Second Borrowing.** The obligation of each Lender to make a Loan as part of a second Borrowing is subject to the following conditions precedent, which shall have been satisfied or waived in writing by the Lenders:

(a) **Borrowing Date.** Such Borrowing shall occur within 4 Business Days of the Amendment No. 1 Effective Date.

(b) **Amount of Borrowing.** The amount of such Borrowing shall equal \$45,000,000.

(c) **Macrilen Acquisition.** The Macrilen License Agreement remains in effect, without any amendment, supplement or other modifications thereto (except for amendments, supplements or modifications reasonably acceptable to the Administrative Agent) and the Macrilen Acquisition shall have been consummated in accordance with the Macrilen License Agreement.

(d) **Payment of Fees.** Lenders shall be satisfied with the arrangements to deduct the fees set forth in the Amended Fee Letter (including the financing fee required pursuant to the Amended Fee Letter) from the proceeds advanced.

(e) **Irish Debenture.** An Irish Debenture duly executed and delivered by the Irish Borrower and Administrative Agent.

(f) **Irish Deed of Confirmation.** An Irish Deed of Confirmation with respect to the Irish Debenture entered into by Parent and Administrative Agent.

(g) **Swedish Security Affirmation.** A Swedish Security Affirmation entered into by Swedish Borrower, Parent and Administrative Agent.

(h) **Amended Perfection Certificate.** The Amended Perfection Certificate duly executed and delivered by the Obligors.

(i) **Approvals.** Certified copies of any material licenses, consents, authorizations and approvals of, and notices to and filings and registrations with, any Governmental Authority (including all foreign exchange approvals), and of all third-party consents and approvals, necessary in connection with the making and performance by the Obligors of the Loan Documents and the Transactions.

**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

(j) **Corporate Documents.** Certified copies of the constitutive documents of each Obligor (if publicly available in such Obligor's jurisdiction of formation or incorporation) and of resolutions of the Board of Directors (and/or shareholders, if applicable) or other applicable governing body of each Obligor authorizing the making and performance by it of the Loan Documents to which it is a party.

(k) **Incumbency Certificate.** A certificate of each Obligor as to the authority, incumbency and specimen signatures of the persons who have executed the Loan Documents and any other documents in connection herewith on behalf of the Obligors.

(l) **Irish Obligors Certificate.** With respect to Parent and Irish Borrower, a certificate of Parent (signed by a director) confirming that it and each other Obligor are members of a group of companies consisting of Parent as holding company, and each other Obligor, as a subsidiary within the meaning of Sections 7 and 8 of the Irish Companies Act and for the purposes of section 243 of the Irish Companies Act.

(m) **Opinions of Counsel.** One or more favorable opinions of counsels to the Obligors and/or the Lenders, as applicable, in each case in form reasonably acceptable to the Lenders and their counsel.

(n) **Warrants.** For the Lenders, *pro rata* in accordance with their Proportionate Shares, the Warrants, duly executed by Parent, for 2.25% of the ordinary shares of the Parent on a Fully-Diluted Basis as of the second Borrowing Date (inclusive of the Warrants granted on such date) at an exercise price equal to \$10.00 per share.

**6.03 Conditions to Third Borrowing.** The obligation of each Lender to make a Loan as part of a third Borrowing is subject to the following conditions precedent, which shall have been satisfied or waived in writing by the Lenders:

(a) **Second Borrowing.** The second Borrowing shall have occurred.

(b) **Borrowing Date.** Such Borrowing shall occur on or prior to September 27, 2018.

(c) **Amount of Borrowing.** The amount of such Borrowing shall not exceed \$10,000,000 or be less than \$1,000,000 and shall be in increments of \$1,000,000.

(d) **Borrowing Milestone.** The Obligors shall have achieved Revenue from the sale of the Product of at least \$[\*\*\*\*] during any consecutive three (3) month period ending on or prior to June 30, 2018;

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(e) **Market Capitalization Condition.** Parent maintains Market Capitalization of at least \$300,000,000 for the twenty (20) consecutive trading days ending on the trading day immediately prior to the third Borrowing Date.

(f) **Notice of Milestone Achievement and Audit.** Lead Borrower shall have delivered to Administrative Agent a notice certifying satisfaction of the condition set forth in **Section 6.03(d)** no later than sixty (60) days thereafter, and Administrative Agent shall have been reasonably satisfied with the results of its audit of the Obligor's Revenue by examining the Obligor's books and records.

(g) **Notice of Borrowing.** A Notice of Borrowing shall have been received no later than sixty (60) calendar days after satisfaction of the condition set forth in **Section 6.03(d)**.

(h) **Warrants.** For the Lenders, *pro rata* in accordance with their Proportionate Shares, the Warrants, duly executed by Parent, for 0.20% of the ordinary shares of the Parent on a Fully-Diluted Basis as of the third Borrowing Date (inclusive of the Warrants granted on such date) at an exercise price equal to 110% of the closing price of Parent's ordinary shares on the date immediately prior to the third Borrowing Date.

**6.04 Conditions to Fourth Borrowing.** The obligation of each Lender to make a Loan as part of a fourth Borrowing is subject to the following conditions precedent, which shall have been satisfied or waived in writing by the Lenders:

(a) **Third Borrowing.** The third Borrowing shall have occurred.

(b) **Borrowing Date.** Such Borrowing shall occur on or prior to March 19, 2019.

(c) **Amount of Borrowing.** The amount of such Borrowing shall not exceed \$5,000,000 or be less than \$1,000,000 and shall be in increments of \$1,000,000.

(d) **Borrowing Milestone.** The Obligor shall have achieved Revenue from the sale of the Product of at least \$[\*\*\*\*] during any consecutive three (3) month period ending on or prior to December 31, 2018.

(e) **Market Capitalization Condition.** Parent maintains Market Capitalization of at least \$325,000,000 for the twenty (20) consecutive trading days ending on the trading day immediately prior to the fourth Borrowing Date.

(f) **Notice of Milestone Achievement and Audit.** Lead Borrower shall have delivered to Administrative Agent a notice certifying satisfaction of the condition set forth in **Section 6.04(d)** no later than sixty (60) days thereafter, and Administrative Agent shall have been reasonably satisfied with the results of its audit of the Obligor's Revenue by examining the Obligor's books and records.



**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

(g) **Notice of Borrowing.** A Notice of Borrowing shall have been received no later than sixty (60) calendar days after satisfaction of the condition set forth in **Section 6.04(d)**.

(h) **Warrants.** For the Lenders, *pro rata* in accordance with their Proportionate Shares, the Warrants, duly executed by Parent, for 0.25% of the ordinary shares of the Parent on a Fully-Diluted Basis as of the fourth Borrowing Date (inclusive of the Warrants granted on such date) at an exercise price equal to 140% of the ten (10) day volume weighted-average price (VWAP) per share of Parent's ordinary shares for the consecutive ten (10)-trading-day period ending on the trading day prior to the fourth Borrowing Date.

**6.05 Conditions to Each Borrowing.** The obligation of each Lender to make a Loan as part of any Borrowing (including the first Borrowing) is also subject to satisfaction of the following further conditions precedent on the applicable Borrowing Date, which shall have been satisfied or waived in writing by the Lenders:

(a) **Commitment Period.** Except in the case of any PIK Loan, such Borrowing Date shall occur during the Commitment Period.

(b) **No Default; Representations and Warranties.** Both immediately prior to the making of such Loan and after giving effect thereto and to the intended use thereof:

(i) no Default shall have occurred and be continuing or would result from such proposed Loan or the application of the proceeds thereof;

(ii) the representations and warranties made in **Section 7** shall be true and correct on and as of the Borrowing Date, and immediately after giving effect to the application of the proceeds of the Borrowing, with the same force and effect as if made on and as of such date (except that the representation regarding representations and warranties that refer to a specific earlier date shall be that they were true and correct on such earlier date);and

(iii) no Material Adverse Effect has occurred since the end of the period covered by the financial statements most recently delivered pursuant to **Section 8.01(b)** or is reasonably likely to occur after giving effect to such proposed Borrowing.

(c) **Notice of Borrowing.** Except in the case of any PIK Loan, Administrative Agent shall have received a Notice of Borrowing as and when required pursuant to **Section 2.02**.

Each Borrowing shall constitute a certification by Lead Borrower to the effect that the conditions set forth in this **Section 6.05** have been fulfilled as of the applicable Borrowing Date.

CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*]  
INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.

**SECTION 7  
REPRESENTATIONS AND WARRANTIES**

Each Obligor represents and warrants to Administrative Agent and the Lenders that:

**7.01 Power and Authority.** Each of Parent and its Subsidiaries (a) is duly organized or incorporated and validly existing under the laws of its jurisdiction of organization or incorporation, (b) has all requisite corporate or other equivalent power, and has all material governmental licenses, authorizations, consents and approvals necessary to own its assets and carry on its business as now being or as proposed to be conducted except to the extent that failure to have the same would not reasonably be expected to have a Material Adverse Effect, (c) is qualified to do business and is in good standing in all jurisdictions in which the nature of the business conducted by it makes such qualification necessary and where failure to so qualify would (either individually or in the aggregate) have a Material Adverse Effect, and (d) has full power, authority and legal right to make and perform each of the Loan Documents to which it is a party and, in the case of Borrowers, to borrow the Loans hereunder.

**7.02 Authorization; Enforceability.** The Transactions are within each Obligor's corporate or equivalent powers and have been duly authorized by all necessary corporate or equivalent action and, if required, by all necessary shareholder action. This Agreement has been duly executed and delivered by each Obligor and constitutes, and each of the other Loan Documents to which it is a party when executed and delivered by such Obligor will constitute, a legal, valid and binding obligation of such Obligor, enforceable against such Obligor in accordance with its terms, except as such enforceability may be limited by (a) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights and (b) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law).

**7.03 Governmental and Other Approvals; No Conflicts.** The Transactions (a) do not require any consent or approval of, registration or filing with, or any other action by, any Governmental Authority or any third party, except for (i) such as have been obtained or made and are in full force and effect and (ii) filings and recordings in respect of the Liens created pursuant to the Security Documents, (b) will not violate any applicable law or regulation or the charter, bylaws, constitutional or other organizational documents of Parent and its Subsidiaries, (c) will not violate any order of any Governmental Authority, (d) will not violate or result in a default under any indenture, agreement or other instrument binding upon Parent and its Subsidiaries or assets, or give rise to a right thereunder to require any payment to be made by any such Person, and (e) will not result in the creation or imposition of any Lien (other than Permitted Liens) on any asset of Parent and its Subsidiaries.

**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**7.04 Financial Statements; Material Adverse Change.**

(a) **Financial Statements.** Parent has heretofore furnished to the Lenders certain financial statements as provided for in **Section 8.01**. Such financial statements present fairly, in all material respects, the financial position and results of operations and cash flows of Parent and its Subsidiaries as of such dates and for such periods in accordance with GAAP, subject to year-end audit adjustments and the absence of footnotes in the case of the previously-delivered statements of the type described in **Section 8.01(a)**. Neither Parent nor any of its Subsidiaries has any material contingent liabilities or unusual forward or long-term commitments not disclosed in the aforementioned financial statements.

(b) **No Material Adverse Change.** Since March 31, 2017, there has been no Material Adverse Change.

**7.05 Properties.**

(a) **Property Generally.** Each Obligor has good and marketable fee simple title to, or valid leasehold interests in, all its real and personal Property material to its business, subject only to Permitted Liens and except for minor defects in title that do not interfere with its ability to conduct its business as currently conducted or to utilize such properties for their intended purposes.

(b) **Intellectual Property.** The Obligors represent and warrant to the Lenders as follows, as of the Amendment No. 1 Effective Date, each Borrowing Notice Date and each Borrowing Date:

(i) **Schedule 7.05(b)(i)** (as amended from time to time by Lead Borrower in accordance with **Section 7.21**) contains:

(A) a complete and accurate list of all applied for or registered Patents, owned by or licensed to any Obligor, including the jurisdiction and patent number;

(B) a complete and accurate list of all applied for or registered Trademarks, owned by or licensed to any Obligor, including the jurisdiction, trademark application or registration number and the application or registration date; and

(C) a complete and accurate list of all applied for or registered Copyrights, owned by or licensed to any Obligor;

(ii) Each Obligor is the absolute beneficial owner of all right, title and interest in and to and have the right to use the Obligor Intellectual Property with no breaks in chain of title with good and marketable title, free and clear of any Liens or Claims of any kind whatsoever

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other than Permitted Liens. Without limiting the foregoing, and except as set forth in **Schedule 7.05(b)(ii)**:

(A) other than with respect to the Material Agreements, or as permitted by **Section 9.09**, the Obligors have not transferred ownership of Material Intellectual Property, in whole or in part, to any other Person who is not an Obligor;

(B) other than (i) the Material Agreements, (ii) customary restrictions in in-bound licenses of Intellectual Property and non-disclosure agreements, or (iii) as would have been or is permitted by **Section 9.09**, there are no judgments, covenants not to sue, permits, grants, licenses, Liens (other than Permitted Liens), Claims, or other agreements or arrangements relating to the Material Intellectual Property, including any development, submission, services, research, license or support agreements, which bind, obligate or otherwise restrict the Obligors;

(C) the use of any of the Obligor Intellectual Property, to any Obligor's Knowledge, does not breach, violate, infringe or interfere with or constitute a misappropriation of any valid rights arising under any Intellectual Property of any other Person;

(D) there are no pending or, to any Obligor's Knowledge, threatened Claims against the Obligors asserted by any other Person relating to the Obligor Intellectual Property, including any Claims of adverse ownership, invalidity (other than any actions asserted during the ordinary course of examination of a patent application or a trademark application before the United States Patent and Trademark Office or any foreign patent and/or trademark office), infringement, misappropriation, violation or other opposition to or conflict with such Intellectual Property; no Obligor has received any written notice from any Person that any Obligor business, the use of the Obligor Intellectual Property, or the manufacture, use or sale of any product or the performance of any service by any Obligor infringes upon, violates or constitutes a misappropriation of, or may infringe upon, violate or constitute a misappropriation of, or otherwise interfere with, any other Intellectual Property of any other Person;

(E) no Obligor has any Knowledge that the Obligor Intellectual Property is being infringed, violated, misappropriated or otherwise used by any other Person without the express authorization of the Obligors. Without limiting the foregoing, no Obligor has put any other Person on notice of actual or potential infringement, violation or misappropriation of any of the Obligor Intellectual Property; no Obligor has initiated the enforcement of any Claim with respect to any of the Obligor Intellectual Property;

(F) all relevant current and former employees and contractors of each Obligor have executed written confidentiality and invention assignment Contracts with such Obligor that irrevocably assign to such Obligor or its designee all of their rights to any Inventions relating to any Obligor's business;

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(G) to the Knowledge of the Obligors, the Obligor Intellectual Property is all the Intellectual Property necessary for the operation of Obligors' business as it is currently conducted or as currently contemplated to be conducted;

(H) each Obligor has taken reasonable precautions to protect the secrecy, confidentiality and value of its Obligor Intellectual Property consisting of trade secrets and confidential information;

(I) each Obligor has delivered to Administrative Agent accurate and complete copies of all Material Agreements relating to the Obligor Intellectual Property;

(J) there are no pending or, to the Knowledge of any of the Obligors, threatened in writing Claims against the Obligors asserted by any other Person relating to the Material Agreements, including any Claims of breach or default under such Material Agreements;

(iii) With respect to the Obligor Intellectual Property consisting of Patents, except as set forth in **Schedule 7.05(b)(ii)**, and without limiting the representations and warranties in **Section 7.05(b)(ii)**:

(A) each of the issued claims in such Patents, to Obligors' Knowledge, is valid and enforceable;

(B) the inventors claimed in such Patents have executed written Contracts with an Obligor or its predecessor-in-interest that properly and irrevocably assign to an Obligor or predecessor-in-interest all of their rights to any of the Inventions claimed in such Patents to the extent permitted by applicable law;

(C) none of the Patents, or the Inventions claimed in them, have been dedicated to the public except as a result of intentional decisions made by the applicable Obligor;

(D) to any Obligor's Knowledge, all prior art material to such Patents was adequately disclosed to or considered by the respective patent offices during prosecution of such Patents to the extent required by applicable law or regulation;

(E) subsequent to the issuance of such Patents, neither any Obligor nor its predecessors in interest have filed any disclaimer (other than terminal disclaimers that may have been filed during the ordinary course of examination before the United States Patent and Trademark Office, or the equivalent thereof in any foreign patent office) or filed any other voluntary reduction in the scope of the Inventions claimed in such Patents;

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(F) no allowable or allowed subject matter of such Patents, to any Obligor's Knowledge, is subject to any competing conception claims of allowable or allowed subject matter of any patent applications or patents of any third party and have not been the subject of any interference, re-examination, inter partes review, post grant review or opposition proceedings, nor are the Obligors aware of any basis for any such interference, re-examination, inter partes review, post grant review or opposition proceedings;

(G) no such Patents, to any Obligor's Knowledge, have ever been finally adjudicated to be invalid, unpatentable or unenforceable for any reason in any administrative, arbitration, judicial or other proceeding, and, with the exception of publicly available documents in the applicable Patent Office recorded with respect to any Patents, no Obligor has received any notice asserting that such Patents are invalid, unpatentable or unenforceable; if any of such Patents is terminally disclaimed to another patent or patent application, all patents and patent applications subject to such terminal disclaimer are included in the Collateral;

(H) no Obligor has received an opinion, whether preliminary in nature or qualified in any manner, which concludes that a challenge to the validity or enforceability of any of such Patents is more likely than not to succeed;

(I) no Obligor has any Knowledge that any Obligor or any prior owner of such Patents or their respective agents or representatives have engaged in any conduct, or omitted to perform any necessary act, the result of which would invalidate or render unpatentable or unenforceable any such Patents; and

(J) all maintenance fees, annuities, and the like due or payable on the Patents have been timely paid or the failure to so pay was the result of an intentional decision by the applicable Obligor or would not reasonably be expected to result in a Material Adverse Change.

(iv) none of the foregoing representations and statements of fact contains any untrue statement of material fact or omits to state any material fact necessary to make any such statement or representation not misleading to a prospective Lender seeking full information as to the Obligor Intellectual Property and the Obligors' business.

(c) **Material Intellectual Property. Schedule 7.05(c)** (as amended from time to time by Lead Borrower in accordance with **Section 7.21**) contains an accurate list of the Obligor Intellectual Property that is material to any Obligor's business with an indication as to whether the applicable Obligor owns or has an exclusive or non-exclusive license to such Obligor Intellectual Property.

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**7.06 No Actions or Proceedings.**

(a) **Litigation.** There is no litigation, investigation or proceeding pending or, to any Obligor's Knowledge, threatened with respect to Parent and its Subsidiaries by or before any Governmental Authority or arbitrator (i) that either individually or in the aggregate would reasonably be expected to have a Material Adverse Effect, except as specified in **Schedule 7.06** or (ii) that involves this Agreement or the Transactions.

(b) **Environmental Matters.** The operations and Property of Parent and its Subsidiaries comply with all applicable Environmental Laws, except to the extent the failure to so comply (either individually or in the aggregate) would not reasonably be expected to have a Material Adverse Effect.

(c) **Labor Matters.** Parent and its Subsidiaries have not engaged in unfair labor practices and there are no material labor actions or disputes involving the employees of Parent or its Subsidiaries.

**7.07 Compliance with Laws and Agreements.** Each of the Obligors is in compliance with all laws, regulations and orders of any Governmental Authority applicable to it or its property and all indentures, agreements and other instruments binding upon it or its property, except where the failure to do so, individually or in the aggregate, would not reasonably be expected to result in a Material Adverse Effect. No Default has occurred and is continuing.

**7.08 Taxes.** All federal, state, material local, foreign income and franchise and other material Tax returns, reports and statements (collectively, the "**Tax Returns**") required to be filed by any Tax Affiliate have been timely filed with the appropriate Governmental Authorities, all such Tax Returns are true, correct and complete in all material respects, and all federal and foreign income Taxes and other material Taxes reflected therein or otherwise due and payable have been timely paid (except for those contested in good faith by appropriate proceedings diligently conducted and for which adequate reserves are maintained on the books of the appropriate Tax Affiliate in accordance with GAAP). No Tax Return is under audit or examination by any Governmental Authority and no notice of any material audit or examination or any assertion of any claim for Taxes has been given or made by any Governmental Authority. Proper and accurate amounts have been withheld by each Tax Affiliate from their respective employees for all periods in full and complete compliance with the Tax, social security and unemployment withholding provisions of applicable Laws and such withholdings have been timely paid to the respective Governmental Authorities. No Tax Affiliate has participated in a "listed transaction" within the meaning of Treasury Regulation Section 1.6011-4(b)(2).

**7.09 Full Disclosure.** Obligors have disclosed to Administrative Agent and the Lenders all Material Agreements to which any Obligor is subject, and all other matters to any Obligor's

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Knowledge, that, individually or in the aggregate, would reasonably be expected to result in a Material Adverse Effect. None of the reports, financial statements, certificates or other information furnished by or on behalf of any Obligor to Administrative Agent or any Lender in connection with the negotiation of this Agreement and the other Loan Documents or delivered hereunder or thereunder (as modified or supplemented by other information so furnished) contains any material misstatement of material fact or omits to state any material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided* that, with respect to projected financial information, Parent represents only that such information was prepared in good faith based upon assumptions believed to be reasonable at the time.

**7.10 Regulation.**

(a) **Investment Company Act.** Neither Parent nor any of its Subsidiaries is an “investment company” as defined in, or subject to regulation under, the Investment Company Act of 1940.

(b) **Margin Stock.** Neither Parent nor any of its Subsidiaries is engaged principally, or as one of its important activities, in the business of extending credit for the purpose, whether immediate, incidental or ultimate, of buying or carrying Margin Stock, and no part of the proceeds of the Loans will be used to buy or carry any Margin Stock in violation of Regulation T, U or X.

(c) **OFAC; Sanctions, Etc.** Neither Parent nor any of its Subsidiaries or, to the knowledge of any Obligor, any Related Person (i) is currently the subject of any Sanctions or is a Sanctioned Person, (ii) is located (or has its assets located), organized or residing in any Sanctioned Jurisdiction, (iii) is or has been (within the previous five (5) years) engaged in any impermissible transaction with any Person who is now or was then the subject of Sanctions or who is located, organized or residing in any Sanctioned Jurisdiction, (iv) directly or indirectly derives revenues from investments in, or transactions with, Sanctioned Persons, (v) has taken any action, directly or indirectly, that would result in a violation by such Persons of any Anti-Corruption Laws, or (vi) has violated any Anti-Money Laundering Laws. No Loan, nor the proceeds from any Loan, has been or will be used, directly or indirectly, to lend, contribute or provide to, or has been or will be otherwise made available to fund, any impermissible activity or business of any Person located, organized or residing in any Sanctioned Jurisdiction or who is the subject of any Sanctions, or in any other manner that will result in any violation by any Person (including the Lender and its Affiliates) of Sanctions or otherwise in violation of any Anti-Corruption Laws or Anti-Money Laundering Laws. Each of Parent and its Subsidiaries has implemented and maintains in effect policies and procedures designed to promote compliance by Parent and its Subsidiaries and their respective directors, officers, employees, agents and Related Persons with the Anti-Corruption Laws.



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**7.11 Solvency.** Lead Borrower is, and the Obligors on a consolidated basis are, and, immediately after giving effect to the Borrowing and the use of proceeds thereof will be, Solvent.

**7.12 Subsidiaries.** Set forth on **Schedule 7.12** is a complete and correct list of all Subsidiaries of the Parent as of the Amendment No. 1 Effective Date. Each such Subsidiary is duly organized and validly existing under the jurisdiction of its organization shown in said **Schedule 7.12**, and the percentage ownership by the direct parent of each such Subsidiary is as shown in said **Schedule 7.12**.

**7.13 Indebtedness and Liens.** Set forth in **Part I** of **Schedule 7.13(a)** is a complete and correct list of all Indebtedness of each Obligor outstanding as of the Amendment No. 1 Effective Date. **Part I** of **Schedule 7.13(b)** is a complete and correct list of all Liens granted by Parent and the other Obligors with respect to their respective Property and outstanding as of the Amendment No. 1 Effective Date.

**7.14 Material Agreements.** Set forth on **Schedule 7.14** (as amended from time to time by Lead Borrower in accordance with **Section 7.21** and as amended effective as of the Amendment No. 1 Effective Date to include the Macrilen License Agreement) is a complete and correct list of (i) each Material Agreement and (ii) each agreement creating or evidencing any Material Indebtedness. No Obligor is in default under any such Material Agreement or agreement creating or evidencing any Material Indebtedness. Except as otherwise disclosed on **Schedule 7.14**, all Material Agreements of the Obligors are in full force and effect without material modification from the form in which the same were disclosed to Administrative Agent and the Lenders.

**7.15 Restrictive Agreements.** None of the Obligors is subject to any indenture, agreement, instrument or other arrangement that prohibits, restricts or imposes any condition upon (a) the ability of Parent or any Subsidiary to create, incur or permit to exist any Lien upon any of its property or assets (other than (x) customary provisions in contracts (including leases and in-bound licenses of Intellectual Property) restricting the assignment thereof and (y) restrictions or conditions imposed by any agreement governing secured Permitted Indebtedness permitted under **Section 9.01(h)**, to the extent that such restrictions or conditions apply only to the property or assets securing such Indebtedness), or (b) the ability of any Subsidiary to pay dividends or other distributions with respect to any shares of its capital stock or share capital, as applicable, or to make or repay loans or advances to Parent or any other Subsidiary or to Guarantee Indebtedness of Parent or any other Subsidiary (each, a "**Restrictive Agreement**"), except those listed on **Schedule 7.15** or otherwise permitted under **Section 9.11**.

**7.16 Real Property.**

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(a) **Generally.** Neither Parent nor any of its Subsidiaries owns or leases (as tenant thereof) any real property, except as described on **Schedule 7.16** (as amended from time to time by Parent in accordance with **Section 7.21**).

(b) **[Reserved].**

**7.17 Pension Matters.** **Schedule 7.17** sets forth, as of the Amendment No. 1 Effective Date, a complete and correct list of, and that separately identifies, (a) all Title IV Plans and (b) all Multiemployer Plans. Each Benefit Plan, and each trust thereunder, intended to qualify for tax exempt status under Section 401 or 501 of the Code or other Requirements of Law so qualifies. Except for those that would not reasonably be expected to have, in the aggregate, have a Material Adverse Effect, (w) each Benefit Plan is in compliance with applicable provisions of ERISA, the Code and other Requirements of Law, (x) there are no existing or pending (or to the Knowledge of any Obligor or Subsidiary thereof, threatened) claims (other than routine claims for benefits in the normal course), sanctions, actions, lawsuits or other proceedings or investigation involving any Benefit Plan to which any Obligor or Subsidiary thereof incurs or otherwise has or could have an obligation or any liability or Claim, (y) no ERISA Event is reasonably expected to occur and, as of the Closing Date, no ERISA Event has occurred in connection with which obligations and liabilities (contingent or otherwise) remain outstanding, and (z) no ERISA Affiliate would have any Withdrawal Liability as a result of a complete withdrawal from any Multiemployer Plan on the date this representation is made. Parent and each of its ERISA Affiliates has met all applicable requirements under the ERISA Funding Rules with respect to each Title IV Plan, and no waiver of the minimum funding standards under the ERISA Funding Rules has been applied for or obtained. As of the most recent valuation date for any Title IV Plan, the funding target attainment percentage (as defined in Section 430(d)(2) of the Code) is at least 60%, and neither Parent nor any of its ERISA Affiliates knows of any facts or circumstances that could reasonably be expected to cause the funding target attainment percentage to fall below 60% as of the most recent valuation date.

**7.18 Collateral; Security Interest.** Each Security Document is effective to create in favor of the Secured Parties a legal, valid and enforceable security interest in the Collateral subject thereto and each such security interest is perfected to the extent required by (and has the priority required by) the applicable Security Document. The Security Documents collectively are effective to create in favor of the Secured Parties a legal, valid and enforceable security interest in the Collateral subject thereto, which security interests are first-priority (subject only to Permitted Priority Liens or except as expressly contemplated by the Security Documents).

**7.19 Regulatory Approvals.** Parent and its Subsidiaries hold, and will continue to hold, either directly or through licensees and agents, all Regulatory Approvals, licenses, permits and similar governmental authorizations of a Governmental Authority necessary or required for Parent and its Subsidiaries to conduct their operations and business in the manner currently

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conducted, except where failure to do so would not reasonably be expected to have a Material Adverse Effect.

**7.20** [Reserved.]

**7.21 Update of Schedules.** Each of **Schedules 7.05(b)(i), 7.05(c), 7.14 and 7.16** may be updated by Lead Borrower from time to time in order to ensure the continued accuracy of such Schedule as of any upcoming date on which representations and warranties are made incorporating the information contained on such Schedule. Such update may be accomplished by Lead Borrower providing to Administrative Agent, in writing (including by electronic means), a revised version of such Schedule in accordance with the provisions of **Section 13.02**. Each such updated Schedule shall be effective immediately upon the receipt thereof by Administrative Agent.

## **SECTION 8 AFFIRMATIVE COVENANTS**

Each Obligor covenants and agrees with Administrative Agent and the Lenders that, until the Commitments have expired or been terminated and all Obligations have been paid in full indefeasibly in cash:

**8.01 Financial Statements and Other Information.** Lead Borrower or Parent, as applicable, will furnish to Administrative Agent (and, in the case of **Sections 8.01(a)** through **(d)** and **(k)** and **(l)**, the VCOC Lender):

(a) as soon as available and in any event within 45 days after the end of the first three fiscal quarters of each fiscal year (or if later, on the date required to be filed with the SEC (after giving effect to any extension granted thereby)), the consolidated balance sheets of Parent and its Subsidiaries as of the end of such quarter, and the related consolidated statements of income, shareholders' equity and cash flows of Parent and its Subsidiaries for such quarter and the portion of the fiscal year through the end of such quarter, prepared in accordance with GAAP consistently applied, all in reasonable detail and setting forth in comparative form the figures for the corresponding period in the preceding fiscal year, together with a certificate of a Responsible Officer of Parent stating that such financial statements fairly present the financial condition of Parent and its Subsidiaries as at such date and the results of operations of Parent and its Subsidiaries for the period ended on such date and have been prepared in accordance with GAAP consistently applied, subject to changes resulting from normal, year-end audit adjustments and except for the absence of notes;

(b) as soon as available and in any event within 90 days after the end of each fiscal year (or, if later, on the date required to be filed with the SEC (after giving effect to any

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extension granted thereby)), the consolidated balance sheets of Parent and its Subsidiaries as of the end of such fiscal year, and the related consolidated statements of income, shareholders' equity and cash flows of Parent and its Subsidiaries for such fiscal year, prepared in accordance with GAAP consistently applied, all in reasonable detail and setting forth in comparative form the figures for the previous fiscal year, accompanied by a report and opinion thereon of Ernst & Young or another firm of independent certified public accountants of recognized national standing acceptable to the Lenders, which report and opinion shall be prepared in accordance with generally accepted auditing standards and shall not be subject to qualification or exception as to the scope of such audit;

(c) [reserved];

(d) together with the financial statements required pursuant to **Sections 8.01(a)** and **(b)**, a compliance certificate of a Responsible Officer as of the end of the applicable accounting period (which delivery may, unless a Lender requests executed originals, be by electronic communication including fax or email and shall be deemed to be an original authentic counterpart thereof for all purposes) in the form of **Exhibit D** (a "**Compliance Certificate**") including details of any material issues that are raised by auditors;

(e) [reserved];

(f) as soon as available, but in no event later than 90 days after the end of each fiscal year, a consolidated financial forecast for Parent and its Subsidiaries for the following fiscal years, including forecasted consolidated balance sheets, consolidated statements of income, shareholders' equity and cash flows of Parent and its Subsidiaries, provided that if Parent delivers a financial forecast for any longer period to its board of directors, Parent shall promptly, and in any event within five (5) Business Days after the same are made available to its board of directors, deliver such longer forecast to Administrative Agent;

(g) promptly, and in any event within five (5) Business Days, after the same are released, copies of all press releases;

(h) promptly, and in any event within ten (10) Business Days after receipt thereof by an Obligor thereof, copies of each notice or other correspondence received from any securities regulator or exchange to the authority of which an Obligor may become subject from time to time concerning any investigation by such agency regarding financial or other operational results of such Obligor;

(i) the information regarding insurance maintained by Parent and its Subsidiaries as required under **Section 8.05**;

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(j) promptly, and in any event within five (5) Business Days, following Administrative Agent's request at any time, proof of compliance with **Section 10.01**; and

(k) within five (5) Business Days of delivery, copies of all statements, reports and notices made available to holders of Permitted Subordinated Debt or Permitted Cure Debt, as applicable.

Notwithstanding the foregoing, documents required to be delivered pursuant to the terms of this **Section 8.01** (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and, if so delivered, shall be deemed to have been delivered on the date on which the Parent posts such documents, or provides a link thereto, on the Parent's website on the internet at the Parent's website address. For purposes of clarity, to the extent documents are posted electronically in accordance with SEC requirements, any requirement for prompt delivery under this Section 8.01 shall be deemed satisfied.

**8.02 Notices of Material Events.** Lead Borrower will furnish to Administrative Agent written notice of the following promptly, and, unless otherwise provided in this Section, in no event later than five (5) Business Days, after a Responsible Officer first learns of the existence of:

(a) the occurrence of any Default;

(b) notice of the occurrence of any event with respect to an Obligor's property or assets resulting in a Loss aggregating \$500,000 (or the Equivalent Amount in other currencies) or more;

(c) (A) any proposed acquisition of stock, assets or property by any Obligor that would reasonably be expected to result in environmental liability under Environmental Laws, and (B)(1) spillage, leakage, discharge, disposal, leaching, migration or release of any Hazardous Material required to be reported to any Governmental Authority under applicable Environmental Laws, and (2) all actions, suits, claims, notices of violation, hearings, investigations or proceedings pending, or to any Obligor's Knowledge, threatened against or affecting Parent or any of its Subsidiaries or with respect to the ownership, use, maintenance and operation of their respective businesses, operations or properties, relating to Environmental Laws or Hazardous Material;

(d) the assertion of any environmental matter by any Person against, or with respect to the activities of, Parent or any of its Subsidiaries and any alleged violation of or non-compliance with any Environmental Laws or any permits, licenses or authorizations which could reasonably be expected to involve damages in excess of \$100,000 other than any environmental

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matter or alleged violation that, if adversely determined, would not (either individually or in the aggregate) have a Material Adverse Effect;

(e) the filing or commencement of any action, suit or proceeding by or before any arbitrator or Governmental Authority against or affecting Parent or any of its Affiliates that, if adversely determined, would reasonably be expected to result in a Material Adverse Effect;

(f) (i) on or prior to any filing by any ERISA Affiliate of any notice of intent to terminate any Title IV Plan, a copy of such notice and (ii) promptly, and in any event within ten days, after any Responsible Officer of any ERISA Affiliate knows or has reason to know that a request for a minimum funding waiver under Section 412 of the Code has been filed with respect to any Title IV Plan or Multiemployer Plan, a notice (which may be made by telephone if promptly confirmed in writing) describing such waiver request and any action that any ERISA Affiliate proposes to take with respect thereto, together with a copy of any notice filed with the PBGC or the IRS pertaining thereto;

(g) (i) the termination of any Material Agreement; (ii) the receipt by Parent or any of its Subsidiaries of any material notice under any Material Agreement; (iii) the entering into of any new Material Agreement by an Obligor; or (iv) any material amendment to a Material Agreement;

(h) the reports and notices as required by the Security Documents;

(i) within 30 days of the date thereof, or, if earlier, on the date of delivery of any financial statements pursuant to **Section 8.01**, notice of any material change in accounting policies or financial reporting practices by the Obligors;

(j) notice of any labor controversy resulting in or threatening to result in any strike, work stoppage, boycott, shutdown or other material labor disruption against or involving an Obligor;

(k) a material licensing agreement or arrangement entered into by Parent or any Subsidiary in connection with any infringement or alleged infringement of the Intellectual Property of another Person;

(l) any other development that results in, or would reasonably be expected to result in, a Material Adverse Effect;

(m) concurrently with the delivery of financial statements under **Section 8.01(b)**, the creation or other acquisition of any Intellectual Property by Parent or any Subsidiary after the Closing Date and during such prior fiscal year which is registered or becomes registered or the

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subject of an application for registration with the U.S. Copyright Office or the U.S. Patent and Trademark Office, as applicable, or with any other equivalent foreign Governmental Authority;

(n) any change to any Obligor's ownership of Deposit Accounts, Securities Accounts and Commodity Accounts, by delivering to Administrative Agent an updated Schedule 7 to the Security Agreement setting forth a complete and correct list of all such accounts as of the date of such change; or

(o) such other information respecting the operations, properties, business or condition (financial or otherwise) of the Obligors (including with respect to the Collateral) as Administrative Agent may from time to time reasonably request.

Each notice delivered under this **Section 8.02** shall be accompanied by a statement of a financial officer or other executive officer of Lead Borrower setting forth the details of the event or development requiring such notice and any action taken or proposed to be taken with respect thereto.

Notwithstanding the foregoing, documents required to be delivered pursuant to the terms of clauses (d), (e), (g), (i) and (j) of this **Section 8.02** (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and, if so delivered, shall be deemed to have been delivered on the date on which the Parent posts such documents, or provides a link thereto, on the Parent's website on the internet at the Parent's website address. For purposes of clarity, to the extent documents required to be delivered pursuant to the terms of clauses (d), (e), (g), (i) and (j) of this **Section 8.02** are posted electronically in accordance with SEC requirements, any requirement for prompt delivery under this Section 8.02 shall be deemed satisfied.

**8.03 Existence; Conduct of Business.** Such Obligor will, and will cause each of its Subsidiaries to, do or cause to be done all things necessary to preserve, renew and keep in full force and effect its legal existence and the rights, licenses, permits, privileges and franchises material to the conduct of its business; *provided* that the foregoing shall not prohibit any merger, amalgamation, consolidation, liquidation or dissolution permitted under **Section 9.03**.

**8.04 Payment of Obligations.** Such Obligor will, and will cause each of its Subsidiaries to, pay and discharge its obligations, including (i) all Taxes, fees, assessments and governmental charges or levies imposed upon it or upon its properties or assets prior to the date on which penalties attach thereto, and all lawful claims for labor, materials and supplies which, if unpaid, might become a Lien upon any properties or assets of Parent or any Subsidiary; and (ii) all lawful claims which, if unpaid, would by law become a Lien upon its property not constituting a Permitted Lien; *provided* that such payment and discharge shall not be required with respect to any such Tax, fees assessments or governmental charges or levies or such claims, so long as the

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validity or amount thereof are being contested in good faith by appropriate proceedings and are adequately reserved against in accordance with GAAP.

**8.05 Insurance.** Such Obligor will maintain, and will cause each of its Subsidiaries to maintain, with financially sound and reputable insurance companies, insurance in such amounts and against such risks as are customarily maintained by companies engaged in the same or similar businesses operating in the same or similar locations. Upon the request of Administrative Agent or the Majority Lenders, such Obligor shall furnish Administrative Agent from time to time with full information as to the insurance carried by it and, if so requested, copies of all such insurance policies. Such Obligor also shall furnish to Administrative Agent from time to time upon the request of Administrative Agent or the Majority Lenders a certificate from such Obligor's insurance broker or other insurance specialist stating that all premiums then due on the policies relating to insurance on the Collateral have been paid, and that such policies are in full force and effect. Such Obligor shall use commercially reasonable efforts to ensure, or cause others to ensure, that all insurance policies required under this **Section 8.05** shall provide that they shall not be terminated or cancelled nor shall any such policy be materially changed in a manner adverse to such Obligor without at least 30 days' prior written notice to such Obligor and Administrative Agent. Receipt of notice of termination or cancellation of any such insurance policies or reduction of coverages or amounts thereunder and, unless the Borrowers have delivered evidence that it has obtained replacement insurance that satisfies the requirements of this Section, shall entitle the Administrative Agent to renew any such policies, cause the coverages and amounts thereof to be maintained at levels required pursuant to the first sentence of this **Section 8.05** or otherwise to obtain similar insurance in place of such policies, in each case at the expense of such Obligor (payable on demand). The amount of any such expenses shall accrue interest at the Default Rate if not paid on demand, and shall constitute "Obligations."

**8.06 Books and Records; Inspection Rights.**

(a) Such Obligor will, and will cause each of its Subsidiaries to, keep proper books of record and account in which full, true and correct entries are made of all dealings and transactions in relation to its business and activities.

(b) Such Obligor will, and will cause each of its Subsidiaries to, permit any representatives designated by Administrative Agent and each VCOC Lender, upon reasonable prior notice, to visit and inspect its properties, to examine and make extracts from its books and records, to inspect its facilities and to discuss its affairs, finances and condition with its officers and independent accountants, all at such reasonable times and intervals (but not more often than once a year unless an Event of Default has occurred and is continuing) as Administrative Agent or a VCOC Lender, as applicable, may request.



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(c) The Obligors shall pay all documented out-of-pocket costs of all such inspections.

(d) If Administrative Agent's or any VCOC Lender's outside counsel determines in writing that other rights of consultation are necessary under applicable legal authorities promulgated after the Closing Date to preserve the qualification of Administrative Agent's, the VCOC Lender's or any Lender's investment as a "venture capital investment" for purposes of ERISA, the Obligors will work in good faith to agree to an amendment to this **Section 8.06** to reflect such other rights.

**8.07 Compliance with Laws and Other Obligations.** Such Obligor will, and will cause each of its Subsidiaries to, (i) comply with all laws, rules, regulations and orders of any Governmental Authority applicable to it or its property (including Environmental Laws) and (ii) comply with all terms of Indebtedness and all other Material Agreements, except in each case where the failure to do so, individually or in the aggregate, would not reasonably be expected to result in a Material Adverse Effect.

**8.08 Maintenance of Properties, Etc.**

(a) Such Obligor shall, and shall cause each of its Subsidiaries to, maintain and preserve all of its properties necessary or useful in the proper conduct of its business in good working order and condition in accordance with the general practice of other Persons of similar character and size, ordinary wear and tear and damage from casualty or condemnation excepted.

(b) [Reserved].

**8.09 Licenses.** Such Obligor shall, and shall cause each of its Subsidiaries to, obtain and maintain all licenses, authorizations, consents, filings, exemptions, registrations and other Governmental Approvals necessary in connection with the execution, delivery and performance of the Loan Documents, the consummation of the Transactions or the operation and conduct of its business and ownership of its properties, except to the extent that failure to do so would not reasonably be expected to have a Material Adverse Effect.

**8.10 Action under Environmental Laws.** Such Obligor shall, and shall cause each of its Subsidiaries to, upon becoming aware of the presence of any Hazardous Materials or the existence of any environmental liability under applicable Environmental Laws with respect to their respective businesses, operations or properties, take all actions, at their cost and expense, as shall be necessary or advisable to investigate and clean up the condition of their respective businesses, operations or properties, including all required removal, containment and remedial actions, and restore their respective businesses, operations or properties to a condition in compliance with applicable Environmental Laws, except to the extent failure to do so would not reasonably be expected to, individually or in the aggregate, have a Material Adverse Effect.

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**8.11 Use of Proceeds.** The proceeds of the Loans will be used only as provided in **Section 2.04**. No part of the proceeds of the Loans will be used, whether directly or indirectly, for any purpose that entails a violation of any of the Regulations of the Board of Governors of the Federal Reserve System, including Regulations T, U and X.

**8.12 Certain Obligations Respecting Subsidiaries; Further Assurances.**

(a) **Subsidiary Guarantors.** Such Obligor will take such action, and will cause each of its Subsidiaries to take such action, from time to time as shall be necessary to ensure that all Subsidiaries (other than any Excluded Foreign Subsidiary not required to be a Subsidiary Guarantor or Borrower under **Section 8.12(b)(i)**), are either, at the discretion of the Administrative Agent, “Subsidiary Guarantors” or Borrowers hereunder; provided that if adding any such Subsidiary as a Borrower would provide a material tax benefit to Borrowers (as reasonably determined by the Parent or Lead Borrower) and would not be materially less advantageous to the rights or remedies of the Administrative Agent and the Lenders (as compared to such Subsidiary being a Subsidiary Guarantor) (as reasonably determined by the Administrative Agent), then such Subsidiary shall become a Borrower hereunder. Without limiting the generality of the foregoing, in the event that Parent or any of its Subsidiaries shall form or acquire any new Subsidiary (other than any new Excluded Foreign Subsidiary not required to be a Subsidiary Guarantor or a Borrower under **Section 8.12(b)(i)**), such Obligor and its Subsidiaries will within thirty (30) days of such formation or acquisition:

(i) cause such new Subsidiary to become a “Subsidiary Guarantor” or “Borrower” hereunder (as applicable), and a “Grantor” under the Security Agreement, pursuant to an Assumption Agreement;

(ii) take such action or cause such Subsidiary to take such action (including delivering such shares of stock or share capital, as applicable, together with undated transfer powers executed in blank or the equivalent thereof in any other jurisdiction) as shall be necessary to create and perfect (to the extent required by the applicable Security Document) valid and enforceable Liens with the priority required by the applicable Security Document (subject to Permitted Priority Liens) on substantially all of the property of such new Subsidiary as collateral security for the obligations of such new Subsidiary hereunder;

(iii) to the extent that the parent of such Subsidiary is not a party to the Security Agreement or has not otherwise pledged Equity Interests in its Subsidiaries in accordance with the terms of the Security Agreement and this Agreement, cause the parent of such Subsidiary to execute and deliver a pledge agreement in favor of the Secured Parties in respect of all outstanding issued shares of such Subsidiary; and

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(iv) deliver such proof of corporate action, incumbency of officers, opinions of counsel and other documents as is consistent with those delivered by each Obligor pursuant to **Section 6.01** or as Administrative Agent or the Majority Lenders shall have requested.

(b) **Excluded Foreign Subsidiaries.**

(i) In the event that, at any time, Excluded Foreign Subsidiaries have, in the aggregate, (A) total revenues constituting 5% or more of the total revenues of Parent and its Subsidiaries on a consolidated basis, or (B) total assets constituting 5% or more of the total assets of Parent and its Subsidiaries on a consolidated basis, promptly (and, in any event, within 30 days after such time) Obligors shall cause one or more of such Excluded Foreign Subsidiaries to become Subsidiary Guarantors or Borrowers in the manner set forth in **Section 8.12(a)**, such that, after such Subsidiaries become Subsidiary Guarantors or Borrowers, the Excluded Foreign Subsidiaries in the aggregate shall cease to have revenues or assets, as applicable, that meet the thresholds set forth in **clauses (A) and (B)** above; *provided* that no Excluded Foreign Subsidiary shall be required to become a Subsidiary Guarantor or Borrower if doing so would result in material adverse tax consequences for Parent and its Subsidiaries, taken as a whole.

(ii) With respect to each First-Tier Foreign Subsidiary that is not a Subsidiary Guarantor or Borrower, such Obligor shall grant a security interest and Lien in 65% of each class of voting Equity Interest and 100% of all other Equity Interests in such First-Tier Foreign Subsidiaries in favor of the Secured Parties as Collateral for the Obligations. Without limiting the generality of the foregoing, in the event that any Obligor shall form or acquire any new Subsidiary that is a First-Tier Foreign Subsidiary, such Obligor will promptly and in any event within thirty (30) days of the formation or acquisition of such Subsidiary (or such longer time as consented to by Administrative Agent in writing) grant a security interest and Lien in 65% of each class of voting Equity Interests and 100% of all other Equity Interests of such Subsidiary in favor of the Secured Parties as Collateral for the Obligations (*provided* that in the case of a First-Tier Foreign Subsidiary that is a Subsidiary Guarantor or Borrower, such Obligor shall grant a security interest and Lien in 100% of the Equity Interests of such Subsidiary in favor of the Secured Parties as Collateral for the Obligations), including entering into any necessary local law security documents and delivery of certificated securities issued by such First-Tier Foreign Subsidiary as required by this Agreement or the Security Agreement.

(c) **Further Assurances.** Such Obligor will, and will cause each of its Subsidiaries to, take such action from time to time as shall reasonably be requested by Administrative Agent or the Majority Lenders to effectuate the purposes and objectives of this Agreement.

Without limiting the generality of the foregoing, each Obligor will, and will cause each Person that is required to be a Subsidiary Guarantor or Borrower to, take such action from time to time (including executing and delivering such assignments, security agreements, control

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agreements, applications and other instruments prepared by the Administrative Agent or its counsel) as shall be reasonably requested by Administrative Agent or the Majority Lenders to create, in favor of the Secured Parties, perfected security interests and Liens in substantially all of the property of such Obligor as collateral security for the Obligations; *provided* that any such security interest or Lien shall be subject to the relevant requirements of, and limitations set forth in, the Security Documents.

Notwithstanding any provision under this Agreement or other Loan Documents to the contrary, (i) the Obligors shall not be required to take any actions in any jurisdiction outside the United States to grant or perfect a security interest in any asset to the extent the Administrative Agent determines that the costs or burdens thereof are disproportionate to the practical benefit obtained by the Secured Parties by reference to the costs or burdens of creating or perfecting the lien versus the value of the assets being secured, (ii) no mortgage shall be required with respect to any real property having a fair market value of less than \$1,000,000; (iii) unless an Event of Default has occurred and is continuing under **Sections 11.01(a), (b), (d)** (solely in respect of **Sections 9 and 10, (h), (i), (j), (m), (n), or (p)**), the Swedish Borrower shall not be required to take any actions in Sweden except as required pursuant to the Swedish Security Documents; (iv) Borrowers shall not be responsible for the reimbursement of legal and filing costs, duties, fees, expenses, stamp taxes, any other Taxes, and other amounts incurred or payable in respect of actions required to perfect the Liens on Intellectual Property in jurisdictions outside of the United States in excess of \$15,000 in respect for each foreign jurisdiction, or \$50,000 in the aggregate for all foreign jurisdictions; provided that the foregoing limitations shall not apply in respect of any such actions required as a result of the Permitted Restructuring; and (v) other than in respect of executing and delivering assignments, security agreements, control agreements, applications and other instruments prepared by the Administrative Agent or its counsel relating to Intellectual Property, no Subsidiary Guarantor or Borrower shall be obligated to take, or cause to be taken, any further steps to perfect any security interest or Lien granted in favor of the Secured Parties in the Intellectual Property (other than Material Intellectual Property) owned by the Obligors as of the Closing Date.

**8.13 Termination of Non-Permitted Liens.** In the event that Parent or any of its Subsidiaries shall become aware or be notified by Administrative Agent or any Lender of the existence of any outstanding Lien against any Property of Parent or any of its Subsidiaries, which Lien is not a Permitted Lien, the applicable Obligor shall use its best efforts to promptly terminate or cause the termination of such Lien.

**8.14 Intellectual Property.** In the event that the Obligors acquire Obligor Intellectual Property during the term of this Agreement, then the provisions of this Agreement shall automatically apply thereto and any such Obligor Intellectual Property shall automatically constitute part of the Collateral under the Security Documents, without further action by any party, in each case from and after the date of such acquisition (except that any representations or

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warranties of any Obligor shall apply to any such Obligor Intellectual Property only from and after the date, if any, subsequent to such acquisition that such representations and warranties are brought down or made anew as provided herein).

**8.15 [Reserved].**

**8.16 Post-Closing Items.**

(a) Lead Borrower shall cause to be delivered duly executed control agreements in favor of Administrative Agent for the benefit of the Secured Parties for all Deposit Accounts, Securities Accounts, and Commodity Accounts owned by the Obligors in the United States on or promptly after the Closing Date (or such later date as the Administrative Agent may agree in writing).

#### **SECTION 9 NEGATIVE COVENANTS**

Each Obligor covenants and agrees with Administrative Agent and the Lenders that, until the Commitments have expired or been terminated and all Obligations have been paid in full indefeasibly in cash:

**9.01 Indebtedness.** Such Obligor will not, and will not permit any of its Subsidiaries to, create, incur, assume or permit to exist any Indebtedness, whether directly or indirectly, except:

- (a) the Obligations;
- (b) Indebtedness existing on the Closing Date and set forth in **Part II of Schedule 7.13(a)** and Permitted Refinancings thereof; *provided* that, in each case, such Indebtedness is subordinated to the Obligations on terms satisfactory to the Majority Lenders;
- (c) Permitted Priority Debt;
- (d) accounts payable to trade creditors for goods and services and current operating liabilities (not the result of the borrowing of money) incurred in the ordinary course of Parent's or such Subsidiary's business in accordance with customary terms and paid within the specified time, unless contested in good faith by appropriate proceedings and reserved for in accordance with GAAP;
- (e) Indebtedness consisting of guarantees resulting from endorsement of negotiable instruments for collection by any Obligor in the ordinary course of business;

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(f) Indebtedness of any Obligor to any other Obligor; provided that such Indebtedness is subordinated to the Obligations on terms reasonably acceptable to the Administrative Agent and the Swedish Borrower shall not incur any Indebtedness to another Obligor except pursuant to a Permitted Restructuring;

(g) Indebtedness owed to Bank of America, N.A., any of its Affiliates or any other financial institution under a corporate credit card program between Borrowers and such lender not to exceed \$250,000 at any time;

(h) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by any Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed \$125,000 at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made);

(i) Permitted Cure Debt;

(j) Indebtedness approved in advance in writing by the Majority Lenders;

(k) Indebtedness consisting of guaranties of performance by the Parent of the contractual obligations (other than any Indebtedness for borrowed money and any Indebtedness of a type described in clause (b) of the definition of Indebtedness) of any other Obligor in the ordinary course of business;

(l) non-cash loans and other credit extensions made by any Obligor to the Swedish Borrower in respect of intercompany liabilities incurred by the Swedish Borrower in its ordinary course of business as permitted under **Section 9.18**.

**9.02 Liens.** Such Obligor will not, and will not permit any of its Subsidiaries to, create, incur, assume or permit to exist any Lien on any property or asset now owned or hereafter acquired by it, or assign or sell any income or revenues (including accounts receivable) or rights in respect of any thereof, except:

(a) Liens securing the Obligations;

(b) any Lien on any property or asset of Parent or any of its Subsidiaries existing on the Closing Date and set forth in **Part II of Schedule 7.13(b)**; *provided* that (i) no such Lien shall extend to any other property or asset of Parent or any of its Subsidiaries and (ii) any such

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Lien shall secure only those obligations which it secures on the Closing Date and extensions, renewals and replacements thereof that do not increase the outstanding principal amount thereof;

- (c) Liens described in the definition of "Permitted Priority Debt";
- (d) Liens securing Indebtedness permitted under **Section 9.01(h)**; *provided* that such Liens are restricted solely to the fixed or capital assets, the acquisition, repair, improvement or construction of which is being financing under **Section 9.01(h)**;
- (e) Liens imposed by law which were incurred in the ordinary course of business securing liabilities in the aggregate amount not to exceed \$25,000, including (but not limited to) carriers', warehousemen's and mechanics' liens and other similar liens arising in the ordinary course of business and which (x) do not in the aggregate materially detract from the value of the Property subject thereto or materially impair the use thereof in the operations of the business of such Person or (y) are being contested in good faith by appropriate proceedings, which proceedings have the effect of preventing the forfeiture or sale of the Property subject to such liens and for which adequate reserves have been made if required in accordance with GAAP;
- (f) pledges or deposits made in the ordinary course of business in connection with workers' compensation, unemployment insurance or other similar social security legislation;
- (g) Liens securing Taxes, assessments and other governmental charges, the payment of which is not yet due or is being contested in good faith by appropriate proceedings promptly initiated and diligently conducted and for which such reserve or other appropriate provisions, if any, as shall be required by GAAP shall have been made;
- (h) servitudes, easements, rights of way, restrictions and other similar encumbrances on real Property imposed by applicable Laws and encumbrances consisting of zoning or building restrictions, easements, licenses, restrictions on the use of property or minor imperfections in title thereto which, in the aggregate, are not material, and which do not in any case materially detract from the value of the property subject thereto or interfere with the ordinary conduct of the business of any of the Obligors;
- (i) with respect to any real Property, (A) such defects or encroachments as might be revealed by an up-to-date survey of such real Property; (B) the reservations, limitations, provisos and conditions expressed in the original grant, deed or patent of such property by the original owner of such real Property pursuant to applicable Laws; and (C) rights of expropriation, access or user or any similar right conferred or reserved by or in applicable Laws, which, in the aggregate for (A), (B) and (C), are not material, and which do not in any case materially detract from the value of the property subject thereto or interfere with the ordinary conduct of the business of any of the Obligors;

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- (j) Bankers liens, rights of setoff and similar Liens incurred on deposits made in the ordinary course of business
- (k) Liens securing Indebtedness permitted under Section 9.01(g); provided that such Liens only attach to cash collateral located in an account of a Borrower held at the lender of such Indebtedness in an amount not to exceed \$250,000 at any one time; and
- (l) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default;

*provided* that no Lien otherwise permitted under any of the foregoing **Sections 9.02(b)** through **(l)** shall apply to any Material Intellectual Property.

**9.03 Fundamental Changes and Acquisitions.** Such Obligor will not, and will not permit any of its Subsidiaries to, (i) enter into any transaction of merger, amalgamation or consolidation (ii) liquidate, wind up or dissolve itself (or suffer any liquidation or dissolution), or (iii) make any Acquisition or otherwise acquire any business or substantially all the property from, or capital stock or share capital, as applicable, of, or be a party to any acquisition of, any Person, except:

- (a) Investments permitted under **Section 9.05(e)**;
- (b) the merger, amalgamation or consolidation of any Obligor with or into any other Obligor; *provided* that, in the case of a merger, amalgamation or consolidation with or into a Borrower, such Borrower shall be the surviving entity and in the case of a merger, amalgamation or consolidation with or into the Lead Borrower, the Lead Borrower shall be the surviving entity;
- (c) the sale, lease, transfer or other disposition by any Obligor (other than the Lead Borrower) of any or all of its property (upon voluntary liquidation or otherwise) to any other Obligor (other than the Swedish Borrower);
- (d) the sale, transfer or other disposition of the capital stock or share capital, as applicable, of any Obligor to any other Obligor (other than the Swedish Borrower);
- (e) (i) the Macrilen Acquisition, and (ii) Permitted Acquisitions for consideration in an amount not exceeding \$10,000,000 in the aggregate; and
- (f) transactions among Obligors in connection with, and pursuant to, the Permitted Restructuring.



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**9.04 Lines of Business.** Such Obligor will not, and will not permit any of its Subsidiaries to, engage to any material extent in any business other than the business engaged in on the Closing Date by Parent or any Subsidiary or a business reasonably related thereto.

**9.05 Investments.** Such Obligor will not, and will not permit any of its Subsidiaries to, make, directly or indirectly, or permit to remain outstanding any Investments except:

- (a) Investments outstanding on the Closing Date and identified in **Schedule 9.05**;
- (b) operating deposit accounts with banks;
- (c) extensions of credit in the nature of accounts receivable or notes receivable arising from the sales of goods or services in the ordinary course of business;
- (d) Permitted Cash Equivalent Investments;
- (e) Investments by any Obligor in any Subsidiary Guarantor, other than the Swedish Borrower (for greater certainty, Parent shall not be permitted to have any direct or indirect Subsidiaries that are not wholly-owned Subsidiaries);
- (f) Hedging Agreements entered into in the ordinary course of Parent's financial planning solely to hedge currency risks (and not for speculative purposes) and in an aggregate notional amount for all such Hedging Agreements not in excess of \$100,000 (or the Equivalent Amount in other currencies);
- (g) Investments consisting of security deposits with utilities and other like Persons made in the ordinary course of business;
- (h) Investments consisting of (i) employee loans, travel advances and guarantees in accordance with a Borrower's usual and customary practices with respect thereto (if permitted by applicable law) and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Parent pursuant to employee stock plans or agreements approved by Parent's Board of Directors, which in the aggregate for clause (i) and (ii) shall not exceed \$100,000 outstanding at any time (or the Equivalent Amount in other currencies);
- (i) Investments received in connection with any Insolvency Proceedings in respect of any customers, suppliers or clients and in settlement of delinquent obligations of, and other disputes with, customers, suppliers or clients;
- (j) non-cash Investments in joint ventures or strategic alliances in the ordinary course of such Obligor's business consisting of the non-exclusive licensing of technology, the development of technology or the providing of technical support;

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- (k) Investments permitted under **Section 9.03**;
- (l) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of any Obligor;
- (m) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business;
- (n) Investments consisting of guaranties of performance by the Parent of the contractual obligations (other than any Indebtedness for borrowed money and any Indebtedness of a type described in clause (b) of the definition of Indebtedness) of any other Obligor in the ordinary course of business;
- (o) Investments in Obligors in connection with, and pursuant to, a Permitted Restructuring; and
- (p) Investments by any Obligor in the Swedish Borrower constituting non-cash loans and other credit extensions by such Obligor to the Swedish Borrower in respect of intercompany liabilities incurred by the Swedish Borrower in its ordinary course of business as permitted under **Section 9.18**.

**9.06 Restricted Payments.** Such Obligor will not, and will not permit any of its Subsidiaries to, declare or make, or agree to pay or make, directly or indirectly, any Restricted Payment, except:

- (a) Parent may declare and pay dividends with respect to its capital stock payable solely in additional ordinary shares;
- (b) any Obligor may pay dividends to any other Obligor (other than the Swedish Borrower); and
- (c) Restricted Payments to Obligors in connection with, and pursuant to, the Permitted Restructuring.

**9.07 Payments of Indebtedness.** Such Obligor will not, and will not permit any of its Subsidiaries to, make any payments in respect of any Indebtedness other than (i) payments of the Obligations, (ii) scheduled payments of other Indebtedness permitted under the terms of any subordination to the Obligations, (iii) repayment of intercompany Indebtedness permitted in reliance upon **Section 9.01(f)**, (iv) repayment of the Permitted Priority Debt, and (v) in connection with, or as a result of, the Permitted Restructuring.

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**9.08 Change in Fiscal Year.** Such Obligor will not, and will not permit any of its Subsidiaries to, change the last day of its fiscal year from that in effect on the Closing Date, except to change the fiscal year of a Subsidiary acquired in connection with an Acquisition to conform its fiscal year to that of Parent.

**9.09 Sales of Assets, Etc.** Such Obligor will not, and will not permit any of its Subsidiaries to, sell, lease, exclusively license (in terms of geography or field of use), transfer, or otherwise dispose of any of its Property (including accounts receivable, Intellectual Property and capital stock or share capital, as applicable, of Subsidiaries) to any Person in one transaction or series of transactions (any thereof, an “*Asset Sale*”), except:

- (a) transfers of cash in the ordinary course of its business for equivalent value;
- (b) sales of inventory in the ordinary course of its business on ordinary business terms;
- (c) development and other collaborative arrangements where such arrangements provide for the licenses or disclosure of Patents, Trademarks, Copyrights or other Intellectual Property rights in the ordinary course of business and consistent with general market practices where such license requires periodic payments based on per unit sales of a product over a period of time; *provided* that each such license does not effect a legal transfer of title to such Intellectual Property rights and that each such license must be a true license as opposed to a license that is a sales transaction in substance;
- (d) transfers of Property by any Subsidiary Guarantor to any other Obligor (other than the Swedish Borrower);
- (e) dispositions of any equipment that is obsolete or worn out or no longer used or useful in the Business;
- (f) any transaction permitted under **Section 9.03** or **9.05**;
- (g) any other Asset Sale the Asset Sale Net Proceeds of which are applied as required under **Section 3.03(b)(i)**;
- (h) transfers of Property to any Obligor in connection with, and pursuant to, the Permitted Restructuring; and
- (i) the abandonment, cancellation and discontinuation of Intellectual Property of the Obligors, other than Material Intellectual Property, in the Obligors’ reasonable business judgment.

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**9.10 Transactions with Affiliates.** Such Obligor will not, and will not permit any of its Subsidiaries to, sell, lease, license or otherwise transfer any assets to, or purchase, lease, license or otherwise acquire any assets from, or otherwise engage in any other transactions with, any of its Affiliates, except:

- (a) transactions between or among Obligors;
- (b) any transaction permitted under **Section 9.01, 9.05, 9.06 or 9.09**;
- (c) customary compensation and indemnification of, and other employment arrangements with, directors, officers and employees of Parent or any Subsidiary in the ordinary course of business,
- (d) Parent may issue Equity Interests to Affiliates in exchange for cash; *provided* that the terms thereof are no less favorable (including the amount of cash received by Parent) to Parent than those that would be obtained in a comparable arm's-length transaction with a Person not an Affiliate of Parent;
- (e) the transactions set forth on **Schedule 9.10**; and
- (f) the Permitted Restructuring.

**9.11 Restrictive Agreements.** Such Obligor will not, and will not permit any of its Subsidiaries to, directly or indirectly, enter into, incur or permit to exist any Restrictive Agreement other than (a) restrictions and conditions imposed by law or by this Agreement and (b) Restrictive Agreements listed on **Schedule 7.15**.

**9.12 Amendments to Material Agreements; Organizational Documents.** Such Obligor will not, and will not permit any of its Subsidiaries to, enter into any amendment to or modification of any Material Agreement or terminate any Material Agreement (unless replaced with another agreement that, viewed as a whole, is on the same or better terms for Parent or such Subsidiary or except to the extent such amendment, modification or termination could not reasonably be expected to result in a Material Adverse Effect). Such Obligor will not, and will not permit any of its Subsidiaries to, enter into any amendment to or modification of its organizational documents in a manner that could be materially adverse to the rights or remedies of Administrative Agent and the Lenders (other than amendments to effect the dissolution of the Swedish Borrower and/or the Cayman Borrower in connection with the Permitted Restructuring).

**9.13 Operating Leases.** Parent will not, and will not permit any of its Subsidiaries to, make any expenditures in respect of operating leases, except for:

- (a) real estate operating leases;

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(b) operating leases between Parent and any of its wholly-owned Subsidiaries or between any of Parent's wholly-owned Subsidiaries; and

(c) operating leases that would not cause Parent and its Subsidiaries, on a consolidated basis, to make payments exceeding \$250,000 (or the Equivalent Amount in other currencies) in any fiscal year.

**9.14 Sales and Leasebacks.** Except as disclosed on **Schedule 9.14**, such Obligor will not, and will not permit any of its Subsidiaries to, become liable, directly or indirectly, with respect to any lease, whether an operating lease or a Capital Lease Obligation, of any property (whether real, personal, or mixed), whether now owned or hereafter acquired, (i) which Parent or such Subsidiary has sold or transferred or is to sell or transfer to any other Person and (ii) which Parent or such Subsidiary intends to use for substantially the same purposes as property which has been or is to be sold or transferred.

**9.15 Hazardous Material.** Such Obligor will not, and will not permit any of its Subsidiaries to, use, generate, manufacture, install, treat, release, store or dispose of any Hazardous Material, except in compliance with all applicable Environmental Laws or where the failure to comply could not reasonably be expected to result in a Material Adverse Change.**9.16 Accounting Changes.** Such Obligor will not, and will not permit any of its Subsidiaries to, make any significant change in accounting treatment or reporting practices, except as required or permitted by GAAP.

**9.17 Compliance with ERISA.** No Obligor or any ERISA Affiliate thereof shall cause or suffer to exist (a) any event that could result in the imposition of a Lien with respect to any Title IV Plan or Multiemployer Plan, (b) any other ERISA Event that would, in the aggregate, have a Material Adverse Effect, or (c) any event that could result in the imposition of a Lien with respect to any Benefit Plan.

**9.18 Swedish Borrower.** The Swedish Borrower shall not incur any liabilities (other than the Obligations under the Loan Documents, intercompany liabilities to other Obligors, obligations incurred in respect of the development of Recorlev and the maintenance of its Intellectual Property and such immaterial liabilities as are incidental to its legal status) or hold any assets (other than Investments in its Subsidiaries, subordinated intercompany receivables, Intellectual Property and regulatory approvals; *provided* that with respect to any Investments acquired after the Closing Date, such Investments are pledged subject to documentation satisfactory to the Administrative Agent in its reasonable discretion); except for assets and liabilities of another Obligor are distributed or otherwise transferred to it pursuant to, and in accordance with, the Permitted Restructuring.

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**SECTION 10  
FINANCIAL COVENANTS**

**10.01 Minimum Liquidity.** The Obligors shall maintain at all times Liquidity in an amount which shall exceed the greater of (i) \$3,000,000 and (ii) to the extent Borrowers have incurred Permitted Priority Debt, the minimum cash balance, if any, required by Borrowers' Permitted Priority Debt creditors.

**10.02 Minimum Revenue.** The Obligors shall have annual Revenue from sales of the Products (for each respective calendar year, the "*Minimum Required Revenue*"):

- (a) during the twelve month period beginning on January 1, 2017, of at least \$[\*\*\*\*];
- (b) during the twelve month period beginning on January 1, 2018, of at least \$[\*\*\*\*];
- (c) during the twelve month period beginning on January 1, 2019, of at least \$[\*\*\*\*];
- (d) during the twelve month period beginning on January 1, 2020, of at least \$[\*\*\*\*];
- (e) during the twelve month period beginning on January 1, 2021, of at least \$[\*\*\*\*]; and
- (f) during the twelve month period beginning on January 1, 2022, of at least \$[\*\*\*\*].

**10.03 Cure Right.**

(a) Notwithstanding anything to the contrary contained in **Section 11**, in the event that Borrowers fail to comply with the covenants contained in **Section 10.02(a)** through **(f)** (such covenants for such applicable periods being the "*Specified Financial Covenants*"), Parent shall have the right within 90 (ninety) days of the end of the respective calendar year:

- (i) to issue additional shares of Equity Interests in exchange for cash (the "*Equity Cure Right*"), or
- (ii) to borrow Permitted Cure Debt (the "*Subordinated Debt Cure Right*" and, collectively with the Equity Cure Right, the "*Cure Right*"),

in an amount equal to (x) two (2) multiplied by (y) the Minimum Required Revenue less annual Revenue from sales of the Product (the "*Cure Amount*"). The cash therefrom immediately shall be contributed as equity or subordinated debt (only as permitted pursuant to **Section 9.01**), as applicable, to Parent, and upon the receipt by Parent of the Cure Amount pursuant to the exercise of such Cure Right, such Cure Amount shall be deemed to constitute Revenue of Parent from

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sales of the Product for purposes of the Specified Financial Covenants and the Specified Financial Covenants shall be recalculated for all purposes under the Loan Documents. If, after giving effect to the foregoing recalculation, Parent shall then be in compliance with the requirements of the Specified Financial Covenants, Parent shall be deemed to have satisfied the requirements of the Specified Financial Covenants as of the relevant date of determination with the same effect as though there had been no failure to comply therewith at such date, and the applicable breach of the Specified Financial Covenants that had occurred, the related Default and Event of Default, shall be deemed cured without any further action of Parent or Lenders for all purposes under the Loan Documents.

(b) Notwithstanding anything herein to the contrary the Cure Amount received by Parent from investors investing in or lending to Parent pursuant to **Section 10.03(a)** shall be used to immediately prepay the Loans, including any fees payable pursuant to the Amended Fee Letter and the applicable Prepayment Premium, credited in the order set forth in **Sections 3.03(b)(i)(A)-(E)**.

## **SECTION 11 EVENTS OF DEFAULT**

**11.01 Events of Default.** Each of the following events shall constitute an “*Event of Default*”:

(a) Borrowers shall fail to pay any principal of any Loan when and as the same shall become due and payable, whether at the due date thereof or at a date fixed for prepayment thereof or otherwise;

(b) (i) any Obligor shall fail to pay any interest on any Loan or any fee due under the Loan Documents when and as the same shall become due and payable, and such failure shall continue unremedied for a period of three (3) Business Days or (ii) any Obligor shall fail to pay any other Obligation (other than an amount referred to in **Section 11.01(a)** and **11.01(b)(i)**) when and as the same shall become due and payable, and such failure shall continue unremedied for a period of five (5) Business Days;

(c) any representation or warranty made or deemed made by or on behalf of Parent or any of its Subsidiaries in or in connection with this Agreement or any other Loan Document or any amendment or modification hereof or thereof, or in any report, certificate, financial statement or other document furnished pursuant to or in connection with this Agreement or any other Loan Document or any amendment or modification hereof or thereof, shall: (i) prove to have been incorrect when made or deemed made to the extent that such representation or warranty contains any materiality or Material Adverse Effect qualifier; or (ii) prove to have been incorrect in any material respect when made or deemed made to the extent that such

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representation or warranty does not otherwise contain any materiality or Material Adverse Effect qualifier;

(d) any Obligor shall fail to observe or perform any covenant, condition or agreement contained in **Section 8.02, 8.03** (with respect to an Obligor's existence), **8.11, 8.12, 8.14, 8.16, 9 or 10**;

(e) any Obligor shall fail to observe or perform any covenant, condition or agreement contained in this Agreement (other than those specified in **Section 11.01(a), (b) or (d)**) or any other Loan Document, and, in the case of any failure that is capable of cure, if such failure shall continue unremedied for a period of 25 or more days;

(f) Parent or any of its Subsidiaries shall fail to make any payment (whether of principal or interest and regardless of amount) in respect of any Material Indebtedness, when and as the same shall become due and payable after giving effect to any applicable grace or cure period as originally provided by the terms of such Indebtedness;

(g) (i) any material breach of, or "event of default" or similar event by any Obligor under, any Material Agreement, (ii) any material breach of, or "event of default" or similar event under, the documentation governing any Material Indebtedness shall occur, or (iii) any event or condition occurs (A) that results in any Material Indebtedness becoming due prior to its scheduled maturity or (B) that enables or permits (with or without the giving of notice, the lapse of time or both) the holder or holders of such Material Indebtedness or any trustee or agent on its or their behalf to cause such Material Indebtedness to become due, or to require the prepayment, repurchase, redemption or defeasance thereof, prior to its scheduled maturity; *provided* that this **Section 11.01(g)** shall not apply to secured Indebtedness that becomes due as a result of the voluntary sale or transfer of the property or assets securing such Material Indebtedness.

(h) any Obligor:

(i) becomes insolvent, or generally does not or becomes unable to pay its debts or meet its liabilities as the same become due, or admits in writing its inability to pay its debts generally, or declares any general moratorium on its indebtedness, or proposes a compromise or arrangement or deed of company arrangement between it and any class of its creditors;

(ii) commits an act of bankruptcy or makes an assignment of its property for the general benefit of its creditors or makes a proposal (or files a notice of its intention to do so);

(iii) institutes any proceeding seeking to adjudicate it an insolvent, or seeking liquidation, dissolution, winding-up, examinership, reorganization, compromise, arrangement, adjustment, protection, moratorium, relief, stay of proceedings of creditors generally (or any



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class of creditors), or composition of it or its debts or any other relief, under any federal, provincial or foreign Law now or hereafter in effect relating to bankruptcy, winding-up, insolvency, examinership, reorganization, receivership, plans of arrangement or relief or protection of debtors or at common law or in equity, or files an answer admitting the material allegations of a petition filed against it in any such proceeding;

(iv) applies for the appointment of, or the taking of possession by, a receiver, interim receiver, receiver/manager, examiner, sequestrator, conservator, custodian, administrator, trustee, liquidator, voluntary administrator, receiver and manager or other similar official for it or any substantial part of its property; or

(v) takes any action, corporate or otherwise, to approve, effect, consent to or authorize any of the actions described in this **Section 11.01(h)** or **(i)**, or otherwise acts in furtherance thereof or fails to act in a timely and appropriate manner in defense thereof;

(i) any petition is filed, application made or other proceeding instituted against or in respect of Parent or any Subsidiary:

(i) seeking to adjudicate it an insolvent;

(ii) seeking a receiving order against it;

(iii) seeking liquidation, dissolution, winding-up, examinership, reorganization, compromise, arrangement, adjustment, protection, moratorium, relief, stay of proceedings of creditors generally (or any class of creditors), deed of company arrangement or composition of it or its debts or any other relief under any federal, provincial or foreign law now or hereafter in effect relating to bankruptcy, winding-up, insolvency, examinership, reorganization, receivership, plans of arrangement or relief or protection of debtors or at common law or in equity; or

(iv) seeking the entry of an order for relief or the appointment of, or the taking of possession by, a receiver, interim receiver, receiver/manager, sequestrator, conservator, custodian, administrator, trustee, liquidator, examiner, voluntary administrator, receiver and manager or other similar official for it or any substantial part of its property, and such petition, application or proceeding continues undismissed, or unstayed and in effect, for a period of sixty (60) days after the institution thereof;

*provided* that if an order, decree or judgment is granted or entered (whether or not entered or subject to appeal) against Parent or such Subsidiary thereunder in the interim, such grace period will cease to apply; *provided further* that if Parent or such Subsidiary files an answer admitting the material allegations of a petition filed against it in any such proceeding, such grace period will cease to apply;

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(j) any other event occurs which, under the laws of any applicable jurisdiction, has an effect equivalent to any of the events referred to in either of **Section 11.01(h)** or **(i)**;

(k) one or more judgments or settlements for the payment of money in an aggregate amount in excess of \$250,000 (or the Equivalent Amount in other currencies) shall be rendered against or entered into by any Obligor or any combination thereof and the same shall remain undischarged for a period of 45 consecutive days during which execution shall not be effectively stayed, or any action shall be legally taken by a judgment or settlement creditor to attach or levy upon any assets of any Obligor to enforce any such judgment or settlement;

(l) (i) an ERISA Event shall have occurred that, when taken together with all other ERISA Events that have occurred, could reasonably be expected to result in liability of Parent and its Subsidiaries in an aggregate amount exceeding (i) \$250,000 in any year or (ii) \$750,000 for all periods until repayment of all Obligations;

(m) a Change of Control shall have occurred;

(n) a Material Adverse Change shall have occurred;

(o) (i) any Lien created by any of the Security Documents shall at any time not constitute a valid and perfected Lien on the applicable Collateral (in accordance with the terms of the Security Documents) in favor of the Secured Parties, free and clear of all other Liens (other than Permitted Liens), other than to the extent such Liens are released in accordance with **Section 12.10**, **Section 12.11** or **Section 12.12** as result of, or in connection with, the Permitted Restructuring, (ii) except for expiration in accordance with its terms, any of the Security Documents or any Guarantee of any of the Obligations (including that contained in **Section 14**) shall for whatever reason cease to be in full force and effect, other than to the extent such Liens are released in accordance with **Section 12.10**, **Section 12.11** or **Section 12.12** as result of, or in connection with, the Permitted Restructuring, or (iii) any of the Security Documents, any Guarantee of any of the Obligations (including that contained in **Section 14**) or the joint and several obligations of the Borrowers as contemplated by **Section 13**, or the enforceability thereof, shall be repudiated or contested by any Obligor; and

(p) any injunction, whether temporary or permanent, shall be rendered against any Obligor that prevents the Obligors from selling or manufacturing the Product or its commercially available successors, or any of their other material and commercially available products in the United States for more than sixty (60) consecutive calendar days.

**11.02 Remedies.** (a) Upon the occurrence of any Event of Default, then, and in every such event (other than an Event of Default described in **Section 11.01(h)**, **(i)** or **(j)**), and at any time thereafter during the continuance of such event, the Majority Lenders may, by notice to Lead

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Borrower, take either or both of the following actions, at the same or different times: (i) terminate the Commitments, and thereupon the Commitments shall terminate immediately, and (ii) declare the Loans then outstanding to be due and payable in whole (or in part, in which case any principal not so declared to be due and payable may thereafter be declared to be due and payable), and thereupon the principal of the Loans so declared to be due and payable, together with accrued interest thereon and all fees and other Obligations (including fees specified in the Amended Fee Letter), shall become due and payable immediately (in the case of the Loans, at the Redemption Price therefor), without presentment, demand, protest or other notice of any kind, all of which are hereby waived by each Obligor.

(a) Upon the occurrence of any Event of Default described in **Section 11.01(h), (i) or (j)**, the Commitments shall automatically terminate and the principal of the Loans then outstanding, together with accrued interest thereon and all fees and other Obligations, shall automatically become due and payable immediately (in the case of the Loans, at the Redemption Price therefor), without presentment, demand, protest or other notice of any kind, all of which are hereby waived by each Obligor.

(b) **Prepayment Premium and Redemption Price.** (i) For the avoidance of doubt, the Prepayment Premium (as a component of the Redemption Price) and the fees specified in the Amended Fee Letter that are payable upon the repayment of the Loans shall be due and payable at any time the Loans become due and payable prior to the Stated Maturity Date for any reason, whether due to acceleration pursuant to the terms of this Agreement (in which case it shall be due immediately, upon the giving of notice to Lead Borrower in accordance with **Section 11.02(a)**), or automatically, in accordance with **Section 11.02(b)**), by operation of law or otherwise (including where bankruptcy filings or the exercise of any bankruptcy right or power, whether in any plan of reorganization or otherwise, results or would result in a payment, discharge, modification or other treatment of the Loans or Loan Documents that would otherwise evade, avoid, or otherwise disappoint the expectations of Lenders in receiving the full benefit of their bargained-for Prepayment Premium or Redemption Price as provided herein). The Obligors and Lenders acknowledge and agree that any Prepayment Premium and the fees specified in the Amended Fee Letter due and payable in accordance with this Agreement shall not constitute unmatured interest, whether under section 502(b)(3) of the Bankruptcy Code or otherwise, but instead is reasonably calculated to ensure that the Lenders receive the benefit of their bargain under the terms of this Agreement. In the event that any portion of the Loans becomes due and payable prior to the Stated Maturity Date, whether as a result of acceleration or any other required prepayment event, the "Redemption Date" for purposes of calculating the Prepayment Premium will be the date of such acceleration or the date of occurrence of the event that triggered such obligation to prepay.

(ii) Each Obligor acknowledges and agrees that the Lenders shall be entitled to recover the full amount of the Redemption Price and the fees specified in the Amended Fee

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Letter in each and every circumstance such amount is due pursuant to or in connection with this Agreement and the Amended Fee Letter, including in the case of any Obligor's bankruptcy filing, so that the Lenders shall receive the benefit of their bargain hereunder and otherwise receive full recovery as agreed under every possible circumstance, and each Borrower hereby waives any defense to payment, whether such defense may be based in public policy, ambiguity, or otherwise. Each Obligor further acknowledges and agrees, and waives any argument to the contrary, that payment of such amounts does not constitute a penalty or an otherwise unenforceable or invalid obligation. Any damages that the Lenders may suffer or incur resulting from or arising in connection with any breach hereof or thereof by any Borrower shall constitute secured obligations owing to the Lenders.

## **SECTION 12 ADMINISTRATIVE AGENT**

**12.01 Appointment and Duties.** (a) **Appointment of Administrative Agent.** Each Lender hereby irrevocably appoints CRG Servicing (together with any successor Administrative Agent pursuant to **Section 12.09**) as Administrative Agent hereunder and authorizes Administrative Agent to (i) execute and deliver the Loan Documents and accept delivery thereof on its behalf from any Obligor or any of its Subsidiaries, (ii) take such action on its behalf and to exercise all rights, powers and remedies and perform the duties as are expressly delegated to Administrative Agent under such Loan Documents, (iii) act as agent of such Lender for purposes of acquiring, holding, enforcing and perfecting all Liens granted by the Obligors on the Collateral to secure any of the Obligations and (iv) exercise such powers as are reasonably incidental thereto.

(a) **Duties as Collateral and Disbursing Agent.** Without limiting the generality of **Section 12.01(a)**, Administrative Agent shall have the sole and exclusive right and authority (to the exclusion of the Lenders), and is hereby authorized, to (i) act as the disbursing and collecting agent for the Lenders with respect to all payments and collections arising in connection with the Loan Documents (including in any proceeding described in **Section 11.01(h), (i) or (j)** or any other bankruptcy, insolvency or similar proceeding), and each Person making any payment in connection with any Loan Document to any Secured Party is hereby authorized to make such payment to Administrative Agent, (ii) file and prove claims and file other documents necessary or desirable to allow the claims of the Secured Parties with respect to any Obligation in any proceeding described in **Section 11.01(h), (i) or (j)** or any other bankruptcy, insolvency or similar proceeding (but not to vote, consent or otherwise act on behalf of such Secured Party), (iii) act as collateral agent for each Secured Party for purposes of acquiring, holding, enforcing and perfecting all Liens created by the Loan Documents and all other purposes stated therein, (iv) manage, supervise and otherwise deal with the Collateral, (v) take such other action as is necessary or desirable to maintain the perfection and priority of the Liens created or purported to be created by the Loan Documents, (vi) except as may be otherwise specified in any Loan Document, exercise all remedies given to Administrative Agent and the other Secured Parties

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with respect to the Collateral, whether under the Loan Documents, applicable Requirements of Law or otherwise, (vii) enter into subordination agreements with respect to Permitted Cure Debt, intercreditor agreements with respect to Permitted Priority Debt or any other subordination agreement or intercreditor agreement with respect to Indebtedness of an Obligor, (viii) enter into non-disturbance agreements and similar agreements and (ix) execute any amendment, consent or waiver under the Loan Documents on behalf of any Lender that has consented in writing to such amendment, consent or waiver; *provided, however*, that Administrative Agent hereby appoints, authorizes and directs each Lender to act as collateral sub-agent for Administrative Agent and the Secured Parties for purposes of the perfection of all Liens with respect to the Collateral, including any deposit account maintained by an Obligor with, and cash and Permitted Cash Equivalent Investments held by, such Lender, and may further authorize and direct any Lender to take further actions as collateral sub-agents for purposes of enforcing such Liens or otherwise to transfer the Collateral subject thereto to Administrative Agent, and each Lender hereby agrees to take such further actions to the extent, and only to the extent, so authorized and directed.

(b) **Limited Duties.** Under the Loan Documents, Administrative Agent (i) is acting solely on behalf of the Lenders (except to the limited extent provided in **Section 12.12**), with duties that are entirely administrative in nature, notwithstanding the use of the defined term “Administrative Agent”, the terms “agent”, “administrative agent” and “collateral agent” and similar terms in any Loan Document to refer to Administrative Agent, which terms are used for title purposes only, (ii) is not assuming any obligation under any Loan Document other than as expressly set forth therein or any role as agent, fiduciary or trustee of or for any Lender or any other Secured Party and (iii) shall have no implied functions, responsibilities, duties, obligations or other liabilities under any Loan Document, and each Lender hereby waives and agrees not to assert any claim against Administrative Agent based on the roles, duties and legal relationships expressly disclaimed in the foregoing **clauses (i)** through **(iii)**.

**12.02 Binding Effect.** Each Lender agrees that (i) any action taken by Administrative Agent or the Majority Lenders (or, if expressly required hereby, a greater proportion of the Lenders) in accordance with the provisions of the Loan Documents, (ii) any action taken by Administrative Agent in reliance upon the instructions of the Majority Lenders (or, where so required, such greater proportion) and (iii) the exercise by Administrative Agent or the Majority Lenders (or, where so required, such greater proportion) of the powers set forth herein or therein, together with such other powers as are reasonably incidental thereto, shall be authorized and binding upon all of the Secured Parties.

**12.03 Use of Discretion.** (a) **No Action without Instructions.** Administrative Agent shall not be required to exercise any discretion or take, or to omit to take, any action, including with respect to enforcement or collection, except any action it is required to take or omit to take (i) under any Loan Document or (ii) pursuant to instructions from the Majority Lenders (or, where expressly required by the terms of this Agreement, a greater proportion of the Lenders).

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(b) **Right Not to Follow Certain Instructions.** Notwithstanding **Section 12.03(a)**, Administrative Agent shall not be required to take, or to omit to take, any action (i) unless, upon demand, Administrative Agent receives an indemnification satisfactory to it from the Lenders (or, to the extent applicable and acceptable to Administrative Agent, any other Secured Party) against all liabilities that, by reason of such action or omission, may be imposed on, incurred by or asserted against Administrative Agent or any Related Person thereof or (ii) that is, in the opinion of Administrative Agent or its counsel, contrary to any Loan Document or applicable Requirement of Law.

**12.04 Delegation of Rights and Duties.** Administrative Agent may, upon any term or condition it specifies, delegate or exercise any of its rights, powers and remedies under, and delegate or perform any of its duties or any other action with respect to, any Loan Document by or through or to any trustee, co-agent, sub-agent, employee, attorney-in-fact and any other Person (including any other Secured Party). Any such Person shall benefit from this **Section 12** to the extent provided by Administrative Agent. Administrative Agent shall not be responsible for the negligence or misconduct of any sub-agent except to the extent that a court of competent jurisdiction determines in a final and nonappealable judgment that Administrative Agent acted with gross negligence or willful misconduct in the selection of such sub-agent.

**12.05 Reliance and Liability.**

(a) Administrative Agent may, without incurring any liability hereunder, (i) consult with any of its Related Persons and, whether or not selected by it, any other advisors, accountants and other experts (including advisors to, and accountants and experts engaged by, any Obligor) and (ii) rely and act upon any document and information and any telephone message or conversation, in each case believed by it to be genuine and transmitted, signed or otherwise authenticated by the appropriate parties. (b) None of Administrative Agent and its Related Persons shall be liable for any action taken or omitted to be taken by any of them under or in connection with any Loan Document, and each Lender and each Obligor hereby waives and shall not assert any right, claim or cause of action based thereon, except to the extent of liabilities resulting primarily from the gross negligence or willful misconduct of Administrative Agent or, as the case may be, such Related Person (each as determined in a final, non-appealable judgment by a court of competent jurisdiction) in connection with the duties expressly set forth herein. Without limiting the foregoing, Administrative Agent:

(i) shall not be responsible or otherwise incur liability for any action or omission taken in reliance upon the instructions of the Majority Lenders or for the actions or omissions of any of its Related Persons selected with reasonable care (other than employees, officers and directors of Administrative Agent, when acting on behalf of Administrative Agent);

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(ii) shall not be responsible to any Secured Party for the due execution, legality, validity, enforceability, effectiveness, genuineness, sufficiency or value of, or the attachment, perfection or priority of any Lien created or purported to be created under or in connection with, any Loan Document;

(iii) makes no warranty or representation, and shall not be responsible, to any Secured Party for any statement, document, information, representation or warranty made or furnished by or on behalf of any Related Person, in or in connection with any Loan Document or any transaction contemplated therein, whether or not transmitted by Administrative Agent, including as to completeness, accuracy, scope or adequacy thereof, or for the scope, nature or results of any due diligence performed by Administrative Agent in connection with the Loan Documents; and

(iv) shall not have any duty to ascertain or to inquire as to the performance or observance of any provision of any Loan Document, whether any condition set forth in any Loan Document is satisfied or waived, as to the financial condition of any Obligor or as to the existence or continuation or possible occurrence or continuation of any Default or Event of Default and shall not be deemed to have notice or knowledge of such occurrence or continuation unless it has received a notice from any Borrower or any Lender describing such Default or Event of Default clearly labeled "notice of default" (in which case Administrative Agent shall promptly give notice of such receipt to all Lenders);

and, for each of the items set forth in **clauses (i) through (iv)** above, each Lender and each Obligor hereby waives and agrees not to assert any right, claim or cause of action it might have against Administrative Agent based thereon.

**12.06 Administrative Agent Individually.** Administrative Agent and its Affiliates may make loans and other extensions of credit to, acquire Equity Interests of, engage in any kind of business with, any Obligor or Affiliate thereof as though it were not acting Administrative Agent and may receive separate fees and other payments therefor. To the extent Administrative Agent or any of its Affiliates makes any Loan or otherwise becomes a Lender hereunder, it shall have and may exercise the same rights and powers hereunder and shall be subject to the same obligations and liabilities as any other Lender and the terms "Lender", "Majority Lender", and any similar terms shall, except where otherwise expressly provided in any Loan Document, include Administrative Agent or such Affiliate, as the case may be, in its individual capacity as Lender or as one of the Majority Lenders, respectively.

**12.07 Lender Credit Decision.** Each Lender acknowledges that it shall, independently and without reliance upon Administrative Agent, any Lender or any of their Related Persons or upon any document solely or in part because such document was transmitted by Administrative Agent or any of its Related Persons, conduct its own independent investigation of the financial

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condition and affairs of each Obligor and make and continue to make its own credit decisions in connection with entering into, and taking or not taking any action under, any Loan Document or with respect to any transaction contemplated in any Loan Document, in each case based on such documents and information as it shall deem appropriate.

**12.08 Expenses; Indemnities.**

(a) Each Lender agrees to reimburse Administrative Agent and each of its Related Persons (to the extent not reimbursed by any Obligor) promptly, upon demand for such Lender's Proportionate Share of any costs and expenses (including fees, charges and disbursements of financial, legal and other advisors and Other Taxes paid in the name of, or on behalf of, any Obligor) that may be incurred by Administrative Agent or any of its Related Persons in connection with the preparation, syndication, execution, delivery, administration, modification, consent, waiver or enforcement (whether through negotiations, through any work-out, bankruptcy, restructuring or other legal or other proceeding or otherwise) of, or legal advice in respect of its rights or responsibilities under, any Loan Document.

(b) Each Lender further agrees to indemnify Administrative Agent and each of its Related Persons (to the extent not reimbursed by any Obligor), from and against such Lender's aggregate Proportionate Share of the liabilities (including Taxes, interests and penalties imposed for not properly withholding or backup withholding on payments made to on or for the account of any Lender) that may be imposed on, incurred by or asserted against Administrative Agent or any of its Related Persons in any matter relating to or arising out of, in connection with or as a result of any Loan Document, any Related Document or any other act, event or transaction related, contemplated in or attendant to any such document, or, in each case, any action taken or omitted to be taken by Administrative Agent or any of its Related Persons under or with respect to any of the foregoing; *provided, however*, that no Lender shall be liable to Administrative Agent or any of its Related Persons to the extent such liability is found in a final, non-appealable judgment by a court of competent jurisdiction to have resulted from such Administrative Agent's or such Related Person's gross negligence or willful misconduct.

**12.09 Resignation of Administrative Agent.** (a) Administrative Agent may resign at any time by delivering notice of such resignation to the Lenders and Lead Borrower, effective on the date set forth in such notice or, if not such date is set forth therein, upon the date such notice shall be effective. If Administrative Agent delivers any such notice, the Majority Lenders shall have the right to appoint a successor Administrative Agent. If, within 30 days after the retiring Administrative Agent having given notice of resignation, no successor Administrative Agent has been appointed by the Majority Lenders that has accepted such appointment, then the retiring Administrative Agent may, on behalf of the Lenders, appoint a successor Administrative Agent from among the Lenders. Each appointment under this **Section 12.09(a)** shall be subject to the prior consent of Lead Borrower, which may not be unreasonably withheld but shall not be required during the continuance of an Event of Default.



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(b) Effective immediately upon its resignation, (i) the retiring Administrative Agent shall be discharged from its duties and obligations under the Loan Documents, (ii) the Lenders shall assume and perform all of the duties of Administrative Agent until a successor Administrative Agent shall have accepted a valid appointment hereunder, (iii) the retiring Administrative Agent and its Related Persons shall no longer have the benefit of any provision of any Loan Document other than with respect to any actions taken or omitted to be taken while such retiring Administrative Agent was, or because such Administrative Agent had been, validly acting as Administrative Agent under the Loan Documents and (iv) subject to its rights under **Section 12.03**, the retiring Administrative Agent shall take such action as may be reasonably necessary to assign to the successor Administrative Agent its rights as Administrative Agent under the Loan Documents. Effective immediately upon its acceptance of a valid appointment as Administrative Agent, a successor Administrative Agent shall succeed to, and become vested with, all the rights, powers, privileges and duties of the retiring Administrative Agent under the Loan Documents.

**12.10 Release of Collateral or Guarantors.** Each Lender hereby consents to the release and hereby directs Administrative Agent to release (or, in the case of **Section 12.10(b)(ii)**, release or subordinate) the following:

(a) any Subsidiary of Parent from its guaranty of any Obligation of any Obligor if all of the Equity Interests in such Subsidiary owned by any Obligor or any of its Subsidiaries are disposed of in an Asset Sale permitted under the Loan Documents (including pursuant to a waiver or consent), to the extent that, after giving effect to such Asset Sale, such Subsidiary would not be required to guaranty any Obligations pursuant to **Section 8.12**;

(b) subject to **Section 12.11**, any Lien held by Administrative Agent for the benefit of the Secured Parties against (i) any Collateral that is disposed of by an Obligor in an Asset Sale permitted by the Loan Documents (including pursuant to a valid waiver or consent), to the extent all Liens required to be granted in such Collateral pursuant to **Section 8.12** after giving effect to such Asset Sale have been granted, (ii) any property subject to a Lien described in **Section 9.02(d)** and (iii) all of the Collateral and all Obligors, upon (A) termination of the Commitments, (B) payment and satisfaction in full of all Loans and all other Obligations that Administrative Agent has been notified in writing are then due and payable, (C) deposit of cash collateral with respect to all contingent Obligations, in amounts and on terms and conditions and with parties satisfactory to the Majority Lenders and each Indemnitee that is owed such Obligations and (D) to the extent requested by Administrative Agent, receipt by the Secured Parties of liability releases from the Obligors each in form and substance acceptable to Administrative Agent;

(c) any Subsidiary of Parent to the extent it is being liquidated, dissolved or merged into another Obligor, or any Lien on any of the Collateral (including any capital stock or share capital of any Subsidiary) to the extent necessary to transfer such Collateral to another Obligor,

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in each case in connection with, and subject to the requirements set forth in the definition of, the Permitted Restructuring; provided that, with respect to the Swedish Borrower, such release is subject to **Section 12.11**;

Each Lender hereby directs Administrative Agent, and Administrative Agent hereby agrees, upon receipt of reasonable advance notice from Lead Borrower, to execute and deliver or file such documents and to perform other actions reasonably necessary to release the guaranties and Liens when and as directed in this **Section 12.10**.

**12.11 Release of Swedish Liens** Notwithstanding any other provisions in this Agreement or in any of the other Loan Documents, the release of any perfected Lien (or Lien which purports to be or is required to be perfected) under any Swedish Security Document shall always be subject to the prior written consent of the Administrative Agent (such consent to be given on a case by case basis and at the sole discretion of the Administrative Agent) other than following the discharge in full of all Loans and all other Obligations. Each Secured Party irrevocably authorizes the Administrative Agent to release such Lien without notification or further reference to the Secured Parties. **12.12 Automatic Releases of Obligors and Liens (other than Swedish Liens)**. Except as otherwise provided in **Section 12.11**, solely in respect of any Lien granted under any Swedish Security Document, the Lenders and the Administrative Agent, each hereby acknowledges and agrees that any releases of Obligors and terminations of Liens pursuant to Section 12.11(c) shall occur automatically, without any further action by the Obligors or the Secured Parties subject to the following conditions:

(a) In the case of any release of an Obligor upon the liquidation, dissolution or merger with and into another Obligor, at the time of such liquidation, dissolution and merger such other or successor Obligor shall remain an Obligor and shall assume and succeed to the Obligations of the liquidated, dissolved or merged Obligor;

(b) In the case of any transfer of Collateral to another Obligor, (i) the release of the particular Lien on the Collateral is necessary to transfer such Collateral to such other Obligor and (ii) immediately upon such transfer, such Collateral shall become subject to a first priority perfected (subject to the last paragraph of Section 8.12(c)) Lien granted to the Administrative Agent for the benefit of the Secured Parties by the transferee Obligor (*provided* that this clause (ii) shall not apply to any transfer to the Swedish Borrower in compliance with the proviso to clause (4) in the definition of Permitted Restructuring).

Except as otherwise provided in **Section 12.11**, solely in respect of any Lien granted under any Swedish Security Document, the Secured Parties hereby agree to execute and deliver, at the expense of the Obligors, all Uniform Commercial Code termination statements, certificates

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for terminating the liens on the Motor Vehicles and such other documentation as shall be reasonably requested by any Obligor to effect the termination and release of the Liens on the Collateral described in the preceding sentence.

**SECTION 13  
MISCELLANEOUS**

**13.01 No Waiver.** No failure on the part of Administrative Agent or any Lender to exercise and no delay in exercising, and no course of dealing with respect to, any right, power or privilege under any Loan Document shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege under any Loan Document preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The remedies provided herein are cumulative and not exclusive of any remedies provided by law.

**13.02 Notices.** All notices, requests, instructions, directions and other communications provided for herein (including any modifications of, or waivers, requests or consents under, this Agreement) shall be given or made in writing (including by telecopy and e-mail) delivered, if to any Borrower, another Obligor, Administrative Agent or any Lender, to its address specified on the signature pages hereto or its Assumption Agreement, as the case may be, or at such other address as shall be designated by such party in a notice to the other parties. Except as otherwise provided in this Agreement, all such communications shall be deemed to have been duly given upon receipt of a legible copy thereof, in each case given or addressed as aforesaid. All such communications provided for herein by telecopy shall be confirmed in writing promptly after the delivery of such communication (it being understood that non-receipt of written confirmation of such communication shall not invalidate such communication). Unless the Administrative Agent otherwise prescribes, notices and other communications sent to an e-mail address shall be deemed received upon the sender's receipt of an acknowledgement from the intended recipient (such as by the "return receipt requested" function, as available, return e-mail or other written acknowledgement).

**13.03 Expenses, Indemnification, Etc.**

(a) **Expenses.** Each Borrower agrees to pay or reimburse (i) Administrative Agent and the Lenders for all of their reasonable out of pocket costs and expenses (including the reasonable fees and expenses of Cooley LLP, special counsel to Administrative Agent and the Lenders, and any sales, goods and services or other similar Taxes applicable thereto, and printing, reproduction, document delivery and travel costs) in connection with (x) the negotiation, preparation, execution and delivery of this Agreement and the other Loan Documents and the making of the Loans (exclusive of post-closing costs), (y) post-closing costs and (z) the negotiation or preparation of any modification, supplement or waiver of any of the terms of this Agreement or any of the other Loan Documents (whether or not consummated) and

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(ii) Administrative Agent and the Lenders for all of their out of pocket costs and expenses (including the fees and expenses of legal counsel) in connection with any enforcement or collection proceedings resulting from the occurrence of an Event of Default; *provided, however*, that Borrowers shall not be required to pay or reimburse any amounts pursuant to **Section 13.03(a)(i)(x)** in excess of the Expense Cap.

(b) **Indemnification.** Each Borrower hereby indemnifies Administrative Agent, each Lender, their respective Affiliates, and their respective directors, officers, employees, attorneys, agents, advisors and controlling parties (each, an “*Indemnified Party*”) from and against, and agrees to hold them harmless against, any and all Claims and Losses of any kind (including reasonable fees and disbursements of counsel), joint or several, that may be incurred by or asserted or awarded against any Indemnified Party, in each case arising out of or in connection with or relating to this Agreement or any of the other Loan Documents or the transactions contemplated hereby or thereby or any use made or proposed to be made with the proceeds of the Loans, and any claim, investigation, litigation or proceeding or the preparation of any defense with respect thereto arising out of or in connection with or relating to any of the foregoing, whether or not any Indemnified Party is a party to an actual or prospective claim, litigation, investigation or proceeding relating to any of the foregoing, whether based in contract, tort or any other theory, and whether or not such investigation, litigation or proceeding is brought by Borrower, any of its shareholders or creditors, and whether or not the conditions precedent set forth in **Section 6** are satisfied or the other transactions contemplated by this Agreement are consummated, except to the extent such Claim or Loss is found in a final, non-appealable judgment by a court of competent jurisdiction to have resulted from such Indemnified Party’s gross negligence or willful misconduct. No Obligor shall assert any claim against any Indemnified Party, on any theory of liability, for consequential, indirect, special or punitive damages arising out of or otherwise relating to this Agreement or any of the other Loan Documents or any of the transactions contemplated hereby or thereby or the actual or proposed use of the proceeds of the Loans. Parent, its Subsidiaries and Affiliates and their respective directors, officers, employees, attorneys, agents, advisors and controlling parties are each sometimes referred to in this Agreement as a “*Borrower Party*.” No Lender shall assert any claim against any Borrower Party, on any theory of liability, for consequential, indirect, special or punitive damages arising out of or otherwise relating to this Agreement or any of the other Loan Documents or any of the transactions contemplated hereby or thereby or the actual or proposed use of the proceeds of the Loans.

**13.04 Amendments, Etc.** Except as otherwise expressly provided in this Agreement, any provision of this Agreement may be modified or supplemented only by an instrument in writing signed by each Borrower and the Majority Lenders (or Administrative Agent on behalf of such Majority Lenders); *provided however*, that:

- (a) the consent of all of the Lenders shall be required to:

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(i) amend, modify, discharge, terminate or waive any of the terms of this Agreement if such amendment, modification, discharge, termination or waiver would increase the amount of the Loans, reduce the fees payable hereunder, reduce interest rates or other amounts payable with respect to the Loans, extend any date fixed for payment of principal, interest or other amounts payable relating to the Loans or extend the repayment dates of the Loans;

(ii) amend the provisions of **Section 6**;

(iii) amend, modify, discharge, terminate or waive any Security Document if the effect is to release a material part of the Collateral subject thereto other than pursuant to the terms hereof or thereof (including without limitation the Permitted Restructuring); or

(iv) amend this **Section 13.04** (including without limitation the Permitted Restructuring); and

(b) no amendment, waiver or consent shall affect the rights or duties under any Loan Document of, or any payment to, Administrative Agent (or otherwise modify any provision of **Section 12** or the application thereof) unless in writing and signed by Administrative Agent in addition to any signature otherwise required.

Notwithstanding anything to the contrary herein, (a) any amendments, modifications and waivers to the definition of Permitted Restructuring and/or the provisions of the Loan Documents relating thereto shall only be subject to the consent of the Administrative Agent; and (b) a Defaulting Lender shall not have any right to approve or disapprove any amendment, waiver or consent hereunder (and any amendment, waiver or consent which by its terms requires the consent of all Lenders or each affected Lender may be effected with the consent of the applicable Lenders other than Defaulting Lenders), except that (x) the Commitment of any Defaulting Lender may not be increased or extended without the consent of such Lender and (y) any waiver, amendment or modification requiring the consent of all Lenders or each affected Lender that by its terms affects any Defaulting Lender more adversely than other affected Lenders shall require the consent of such Defaulting Lender.

**13.05 Successors and Assigns.**

(a) **General.** The provisions of this Agreement and the other Loan Documents shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns permitted hereby, except that no Borrower may assign or otherwise transfer any of its rights or obligations hereunder or under any of the other Loan Documents without the prior written consent of the Lenders. Any of the Lenders may assign or otherwise transfer any of their rights or obligations hereunder or under any of the other Loan Documents to an assignee (i) in

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accordance with the provisions of **Section 13.05(b)**, (ii) by way of participation in accordance with the provisions of **Section 13.05(e)** or (iii) by way of pledge or assignment of a security interest subject to the restrictions of **Section 13.05(g)**. Nothing in this Agreement, expressed or implied, shall be construed to confer upon any Person (other than the parties hereto, their respective successors and assigns permitted hereby, Participants to the extent provided in **Section 13.05(e)** and, to the extent expressly contemplated hereby, the Indemnified Parties) any legal or equitable right, remedy or claim under or by reason of this Agreement.

(b) **Assignments by Lenders.** Any of the Lenders may at any time assign to one or more Eligible Transferees (or, if an Event of Default has occurred and is continuing, to any Person (other than a natural Person)) all or a portion of their rights and obligations under this Agreement (including all or a portion of the Commitment and the Loans at the time owing to it); *provided, however*, that no such assignment shall be made to any Borrower, an Affiliate of any Borrower, or any employees or directors of any Borrower at any time. Subject to the recording thereof by Administrative Agent pursuant to **Section 13.05(d)**, from and after the effective date specified in each Assignment and Assumption, the assignee thereunder shall be a party to this Agreement and, to the extent of the interest assigned by such Assignment and Assumption, have the rights and obligations of the Lenders under this Agreement and the other Loan Documents, and correspondingly the assigning Lender shall, to the extent of the interest assigned by such Assignment and Assumption, be released from its obligations under this Agreement (and, in the case of an Assignment and Assumption covering all of a Lender's rights and obligations under this Agreement, such Lender shall cease to be a party hereto) and the other Loan Documents but shall continue to be entitled to the benefits of **Section 5** and **Section 13.03**. Any assignment or transfer by a Lender of rights or obligations under this Agreement that does not comply with this **Section 13.05(b)** shall be treated for purposes of this Agreement as a sale by such Lender of a participation in such rights and obligations in accordance with **Section 13.05(e)**.

(c) **Amendments to Loan Documents.** Each of Administrative Agent, the Lenders and the Obligors agrees to enter into such amendments to the Loan Documents, and such additional Security Documents and other instruments and agreements, in each case in form and substance reasonably acceptable to Administrative Agent, the Lenders and the Obligors, as shall reasonably be necessary to implement and give effect to any assignment made under this **Section 13.05**.

(d) **Register.** Administrative Agent, acting solely for this purpose as an agent of each Borrower, shall maintain at one of its offices a register for the recordation of the name and address of any assignee of the Lenders and the Commitment and outstanding principal amount of the Loans owing thereto (the "**Register**"). The entries in the Register shall be conclusive, absent manifest error, and each Borrower shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as the "Lender" hereunder for all purposes of this Agreement,

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notwithstanding notice to the contrary. The Register shall be available for inspection by any Borrower, at any reasonable time and from time to time upon reasonable prior notice.

(e) **Participations.** Any of the Lenders may at any time, without the consent of, or notice to, any Borrower, sell participations to any Person (other than a natural person or any Borrower or any of a Borrower's Affiliates or Subsidiaries) (each, a "**Participant**") in all or a portion of such Lender's rights and/or obligations under this Agreement (including all or a portion of the Commitment and/or the Loans owing to it); *provided* that (i) such Lender's obligations under this Agreement shall remain unchanged, (ii) such Lender shall remain solely responsible to the other parties hereto for the performance of such obligations and (iii) each Borrower shall continue to deal solely and directly with the Lenders in connection therewith.

Any agreement or instrument pursuant to which a Lender sells such a participation shall provide that such Lender shall retain the sole right to enforce this Agreement and to approve any amendment, modification or waiver of any provision of this Agreement; *provided* that such agreement or instrument may provide that such Lender will not, without the consent of the Participant, agree to any amendment, modification or waiver that would (i) increase or extend the term of such Lender's Commitment, (ii) extend the date fixed for the payment of principal of or interest on the Loans or any portion of any fee hereunder payable to the Participant, (iii) reduce the amount of any such payment of principal, or (iv) reduce the rate at which interest is payable thereon to a level below the rate at which the Participant is entitled to receive such interest. Subject to **Section 13.05(f)**, each Borrower agrees that each Participant shall be entitled to the benefits of **Section 5** to the same extent as if it were a Lender and had acquired its interest by assignment pursuant to **Section 13.05(b)**. To the extent permitted by law, each Participant also shall be entitled to the benefits of **Section 4.04(a)** as though it were the Lender.

(f) **Limitations on Rights of Participants.** A Participant shall not be entitled to receive any greater payment under **Section 5.01** or **5.03** than a Lender would have been entitled to receive with respect to the participation sold to such Participant. Each Lender that sells a participation shall, acting solely for this purpose as a non-fiduciary agent of each Borrower, maintain a register on which it enters the name and address of each Participant and the principal amounts (and stated interest) of each Participant's interest in the Loans or other obligations under the Loan Documents (the "**Participant Register**"); *provided* that no Lender shall have any obligation to disclose all or any portion of the Participant Register (including the identity of any Participant or any information relating to a Participant's interest in any commitment, loan, letter of credit or other obligations under any Loan Document) to any Person except to the extent that such disclosure is necessary to establish that such commitment, loan, letters of credit or other obligation is in registered form under Section 5f.103-1(c) of the United States Treasury Regulations. The entries in the Participant Register shall be conclusive absent manifest error, and such Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the

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contrary. For the avoidance of doubt, Administrative Agent (in its capacity as Administrative Agent) shall have no responsibility for maintaining a Participant Register.

(g) **Certain Pledges.** The Lenders may at any time pledge or assign a security interest in all or any portion of its rights under this Agreement and any other Loan Document to secure obligations of the Lenders, including any pledge or assignment to secure obligations to a Federal Reserve Bank; *provided* that no such pledge or assignment shall release the Lenders from any of their obligations hereunder or substitute any such pledgee or assignee for the Lenders as a party hereto.

**13.06 Survival.** The obligations of the Obligor under Sections 5.01, 5.02, 5.03, 13.03, 13.05, 13.09, 13.10, 13.11, 13.12, 13.13, 13.14, 13.20 and Section 14 (solely to the extent guaranteeing any of the obligations under the foregoing Sections) shall survive the repayment of the Obligations and the termination of the Commitment and, in the case of the Lenders' assignment of any interest in the Commitment or the Loans hereunder, shall survive, in the case of any event or circumstance that occurred prior to the effective date of such assignment, the making of such assignment, notwithstanding that the Lenders may cease to be "Lenders" hereunder. In addition, each representation and warranty made, or deemed to be made by a Notice of Borrowing, herein or pursuant hereto shall survive the making of such representation and warranty.

**13.07 Captions.** The table of contents and captions and section headings appearing herein are included solely for convenience of reference and are not intended to affect the interpretation of any provision of this Agreement.**13.08 Counterparts.** This Agreement may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Agreement by signing any such counterpart.

**13.09 Governing Law.** This Agreement and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction; *provided* that Section 5-1401 of the New York General Obligations Law shall apply.

**13.10 Jurisdiction, Service of Process and Venue.**

(a) **Submission to Jurisdiction.** Each Obligor agrees that any suit, action or proceeding with respect to this Agreement or any other Loan Document to which it is a party or any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in Houston, Texas or in the courts of its own corporate domicile and irrevocably submits to the non-exclusive jurisdiction of each such court for the purpose of any such suit,



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action, proceeding or judgment. This **Section 13.10(a)** is for the benefit of Administrative Agent and the Lenders only and, as a result, neither Administrative Agent nor any Lender shall be prevented from taking proceedings in any other courts with jurisdiction. To the extent allowed by applicable Laws, Administrative Agent and the Lenders may take concurrent proceedings in any number of jurisdictions.

(b) **Alternative Process.** Nothing herein shall in any way be deemed to limit the ability of Administrative Agent or the Lenders to serve any such process or summonses in any other manner permitted by applicable law.

(c) **Waiver of Venue, Etc.** Each Obligor irrevocably waives to the fullest extent permitted by law any objection that it may now or hereafter have to the laying of the venue of any suit, action or proceeding arising out of or relating to this Agreement or any other Loan Document and hereby further irrevocably waives to the fullest extent permitted by law any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. A final judgment (in respect of which time for all appeals has elapsed) in any such suit, action or proceeding shall be conclusive and may be enforced in any court to the jurisdiction of which such Obligor is or may be subject, by suit upon judgment.

**13.11 Waiver of Jury Trial.** EACH OBLIGOR, THE ADMINISTRATIVE AGENT AND EACH LENDER HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE OTHER LOAN DOCUMENTS OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

**13.12 Waiver of Immunity.** To the extent that any Obligor may be or become entitled to claim for itself or its Property or revenues any immunity on the ground of sovereignty or the like from suit, court jurisdiction, attachment prior to judgment, attachment in aid of execution of a judgment or execution of a judgment, and to the extent that in any such jurisdiction there may be attributed such an immunity (whether or not claimed), such Obligor hereby irrevocably agrees not to claim and hereby irrevocably waives such immunity with respect to its obligations under this Agreement and the other Loan Documents.

**13.13 Entire Agreement.** This Agreement and the other Loan Documents constitute the entire agreement among the parties with respect to the subject matter hereof and thereof and supersede any and all previous agreements and understandings, oral or written, relating to the subject matter hereof. EACH OBLIGOR ACKNOWLEDGES, REPRESENTS AND WARRANTS THAT IN DECIDING TO ENTER INTO THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS OR IN TAKING OR NOT TAKING ANY ACTION HEREUNDER OR THEREUNDER, IT HAS NOT RELIED, AND WILL NOT RELY, ON ANY STATEMENT,

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REPRESENTATION, WARRANTY, COVENANT, AGREEMENT OR UNDERSTANDING, WHETHER WRITTEN OR ORAL, OF OR WITH ADMINISTRATIVE AGENT OR THE LENDERS OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS.

**13.14 Severability.** If any provision hereof is found by a court to be invalid or unenforceable, to the fullest extent permitted by applicable law the parties agree that such invalidity or unenforceability shall not impair the validity or enforceability of any other provision hereof.

**13.15 No Fiduciary Relationship.** Each Obligor acknowledges that Administrative Agent and the Lenders have no fiduciary relationship with, or fiduciary duty to, any Borrower arising out of or in connection with this Agreement or the other Loan Documents, and the relationship between the Lenders and the Borrowers is solely that of creditor and debtor. This Agreement and the other Loan Documents do not create a joint venture among the parties.

**13.16 Confidentiality.** Each of Administrative Agent and the Lenders agree to maintain the confidentiality of the Information (as defined below), except that Information may be disclosed (a) to its Related Persons (it being understood that the Persons to whom such disclosure is made will be informed of the confidential nature of such Information and shall undertake in writing or shall otherwise be obligated to keep such Information confidential); (b) to the extent required or requested by any regulatory authority purporting to have jurisdiction over such Person or its Related Persons (including any self-regulatory authority, such as the National Association of Insurance Commissioners); (c) to the extent required by applicable laws or regulations or by any subpoena or similar legal process; (d) to any other party hereto; (e) in connection with the exercise of any remedies hereunder or under any other Loan Document or any action or proceeding relating to this Agreement or any other Loan Document or the enforcement of rights hereunder or thereunder; (f) subject to a binding agreement containing provisions substantially the same as those of this **Section 13.16**, to (i) any assignee of or Participant in, or any prospective assignee of or Participant in, any of its rights and obligations under this Agreement or (ii) any actual or prospective party (or its Related Persons) to any swap, derivative or other transaction under which payments are to be made by reference to a Borrower and its obligations, this Agreement or payments hereunder; (g) on a confidential basis to (i) any rating agency in connection with rating any Borrower or its Subsidiaries or the Loans or (ii) the CUSIP Global Services or any similar agency in connection with the issuance and monitoring of CUSIP numbers with respect to the Loans; (h) with the consent of the Lead Borrower; or (i) to the extent such Information (x) becomes publicly available other than as a result of a breach of this **Section 13.16**, or (y) becomes available to Administrative Agent, any Lender or any of their respective Affiliates on a nonconfidential basis from a source other than Borrowers if such source was not, to the knowledge of Administrative Agent or such Lender or their respective Affiliates, as applicable, prohibited from disclosing such Information by a legal, contractual or fiduciary obligation. In addition, Administrative Agent and the Lenders may disclose the existence of this

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Agreement and the material terms thereof to market data collectors, similar service providers to the lending industry and service providers to Administrative Agent and the Lenders in connection with the administration of this Agreement, the other Loan Documents and the Commitments.

For purposes of this Section, “*Information*” means all information furnished by Parent or any of its Subsidiaries relating to Parent or any of its Subsidiaries or any of their respective businesses, other than any such information that is available to Administrative Agent or any Lender on a nonconfidential basis prior to disclosure by Parent or any of its Subsidiaries; provided that the source was not, to the knowledge of the Administrative Agent or such Lender, prohibited from disclosing such Information by a legal, contractual or fiduciary obligation. Any Person required to maintain the confidentiality of Information as provided in this **Section 13.16** shall be considered to have complied with its obligation to do so if such Person has exercised the same degree of care to maintain the confidentiality of such Information as such Person would accord to its own confidential information.

**13.17 USA PATRIOT Act.** Administrative Agent and the Lenders hereby notify the Obligor that pursuant to the requirements of the USA PATRIOT Act (Title III of Pub. L. 107-56 (signed into law October 26, 2001)) (the “*Act*”) or any Anti-Money Laundering Laws, they are required to obtain, verify and record information that identifies such Obligor, which information includes the name and address of such Obligor and other information that will allow such Lender to identify such Obligor in accordance with the Act or other Anti-Money Laundering Laws.

**13.18 Maximum Rate of Interest.** Notwithstanding anything to the contrary contained in any Loan Document, the interest paid or agreed to be paid under the Loan Documents shall not exceed the maximum rate of non-usurious interest permitted by applicable Law (in each case, the “*Maximum Rate*”). If the Lenders shall receive interest in an amount that exceeds the Maximum Rate, the excess interest shall be applied to the principal of the Loans, and not to the payment of interest, or, if the excessive interest exceeds such unpaid principal, the amount exceeding the unpaid balance shall be refunded to the applicable Obligor. In determining whether the interest contracted for, charged, or received by the Lenders exceeds the Maximum Rate, the Lenders may, to the extent permitted by applicable Law, (a) characterize any payment that is not principal as an expense, fee, or premium rather than interest, (b) exclude voluntary prepayments and the effects thereof, (c) amortize, prorate, allocate, and spread in equal or unequal parts the total amount of interest throughout the contemplated term of the Indebtedness and other obligations of any Obligor hereunder, or (d) allocate interest between portions of such Indebtedness and other obligations under the Loan Documents to the end that no such portion shall bear interest at a rate greater than that permitted by applicable Law.

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**13.19 Certain Waivers.**

(a) [Reserved].

(b) **Waiver of Marshaling.** WITHOUT LIMITING THE FOREGOING IN ANY WAY, EACH OBLIGOR HEREBY IRREVOCABLY WAIVES AND RELEASES, TO THE EXTENT PERMITTED BY LAW, ANY AND ALL RIGHTS IT MAY HAVE AT ANY TIME (WHETHER ARISING DIRECTLY OR INDIRECTLY, BY OPERATION OF LAW, CONTRACT OR OTHERWISE) TO REQUIRE THE MARSHALING OF ANY ASSETS OF ANY OBLIGOR, WHICH RIGHT OF MARSHALING MIGHT OTHERWISE ARISE FROM ANY PAYMENTS MADE OR OBLIGATIONS PERFORMED.

**13.20 Tax Treatment.** The parties hereto agree (a) that any contingency associated with the Loans is described in Treasury Regulations Section 1.1272-1(c) and/or Treasury Regulations Section 1.1275-2(h), and therefore no Loan is governed by the rules set out in Treasury Regulations Section 1.1275-4, (b) except for a Lender described in Sections 871(h)(3) or 881(c)(3) of the Code, absent a Change in a Requirement of Law, all interest on the Loans is "portfolio interest" within the meaning of Sections 871(h) or 881(c) of the Code, and therefore is exempt from withholding tax under Sections 1441(c)(9) or 1442(a) of the Code, and (c) to adhere to this Section 13.20 for federal income and any other applicable tax purposes and not to take any action or file any Tax Return, report or declaration inconsistent herewith.

**13.21 Original Issue Discount.** For purposes of Sections 1272, 1273 and 1275 of the Code, each Loan is being issued with original issue discount; please contact Brian Davis, Chief Financial Officer, 900 Northbrook Drive, Suite 200, Trevose, PA, telephone: 484-254-6865 to obtain information regarding the issue price, the amount of original issue discount and the yield to maturity.

**13.22 Co-Borrower Provisions.**

(a) **Borrower Agent.** Each Borrower appoints Lead Borrower its agent for purposes of the giving and receiving of any notice, and the agreement to any consent or waiver under this Agreement (Lead Borrower, in such capacity, "**Borrower Agent**"). Any notice required by this Agreement to be delivered to any Borrower shall be deemed to have been delivered to such Borrower upon delivery of such notice to Borrower Agent, and receipt of any notice by Borrower Agent shall constitute receipt of such notice by each Borrower. Any notice or consent to be delivered hereunder by any Borrower shall be deemed to have been delivered by such Borrower upon delivery thereof by Borrower Agent.

(b) **Joint and Several Nature of the Obligations; Obligations Unconditional.** All Loans and other extensions of credit hereunder shall be deemed to have been made to all Borrowers. The obligations of Borrowers under the Loan Documents (other than the Warrant)

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are absolute and unconditional, joint and several, irrespective of the value, genuineness, validity, regularity or enforceability of the obligations of any other Obligor under this Agreement or any other Loan Document or agreement or instrument referred to herein, or any substitution, release or exchange of any other guarantee of or security for any of the Obligations, and, to the fullest extent permitted by applicable law, irrespective of any other circumstance whatsoever that might otherwise constitute a legal or equitable discharge or defense of a surety or guarantor. The liability of each Borrower hereunder is irrevocable, continuing, absolute and unconditional.

(c) **Co-Borrower Waivers.**(i) Without limiting the generality of the foregoing, it is agreed that the occurrence of any one or more of the following shall not discharge, alter, impair or otherwise affect the liability of Borrowers hereunder, which shall remain absolute and unconditional as described above, and each Borrower hereby irrevocably waives any defenses to enforcement it may have (now or in the future) by reason of:

(A) any change in the time, including the time for any performance or compliance with, place or manner of payment of, or in any other term of, the Obligations or any other obligation of any other Obligor under any Loan Document, or any rescission, waiver, amendment or other modification of any Loan Document or any other agreement, including any increase in the Obligations resulting from any extension of additional credit or otherwise;

(B) any of the acts mentioned in any of the provisions of this Agreement or any other agreement or instrument referred to herein shall be done or omitted;

(C) the maturity of any of the Obligations shall be accelerated, or any of the Obligations shall be modified, supplemented or amended in any respect, or any right under this Agreement or any other agreement or instrument referred to herein shall be waived or any other guarantee of any of the Obligations or any security therefor shall be released or exchanged in whole or in part or otherwise dealt with;

(D) any taking, exchange, substitution, release, impairment or non-perfection of any Collateral, any taking, release, impairment, amendment, waiver or other modification of any guaranty, for the Obligations or any lien or security interest granted to, or in favor of, the Secured Parties as security for any of the Obligations shall fail to be perfected; and

(E) the failure of any other Person to execute or deliver this Agreement, any Loan Document or any other guaranty or agreement or the release or reduction of liability of any Obligor or other guarantor or surety with respect to the Obligations.

(ii) Borrowers hereby expressly waive diligence, presentment, demand of payment, protest and all notices whatsoever, and any requirement that any Secured Party exhaust

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any right, power or remedy against any Borrower, or proceed against any Borrower, or select one action or election of remedy, under this Agreement or any other agreement or instrument referred to herein, or against any other Person under any other guarantee of, or security for, any of the Obligations.

(d) **Subrogation.** Borrowers hereby jointly and severally agree that until the payment and satisfaction in full of all Obligations and the expiration and termination of the Commitments under this Agreement, they shall not exercise any right or remedy to seek contribution, indemnification or any other form of reimbursement from any other Obligor or any other Person, whether by subrogation or otherwise, for any payment made or security provided in respect of the Obligations. Any agreement providing for contribution, indemnification or any other form of reimbursement prohibited under this **Section 13.22(d)** shall be null and void. If any payment is made to any Obligor or any of its Subsidiaries in contravention of this **Section 13.22(d)**, such Obligor or such Subsidiary shall hold such payment in trust for the Lenders and Administrative Agent and such payment shall be promptly, and in any event within five (5) Business Days, delivered to Administrative Agent for application to the Obligations, whether matured or unmatured.

#### **SECTION 14 GUARANTEE**

**14.01 The Guarantee.** The Subsidiary Guarantors hereby jointly and severally guarantee to the Secured Parties and their respective successors and assigns the prompt payment in full when due (whether at stated maturity, by acceleration or otherwise) of the principal of and interest on the Loans and all fees and other amounts from time to time owing to the Secured Parties by any Borrower under this Agreement or under any other Loan Document (other than the Warrant) and by any other Obligor under any of the Loan Documents (other than the Warrant), in each case strictly in accordance with the terms thereof (such obligations being herein collectively called the “**Guaranteed Obligations**”). The Subsidiary Guarantors hereby further jointly and severally agree that if any Borrower shall fail to pay in full when due (whether at stated maturity, by acceleration or otherwise) any of the Guaranteed Obligations, the Subsidiary Guarantors will promptly pay the same, without any demand or notice whatsoever, and that in the case of any extension of time of payment or renewal of any of the Guaranteed Obligations, the same will be promptly paid in full when due (whether at extended maturity, by acceleration or otherwise) in accordance with the terms of such extension or renewal.

**14.02 Obligations Unconditional; Subsidiary Guarantor Waivers.** The obligations of the Subsidiary Guarantors under **Section 14.01** are absolute and unconditional, joint and several, irrespective of the value, genuineness, validity, regularity or enforceability of the obligations of any Borrower under this Agreement or any other agreement or instrument referred to herein, or any substitution, release or exchange of any other guarantee of or security for any of the

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Guaranteed Obligations, and, to the fullest extent permitted by applicable law, irrespective of any other circumstance whatsoever that might otherwise constitute a legal or equitable discharge or defense of a surety or guarantor. The liability of each Subsidiary Guarantor is irrevocable, continuing, absolute and unconditional. Without limiting the generality of the foregoing, it is agreed that the occurrence of any one or more of the following shall not discharge, alter, impair or otherwise affect the liability of the Subsidiary Guarantors hereunder, which shall remain absolute and unconditional as described above, and each Subsidiary Guarantor hereby irrevocably waives any defenses to enforcement it may have (now or in the future) by reason of:

(a) any change in the time, including the time for any performance or compliance with, place or manner of payment of, or in any other term of, the Guaranteed Obligations or any other obligation of any Obligor under any Loan Document, or any rescission, waiver, amendment or other modification of any Loan Document or any other agreement, including any increase in the Guaranteed Obligations resulting from any extension of additional credit or otherwise;;

(b) any of the acts mentioned in any of the provisions of this Agreement or any other agreement or instrument referred to herein shall be done or omitted;

(c) the maturity of any of the Guaranteed Obligations shall be accelerated, or any of the Guaranteed Obligations shall be modified, supplemented or amended in any respect, or any right under this Agreement or any other agreement or instrument referred to herein shall be waived or any other guarantee of any of the Guaranteed Obligations or any security therefor shall be released or exchanged in whole or in part or otherwise dealt with;

(d) any taking, exchange, substitution, release, impairment or non-perfection of any Collateral, any taking, release, impairment, amendment, waiver or other modification of any guaranty, for the Guaranteed Obligations or any lien or security interest granted to, or in favor of, the Secured Parties as security for any of the Guaranteed Obligations shall fail to be perfected; and

(e) the failure of any other Person to execute or deliver this Agreement, any Loan Document or any other guaranty or agreement or the release or reduction of liability of any Obligor or other guarantor or surety with respect to the Guaranteed Obligations.

The Subsidiary Guarantors hereby expressly waive diligence, presentment, demand of payment, protest and all notices whatsoever, and any requirement that any Secured Party exhaust any right, power or remedy or proceed against any Borrower under this Agreement or any other agreement or instrument referred to herein, or against any other Person under any other guarantee of, or security for, any of the Guaranteed Obligations.

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**14.03 Reinstatement.** The obligations of the Subsidiary Guarantors under this **Section 14** shall be automatically reinstated if and to the extent that for any reason any payment by or on behalf of any Borrower in respect of the Guaranteed Obligations is rescinded or must be otherwise restored by any holder of any of the Guaranteed Obligations, whether as a result of any proceedings in bankruptcy or reorganization or otherwise, and the Subsidiary Guarantors jointly and severally agree that they will indemnify the Secured Parties on demand for all reasonable costs and expenses (including fees of counsel) incurred by the Lenders in connection with such rescission or restoration, including any such costs and expenses incurred in defending against any claim alleging that such payment constituted a preference, fraudulent transfer or similar payment under any bankruptcy, insolvency or similar law.

**14.04 Subrogation.** The Subsidiary Guarantors hereby jointly and severally agree that until the payment and satisfaction in full of all Guaranteed Obligations and the expiration and termination of the Commitments under this Agreement, they shall not exercise any right or remedy arising by reason of any performance by them of their guarantee in **Section 14.01**, whether by subrogation or otherwise, against any Borrower or any other guarantor of any of the Guaranteed Obligations or any security for any of the Guaranteed Obligations.

**14.05 Remedies.** The Subsidiary Guarantors jointly and severally agree that, as between the Subsidiary Guarantors and the Secured Parties, the obligations of Borrowers under this Agreement and under the other Loan Documents may be declared to be forthwith due and payable as provided in **Section 11** (and shall be deemed to have become automatically due and payable in the circumstances provided in **Section 11**) for purposes of **Section 14.01** notwithstanding any stay, injunction or other prohibition preventing such declaration (or such obligations from becoming automatically due and payable) as against Borrowers and that, in the event of such declaration (or such obligations being deemed to have become automatically due and payable), such obligations (whether or not due and payable by a Borrower) shall forthwith become due and payable by the Subsidiary Guarantors for purposes of **Section 14.01**.

**14.06 Instrument for the Payment of Money.** Each Subsidiary Guarantor hereby acknowledges that the guarantee in this **Section 14** constitutes an instrument for the payment of money, and consents and agrees that the Secured Parties, at their sole option, in the event of a dispute by such Subsidiary Guarantor in the payment of any moneys due hereunder, shall have the right to proceed by motion for summary judgment in lieu of complaint pursuant to N.Y. Civ. Prac. L&R § 3213.

**14.07 Continuing Guarantee.** The guarantee in this **Section 14** is a continuing guarantee, and shall apply to all Guaranteed Obligations whenever arising.

**14.08 Rights of Contribution.** The Subsidiary Guarantors hereby agree, as between themselves, that if any Subsidiary Guarantor shall become an Excess Funding Guarantor (as



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defined below) by reason of the payment by such Subsidiary Guarantor of any Guaranteed Obligations, each other Subsidiary Guarantor shall, on demand of such Excess Funding Guarantor (but subject to the next sentence), pay to such Excess Funding Guarantor an amount equal to such Subsidiary Guarantor's *Pro rata* Share (as defined below and determined, for this purpose, without reference to the properties, debts and liabilities of such Excess Funding Guarantor) of the Excess Payment (as defined below) in respect of such Guaranteed Obligations. The payment obligation of a Subsidiary Guarantor to any Excess Funding Guarantor under this **Section 14.08** shall be subordinate and subject in right of payment to the prior payment in full of the obligations of such Subsidiary Guarantor under the other provisions of this **Section 14** and such Excess Funding Guarantor shall not exercise any right or remedy with respect to such excess until payment and satisfaction in full of all of such obligations. For purposes of this **Section 14.08**, (i) "**Excess Funding Guarantor**" means, in respect of any Guaranteed Obligations, a Subsidiary Guarantor that has paid an amount in excess of its *Pro rata* Share of such Guaranteed Obligations, (ii) "**Excess Payment**" means, in respect of any Guaranteed Obligations, the amount paid by an Excess Funding Guarantor in excess of its *Pro rata* Share of such Guaranteed Obligations and (iii) "**Pro Rata Share**" means, for any Subsidiary Guarantor, the ratio (expressed as a percentage) of (x) the amount by which the aggregate present fair saleable value of all properties of such Subsidiary Guarantor (excluding any shares of stock or share capital, as applicable, of any other Subsidiary Guarantor) exceeds the amount of all the debts and liabilities of such Subsidiary Guarantor (including contingent, subordinated, unmatured and unliquidated liabilities, but excluding the obligations of such Subsidiary Guarantor hereunder and any obligations of any other Subsidiary Guarantor that have been Guaranteed by such Subsidiary Guarantor) to (y) the amount by which the aggregate fair saleable value of all properties of all of the Subsidiary Guarantors exceeds the amount of all the debts and liabilities (including contingent, subordinated, unmatured and unliquidated liabilities, but excluding the obligations of each Borrower and the Subsidiary Guarantors hereunder and under the other Loan Documents) of all of the Subsidiary Guarantors, determined (A) with respect to any Subsidiary Guarantor that is a party hereto on the first Borrowing Date, as of such Borrowing Date, and (B) with respect to any other Subsidiary Guarantor, as of the date such Subsidiary Guarantor becomes a Subsidiary Guarantor hereunder.

**14.09 General Limitation on Guaranteed Obligations.** In any action or proceeding involving any provincial, territorial or state corporate law, or any state or federal bankruptcy, insolvency, reorganization or other law affecting the rights of creditors generally, if the obligations of any Subsidiary Guarantor under **Section 14.01** (and/or any Borrower under **Section 13.22** to the extent such co-borrowership would be deemed to constitute a guarantee by any Borrower under the laws of its jurisdiction of incorporation) would otherwise, taking into account the provisions of **Section 14.08**, be held or determined to be void, invalid or unenforceable, or subordinated to the claims of any other creditors, on account of the amount of its liability under **Section 14.01** (and/or **Section 13.22**, as applicable), then, notwithstanding any other provision hereof to the

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contrary, the amount of such liability shall, without any further action by such Subsidiary Guarantor (or, in relation to **Section 13.22**, Borrower), any Secured Party or any other Person, be automatically limited and reduced to the highest amount that is valid and enforceable and not subordinated to the claims of other creditors as determined in such action or proceeding..

**14.10 Irish Companies Act Limitation on Guaranteed Obligations.** The guarantee in Section 14.01 does not apply to any liability to the extent that it would result in such guarantee constituting unlawful financial assistance within the meaning of Section 82 of the Irish Companies Act.

## **SECTION 15 INTERCOMPANY SUBORDINATION AGREEMENT**

### **15.01 Subordination of Intercompany Obligations.**

(a) Each Obligor agrees that all Subordinated Intercompany Indebtedness shall be subordinate and junior in right of payment, to the extent and in the manner hereinafter set forth, to all Obligations of the Obligors under this Agreement (and other indebtedness and obligations in connection with any renewal, refunding, restructuring or refinancing thereof, including interest thereon accruing after the commencement of any proceedings referred to in clause (b) below, whether or not such interest is an allowed claim in such proceeding, being hereinafter collectively referred to in this **Section 15.01** as “*Senior Indebtedness*”). For purposes hereof, “*Subordinated Intercompany Indebtedness*” shall mean all obligations, liabilities and Indebtedness of an Obligor owed to another Obligor, whether direct or indirect, absolute or contingent, due or to become due, or now existing or hereafter incurred, including without limitation, principal, premium (if any), interest, fees, charges, expenses, costs, professional fees and expenses and reimbursement obligations.

(b) In the event of any insolvency or bankruptcy proceedings, and any receivership, examinership, liquidation, reorganization or other similar proceedings in connection therewith, relative to any Obligor or to its creditors, as such, or to its property, and in the event of any proceedings for voluntary liquidation, dissolution or other winding up of such Obligor, whether or not involving insolvency or bankruptcy (other than in connection with, or pursuant to, the Permitted Restructuring), then (x) the holders of Senior Indebtedness shall be paid in full in cash in respect of all amounts constituting Senior Indebtedness before any other Obligor is entitled to receive (whether directly or indirectly), or make any demands for, any payment on account of any Subordinated Intercompany Indebtedness and (y) until the holders of Senior Indebtedness are paid in full in cash in respect of all amounts constituting Senior Indebtedness, any payment or distribution to which such Obligor would otherwise be entitled (other than debt securities of such Obligor that are subordinated, to at least the same extent as this **Section 15.01**, to the

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payment of all Senior Indebtedness then outstanding (such securities being hereinafter referred to in this **Section 15.01** as “*Restructured Debt Securities*”) shall be made to the holders of Senior Indebtedness.

(c) Upon the occurrence and during the continuation of an Event of Default, each Obligor agrees it shall not make, and shall not be entitled to receive, any payment or distribution of any kind or character with respect to the Subordinated Intercompany Indebtedness except as expressly permitted under this **Section 15.01**.

(d) If any payment or distribution of any character by any Obligor, whether in cash, securities or other property (other than Restructured Debt Securities), in respect of any Subordinated Intercompany Indebtedness shall (despite these subordination provisions) be received by any such Obligor in violation of clause (a) or (b) before all Senior Indebtedness shall have been paid in full in cash, such payment or distribution shall be held in trust for the benefit of, and shall be paid over or delivered to the Administrative Agent, as applicable, on behalf of the holders of Obligations, to the extent necessary to pay all Senior Indebtedness in full in cash.

(e) To the fullest extent permitted by law, no present or future holder of Senior Indebtedness shall be prejudiced in its right to enforce the subordination of this **Section 15.01** by any act or failure to act on the part of any such Obligor or by any act or failure to act on the part of such holder or any trustee or agent for such holder.

(f) This **Section 15.01** is intended to constitute and shall be deemed to constitute a “subordination agreement” within the meaning of Section 510(a) of the Bankruptcy Code and is intended and shall be interpreted to be enforceable against the Obligors to the maximum extent permitted pursuant to applicable non-bankruptcy law. All references to any Obligor shall include such Obligor as debtor and debtor-in-possession and any receiver or trustee for such Obligor in connection with any case under the Bankruptcy Code or in connection with any Insolvency Proceeding.

(g) Nothing contained in this **Section 15.01** is intended to or will impair, as between the Obligors, the obligations of any Obligor, which are absolute and unconditional, to pay to such other Obligor the principal of and interest on the intercompany Indebtedness as and when due and payable in accordance with its terms, or is intended to or will affect the relative rights of such payee and other creditors of such payor other than the holders of Senior Indebtedness.

[Signature Pages Follow]

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed and delivered as of the day and year first above written.

BORROWERS:

**STRONGBRIDGE U.S. INC.**

By \_\_\_\_\_

Name: Stephen J. Long  
Title: Chief Legal Officer

Address for Notices:  
900 Northbrook Drive  
Suite 200  
Trevose, PA 19053  
Attn: Chief Legal Officer  
Tel.: 610-254-9225  
Fax: 215-355-7389  
Email: s.long@strongbridgebio.com

**STRONGBRIDGE BIOPHARMA PLC**

By \_\_\_\_\_

Name: A. Brian Davis  
Title: Chief Financial Officer

Address for Notices:  
900 Northbrook Drive  
Suite 200  
Trevose, PA 19053  
Attn: Chief Legal Officer  
Tel.: 610-254-9225  
Fax: 215-355-7389  
Email: s.long@strongbridgebio.com

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**CORTENDO AB (PUBL)**

By \_\_\_\_\_

Name: Stephen J. Long  
Title: Authorized Signatory

Address for Notices:  
900 Northbrook Drive  
Suite 200  
Trevose, PA 19053  
Attn: Chief Legal Officer  
Tel.: 610-254-9225  
Fax: 215-355-7389  
Email: s.long@strongbridgebio.com

**CORTENDO CAYMAN LTD.**

By \_\_\_\_\_

Name: A. Brian Davis  
Title: Director

Address for Notices:  
900 Northbrook Drive  
Suite 200  
Trevose, PA 19053  
Attn: Chief Legal Officer  
Tel.: 610-254-9225  
Fax: 215-355-7389  
Email: s.long@strongbridgebio.com

**STRONGBRIDGE IRELAND LIMITED**

By \_\_\_\_\_

Name: Stephen J. Long  
Title: Secretary

Address for Notices:  
900 Northbrook Drive  
Suite 200  
Trevose, PA 19053

---

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MATERIAL HAS BEEN FILED SEPARATELY WITH THE  
COMMISSION.**

Attn: Chief Legal Officer  
Tel.: 610-254-9225  
Fax: 215-355-7389  
Email: [s.long@strongbridgebio.com](mailto:s.long@strongbridgebio.com)

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ADMINISTRATIVE AGENT:

**CRG SERVICING LLC**

By

\_\_\_\_\_  
Name:  
Title:

Address for Notices:  
1000 Main Street, Suite 2500  
Houston, TX 77002  
Attn: Portfolio Reporting  
Tel.: 713.209.7350  
Fax: 713.209.7351  
Email: [notices@crglp.com](mailto:notices@crglp.com)

---

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LENDERS:

**CRG PARTNERS III L.P.**

By CRG PARTNERS III GP L.P., its General Partner  
By CRG PARTNERS III GP LLC, its General Partner

By \_\_\_\_\_  
Name:  
Title:

Address for Notices:  
1000 Main Street, Suite 2500  
Houston, TX 77002  
Attn: Portfolio Reporting  
Tel.: 713.209.7350  
Fax: 713.209.7351  
Email: notices@crglp.com

**CRG PARTNERS III – PARALLEL FUND “A” L.P.**

By CRG PARTNERS III – PARALLEL FUND “A” GP L.P., its General Partner  
Partner  
By CRG PARTNERS III – PARALLEL FUND “A” GP LLC, its General Partner

By \_\_\_\_\_  
Name:  
Title:

Address for Notices:  
1000 Main Street, Suite 2500  
Houston, TX 77002  
Attn: Portfolio Reporting  
Tel.: 713.209.7350  
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**CRG PARTNERS III (CAYMAN) LEV AIV I L.P.**

By CRG PARTNERS III (CAYMAN) GP L.P., its General Partner  
By CRG PARTNERS III (CAYMAN) GP LLC, its General Partner

By \_\_\_\_\_  
Name: Nathan Hukill  
Title: Authorized Signatory

Witness: \_\_\_\_\_

Name: \_\_\_\_\_

Address for Notices:  
1000 Main Street, Suite 2500  
Houston, TX 77002  
Attn: Portfolio Reporting  
Tel.: 713.209.7350  
Fax: 713.209.7351  
Email: notices@crglp.com

**CRG PARTNERS III (CAYMAN) UNLEV AIV I L.P.**

By CRG PARTNERS III (CAYMAN) GP L.P., its General Partner  
By CRG PARTNERS III (CAYMAN) GP LLC, its General Partner

By \_\_\_\_\_  
Name: Nathan Hukill  
Title: Authorized Signatory

Witness: \_\_\_\_\_

Name: \_\_\_\_\_

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Tel.: 713.209.7350  
Fax: 713.209.7351  
Email: notices@crglp.com

**CRG PARTNERS III - PARALLEL FUND "B" (CAYMAN) L.P.**  
By CRG PARTNERS III (CAYMAN) GP L.P., its General Partner  
By CRG PARTNERS III (CAYMAN) GP LLC, its General Partner

By \_\_\_\_\_  
Name:  
Title:

Witness: \_\_\_\_\_

Name: \_\_\_\_\_

Address for Notices:  
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VCOC LENDER:

**CRG PARTNERS III L.P.**

By CRG PARTNERS III GP L.P., its General Partner

By CRG PARTNERS III GP LLC, its General Partner

By \_\_\_\_\_

Name:

Title:

Address for Notices:

1000 Main Street, Suite 2500

Houston, TX 77002

Attn: Portfolio Reporting

Tel.: 713.209.7350

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Schedule 1  
to Term Loan Agreement

COMMITMENTS

Lender	Commitment	Proportionate Share
CRG Partners III – Parallel Fund “A” L.P.	\$8,300,000.00	8.30%
CRG Partners III L.P.	\$16,700,000.00	16.70%
CRG Partners III (Cayman) Lev AIV I L.P.	\$30,230,000.00	30.23%
CRG Partners III (Cayman) Unlev AIV I L.P.	\$5,270,000.00	5.27%
CRG Partners III – Parallel Fund “B” (Cayman) L.P.	\$39,500,000.00	39.50%
<b>TOTAL</b>	<b>\$100,000,000</b>	<b>100%</b>

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**Schedule 6.01  
to Term Loan Agreement**

FOREIGN SECURITY DOCUMENTS

1. Swedish share pledge agreement entered into by Strongbridge Biopharma plc with respect to the shares of Cortendo AB (publ)
  2. Swedish IP Pledge Agreement entered into by Cortendo AB (publ)
  3. Irish Debenture entered into by Strongbridge Biopharma plc
  4. Cayman Share Charge entered into by Cortendo AB (publ) with respect to the shares of Cortendo Cayman Ltd.
  5. Cayman Fixed and Floating Charge entered into by Cortendo Cayman Ltd.
-

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**Schedule 7.05(b)(i)  
to Term Loan Agreement**

CERTAIN INTELLECTUAL PROPERTY

[See attached.]

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**SCHEDULE 7.05(b)(i)- Intellectual Property**

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**COR-003**

<b>Title / Owner / Inventor</b>	<b>Country/Number</b>
<b>Methods And Compositions For Treating Diabetes, Metabolic Syndrome And Other Conditions</b>  <b>Cortendo AB</b>  <b>Per Märin</b>	Australia - 2006204334 Canada - 2594433 China - 101141964 Hong Kong - 1118449 Indonesia - 32847 Israel - 184459 Japan - 5358095 South Korea - 1013879100000 Mexico - 294589 New Zealand - 560481 Norway 339007 Singapore - 133978 South Africa - 2007/06020 Europe - 1853266 *countries designated (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SE, SL, SK, TR)  US 15/088,539
<b>Ketoconazole Enantiomer in Humans</b>  <b>Cortendo AB</b>  <b>Timothy Andrew Stewart</b>	US 9,198,906 New Zealand – 576569
<b>Methods And Compositions For The Treatment Of Cushing’s Syndrome Using 2S,4R Ketoconazole</b>  <b>Cortendo AB</b> <b>Theodore Richard Koziol (titration)</b>	15/468,217
<b>Ketoconazole Enantiomer in Humans</b>  <b>Cortendo AB</b>  <b>Timothy Andrew Stewart</b>  <b>(combination)</b>	US 14/944,258 (continuation application filed on January 9, 2018 under US 15/865,631)
<b>Pharmaceutical Compositions And Methods Of Treating Hormone-Refractory Cancers</b>  <b>Fred Cohen</b>	US 62/461,289 (Prov)

**SCHEDULE 7.05(b)(i)- Intellectual Property**

**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**COR-005**

<b>Title / Owner / Inventor</b>	<b>Country/Number</b>
<b>Conformationally Constrained Backbone Cyclized Somatostatin Analogues</b>  <b>Cortendo AB</b>  <b>Vered Hornik Gary Gellerman Michel M Afargan</b>  <b>*The patents in Europe, are in the process of being assigned from Aspireo to Cortendo AB</b>	US 7,060,679 Canada 2335488 Israel 139956 New Zealand 508956 South Africa 2000/7496 Europe 1085896 *countries designated (DE, ES, FR, IT, GB)
<b>Pharmaceutical Compositions Of Water Soluble Peptides With Poor Solubility In Isotonic Conditions And Methods For Their Use</b>  <b>Strongbridge Biopharma PLC</b>  <b>Michel Afargan</b>	PCT/IB17/00194  US 15/487,731

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SCHEDULE 7.05(b)(i)- Intellectual Property

CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.

NEXT GENERATION

Title / Owner / Inventor	Country/Number
<b>Novel Functionalized 4-(Phenoxymethyl(-1,3-Dioxolane Analogs Exhibiting Cytochrome P450 Inhibition And Their Method Of Use</b>  Cortendo AB  Wayne Childers Magid A. Abou-Gharbia Benjamin Eric Blass	CA 2898574
<b>Novel Cytochrome P450 Inhibitors And Their Method Of Use</b>  Cortendo AB  Benjamin Eric Blass Magid A. Abou-Gharbia Wayne Childers Pravin Iyer Joshodeep Boruwa	US 15/021,532

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**SCHEDULE 7.05(b)(i)- Intellectual Property**

**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**TRADEMARKS**

<b>Mark/ Owner</b>	<b>Country/Number</b>
<b>NORMOCORT</b>	Europe - CTM 010869048
<b>Cortendo AB</b> <b>STRONGBRIDGE</b> <b>BIOPHARMA</b>	WO 1279854  US 86/701,398  Australia 1279854 China 1279854 Europe - CTM 1279854 Israel 1279854  India 1279854 Japan 1279854 Mexico 1279854 Turkey 1279854 Brazil 910544115 Canada 1741329
<b>Cortendo AB</b>	
<b>CORYNTHIA</b>	WO 1284986
<b>Cortendo AB</b>	US 86/758,862  Australia 1284986 China 1284986 Europe - CTM 1284986 Israel 1284986 India 1284986 Japan 1284986 Turkey 1284986 Brazil 910758875 Canada 1746437
<b>RECORLEV</b>	WO 1297646
<b>Cortendo AB</b>	US 86/865,505  Canada 1761974 Brazil 911007903 Australia 1297646 China 1297646 Europe - CTM 1297646 Israel 1297646 India 1297646 Japan 1297646

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SCHEDULE 7.05(b)(i)- Intellectual Property

CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.

	Mexico 1297646 Turkey 1297646
<b>KEVEYIS</b> <b>Taro Pharmaceuticals</b>	US 5,034,655

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**Schedule 7.05(b)(ii)  
to Term Loan Agreement**

**INTELLECTUAL PROPERTY EXCEPTIONS**

None.

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R.  
SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*]  
INDICATES OMITTED MATERIAL THAT IS THE SUBJECT  
OF A CONFIDENTIAL TREATMENT REQUEST FILED  
SEPARATELY WITH THE COMMISSION. THE OMITTED  
MATERIAL HAS BEEN FILED SEPARATELY WITH THE  
COMMISSION.**

**Schedule 7.05(c)  
to Term Loan Agreement**

MATERIAL INTELLECTUAL PROPERTY

[See attached.]

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CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.

SCHEDULE 7.05(c)- Material Intellectual Property  
Patents and Patent Applications

COR-003

Title / Owner / Inventor	Country/Number
<b>Methods And Compositions For Treating Diabetes, Metabolic Syndrome And Other Conditions</b>  <b>Cortendo AB</b>  <b>Per Mårin</b>	Canada - 2594433 Europe - 1853266 *countries designated (DE, ES, FR, GB, IT)  US 15/088,539
<b>Ketoconazole Enantiomer in Humans Cortendo AB</b>  <b>Timothy Andrew Stewart</b>	US 9,198,906

COR-005

Title / Owner / Inventor	Country/Number
<b>Pharmaceutical Compositions Of Water Soluble Peptides With Poor Solubility In Isotonic Conditions And Methods For Their Use</b>  <b>Strongbridge Biopharma PLC Michel Afargan</b>	PCT/IB17/00194  US 15/487,731

**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**SCHEDULE 7.05(c)- Material Intellectual Property  
Trademarks and Trademark Applications**

<b>Mark / Owner</b>	<b>Country/Number</b>
<b>STRONGBRIDGE BIOPHARMA</b>	US 86/701,398
<b>Cortendo AB</b>	Europe - CTM 1279854 Canada 1741329
<b>RECORLEV</b>	US 86/865,505
<b>Cortendo AB</b>	Canada 1761974 Europe - CTM 1297646
<b>KEVEYIS</b>	US 5,034,655
<b>Taro Pharmaceuticals</b>	

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**Schedule 7.06  
to Term Loan Agreement**

CERTAIN LITIGATION

None.

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**Schedule 7.12  
to Term Loan Agreement**

**INFORMATION REGARDING SUBSIDIARIES**

<b>Subsidiary</b>	<b>Jurisdiction of Organization</b>	<b>Direct Equity Holder</b>	<b>Percentage of Subsidiary held by Direct Equity Holder</b>
Cortendo AB (publ)	Sweden	Strongbridge Biopharma plc	100%
Strongbridge U.S. Inc.	Delaware	Cortendo AB (publ)	100%
Cortendo Cayman Ltd.	Cayman Islands	Cortendo AB (publ)	100%
Strongbridge Ireland Limited	Ireland	Strongbridge Biopharma plc	100%

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CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.

Schedule 7.13(a)  
to Term Loan Agreement

EXISTING INDEBTEDNESS OF BORROWER AND ITS SUBSIDIARIES

Part I

None.

Part II

None.

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**Schedule 7.13(b)  
to Term Loan Agreement**

LIENS GRANTED BY THE OBLIGORS

Part I

1. Security deposit in the amount of \$39,314.72 in favor of landlord at 900 Northbrook Dr., Suite 200, Trevose, PA, 19053.
2. Security deposit in the amount of \$10,000 in favor of landlord at 555 E. Lancaster Ave., Radnor, PA 19087.
3. Sublease on leased property of Strongbridge U.S. Inc. at 555 E. Lancaster Ave., Radnor, PA 19087.

Part II

1. Security deposit in the amount of \$39,314.72 in favor of landlord at 900 Northbrook Dr., Suite 200, Trevose, PA, 19053.
  2. Security deposit in the amount of \$10,000 in favor of landlord at 555 E. Lancaster Ave., Radnor, PA 19087.
  3. Sublease on leased property of Strongbridge U.S. Inc. at 555 E. Lancaster Ave., Radnor, PA 19087.
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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**Schedule 7.14  
to Term Loan Agreement**

MATERIAL AGREEMENTS OF OBLIGORS

1. Asset Purchase Agreement, dated as of December 12, 2016, between Taro Pharmaceutical North America, Inc. and Strongbridge Biopharma plc.
  2. Supply Agreement, dated as of December 12, 2016, between Taro Pharmaceutical North America, Inc. and Strongbridge Biopharma plc.
  3. License and Assignment Agreement, dated as of January 16, 2018, between Aeterna Zentaris GmbH and Strongbridge Ireland Limited.
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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**Schedule 7.15  
to Term Loan Agreement**

RESTRICTIVE AGREEMENTS

None.

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**Schedule 7.16  
to Term Loan Agreement**

REAL PROPERTY OWNED OR LEASED BY BORROWER OR ANY SUBSIDIARY

1. Owned Property

None

2. Leased Property

<u>Name of Borrower</u>	<u>Address/City/State/Zip Code (County)</u>	<u>Description of Assets and Value</u>
Strongbridge U.S. Inc.	900 Northbrook Dr, Trevoise PA	Leased office
Strongbridge U.S. Inc.	555 E Lancaster Ave Radnor PA	Leased office*
*This has been subleased out		

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**Schedule 7.17  
to Term Loan Agreement**

PENSION MATTERS

None.

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**Schedule 9.05  
to Term Loan Agreement**

EXISTING INVESTMENTS

None.

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**Schedule 9.10  
to Term Loan Agreement**

TRANSACTIONS WITH AFFILIATES

None.

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**Schedule 9.14  
to Term Loan Agreement**

PERMITTED SALES AND LEASEBACKS

None.

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CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.

Exhibit A  
to Term Loan Agreement

FORM OF [GUARANTEE][CO-BORROWER] ASSUMPTION AGREEMENT

[GUARANTEE][CO-BORROWER] ASSUMPTION AGREEMENT dated as of [DATE] by [NAME OF ADDITIONAL [SUBSIDIARY GUARANTOR][BORROWER], a \_\_\_\_\_ [corporation][limited liability company][*other type of business entity*] (the "**Additional Obligor**")], in favor of CRG SERVICING LLC, as administrative agent and collateral agent (the "**Administrative Agent**") for the benefit of the Secured Parties under that certain Term Loan Agreement, dated as of July 14, 2017 (as amended, amended and restated, supplemented or otherwise modified, renewed, refinanced or replaced, the "**Loan Agreement**"), among STRONGBRIDGE U.S. INC., a Delaware corporation ("**U.S. Borrower**"), STRONGBRIDGE BIOPHARMA PUBLIC LIMITED COMPANY, a public limited company incorporated under the laws of Ireland ("**Parent**"), STRONGBRIDGE IRELAND LIMITED, a private limited company incorporated under the laws of Ireland ("**Irish Borrower**"), CORTENDO CAYMAN LTD., an exempted company incorporated in the Cayman Islands ("**Cayman Borrower**"), CORTENDO AB (PUBL), a public limited liability company incorporated under the laws of Sweden with registration number 556537-6554 ("**Swedish Borrower**") and together with the U.S. Borrower, Parent, Irish Borrower, Cayman Borrower, and each other Person that becomes, or is required to become, a "Borrower" after the date hereof pursuant to **Section 8.12(a)** or **(b)** thereof, each a "**Borrower**" and collectively, "**Borrowers**"), Administrative Agent, the lenders from time to time party thereto and the Subsidiary Guarantors from time to time party thereto. The terms defined in the Loan Agreement are herein used as therein defined.

Pursuant to **Section 8.12(a)** of the Loan Agreement, the Additional Obligor hereby agrees to become a ["Subsidiary Guarantor"] ["Borrower"] for all purposes of the Loan Agreement, and a "Grantor" for all purposes of the Security Agreement. Without limiting the foregoing, the Additional Obligor hereby[, jointly and severally with the other Guarantors, guarantees to the Lenders and their successors and assigns the prompt payment in full when due (whether at stated maturity, by acceleration or otherwise) of all Guaranteed Obligations (as defined in **Section 14.01** of the Loan Agreement) in the same manner and to the same extent as is provided in **Section 14** of the Loan Agreement][assumes all Obligations on an absolute and unconditional, joint and several with the other Borrowers, basis, irrespective of the value, genuineness, validity, regularity or enforceability of the Obligations of any Obligor or any substitution, release or exchange of any other guarantee of or security for any of the Obligations, and, to the fullest extent permitted by applicable law, irrespective of any other circumstance whatsoever that might otherwise constitute a legal or equitable discharge or defense of a surety or guarantor, as further provided under **Section 13.22** of the Loan Agreement]. In addition, as of the date hereof, the Additional Obligor hereby makes the representations and warranties set forth in **Sections 7.01, 7.02, 7.03, 7.05(a), 7.06, 7.07, 7.08** and **7.18** of the Loan Agreement, and in **Section 2** of the Security Agreement, with respect to itself and its obligations under this Agreement and the other

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

Loan Documents, as if each reference in such Sections to the Loan Documents included reference to this Agreement, such representations and warranties to be made as of the date hereof.

The Additional Obligor hereby instructs its counsel to deliver the opinions referred to in **Section 8.12(a)** of the Loan Agreement to Administrative Agent.

IN WITNESS WHEREOF, the Additional Obligor has caused this [Borrower][Guarantee] Assumption Agreement to be duly executed and delivered as of the day and year first above written.

[ADDITIONAL SUBSIDIARY  
GUARANTOR][BORROWER]

By \_\_\_\_\_  
Name:  
Title:

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CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.

Exhibit C-1  
to Term Loan Agreement

FORM OF U.S. TAX COMPLIANCE CERTIFICATE

(For Foreign Lenders That Are Not Partnerships For U.S. Federal Income Tax Purposes)

Reference is hereby made to the Term Loan Agreement dated as of July 14, 2017 (as amended by Amendment No. 1 dated as of January [ ], 2018 and as further amended, amended and restated, supplemented or otherwise modified from time to time, the "*Loan Agreement*"), among STRONGBRIDGE U.S. INC., a Delaware corporation (the "*Lead Borrower*"), STRONGBRIDGE BIOPHARMA PUBLIC LIMITED COMPANY, a public limited company incorporated under the laws of Ireland ("*Parent*"), STRONGBRIDGE IRELAND LIMITED, a private limited company incorporated under the laws of Ireland ("*Irish Borrower*"), CORTENDO CAYMAN LTD., an exempted company incorporated in the Cayman Islands ("*Cayman Borrower*"), CORTENDO AB (PUBL), a public limited liability company incorporated under the laws of Sweden with registration number 556537-6554 ("*Swedish Borrower*") and together with the Lead Borrower, Parent, Irish Borrower, Cayman Borrower and each other Person that becomes, or is required to become, a "Borrower" after the date thereof pursuant to Section 8.12(a) or (b) thereof, each a "*Borrower*" and collectively, "*Borrowers*"), CRG Servicing LLC, as administrative agent and collateral agent (in such capacities, the "*Administrative Agent*"), and each lender from time to time party thereto.

Pursuant to the provisions of Section 5.03 of the Term Loan Agreement, the undersigned hereby certifies that (i) it is the sole record and beneficial owner of the Loan(s) in respect of which it is providing this certificate, (ii) it is not a bank within the meaning of Section 881(c)(3)(A) of the Code, (iii) it is not a ten percent shareholder of the Borrowers within the meaning of Section 871(h)(3)(B) of the Code and (iv) it is not a controlled foreign corporation related to the Borrowers as described in Section 881(c)(3)(C) of the Code.

The undersigned has furnished the Administrative Agent and the Borrower with a certificate of its non-U.S. Person status on IRS Form W-8BEN or W-8BEN-E, as applicable. By executing this certificate, the undersigned agrees that (1) if the information provided on this certificate changes, the undersigned shall promptly so inform the Lead Borrower and the Administrative Agent, and (2) the undersigned shall have at all times furnished the Lead Borrower and the Administrative Agent with a properly completed and currently effective certificate in either the calendar year in which each payment is to be made to the undersigned, or in either of the two calendar years preceding such payments.

Exhibit C-1-1

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

Unless otherwise defined herein, terms defined in the Loan Agreement and used herein shall have the meanings given to them in the Loan Agreement.

[Signature follows]

Exhibit C-1-2

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

IN WITNESS WHEREOF, the undersigned has caused this certificate to be duly executed and delivered as of the date indicated below.

[NAME OF NON-U.S. LENDER]

By \_\_\_\_\_

Name:

Title:

Date: \_\_\_\_\_

CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.

Exhibit C-2  
to Term Loan Agreement

FORM OF U.S. TAX COMPLIANCE CERTIFICATE

(For Foreign Participants That Are Not Partnerships For U.S. Federal Income Tax Purposes)

Reference is hereby made to the Term Loan Agreement dated as of July 14, 2017 (as amended by Amendment No. 1 dated as of January 16, 2018 and as further amended, amended and restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"), among STRONGBRIDGE U.S. INC., a Delaware corporation ("**Lead Borrower**"), STRONGBRIDGE BIOPHARMA PUBLIC LIMITED COMPANY, a public limited company incorporated under the laws of Ireland ("**Parent**"), STRONGBRIDGE IRELAND LIMITED, a private limited company incorporated under the laws of Ireland ("**Irish Borrower**"), CORTENDO CAYMAN LTD., an exempted company incorporated in the Cayman Islands ("**Cayman Borrower**"), CORTENDO AB (PUBL), a public limited liability company incorporated under the laws of Sweden with registration number 556537-6554 ("**Swedish Borrower**") and together with the Lead Borrower, Parent, Irish Borrower, Cayman Borrower and each other Person that becomes, or is required to become, a "Borrower" after the date thereof pursuant to **Section 8.12(a)** or **(b)** thereof, each a "**Borrower**" and collectively, "**Borrowers**"), CRG Servicing LLC, as administrative agent and collateral agent (in such capacities, the "**Administrative Agent**"), and each lender from time to time party thereto.

Pursuant to the provisions of Section 5.03 of the Loan Agreement, the undersigned hereby certifies that (i) it is the sole record and beneficial owner of the participation in respect of which it is providing this certificate, (ii) it is not a bank within the meaning of Section 881(c)(3)(A) of the Code, (iii) it is not a ten percent shareholder of the Borrowers within the meaning of Section 871(h)(3)(B) of the Code, and (iv) it is not a controlled foreign corporation related to the Borrowers as described in Section 881(c)(3)(C) of the Code.

The undersigned has furnished its participating Lender with a certificate of its non-U.S. Person status on IRS Form W-8BEN or W-8BEN-E, as applicable. By executing this certificate, the undersigned agrees that (1) if the information provided on this certificate changes, the undersigned shall promptly so inform such Lender in writing, and (2) the undersigned shall have at all times furnished such Lender with a properly completed and currently effective certificate in either the calendar year in which each payment is to be made to the undersigned, or in either of the two calendar years preceding such payments.

Exhibit C-2-1

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

Unless otherwise defined herein, terms defined in the Loan Agreement and used herein shall have the meanings given to them in the Loan Agreement.

[Signature follows]

Exhibit C-2-2

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

IN WITNESS WHEREOF, the undersigned has caused this certificate to be duly executed and delivered as of the date indicated below.

[NAME OF NON-U.S. PARTICIPANT]

By \_\_\_\_\_

Name:

Title:

Date: \_\_\_\_\_

CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.

Exhibit C-3  
to Term Loan Agreement

FORM OF U.S. TAX COMPLIANCE CERTIFICATE

(For Foreign Participants That Are Partnerships For U.S. Federal Income Tax Purposes)

Reference is hereby made to the Term Loan Agreement dated as of July 14, 2017 (as amended by Amendment No. 1 dated as of January 16, 2018 and as further amended, amended and restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"), among STRONGBRIDGE U.S. INC., a Delaware corporation ("**Lead Borrower**"), STRONGBRIDGE BIOPHARMA PUBLIC LIMITED COMPANY, a public limited company incorporated under the laws of Ireland ("**Parent**"), STRONGBRIDGE IRELAND LIMITED, a private limited company incorporated under the laws of Ireland ("**Irish Borrower**"), CORTENDO CAYMAN LTD., an exempted company incorporated in the Cayman Islands ("**Cayman Borrower**"), CORTENDO AB (PUBL), a public limited liability company incorporated under the laws of Sweden with registration number 556537-6554 ("**Swedish Borrower**") and together with the Lead Borrower, Parent, Irish Borrower, Cayman Borrower and each other Person that becomes, or is required to become, a "Borrower" after the date thereof pursuant to **Section 8.12(a)** or **(b)** thereof, each a "**Borrower**" and collectively, "**Borrowers**"), CRG Servicing LLC, as administrative agent and collateral agent (in such capacities, the "**Administrative Agent**"), and each lender from time to time party thereto.

Pursuant to the provisions of Section 5.03 of the Loan Agreement, the undersigned hereby certifies that (i) it is the sole record owner of the participation in respect of which it is providing this certificate, (ii) its direct or indirect partners/members are the sole beneficial owners of such participation, (iii) with respect such participation, neither the undersigned nor any of its direct or indirect partners/members is a bank extending credit pursuant to a loan agreement entered into in the ordinary course of its trade or business within the meaning of Section 881(c)(3)(A) of the Code, (iv) none of its direct or indirect partners/members is a ten percent shareholder of the Borrower within the meaning of Section 871(h)(3)(B) of the Code and (v) none of its direct or indirect partners/members is a controlled foreign corporation related to the Borrowers as described in Section 881(c)(3)(C) of the Code.

The undersigned has furnished its participating Lender with IRS Form W-8IMY accompanied by one of the following forms from each of its partners/members that is claiming the portfolio interest exemption: (i) an IRS Form W-8BEN or W-8BEN-E, as applicable, or (ii) an IRS Form W-8IMY accompanied by an IRS Form W-8BEN or W-8BEN-E, as applicable, from each of such partner's/member's beneficial owners that is claiming the portfolio interest exemption. By executing this certificate, the undersigned agrees that (1) if the information

Exhibit C-3-1

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

provided on this certificate changes, the undersigned shall promptly so inform such Lender and (2) the undersigned shall have at all times furnished such Lender with a properly completed and currently effective certificate in either the calendar year in which each payment is to be made to the undersigned, or in either of the two calendar years preceding such payments.

Unless otherwise defined herein, terms defined in the Loan Agreement and used herein shall have the meanings given to them in the Loan Agreement.

[Signature follows]

Exhibit C-3-2

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

IN WITNESS WHEREOF, the undersigned has caused this certificate to be duly executed and delivered as of the date indicated below.

[NAME OF NON-U.S. PARTICIPANT]

By \_\_\_\_\_

Name:

Title:

Date: \_\_\_\_\_

CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.

Exhibit C-4  
to Term Loan Agreement

FORM OF U.S. TAX COMPLIANCE CERTIFICATE

(For Foreign Lenders That Are Partnerships For U.S. Federal Income Tax Purposes)

Reference is hereby made to the Term Loan Agreement dated as of July 14, 2017 (as amended by Amendment No. 1 dated as of January 16, 2018 and as further amended, amended and restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"), among STRONGBRIDGE U.S. INC., a Delaware corporation ("**Lead Borrower**"), STRONGBRIDGE BIOPHARMA PUBLIC LIMITED COMPANY, a public limited company incorporated under the laws of Ireland ("**Parent**"), STRONGBRIDGE IRELAND LIMITED, a private limited company incorporated under the laws of Ireland ("**Irish Borrower**"), CORTENDO CAYMAN LTD., an exempted company incorporated in the Cayman Islands ("**Cayman Borrower**"), CORTENDO AB (PUBL), a public limited liability company incorporated under the laws of Sweden with registration number 556537-6554 ("**Swedish Borrower**") and together with the Lead Borrower, Parent, Irish Borrower, Cayman Borrower and each other Person that becomes, or is required to become, a "Borrower" after the date thereof pursuant to **Section 8.12(a)** or **(b)** thereof, each a "**Borrower**" and collectively, "**Borrowers**"), CRG Servicing LLC, as administrative agent and collateral agent (in such capacities, the "**Administrative Agent**"), and each lender from time to time party thereto.

Pursuant to the provisions of Section 5.03 of the Loan Agreement, the undersigned hereby certifies that (i) it is the sole record owner of the Loan(s) in respect of which it is providing this certificate, (ii) its direct or indirect partners/members are the sole beneficial owners of such Loan(s), (iii) with respect to the extension of credit pursuant to this Loan Agreement or any other Loan Document, neither the undersigned nor any of its direct or indirect partners/members is a bank extending credit pursuant to a loan agreement entered into in the ordinary course of its trade or business within the meaning of Section 881(c)(3)(A) of the Code, (iv) none of its direct or indirect partners/members is a ten percent shareholder of the Borrower within the meaning of Section 871(h)(3)(B) of the Code and (v) none of its direct or indirect partners/members is a controlled foreign corporation related to the Borrowers as described in Section 881(c)(3)(C) of the Code.

The undersigned has furnished the Administrative Agent and the Borrower with IRS Form W-8IMY accompanied by one of the following forms from each of its partners/members that is claiming the portfolio interest exemption: (i) an IRS Form W-8BEN or W-8BEN-E, as applicable, or (ii) an IRS Form W-8IMY accompanied by an IRS Form W-8BEN or W-8BEN-E, as applicable, from each of such partner's/member's beneficial owners that is claiming the

Exhibit C-4-1

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

portfolio interest exemption. By executing this certificate, the undersigned agrees that (1) if the information provided on this certificate changes, the undersigned shall promptly so inform the Lead Borrower and the Administrative Agent, and (2) the undersigned shall have at all times furnished the Lead Borrower and the Administrative Agent with a properly completed and currently effective certificate in either the calendar year in which each payment is to be made to the undersigned, or in either of the two calendar years preceding such payments.

Unless otherwise defined herein, terms defined in the Loan Agreement and used herein shall have the meanings given to them in the Loan Agreement.

[Signature follows]

Exhibit C-3-2

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

IN WITNESS WHEREOF, the undersigned has caused this certificate to be duly executed and delivered as of the date indicated below.

[NAME OF NON-U.S. LENDER]

By \_\_\_\_\_

Name:

Title:

Date: \_\_\_\_\_



CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.

Exhibit D  
to Term Loan Agreement

FORM OF COMPLIANCE CERTIFICATE

[DATE]

This certificate is delivered pursuant to **Section 8.01(d)** of the Term Loan Agreement, dated as of July 14, 2017 (as the same may be amended, amended and restated, supplemented or otherwise modified from time to time, the "*Loan Agreement*"), among STRONGBRIDGE U.S. INC., a Delaware corporation ("*Lead Borrower*"), STRONGBRIDGE BIOPHARMA PUBLIC LIMITED COMPANY, a public limited company incorporated under the laws of Ireland ("*Parent*"), STRONGBRIDGE IRELAND LIMITED, a private limited company incorporated under the laws of Ireland, CORTENDO CAYMAN LTD., an exempted company incorporated in the Cayman Islands, CORTENDO AB (PUBL), a public limited liability company incorporated under the laws of Sweden with registration number 556537-6554, CRG Servicing LLC, as administrative agent and collateral agent (in such capacities, the "*Administrative Agent*"), and the lenders, the other borrowers from time to time party thereto and the subsidiary guarantors from time to time party thereto. Capitalized terms used herein and not otherwise defined herein are used herein as defined in the Loan Agreement.

The undersigned, a duly authorized Responsible Officer of Lead Borrower having the name and title set forth below under his signature, hereby certifies, on behalf of Lead Borrower for the benefit of the Secured Parties and pursuant to **Section 8.01(d)** of the Loan Agreement that such Responsible Officer of Lead Borrower is familiar with the Loan Agreement and that, in accordance with each of the following sections of the Loan Agreement, each of the following is true on the date hereof, both before and after giving effect to any Loan to be made on or before the date hereof:

In accordance with Section **8.01(a)(b)** of the Loan Agreement, attached hereto as **Annex A** are the financial statements for the [fiscal quarter/fiscal year] ended [\_\_\_\_\_] required to be delivered pursuant to **Section 8.01(a)(b)** of the Loan Agreement. Such financial statements fairly present in all material respects the consolidated financial position, results of operations and cash flow of Parent and its Subsidiaries as at the dates indicated therein and for the periods indicated therein in accordance with GAAP [(subject to the absence of footnote disclosure and normal year-end audit adjustments)]<sup>1</sup> [without qualification as to the scope of the audit. The examination by such auditors in connection with such financial statements has been made in accordance with the standards of the United States' Public Company accounting Oversight Board (or any successor entity).]<sup>2</sup>

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<sup>1</sup> Insert language in brackets only for quarterly certifications.

<sup>2</sup> Insert language in brackets only for annual certifications.

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

Attached hereto as **Annex B** are the calculations used to determine compliance with each financial covenant contained in **Section 10** of the Loan Agreement.

No Default or Event of Default is continuing as of the date hereof[, except as provided for on **Annex C** attached hereto, with respect to each of which Lead Borrower proposes to take the actions set forth on **Annex C**].

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

IN WITNESS WHEREOF, the undersigned has executed this certificate on the date first written above.

**STRONGBRIDGE U.S. INC.**

By \_\_\_\_\_  
Name:  
Title:

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**Annex A to Compliance Certificate**

FINANCIAL STATEMENTS

[see attached]

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**Annex B to Compliance Certificate**

CALCULATIONS OF FINANCIAL COVENANT COMPLIANCE

<b>I.</b>	<b>Section 10.01: Minimum Liquidity</b>	
A.	Amount of unencumbered (other than by Liens described in <b>Sections 9.02(a), 9.02(c)</b> (provided that there is no default under the documentation governing the Permitted Priority Debt) and <b>9.02(j)</b> ) cash and Permitted Cash Equivalent Investments (which for greater certainty shall not include any undrawn credit lines), in each case, to the extent held in an account over which the Lenders have a perfected security interest:	\$ _____
B.	The greater of:	\$ _____
	(1) \$3,000,000 and	
	(2) to the extent Borrower has incurred Permitted Priority Debt, the minimum cash balance required of Borrower by Borrower's Permitted Priority Debt creditors	
	<i>Is Line IA greater than Line IB?:</i>	<i>Yes: In compliance; No: Not in compliance</i>
<b>II.</b>	<b>Section 10.02(a)-(e): Minimum Revenue—Subsequent Periods<sup>3</sup></b>	
A.	Revenues during the twelve month period beginning on January 1, 2017	\$ _____
	<i>[Is line II.A equal to or greater than \$[****]?</i>	<i>Yes: In compliance; No: Not in compliance<sup>4</sup></i>
B.	Revenues during the twelve month period beginning on January 1, 2018	\$ _____

<sup>3</sup> Include Part II starting with the Compliance Certificate to be delivered within 90 days of the end of 2017 pursuant to Section 8.01(d) of the Loan Agreement

<sup>4</sup> Include bracketed entry only on the Compliance Certificate to be delivered within 90 days of the end of 2017 pursuant to Section 8.01(d) of the Loan Agreement.

**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

	<i>[Is line II.B equal to or greater than \$[****]?</i>	<i>Yes: In compliance; No: Not in compliance]<sup>5</sup></i>
C.	Revenues during the twelve month period beginning on January 1, 2019	\$ _____
	<i>[Is line II.C equal to or greater than \$[****]?</i>	<i>Yes: In compliance; No: Not in compliance]<sup>6</sup></i>
D.	Revenues during the twelve month period beginning on January 1, 2020	\$ _____
	<i>[Is line II.D equal to or greater than \$[****]?</i>	<i>Yes: In compliance; No: Not in compliance]<sup>7</sup></i>
E.	Revenues during the twelve month period beginning on January 1, 2021	\$ _____
	<i>[Is line II.E equal to or greater than \$[****]?</i>	<i>Yes: In compliance; No: Not in compliance]<sup>8</sup></i>
F.	Revenues during the twelve month period beginning on January 1, 2022	\$ _____
	<i>[Is line II.E equal to or greater than \$[****]?</i>	<i>Yes: In compliance; No: Not in compliance]<sup>9</sup></i>

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<sup>5</sup> Include bracketed entry only on the Compliance Certificate to be delivered within 90 days of the end of 2018 pursuant to Section 8.01(d) of the Loan Agreement.

<sup>6</sup> Include bracketed entry only on the Compliance Certificate to be delivered within 90 days of the end of 2019 pursuant to Section 8.01(d) of the Loan Agreement.

<sup>7</sup> Include bracketed entry only on the Compliance Certificate to be delivered within 90 days of the end of 2020 pursuant to Section 8.01(d) of the Loan Agreement.

<sup>8</sup> Include bracketed entry only on the Compliance Certificate to be delivered within 90 days of the end of 2021 pursuant to Section 8.01(d) of the Loan Agreement.

<sup>9</sup> Include bracketed entry only on the Compliance Certificate to be delivered within 90 days of the end of 2022 pursuant to Section 8.01(d) of the Loan Agreement.

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CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.

Exhibit I  
to Term Loan Agreement

[FORM OF WARRANT]

THIS WARRANT AND THE UNDERLYING SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE “*ACT*”), OR UNDER THE SECURITIES LAWS OF ANY STATE. THESE SECURITIES MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED EXCEPT AS PERMITTED UNDER THE ACT AND APPLICABLE STATE SECURITIES LAWS IN ACCORDANCE WITH APPLICABLE REGISTRATION REQUIREMENTS OR AN EXEMPTION THEREFROM. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE ISSUER THAT SUCH OFFER, SALE, TRANSFER, PLEDGE OR HYPOTHECATION OTHERWISE COMPLIES WITH THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS. THIS WARRANT MUST BE SURRENDERED TO THE COMPANY OR ITS TRANSFER AGENT AS A CONDITION PRECEDENT TO THE SALE, TRANSFER, PLEDGE OR HYPOTHECATION OF ANY INTEREST IN ANY OF THE SECURITIES REPRESENTED HEREBY.

WARRANT TO PURCHASE ORDINARY SHARES  
OF  
STRONGBRIDGE BIOPHARMA PLC

Dated as of [ ], [ ] (the “Issue Date”)  
Void after the date specified in Section 8

Warrant to Purchase  
[ ] Ordinary Shares

(subject to adjustment)

THIS CERTIFIES THAT, for value received, [ ], or its registered assigns (the “*Holder*”), is entitled, subject to the provisions and upon the terms and conditions set forth herein, to purchase from STRONGBRIDGE BIOPHARMA PLC, a public limited company incorporated under the laws of Ireland (the “*Company*”), that number of shares (the “*Shares*”) of the Company’s ordinary shares, of nominal value \$0.01 per share (the “*Ordinary Shares*”), at such times and at the price per Share, set forth in Section 1. The term “*Warrant*” as used herein shall include this Warrant and any warrants delivered in substitution or exchange therefor as provided herein. This Warrant is issued in connection with the transactions described in the Term Loan Agreement, dated as of July 14, 2017, and amended as of January 16, 2018, by and between the Company, the Subsidiary Guarantors from time to time party thereto, the Lenders from time to time party thereto and CRG Servicing LLC.

The following is a statement of the rights of the Holder and the conditions to which this Warrant is subject, and to which Holder, by acceptance of this Warrant, agrees:

1. **Number and Price of Shares; Exercise Period.**

(a) *Number of Shares.* Subject to any previous exercise of the Warrant, the Holder shall have the right to purchase up to [ ] Shares, as may be adjusted pursuant hereto prior to (or in connection with) the expiration of this Warrant as provided in Section 8.

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

(b) *Exercise Price.* The exercise price per Share shall be equal to [ ], subject to adjustment pursuant hereto (the “*Exercise Price*”), provided however, the exercise price shall never be less than the nominal value of an Ordinary Share.

(c) *Exercise Period.* This Warrant shall be exercisable, in whole or in part, prior to (or in connection with) the expiration of this Warrant as set forth in Section 8.

## 2. Exercise of the Warrant.

(a) *Exercise.* The purchase rights represented by this Warrant may be exercised at the election of the Holder, in whole or in part, in accordance with Section 1, by:

(i) the tender to the Company at its principal office (or such other office or agency as the Company may designate) of a notice of exercise in the form of Exhibit A (the “*Notice of Exercise*”), duly completed and executed by or on behalf of the Holder, together with the surrender of this Warrant; and

(ii) the payment to the Company of an amount equal to (x) the Exercise Price multiplied by (y) the number of Shares being purchased, by wire transfer or certified, cashier’s or other check acceptable to the Company and payable to the order of the Company.

(b) *Net Issue Exercise.* In lieu of exercising this Warrant pursuant to Section 2(a)(ii), if the fair market value of one Share is greater than the Exercise Price (at the date of calculation as set forth below), the Holder may elect to receive a number of Shares, paid-up to their nominal value, equal to the value of this Warrant (or of any portion of this Warrant being canceled) by surrender of this Warrant at the principal office of the Company (or such other office or agency as the Company may designate) together with a properly completed and executed Notice of Exercise reflecting such election and the payment to the Company of an amount equal to (x) the nominal value of a Share multiplied by (y) the number of Shares being purchased (the “Nominal Value Payment Amount”), by wire transfer or certified, cashier’s or other check acceptable to the Company and payable to the order of the Company, in which event the Company shall issue to the Holder that number of Shares computed using the following formula:

$$X = \frac{Y(A - B)}{A}$$

LANDLORDWhere:

X = The number of Shares to be issued to the Holder

Y = The number of Shares to be purchased (as specified in paragraph 1 of the applicable Notice of Exercise)

A = The fair market value of one Ordinary Share (at the date of such calculation)

B = The Exercise Price (as adjusted to the date of such calculation) less the nominal value of one Ordinary Share

For purposes of the calculation above, the fair market value of one Share shall be determined as follows:

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

(i) if the Ordinary Shares are traded on any securities exchange or quoted on an established automated over-the-counter market, the fair market value shall be deemed to be the average of the closing prices over a ten (10) Trading Day period ending five (5) Trading Days before the date of calculation; or

(ii) if at any time the Ordinary Shares are not listed on any securities exchange or quoted on an established automated over-the-counter market, the fair market value of Ordinary Shares shall be the price per Ordinary Share which the Company could obtain from a willing buyer (not a current employee or director) for Ordinary Shares sold by the Company, from authorized but unissued Ordinary Shares, as determined in good faith by its Board of Directors, unless the Company shall become subject to a Reorganization, in which case the fair market value of the Ordinary Shares shall be deemed to be the per share value received by the holders of the Company's Ordinary Shares pursuant to such Reorganization.

For purposes hereof, the date of calculation shall be the date the Holder sends to the Company a Notice of Exercise. "**Trading Day**" means a day in which trading in the Ordinary Shares generally occurs on The Nasdaq Global Select Market or if the Ordinary Shares are not then listed on The Nasdaq Global Select Market, on the principal other U.S. national or regional securities exchange on which the Ordinary Shares are then listed, or if the Ordinary Shares are not then listed on a U.S. national or regional securities exchange, on the principal other market on which the Ordinary Shares are then traded. If the Ordinary Shares are not so listed or traded, "Trading Day" means any Business Day. "**Business Day**" means any day other than a Saturday, a Sunday or a day on which the Federal Reserve Bank of New York is authorized or required by law or executive order to close or be closed.

(c) **Exercise Prior to Expiration.** To the extent this Warrant is not previously exercised as to all Shares subject hereto, and if the fair market value of one Share is greater than the Exercise Price then in effect, this Warrant shall be deemed automatically exercised pursuant to Section 2(b) (even if not surrendered) immediately before its expiration and the Holder shall be deemed to have provided, in connection with such exercise, an undertaking to pay the Nominal Value Payment Amount to the Company in cash on demand. For purposes of such automatic exercise, the fair market value of one Share upon such expiration shall be determined pursuant to Section 2(b). To the extent this Warrant or any portion thereof is deemed automatically exercised pursuant to this Section 2(c), the Company agrees to promptly notify the Holder of the number of Shares, if any, the Holder is to receive by reason of such automatic exercise.

(d) **Share Certificates.** This Warrant shall be deemed to have been exercised and the Shares issuable upon such exercise shall be deemed to have been issued immediately prior to the close of business on the date this Warrant is exercised in accordance with its terms, and the person entitled to receive the Shares issuable upon such exercise shall be treated for all purposes as the holder of record of such Shares as of the close of business on such date. As promptly as reasonably practicable on or after such date, the Company shall issue and deliver to the person or persons entitled to receive the same a certificate or certificates for that number of Shares issuable upon such exercise. In the event that this Warrant is exercised in part and has not expired, the Company shall execute and deliver a new Warrant reflecting the number of Shares that remain subject to this Warrant.

(e) **No Fractional Shares or Scrip.** No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. In lieu of such fractional share to which the Holder would otherwise be entitled, the Company shall make a cash payment equal to the Exercise Price multiplied by such fraction.

(f) **Conditional Exercise.** The Holder may exercise this Warrant conditioned upon (and effective immediately prior to) consummation of any transaction that would cause the expiration of this Warrant pursuant to Section 8 by so indicating in the notice of exercise.

(g) **Reservation of Shares.** The Company agrees during the term this Warrant is exercisable to reserve and keep available from its authorized and unissued Ordinary Shares such number of Ordinary Shares as shall

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

from time to time be sufficient to effect the exercise of this Warrant; and if at any time the number of authorized but unissued Ordinary Shares shall not be sufficient for purposes of the exercise of this Warrant in accordance with its terms, without limitation of such other remedies as may be available to the Holder, the Company will use all reasonable efforts to take such corporate action as may be necessary to increase its authorized and unissued Ordinary Shares of the Company to a number of Ordinary Shares as shall be sufficient for such purposes. The Company represents and warrants that all Shares that may be issued upon the exercise of this Warrant will, when issued in accordance with the terms hereof, be validly issued, fully paid and nonassessable.

(h) *Issued Securities.* The Company represents and warrants to the Holder that all issued and outstanding Ordinary Shares or any other securities of the Company have been duly authorized and validly issued and are fully paid and nonassessable. All outstanding Ordinary Shares and any other securities were issued in full compliance with all federal and state securities laws. In addition, as of the date immediately preceding the date of this Warrant:

(i) A description of the Company's capitalization attached hereto as Schedule A is true and complete, in all material respects, as of the Issue Date.

(ii) Except for this Warrant and as otherwise disclosed on Schedule A, there are no other options, warrants, conversion privileges or other rights presently outstanding to purchase or otherwise acquire any authorized but unissued shares of the Company's share capital or other securities of the Company.

**3. Replacement of the Warrant.** Subject to the receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, on delivery of an indemnity agreement reasonably satisfactory in form and substance to the Company or, in the case of mutilation, on surrender and cancellation of this Warrant, the Company at the expense of the Holder shall execute and deliver, in lieu of this Warrant, a new warrant of like tenor and amount.

**4. Transfer of the Warrant.**

(a) *Warrant Register.* The Company shall maintain a register (the "*Warrant Register*") containing the name and address of the Holder or Holders. Until this Warrant is transferred on the Warrant Register in accordance herewith, the Company may treat the Holder as shown on the Warrant Register as the absolute owner of this Warrant for all purposes, notwithstanding any notice to the contrary. Any Holder of this Warrant (or of any portion of this Warrant) may change its address as shown on the Warrant Register by written notice to the Company requesting a change.

(b) *Warrant Agent.* The Company may appoint an agent for the purpose of maintaining the Warrant Register referred to in Section 4(a), issuing the Shares or other securities then issuable upon the exercise of this Warrant, exchanging this Warrant, replacing this Warrant or conducting related activities.

(c) *Transferability of the Warrant.* Subject to the provisions of this Warrant with respect to compliance with the Securities Act of 1933, as amended (the "*Securities Act*"), as set forth in Section 5, title to this Warrant may be transferred by endorsement (by the transferor and the transferee executing the assignment form attached as Exhibit B (the "*Assignment Form*")) and delivery in the same manner as a negotiable instrument transferable by endorsement and delivery.

(d) *Exchange of the Warrant upon a Transfer.* On surrender of this Warrant (and a properly endorsed Assignment Form) for exchange, subject to the provisions of this Warrant with respect to compliance with the Securities Act and limitations on assignments and transfers, the Company shall issue to or on the order of the Holder a new warrant or warrants of like tenor, in the name of the Holder or as the Holder (on payment by the Holder

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**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

of any applicable transfer taxes) may direct, for the number of shares issuable upon exercise hereof, and the Company shall register any such transfer upon the Warrant Register. This Warrant (and the securities issuable upon exercise of this Warrant) must be surrendered to the Company or its warrant or transfer agent, as applicable, as a condition precedent to the sale, pledge, hypothecation or other transfer of any interest in any of the securities represented hereby.

(e) **Taxes.** In no event shall the Company be required to pay any tax which may be payable in respect of any transfer involved in the issue and delivery of any certificate in a name other than that of the Holder, and the Company shall not be required to issue or deliver any such certificate unless and until the person or persons requesting the issue thereof shall have paid to the Company the amount of such tax or shall have established to the satisfaction of the Company that such tax has been paid or is not payable.

**5. Compliance with Securities Laws.** By acceptance of this Warrant, the Holder agrees to comply with the following:

(a) **Restrictions on Transfers.** Any transfer of this Warrant or the Shares (the “*Securities*”) must be in compliance with all applicable federal and state securities laws. The Holder agrees not to make any sale, assignment, transfer, pledge or other disposition of all or any portion of the Securities, or any beneficial interest therein, unless and until the transferee thereof has agreed in writing for the benefit of the Company to take and hold such Securities subject to, and to be bound by, the terms and conditions set forth in this Warrant to the same extent as if the transferee were the original Holder hereunder, and either:

(i) there is then in effect a registration statement under the Securities Act covering such proposed disposition and such disposition is made in accordance with such registration statement, or

(ii) (A) such Holder shall have given prior written notice to the Company of such Holder’s intention to make such disposition and shall have furnished the Company with a reasonable detailed description of the manner and circumstances of the proposed disposition, (B) the transferee shall have made the representations set forth in Section 10 with respect to itself as a Holder and (C) if requested by the Company, such Holder shall have furnished the Company, at the Holder’s expense, with (i) evidence reasonably satisfactory to the Company that such disposition will not require registration of such Securities under the Securities Act or (ii) a legal opinion to the effect that the transfer of such Securities may be effected in compliance with the terms of the Securities Act. Notwithstanding the foregoing, compliance with clauses (B) and (C) above shall not be required for any transfer in compliance with Rule 144 and compliance with clause (C) above shall not be required for any transfer by the Holder to any affiliate of the Holder (or any fund or partnership under common control with one of more general partners or managing members of, or shares the same management company with, the Holder) or a transfer by the Holder to any of the Holder’s partners, members or other equity owners, or retired partners, members or other equity owners or the estate of any partners, members or other equity owners or retired partners, members or other equity owners.

(b) **Investment Representation Statement.** Unless this Warrant is exercised pursuant to an effective registration statement under the Securities Act that includes the Shares with respect to which the Warrant was exercised or pursuant to Section 2(b) that results in the Shares issued upon exercise being eligible for resale under Rule 144, it shall be a condition to any exercise of this Warrant that the Holder shall have confirmed the representations set forth in Section 10 hereof.

(c) **Securities Law Legend.** Subject to Section 5(e), the Securities shall (unless otherwise permitted by the provisions of this Warrant) be stamped or imprinted with a legend substantially similar to the following (in addition to any legend required by state securities laws):

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE “ACT”), OR UNDER THE SECURITIES LAWS OF

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CERTAIN STATES. THESE SECURITIES MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED EXCEPT AS PERMITTED UNDER THE ACT AND APPLICABLE STATE SECURITIES LAWS IN ACCORDANCE WITH APPLICABLE REGISTRATION REQUIREMENTS OR AN EXEMPTION THEREFROM. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE ISSUER THAT SUCH OFFER, SALE OR TRANSFER, PLEDGE OR HYPOTHECATION OTHERWISE COMPLIES WITH THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS. THIS CERTIFICATE MUST BE SURRENDERED TO THE COMPANY OR ITS TRANSFER AGENT AS A CONDITION PRECEDENT TO THE SALE, TRANSFER, PLEDGE OR HYPOTHECATION OF ANY INTEREST IN ANY OF THE SECURITIES REPRESENTED HEREBY.

(d) **Instructions Regarding Transfer Restrictions.** Subject to Section 5(e), the Holder consents to the Company making a notation on its records and giving instructions to any transfer agent in order to implement the restrictions on transfer established in this Section 5.

(e) **Removal of Legend.** The legend referring to federal and state securities laws identified in Section 5(c) stamped on a certificate evidencing the Shares and the transfer instructions and record notations with respect to the Securities shall be removed promptly upon request by the Holder and the Company shall issue a certificate without such legend to the holder of such Securities if (i) such Securities are registered under the Securities Act, (ii) such securities are eligible for resale under Rule 144, or (iii) such holder provides the Company with an opinion of counsel reasonably acceptable to the Company to the effect that a sale or transfer of such securities may be made without registration or qualification.

(f) **Compliance with Securities Laws.** The Holder is aware of the restrictions imposed by the United States securities laws on the purchase or sale of securities by any person who has received material, non-public information from the issuer of such securities and on the communication of such information to any other person when it is reasonably foreseeable that such other person is likely to purchase or sell such securities in reliance upon such information.

6. **Adjustments.** Subject to the expiration of this Warrant pursuant to Section 8, the number and kind of shares purchasable hereunder and the Exercise Price therefor are subject to adjustment from time to time, as follows:

(a) **Merger or Reorganization.** If at any time there shall be any reorganization, recapitalization, merger or consolidation (a "**Reorganization**") involving the Company (other than as otherwise provided for herein or as would cause the expiration of this Warrant under Section 8) in which Ordinary Shares of the Company are converted into or exchanged for securities, cash or other property, then, as a part of such Reorganization, lawful provision shall be made so that the Holder shall thereafter be entitled to receive upon exercise of this Warrant, the kind and amount of securities, cash or other property of the successor corporation resulting from such Reorganization (collectively, "**Reference Property**"), equivalent in value to that which a holder of the Shares deliverable upon exercise of this Warrant would have been entitled to receive in such Reorganization if the right to purchase the Shares hereunder had been exercised immediately prior to such Reorganization. In any such case, appropriate adjustment (as determined in good faith by the Board of Directors of the successor corporation) shall be made in the application of the provisions of this Warrant with respect to the rights and interests of the Holder after such Reorganization to the end that the provisions of this Warrant shall be applicable after the event, as near as reasonably may be, in relation to any shares or other securities deliverable after that event upon the exercise of this Warrant. Without limiting the foregoing, in connection with any Reorganization, upon the closing thereof, the successor or surviving entity shall assume the obligations of this Agreement. The provisions of this Section 6(a) shall similarly apply to successive Reorganizations.

(b) **Reclassification of Shares.** If the securities issuable upon exercise of this Warrant are changed into the same or a different number of securities of any other class or classes by reclassification, capital reorganization

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or otherwise (other than as otherwise provided for herein) (a “*Reclassification*”), then, in any such event, in lieu of the number of Shares which the Holder would otherwise have been entitled to receive, the Holder shall have the right thereafter to exercise this Warrant for a number of Shares of such other class or classes of shares that a holder of the number of securities deliverable upon exercise of this Warrant immediately before that change would have been entitled to receive in such Reclassification, all subject to further adjustment as provided herein with respect to such other shares.

(c) *Subdivisions and Combinations.* In the event that the outstanding Ordinary Shares are subdivided (by shares split, by payment of a shares dividend or otherwise) into a greater number of Ordinary Shares, the number of Shares issuable upon exercise of the this Warrant immediately prior to such subdivision shall, concurrently with the effectiveness of such subdivision, be proportionately increased, and the Exercise Price shall be proportionately decreased, and in the event that the outstanding Ordinary Shares are combined (by reclassification or otherwise) into a lesser number of Ordinary Shares, the number of Shares issuable upon exercise of the this Warrant immediately prior to such combination shall, concurrently with the effectiveness of such combination, be proportionately decreased, and the Exercise Price shall be proportionately increased.

(d) *Notice of Adjustments.* Upon any adjustment in accordance with this Section 6, the Company shall give notice thereof to the Holder, which notice shall state the event giving rise to the adjustment, the Exercise Price as adjusted and the number of securities or other property purchasable upon the exercise of this Warrant, setting forth in reasonable detail the method of calculation of each. The Company shall, upon the written request of any Holder, furnish or cause to be furnished to such Holder a certificate setting forth (i) such adjustments, (ii) the Exercise Price at the time in effect and (iii) the number of securities and the amount, if any, of other property that at the time would be received upon exercise of this Warrant.

**7. Notification of Certain Events.** Prior to the expiration of this Warrant pursuant to Section 8, in the event that the Company shall authorize:

(a) the issuance of any dividend or other distribution on the share capital of the Company (other than (i) dividends or distributions otherwise provided for in Section 6, (ii) repurchases of Ordinary Shares issued to or held by employees, officers, directors or consultants of the Company or its subsidiaries upon termination of their employment or services pursuant to agreements providing for the right of said repurchase; (iii) repurchases of Ordinary Shares issued to or held by employees, officers, directors or consultants of the Company or its subsidiaries pursuant to rights of first refusal or first offer contained in agreements providing for such rights; or (iv) repurchases of Ordinary Shares in connection with the settlement of disputes with any shareholder ), whether in cash, property, shares or other securities;

(b) the voluntary liquidation, dissolution or winding up of the Company; or

(c) any transaction resulting in the expiration of this Warrant pursuant to Section 8(b);

the Company shall send to the Holder of this Warrant at least ten (10) calendar days prior written notice of the date on which a record shall be taken for any such dividend or distribution specified in clause (a) or the expected effective date of any such other event specified in clause (b) or (c), as applicable. The notice provisions set forth in this section may be shortened or waived prospectively or retrospectively by the consent of the Holder of this Warrant.

**8. Expiration of the Warrant.** This Warrant shall expire and shall no longer be exercisable as of the earlier of:

(a) 5:00 p.m., Pacific time, on [ ], [ ]; or

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(b) (i) the acquisition of the Company by another entity by means of any transaction or series of related transactions to which the Company is a party (including, without limitation, any share acquisition, reorganization, merger or consolidation, but excluding any sale of shares for capital raising purposes and any transaction effected primarily for purposes of changing the Company's jurisdiction of incorporation) other than a transaction or series of related transactions in which the holders of the voting securities of the Company outstanding immediately prior to such transaction or series of related transactions receive voting securities of such other surviving or resulting entity (or if the Company or such other surviving or resulting entity is a wholly-owned subsidiary immediately following such acquisition, its parent), or (ii) a sale, lease or other disposition of all or substantially all of the assets of the Company and its subsidiaries taken as a whole by means of any transaction or series of related transactions, except where such sale, lease or other disposition is to a wholly-owned subsidiary of the Company; provided that the holders of Shares in the transaction described in (i) or (ii) above receive cash or cash equivalents in such transaction with an aggregate value per Ordinary Share greater than two times the Exercise Price.

9. **No Rights as a Shareholder.** Nothing contained herein shall entitle the Holder to any rights as a shareholder of the Company or to be deemed the holder of any securities that may at any time be issuable on the exercise of the rights hereunder for any purpose nor shall anything contained herein be construed to confer upon the Holder, as such, any right to vote for the election of directors or upon any matter submitted to shareholders at any meeting thereof, or to give or withhold consent to any corporate action (whether upon any recapitalization, issuance of shares, reclassification of shares, change of nominal value or change of shares to no nominal value, consolidation, merger, conveyance or otherwise) or to receive notice of meetings, or to receive dividends or subscription rights or any other rights of a shareholder of the Company until this Warrant shall have been exercised.

10. **Representations and Warranties of the Holder.** By acceptance of this Warrant, the Holder represents and warrants to the Company as follows:

(a) **No Registration.** The Holder understands that the Securities have not been, and will not be, registered under the Securities Act by reason of a specific exemption from the registration provisions of the Securities Act, the availability of which depends upon, among other things, the *bona fide* nature of the investment intent and the accuracy of the Holder's representations as expressed herein or otherwise made pursuant hereto.

(b) **Investment Intent.** The Holder is acquiring the Securities for investment for its own account, not as a nominee or agent, and not with a view to, or for resale in connection with, any distribution thereof. The Holder has no present intention of selling, granting any participation in, or otherwise distributing the Securities, nor does it have any contract, undertaking, agreement or arrangement for the same.

(c) **Investment Experience.** The Holder has substantial experience in evaluating and investing in private placement transactions of securities in companies similar to the Company, and has such knowledge and experience in financial or business matters so that it is capable of evaluating the merits and risks of its investment in the Company and protecting its own interests.

(d) **Speculative Nature of Investment.** The Holder understands and acknowledges that its investment in the Company is highly speculative and involves substantial risks. The Holder can bear the economic risk of its investment and is able, without impairing its financial condition, to hold the Securities for an indefinite period of time and to suffer a complete loss of its investment.

(e) **Accredited Investor.** The Holder is an "accredited investor" within the meaning of Regulation D, Rule 501(a), promulgated by the Securities and Exchange Commission and agrees to submit to the Company such further assurances of such status as may be reasonably requested by the Company. The Holder has furnished or made available any and all information requested by the Company or otherwise necessary to satisfy any applicable verification requirements as to "accredited investor" status. Any such information is true, correct, timely and complete.

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(f) *Residency.* The residency of the Holder (or, in the case of a partnership or corporation, such entity's principal place of business) is correctly set forth on the signature page hereto.

(g) *Restrictions on Resales.* The Holder acknowledges that the Securities must be held indefinitely unless subsequently registered under the Securities Act or an exemption from such registration is available. The Holder is aware of the provisions of Rule 144 promulgated under the Securities Act, which permit resale of shares purchased in a private placement subject to the satisfaction of certain conditions, which may include, among other things, the availability of certain current public information about the Company; the resale occurring not less than a specified period after a party has purchased and paid for the security to be sold; the number of shares being sold during any three-month period not exceeding specified limitations; the sale being effected through a "broker's transaction," a transaction directly with a "market maker" or a "riskless principal transaction" (as those terms are defined in the Securities Act or the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder); and the filing of a Form 144 notice, if applicable. The Holder acknowledges and understands that the Company may not be satisfying the current public information requirement of Rule 144 at the time the Holder wishes to sell the Securities and that, in such event, the Holder may be precluded from selling the Securities under Rule 144 even if the other applicable requirements of Rule 144 have been satisfied. The Holder acknowledges that, in the event the applicable requirements of Rule 144 are not met, registration under the Securities Act or an exemption from registration will be required for any disposition of the Securities. The Holder understands that, although Rule 144 is not exclusive, the Securities and Exchange Commission has expressed its opinion that persons proposing to sell restricted securities received in a private offering other than in a registered offering or pursuant to Rule 144 will have a substantial burden of proof in establishing that an exemption from registration is available for such offers or sales and that such persons and the brokers who participate in the transactions do so at their own risk.

**11. Miscellaneous.**

(a) *Amendments.* Except as expressly provided herein, neither this Warrant nor any term hereof may be amended, waived, discharged or terminated other than by a written instrument referencing this Warrant and signed by the Company and the Holder of this Warrant.

(b) *Waivers.* No waiver of any single breach or default shall be deemed a waiver of any other breach or default theretofore or thereafter occurring.

(c) *Notices.* All notices and other communications required or permitted hereunder shall be in writing and shall be mailed by registered or certified mail, postage prepaid, sent by facsimile or electronic mail (if to the Holder) or otherwise delivered by hand, messenger or courier service addressed:

(i) if to the Holder, to the Holder at the Holder's address, facsimile number or electronic mail address as show on the signature page hereto, or at such other current address as the Holder shall have furnished to the Company; or

(ii) if to the Company, to the attention of the Chief Executive Officer or Chief Financial Officer of the Company at the Company's address, facsimile number or electronic mail address as shown on the signature page hereto, or at such other current address as the Company shall have furnished to the Holder.

Each such notice or other communication shall for all purposes of this Warrant be treated as effective or having been given (i) if delivered by hand, messenger or courier service, when delivered (or if sent via a nationally-recognized overnight courier service, freight prepaid, specifying next-business-day delivery, one business day after deposit with the courier), or (ii) if sent via mail, at the earlier of its receipt or five days after the same has been deposited in a regularly-maintained receptacle for the deposit of the United States mail, addressed and mailed as

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aforesaid, or (iii) if sent via facsimile, upon confirmation of facsimile transfer or, if sent via electronic mail, upon confirmation of delivery when directed to the relevant electronic mail address, if sent during normal business hours of the recipient, or if not sent during normal business hours of the recipient, then on the recipient's next business day. In the event of any conflict between the Company's books and records and this Warrant or any notice delivered hereunder, the Company's books and records will control absent fraud or error.

(d) **Governing Law.** This Warrant and all actions arising out of or in connection with this Warrant shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflicts of law provisions of the State of New York, or of any other state.

(e) **Jurisdiction and Venue.** The Company agrees that any suit, action or proceeding with respect to this Agreement or any other Loan Document to which it is a party or any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in Houston, Texas or in the courts of its own corporate domicile and irrevocably submits to the non-exclusive jurisdiction of each such court for the purpose of any such suit, action, proceeding or judgment. This Section 13.10(a) is for the benefit of the Holder only and, as a result, Holder shall not be prevented from taking proceedings in any other courts with jurisdiction. Nothing herein shall in any way be deemed to limit the ability of the Holder to serve any such process or summonses in any other manner permitted by applicable law. The Company irrevocably waives to the fullest extent permitted by law any objection that it may now or hereafter have to the laying of the venue of any suit, action or proceeding arising out of or relating to this Warrant and hereby further irrevocably waives to the fullest extent permitted by law any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. A final judgment (in respect of which time for all appeals has elapsed) in any such suit, action or proceeding shall be conclusive and may be enforced in any court to the jurisdiction of which the Company is or may be subject, by suit upon judgment.

(f) **Titles and Subtitles.** The titles and subtitles used in this Warrant are used for convenience only and are not to be considered in construing or interpreting this Warrant. All references in this Warrant to sections, paragraphs and exhibits shall, unless otherwise provided, refer to sections and paragraphs hereof and exhibits attached hereto.

(g) **Severability.** If any provision of this Warrant becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, portions of such provision, or such provision in its entirety, to the extent necessary, shall be severed from this Warrant, and such illegal, unenforceable or void provision shall be replaced with a valid and enforceable provision that will achieve, to the extent possible, the same economic, business and other purposes of the illegal, unenforceable or void provision. The balance of this Warrant shall be enforceable in accordance with its terms.

(h) **Waiver of Jury Trial.** EACH OF THE HOLDER AND THE COMPANY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATED TO THIS WARRANT.

(i) **California Corporate Securities Law.** THE SALE OF THE SECURITIES THAT ARE THE SUBJECT OF THIS WARRANT HAS NOT BEEN QUALIFIED WITH THE COMMISSIONER OF CORPORATIONS OF THE STATE OF CALIFORNIA AND THE ISSUANCE OF SUCH SECURITIES OR THE PAYMENT OR RECEIPT OF ANY PART OF THE CONSIDERATION THEREFOR PRIOR TO SUCH QUALIFICATION IS UNLAWFUL, UNLESS THE SALE OF SECURITIES IS EXEMPT FROM QUALIFICATION BY SECTION 25100, 25102, OR 25105 OF THE CALIFORNIA CORPORATIONS CODE. THE RIGHTS OF ALL PARTIES TO THIS WARRANT ARE EXPRESSLY CONDITIONED UPON THE QUALIFICATION BEING OBTAINED, UNLESS THE SALE IS SO EXEMPT.

(j) **Saturdays, Sundays and Holidays.** If the last or appointed day for the taking of any action or the

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expiration of any right required or granted herein shall be a Saturday, Sunday or U.S. federal holiday, then such action may be taken or such right may be exercised on the next succeeding day that is not a Saturday, Sunday or U.S. federal holiday.

(k) *Rights and Obligations Survive Exercise of the Warrant.* Except as otherwise provided herein, the rights and obligations of the Company and the Holder under this Warrant shall survive exercise of this Warrant.

(l) *Entire Agreement.* Except as expressly set forth herein, this Warrant (including the exhibits attached hereto) constitutes the entire agreement and understanding of the Company and the Holder with respect to the subject matter hereof and supersedes all prior agreements and understandings relating to the subject matter hereof.

*(signature page follows)*

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The Company and the Holder sign this Warrant as of the date stated on the first page.

COMPANY:

**STRONGBRIDGE BIOPHARMA PLC**

By \_\_\_\_\_

Name:

Title:

Address for Notices:

900 Northbrook Drive  
Suite 200  
Trevose, PA 19053

Attn:

Tel.: (610) 254-9200

Fax:

Email:

With a copy (which shall not constitute notice) to:

Reed Smith LLP  
599 Lexington Avenue  
New York, New York 10022  
Attention: Aron Izower  
Tel.: (212) 549-0393  
Fax: (212) 521-5450  
Email: aizower@reedsmith.com

**AGREED AND ACKNOWLEDGED,**

HOLDER:

By \_\_\_\_\_

Name:

Title:

Address for Notices:

Attn:

Tel.:

Fax:

Email:

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SCHEDULE A

Capitalization

Class & Number of Shares	Par Value	Authorized	Issued	Outstanding
Preferred Shares	\$0.01	[ ]	[ ]	[ ]
Ordinary Shares	\$0.01	[ ]	[ ]	[ ]
Deferred Ordinary Shares	€0.01	[ ]	[ ]	[ ]

**Outstanding Options:** [ ] with weighted average exercise price of \$[ ].

**Outstanding Warrants –**

- [ ] Warrants with exercise price of \$[ ]
- [ ] Warrants with exercise price of \$[ ]

**Outstanding Restricted Stock Units:** [ ]

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EXHIBIT A  
NOTICE OF EXERCISE

TO: [ ] (the "Company")

Attention: CHIEF FINANCIAL OFFICER

(1) **Exercise.** The undersigned elects to purchase the following pursuant to the terms of the attached warrant:

Number of shares: \_\_\_\_\_  
Type of security: \_\_\_\_\_

(2) **Method of Exercise.** The undersigned elects to exercise the attached warrant pursuant to:

A cash payment, and tenders herewith payment of the purchase price for such shares in full, together with all applicable transfer taxes, if any.

The net issue exercise provisions of Section 2(b) of the attached warrant.

(3) **Conditional Exercise.** Is this a conditional exercise pursuant to Section 2(f):

Yes  No

If "Yes," indicate the applicable condition:

(4) **Share Certificate.** Please issue a certificate or certificates representing the shares in the name of:

The undersigned

Other—Name: \_\_\_\_\_  
Address: \_\_\_\_\_

(5) **Unexercised Portion of the Warrant.** Please issue a new warrant for the unexercised portion of the attached warrant in the name of:

The undersigned

Other—Name: \_\_\_\_\_  
Address: \_\_\_\_\_

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Not applicable

- (6) **[Investment Intent.** The undersigned represents and warrants that the aforesaid shares are being acquired for investment for its own account and not with a view to, or for resale in connection with, the distribution thereof, and that the undersigned has no present intention of selling, granting any participation in, or otherwise distributing the shares, nor does it have any contract, undertaking, agreement or arrangement for the same, and all representations and warranties of the undersigned set forth in Section 10 of the attached warrant are true and correct as of the date hereof. ]<sup>10</sup>

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*(Print name of the warrant holder)*

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*(Signature)*

---

*(Name and title of signatory, if applicable)*

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*(Date)*

---

*(Fax number)*

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*(Email address)*

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<sup>10</sup> Include if exercised pursuant to Section 2(a).

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EXHIBIT B  
ASSIGNMENT FORM

ASSIGNOR: \_\_\_\_\_

COMPANY:

WARRANT: THE WARRANT TO PURCHASE SHARES OF ORDINARY SHARES ISSUED ON [ ], [ ] (THE "WARRANT")

DATE: \_\_\_\_\_

- (1) **Assignment.** The undersigned registered holder of the Warrant ("*Assignor*") assigns and transfers to the assignee named below ("*Assignee*") all of the rights of Assignor under the Warrant, with respect to the number of shares set forth below:

Name of Assignee: \_\_\_\_\_

Address of Assignee: \_\_\_\_\_

Number of Shares Assigned: \_\_\_\_\_

and does irrevocably constitute and appoint \_\_\_\_\_ as attorney to make such transfer on the books of Strongbridge Biopharma plc, maintained for the purpose, with full power of substitution in the premises.

- (2) **Obligations of Assignee.** Assignee agrees to take and hold the Warrant and any shares to be issued upon exercise of the rights thereunder (the "*Securities*") subject to, and to be bound by, the terms and conditions set forth in the Warrant to the same extent as if Assignee were the original holder thereof.
- (3) **[Investment Intent.** Assignee represents and warrants that the Securities are being acquired for investment for its own account, not as a nominee or agent, and not with a view to, or for resale in connection with, the distribution thereof, and that Assignee has no present intention of selling, granting any participation in, or otherwise distributing the shares, nor does it have any contract, undertaking, agreement or arrangement for the same, and all representations and warranties set forth in Section 10 of the Warrant are true and correct as to Assignee as of the date hereof.]<sup>11</sup>

<sup>11</sup> Include to the extent required pursuant to Section 5(a).

**CONFIDENTIAL TREATMENT REQUESTED UNDER C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. [\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

Assignor and Assignee are signing this Assignment Form on the date first set forth above.

**ASSIGNOR**

**ASSIGNEE**

\_\_\_\_\_

*(Print name of Assignor)*

\_\_\_\_\_

*(Print name of Assignee)*

\_\_\_\_\_

*(Signature of Assignor)*

\_\_\_\_\_

*(Signature of Assignee)*

\_\_\_\_\_

*(Print name of signatory, if applicable)*

\_\_\_\_\_

*(Print name of signatory, if applicable)*

\_\_\_\_\_

*(Print title of signatory, if applicable)*

\_\_\_\_\_

*(Print title of signatory, if applicable)*

Address:

Address:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Exhibit I  
to Term Loan Agreement**

FORM OF WARRANT

**THIS WARRANT AND THE UNDERLYING SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE “ACT”), OR UNDER THE SECURITIES LAWS OF ANY STATE. THESE SECURITIES MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED EXCEPT AS PERMITTED UNDER THE ACT AND APPLICABLE STATE SECURITIES LAWS IN ACCORDANCE WITH APPLICABLE REGISTRATION REQUIREMENTS OR AN EXEMPTION THEREFROM. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE ISSUER THAT SUCH OFFER, SALE, TRANSFER, PLEDGE OR HYPOTHECATION OTHERWISE COMPLIES WITH THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS. THIS WARRANT MUST BE SURRENDERED TO THE COMPANY OR ITS TRANSFER AGENT AS A CONDITION PRECEDENT TO THE SALE, TRANSFER, PLEDGE OR HYPOTHECATION OF ANY INTEREST IN ANY OF THE SECURITIES REPRESENTED HEREBY.**

**WARRANT TO PURCHASE ORDINARY SHARES  
OF  
STRONGBRIDGE BIOPHARMA PLC**

**Dated as of [ ], [ ] (the “Issue Date”)  
Void after the date specified in Section 8**

**Warrant to Purchase  
[ ] Ordinary Shares**

**(subject to adjustment)**

THIS CERTIFIES THAT, for value received, [ ], or its registered assigns (the “*Holder*”), is entitled, subject to the provisions and upon the terms and conditions set forth herein, to purchase from STRONGBRIDGE BIOPHARMA PLC, a public limited company incorporated under the laws of Ireland (the “*Company*”), that number of shares (the “*Shares*”) of the Company’s ordinary shares, of nominal value \$0.01 per share (the “*Ordinary Shares*”), at such times and at the price per Share, set forth in Section 1. The term “*Warrant*” as used herein shall include this Warrant and any warrants delivered in substitution or exchange therefor as provided herein. This Warrant is issued in connection with the transactions described in the Term Loan Agreement, dated as of July 14, 2017, and amended as of January 16, 2018, by and between the Company, the Subsidiary Guarantors from time to time party thereto, the Lenders from time to time party thereto and CRG Servicing LLC.

The following is a statement of the rights of the Holder and the conditions to which this Warrant is subject, and to which Holder, by acceptance of this Warrant, agrees:

**1. Number and Price of Shares; Exercise Period.**

(a) **Number of Shares.** Subject to any previous exercise of the Warrant, the Holder shall have the right to purchase up to [ ] Shares, as may be adjusted pursuant hereto prior to (or in connection with) the expiration of this Warrant as provided in Section 8.

(b) **Exercise Price.** The exercise price per Share shall be equal to [ ], subject to adjustment pursuant hereto (the “**Exercise Price**”), provided however, the exercise price shall never be less than the nominal value of an Ordinary Share.



(c) **Exercise Period.** This Warrant shall be exercisable, in whole or in part, prior to (or in connection with) the expiration of this Warrant as set forth in Section 8.

## 2. Exercise of the Warrant.

(a) **Exercise.** The purchase rights represented by this Warrant may be exercised at the election of the Holder, in whole or in part, in accordance with Section 1, by:

(i) the tender to the Company at its principal office (or such other office or agency as the Company may designate) of a notice of exercise in the form of Exhibit A (the “**Notice of Exercise**”), duly completed and executed by or on behalf of the Holder, together with the surrender of this Warrant; and

(ii) the payment to the Company of an amount equal to (x) the Exercise Price multiplied by (y) the number of Shares being purchased, by wire transfer or certified, cashier’s or other check acceptable to the Company and payable to the order of the Company.

(b) **Net Issue Exercise.** In lieu of exercising this Warrant pursuant to Section 2(a)(ii), if the fair market value of one Share is greater than the Exercise Price (at the date of calculation as set forth below), the Holder may elect to receive a number of Shares, paid-up to their nominal value, equal to the value of this Warrant (or of any portion of this Warrant being canceled) by surrender of this Warrant at the principal office of the Company (or such other office or agency as the Company may designate) together with a properly completed and executed Notice of Exercise reflecting such election and the payment to the Company of an amount equal to (x) the nominal value of a Share multiplied by (y) the number of Shares being purchased (the “Nominal Value Payment Amount”), by wire transfer or certified, cashier’s or other check acceptable to the Company and payable to the order of the Company, in which event the Company shall issue to the Holder that number of Shares computed using the following formula:

$$X = \frac{Y(A - B)}{A}$$

Where:

X = The number of Shares to be issued to the Holder

Y = The number of Shares to be purchased (as specified in paragraph 1 of the applicable Notice of Exercise)

A = The fair market value of one Ordinary Share (at the date of such calculation)

B = The Exercise Price (as adjusted to the date of such calculation) less the nominal value of one Ordinary Share

For purposes of the calculation above, the fair market value of one Share shall be determined as follows:

(i) if the Ordinary Shares are traded on any securities exchange or quoted on an established automated over-the-counter market, the fair market value shall be deemed to be the average of the closing prices over a ten (10) Trading Day period ending five (5) Trading Days before the date of calculation; or

(i) if at any time the Ordinary Shares are not listed on any securities exchange or quoted on an established automated over-the-counter market, the fair market value of Ordinary Shares shall be the price per Ordinary Share which the Company could obtain from a willing buyer (not a current employee or director) for Ordinary Shares sold by the Company, from authorized but unissued Ordinary Shares, as determined in good faith by its Board of Directors, unless the Company shall become subject to a Reorganization, in which case the fair market value of the Ordinary Shares shall be deemed to be the per share value received by the holders of the Company’s Ordinary Shares pursuant to such Reorganization.

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For purposes hereof, the date of calculation shall be the date the Holder sends to the Company a Notice of Exercise. “**Trading Day**” means a day in which trading in the Ordinary Shares generally occurs on The Nasdaq Global Select Market or if the Ordinary Shares are not then listed on The Nasdaq Global Select Market, on the principal other U.S. national or regional securities exchange on which the Ordinary Shares are then listed, or if the Ordinary Shares are not then listed on a U.S. national or regional securities exchange, on the principal other market on which the Ordinary Shares are then traded. If the Ordinary Shares are not so listed or traded, “Trading Day” means any Business Day. “**Business Day**” means any day other than a Saturday, a Sunday or a day on which the Federal Reserve Bank of New York is authorized or required by law or executive order to close or be closed.

(c) **Exercise Prior to Expiration.** To the extent this Warrant is not previously exercised as to all Shares subject hereto, and if the fair market value of one Share is greater than the Exercise Price then in effect, this Warrant shall be deemed automatically exercised pursuant to Section 2(b) (even if not surrendered) immediately before its expiration and the Holder shall be deemed to have provided, in connection with such exercise, an undertaking to pay the Nominal Value Payment Amount to the Company in cash on demand. For purposes of such automatic exercise, the fair market value of one Share upon such expiration shall be determined pursuant to Section 2(b). To the extent this Warrant or any portion thereof is deemed automatically exercised pursuant to this Section 2(c), the Company agrees to promptly notify the Holder of the number of Shares, if any, the Holder is to receive by reason of such automatic exercise.

(d) **Share Certificates.** This Warrant shall be deemed to have been exercised and the Shares issuable upon such exercise shall be deemed to have been issued immediately prior to the close of business on the date this Warrant is exercised in accordance with its terms, and the person entitled to receive the Shares issuable upon such exercise shall be treated for all purposes as the holder of record of such Shares as of the close of business on such date. As promptly as reasonably practicable on or after such date, the Company shall issue and deliver to the person or persons entitled to receive the same a certificate or certificates for that number of Shares issuable upon such exercise. In the event that this Warrant is exercised in part and has not expired, the Company shall execute and deliver a new Warrant reflecting the number of Shares that remain subject to this Warrant.

(e) **No Fractional Shares or Scrip.** No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. In lieu of such fractional share to which the Holder would otherwise be entitled, the Company shall make a cash payment equal to the Exercise Price multiplied by such fraction.

(f) **Conditional Exercise.** The Holder may exercise this Warrant conditioned upon (and effective immediately prior to) consummation of any transaction that would cause the expiration of this Warrant pursuant to Section 8 by so indicating in the notice of exercise.

(g) **Reservation of Shares.** The Company agrees during the term this Warrant is exercisable to reserve and keep available from its authorized and unissued Ordinary Shares such number of Ordinary Shares as shall from time to time be sufficient to effect the exercise of this Warrant; and if at any time the number of authorized but unissued Ordinary Shares shall not be sufficient for purposes of the exercise of this Warrant in accordance with its terms, without limitation of such other remedies as may be available to the Holder, the Company will use all reasonable efforts to take such corporate action as may be necessary to increase its authorized and unissued Ordinary Shares of the Company to a number of Ordinary Shares as shall be sufficient for such purposes. The Company represents and warrants that all Shares that may be issued upon the exercise of this Warrant will, when issued in accordance with the terms hereof, be validly issued, fully paid and nonassessable.

(h) **Issued Securities.** The Company represents and warrants to the Holder that all issued and outstanding Ordinary Shares or any other securities of the Company have been duly authorized and validly issued and are fully paid and nonassessable. All outstanding Ordinary Shares and any other securities were issued in full compliance with all federal and state securities laws. In addition, as of the date immediately preceding the date of this Warrant:

(i) A description of the Company’s capitalization attached hereto as Schedule A is true and complete, in all material respects, as of the Issue Date.

(ii) Except for this Warrant and as otherwise disclosed on Schedule A, there are no

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other options, warrants, conversion privileges or other rights presently outstanding to purchase or otherwise acquire any authorized but unissued shares of the Company's share capital or other securities of the Company.

**3. Replacement of the Warrant.** Subject to the receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, on delivery of an indemnity agreement reasonably satisfactory in form and substance to the Company or, in the case of mutilation, on surrender and cancellation of this Warrant, the Company at the expense of the Holder shall execute and deliver, in lieu of this Warrant, a new warrant of like tenor and amount.

**4. Transfer of the Warrant.**

(a) **Warrant Register.** The Company shall maintain a register (the "**Warrant Register**") containing the name and address of the Holder or Holders. Until this Warrant is transferred on the Warrant Register in accordance herewith, the Company may treat the Holder as shown on the Warrant Register as the absolute owner of this Warrant for all purposes, notwithstanding any notice to the contrary. Any Holder of this Warrant (or of any portion of this Warrant) may change its address as shown on the Warrant Register by written notice to the Company requesting a change.

(b) **Warrant Agent.** The Company may appoint an agent for the purpose of maintaining the Warrant Register referred to in Section 4(a), issuing the Shares or other securities then issuable upon the exercise of this Warrant, exchanging this Warrant, replacing this Warrant or conducting related activities.

(c) **Transferability of the Warrant.** Subject to the provisions of this Warrant with respect to compliance with the Securities Act of 1933, as amended (the "**Securities Act**"), as set forth in Section 5, title to this Warrant may be transferred by endorsement (by the transferor and the transferee executing the assignment form attached as Exhibit B (the "**Assignment Form**")) and delivery in the same manner as a negotiable instrument transferable by endorsement and delivery.

(d) **Exchange of the Warrant upon a Transfer.** On surrender of this Warrant (and a properly endorsed Assignment Form) for exchange, subject to the provisions of this Warrant with respect to compliance with the Securities Act and limitations on assignments and transfers, the Company shall issue to or on the order of the Holder a new warrant or warrants of like tenor, in the name of the Holder or as the Holder (on payment by the Holder of any applicable transfer taxes) may direct, for the number of shares issuable upon exercise hereof, and the Company shall register any such transfer upon the Warrant Register. This Warrant (and the securities issuable upon exercise of this Warrant) must be surrendered to the Company or its warrant or transfer agent, as applicable, as a condition precedent to the sale, pledge, hypothecation or other transfer of any interest in any of the securities represented hereby.

(e) **Taxes.** In no event shall the Company be required to pay any tax which may be payable in respect of any transfer involved in the issue and delivery of any certificate in a name other than that of the Holder, and the Company shall not be required to issue or deliver any such certificate unless and until the person or persons requesting the issue thereof shall have paid to the Company the amount of such tax or shall have established to the satisfaction of the Company that such tax has been paid or is not payable.

**5. Compliance with Securities Laws.** By acceptance of this Warrant, the Holder agrees to comply with the following:

(a) **Restrictions on Transfers.** Any transfer of this Warrant or the Shares (the "**Securities**") must be in compliance with all applicable federal and state securities laws. The Holder agrees not to make any sale, assignment, transfer, pledge or other disposition of all or any portion of the Securities, or any beneficial interest therein, unless and until the transferee thereof has agreed in writing for the benefit of the Company to take and hold such Securities subject to, and to be bound by, the terms and conditions set forth in this Warrant to the same extent as if the transferee were the original Holder hereunder, and either:

(i) there is then in effect a registration statement under the Securities Act covering such proposed disposition and such disposition is made in accordance with such registration statement, or

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(ii) (A) such Holder shall have given prior written notice to the Company of such Holder's intention to make such disposition and shall have furnished the Company with a reasonable detailed description of the manner and circumstances of the proposed disposition, (B) the transferee shall have made the representations set forth in Section 10 with respect to itself as a Holder and (C) if requested by the Company, such Holder shall have furnished the Company, at the Holder's expense, with (i) evidence reasonably satisfactory to the Company that such disposition will not require registration of such Securities under the Securities Act or (ii) a legal opinion to the effect that the transfer of such Securities may be effected in compliance with the terms of the Securities Act. Notwithstanding the foregoing, compliance with clauses (B) and (C) above shall not be required for any transfer in compliance with Rule 144 and compliance with clause (C) above shall not be required for any transfer by the Holder to any affiliate of the Holder (or any fund or partnership under common control with one of more general partners or managing members of, or shares the same management company with, the Holder) or a transfer by the Holder to any of the Holder's partners, members or other equity owners, or retired partners, members or other equity owners or the estate of any partners, members or other equity owners or retired partners, members or other equity owners.

(b) **Investment Representation Statement.** Unless this Warrant is exercised pursuant to an effective registration statement under the Securities Act that includes the Shares with respect to which the Warrant was exercised or pursuant to Section 2(b) that results in the Shares issued upon exercise being eligible for resale under Rule 144, it shall be a condition to any exercise of this Warrant that the Holder shall have confirmed the representations set forth in Section 10 hereof.

(c) **Securities Law Legend.** Subject to Section 5(e), the Securities shall (unless otherwise permitted by the provisions of this Warrant) be stamped or imprinted with a legend substantially similar to the following (in addition to any legend required by state securities laws):

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR UNDER THE SECURITIES LAWS OF CERTAIN STATES. THESE SECURITIES MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED EXCEPT AS PERMITTED UNDER THE ACT AND APPLICABLE STATE SECURITIES LAWS IN ACCORDANCE WITH APPLICABLE REGISTRATION REQUIREMENTS OR AN EXEMPTION THEREFROM. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE ISSUER THAT SUCH OFFER, SALE OR TRANSFER, PLEDGE OR HYPOTHECATION OTHERWISE COMPLIES WITH THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS. THIS CERTIFICATE MUST BE SURRENDERED TO THE COMPANY OR ITS TRANSFER AGENT AS A CONDITION PRECEDENT TO THE SALE, TRANSFER, PLEDGE OR HYPOTHECATION OF ANY INTEREST IN ANY OF THE SECURITIES REPRESENTED HEREBY.

(d) **Instructions Regarding Transfer Restrictions.** Subject to Section 5(e), the Holder consents to the Company making a notation on its records and giving instructions to any transfer agent in order to implement the restrictions on transfer established in this Section 5.

(e) **Removal of Legend.** The legend referring to federal and state securities laws identified in Section 5(c) stamped on a certificate evidencing the Shares and the transfer instructions and record notations with respect to the Securities shall be removed promptly upon request by the Holder and the Company shall issue a certificate without such legend to the holder of such Securities if (i) such Securities are registered under the Securities Act, (ii) such securities are eligible for resale under Rule 144, or (iii) such holder provides the Company with an opinion of counsel reasonably acceptable to the Company to the effect that a sale or transfer of such securities may be made without registration or qualification.

(f) **Compliance with Securities Laws.** The Holder is aware of the restrictions imposed by the United States securities laws on the purchase or sale of securities by any person who has received material, non-public information from the issuer of such securities and on the communication of such information to any other person when it is reasonably foreseeable that such other person is likely to purchase or sell such securities in reliance upon such information.

6. **Adjustments.** Subject to the expiration of this Warrant pursuant to Section 8, the number and kind of

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shares purchasable hereunder and the Exercise Price therefor are subject to adjustment from time to time, as follows:

(a) **Merger or Reorganization.** If at any time there shall be any reorganization, recapitalization, merger or consolidation (a “**Reorganization**”) involving the Company (other than as otherwise provided for herein or as would cause the expiration of this Warrant under Section 8) in which Ordinary Shares of the Company are converted into or exchanged for securities, cash or other property, then, as a part of such Reorganization, lawful provision shall be made so that the Holder shall thereafter be entitled to receive upon exercise of this Warrant, the kind and amount of securities, cash or other property of the successor corporation resulting from such Reorganization (collectively, “**Reference Property**”), equivalent in value to that which a holder of the Shares deliverable upon exercise of this Warrant would have been entitled to receive in such Reorganization if the right to purchase the Shares hereunder had been exercised immediately prior to such Reorganization. In any such case, appropriate adjustment (as determined in good faith by the Board of Directors of the successor corporation) shall be made in the application of the provisions of this Warrant with respect to the rights and interests of the Holder after such Reorganization to the end that the provisions of this Warrant shall be applicable after the event, as near as reasonably may be, in relation to any shares or other securities deliverable after that event upon the exercise of this Warrant. Without limiting the foregoing, in connection with any Reorganization, upon the closing thereof, the successor or surviving entity shall assume the obligations of this Agreement. The provisions of this Section 6(a) shall similarly apply to successive Reorganizations.

(b) **Reclassification of Shares.** If the securities issuable upon exercise of this Warrant are changed into the same or a different number of securities of any other class or classes by reclassification, capital reorganization or otherwise (other than as otherwise provided for herein) (a “**Reclassification**”), then, in any such event, in lieu of the number of Shares which the Holder would otherwise have been entitled to receive, the Holder shall have the right thereafter to exercise this Warrant for a number of Shares of such other class or classes of shares that a holder of the number of securities deliverable upon exercise of this Warrant immediately before that change would have been entitled to receive in such Reclassification, all subject to further adjustment as provided herein with respect to such other shares.

(c) **Subdivisions and Combinations.** In the event that the outstanding Ordinary Shares are subdivided (by shares split, by payment of a shares dividend or otherwise) into a greater number of Ordinary Shares, the number of Shares issuable upon exercise of the this Warrant immediately prior to such subdivision shall, concurrently with the effectiveness of such subdivision, be proportionately increased, and the Exercise Price shall be proportionately decreased, and in the event that the outstanding Ordinary Shares are combined (by reclassification or otherwise) into a lesser number of Ordinary Shares, the number of Shares issuable upon exercise of the this Warrant immediately prior to such combination shall, concurrently with the effectiveness of such combination, be proportionately decreased, and the Exercise Price shall be proportionately increased.

(d) **Notice of Adjustments.** Upon any adjustment in accordance with this Section 6, the Company shall give notice thereof to the Holder, which notice shall state the event giving rise to the adjustment, the Exercise Price as adjusted and the number of securities or other property purchasable upon the exercise of this Warrant, setting forth in reasonable detail the method of calculation of each. The Company shall, upon the written request of any Holder, furnish or cause to be furnished to such Holder a certificate setting forth (i) such adjustments, (ii) the Exercise Price at the time in effect and (iii) the number of securities and the amount, if any, of other property that at the time would be received upon exercise of this Warrant.

**7. Notification of Certain Events.** Prior to the expiration of this Warrant pursuant to Section 8, in the event that the Company shall authorize:

(a) the issuance of any dividend or other distribution on the share capital of the Company (other than (i) dividends or distributions otherwise provided for in Section 6, (ii) repurchases of Ordinary Shares issued to or held by employees, officers, directors or consultants of the Company or its subsidiaries upon termination of their employment or services pursuant to agreements providing for the right of said repurchase; (iii) repurchases of Ordinary Shares issued to or held by employees, officers, directors or consultants of the Company or its subsidiaries pursuant to rights of first refusal or first offer contained in agreements providing for such rights; or (iv) repurchases of Ordinary Shares in connection with the settlement of disputes with any shareholder ), whether in cash, property, shares or other securities;

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(b) the voluntary liquidation, dissolution or winding up of the Company; or

(c) any transaction resulting in the expiration of this Warrant pursuant to Section 8(b);

the Company shall send to the Holder of this Warrant at least ten (10) calendar days prior written notice of the date on which a record shall be taken for any such dividend or distribution specified in clause (a) or the expected effective date of any such other event specified in clause (b) or (c), as applicable. The notice provisions set forth in this section may be shortened or waived prospectively or retrospectively by the consent of the Holder of this Warrant.

**8. Expiration of the Warrant.** This Warrant shall expire and shall no longer be exercisable as of the earlier of:

(a) 5:00 p.m., Pacific time, on [ ], [ ]; or

(b) (i) the acquisition of the Company by another entity by means of any transaction or series of related transactions to which the Company is a party (including, without limitation, any share acquisition, reorganization, merger or consolidation, but excluding any sale of shares for capital raising purposes and any transaction effected primarily for purposes of changing the Company's jurisdiction of incorporation) other than a transaction or series of related transactions in which the holders of the voting securities of the Company outstanding immediately prior to such transaction or series of related transactions receive voting securities of such other surviving or resulting entity (or if the Company or such other surviving or resulting entity is a wholly-owned subsidiary immediately following such acquisition, its parent), or (ii) a sale, lease or other disposition of all or substantially all of the assets of the Company and its subsidiaries taken as a whole by means of any transaction or series of related transactions, except where such sale, lease or other disposition is to a wholly-owned subsidiary of the Company; provided that the holders of Shares in the transaction described in (i) or (ii) above receive cash or cash equivalents in such transaction with an aggregate value per Ordinary Share greater than two times the Exercise Price.

**9. No Rights as a Shareholder.** Nothing contained herein shall entitle the Holder to any rights as a shareholder of the Company or to be deemed the holder of any securities that may at any time be issuable on the exercise of the rights hereunder for any purpose nor shall anything contained herein be construed to confer upon the Holder, as such, any right to vote for the election of directors or upon any matter submitted to shareholders at any meeting thereof, or to give or withhold consent to any corporate action (whether upon any recapitalization, issuance of shares, reclassification of shares, change of nominal value or change of shares to no nominal value, consolidation, merger, conveyance or otherwise) or to receive notice of meetings, or to receive dividends or subscription rights or any other rights of a shareholder of the Company until this Warrant shall have been exercised.

**10. Representations and Warranties of the Holder.** By acceptance of this Warrant, the Holder represents and warrants to the Company as follows:

(a) **No Registration.** The Holder understands that the Securities have not been, and will not be, registered under the Securities Act by reason of a specific exemption from the registration provisions of the Securities Act, the availability of which depends upon, among other things, the *bona fide* nature of the investment intent and the accuracy of the Holder's representations as expressed herein or otherwise made pursuant hereto.

(b) **Investment Intent.** The Holder is acquiring the Securities for investment for its own account, not as a nominee or agent, and not with a view to, or for resale in connection with, any distribution thereof. The Holder has no present intention of selling, granting any participation in, or otherwise distributing the Securities, nor does it have any contract, undertaking, agreement or arrangement for the same.

(c) **Investment Experience.** The Holder has substantial experience in evaluating and investing in private placement transactions of securities in companies similar to the Company, and has such knowledge and experience in financial or business matters so that it is capable of evaluating the merits and risks of its investment in the Company and protecting its own interests.

(d) **Speculative Nature of Investment.** The Holder understands and acknowledges that its investment in the Company is highly speculative and involves substantial risks. The Holder can bear the economic

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risk of its investment and is able, without impairing its financial condition, to hold the Securities for an indefinite period of time and to suffer a complete loss of its investment.

(e) **Accredited Investor.** The Holder is an “accredited investor” within the meaning of Regulation D, Rule 501(a), promulgated by the Securities and Exchange Commission and agrees to submit to the Company such further assurances of such status as may be reasonably requested by the Company. The Holder has furnished or made available any and all information requested by the Company or otherwise necessary to satisfy any applicable verification requirements as to “accredited investor” status. Any such information is true, correct, timely and complete.

(f) **Residency.** The residency of the Holder (or, in the case of a partnership or corporation, such entity’s principal place of business) is correctly set forth on the signature page hereto.

(g) **Restrictions on Resales.** The Holder acknowledges that the Securities must be held indefinitely unless subsequently registered under the Securities Act or an exemption from such registration is available. The Holder is aware of the provisions of Rule 144 promulgated under the Securities Act, which permit resale of shares purchased in a private placement subject to the satisfaction of certain conditions, which may include, among other things, the availability of certain current public information about the Company; the resale occurring not less than a specified period after a party has purchased and paid for the security to be sold; the number of shares being sold during any three-month period not exceeding specified limitations; the sale being effected through a “broker’s transaction,” a transaction directly with a “market maker” or a “riskless principal transaction” (as those terms are defined in the Securities Act or the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder); and the filing of a Form 144 notice, if applicable. The Holder acknowledges and understands that the Company may not be satisfying the current public information requirement of Rule 144 at the time the Holder wishes to sell the Securities and that, in such event, the Holder may be precluded from selling the Securities under Rule 144 even if the other applicable requirements of Rule 144 have been satisfied. The Holder acknowledges that, in the event the applicable requirements of Rule 144 are not met, registration under the Securities Act or an exemption from registration will be required for any disposition of the Securities. The Holder understands that, although Rule 144 is not exclusive, the Securities and Exchange Commission has expressed its opinion that persons proposing to sell restricted securities received in a private offering other than in a registered offering or pursuant to Rule 144 will have a substantial burden of proof in establishing that an exemption from registration is available for such offers or sales and that such persons and the brokers who participate in the transactions do so at their own risk.

(h) **Authorization.** The Holder has full legal capacity, power and authority to execute and deliver this Warrant and to perform its obligations hereunder. This Warrant constitutes the valid and binding obligations of the Holder, enforceable in accordance with its terms, except as limited by bankruptcy, insolvency or other laws of general application relating to or affecting the enforcement of creditors’ rights generally and general principles of equity.

#### 11. Miscellaneous.

(a) **Amendments.** Except as expressly provided herein, neither this Warrant nor any term hereof may be amended, waived, discharged or terminated other than by a written instrument referencing this Warrant and signed by the Company and the Holder of this Warrant.

(b) **Waivers.** No waiver of any single breach or default shall be deemed a waiver of any other breach or default theretofore or thereafter occurring.

(c) **Notices.** All notices and other communications required or permitted hereunder shall be in writing and shall be mailed by registered or certified mail, postage prepaid, sent by facsimile or electronic mail (if to the Holder) or otherwise delivered by hand, messenger or courier service addressed:

(i) if to the Holder, to the Holder at the Holder’s address, facsimile number or electronic mail address as show on the signature page hereto, or at such other current address as the Holder shall have furnished to the Company; or

(ii) if to the Company, to the attention of the Chief Executive Officer or Chief

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Financial Officer of the Company at the Company's address, facsimile number or electronic mail address as shown on the signature page hereto, or at such other current address as the Company shall have furnished to the Holder.

Each such notice or other communication shall for all purposes of this Warrant be treated as effective or having been given (i) if delivered by hand, messenger or courier service, when delivered (or if sent via a nationally-recognized overnight courier service, freight prepaid, specifying next-business-day delivery, one business day after deposit with the courier), or (ii) if sent via mail, at the earlier of its receipt or five days after the same has been deposited in a regularly-maintained receptacle for the deposit of the United States mail, addressed and mailed as aforesaid, or (iii) if sent via facsimile, upon confirmation of facsimile transfer or, if sent via electronic mail, upon confirmation of delivery when directed to the relevant electronic mail address, if sent during normal business hours of the recipient, or if not sent during normal business hours of the recipient, then on the recipient's next business day. In the event of any conflict between the Company's books and records and this Warrant or any notice delivered hereunder, the Company's books and records will control absent fraud or error.

(d) **Governing Law.** This Warrant and all actions arising out of or in connection with this Warrant shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflicts of law provisions of the State of New York, or of any other state.

(e) **Jurisdiction and Venue.** The Company agrees that any suit, action or proceeding with respect to this Agreement or any other Loan Document to which it is a party or any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in Houston, Texas or in the courts of its own corporate domicile and irrevocably submits to the non-exclusive jurisdiction of each such court for the purpose of any such suit, action, proceeding or judgment. This Section 13.10(a) is for the benefit of the Holder only and, as a result, Holder shall not be prevented from taking proceedings in any other courts with jurisdiction. Nothing herein shall in any way be deemed to limit the ability of the Holder to serve any such process or summonses in any other manner permitted by applicable law. The Company irrevocably waives to the fullest extent permitted by law any objection that it may now or hereafter have to the laying of the venue of any suit, action or proceeding arising out of or relating to this Warrant and hereby further irrevocably waives to the fullest extent permitted by law any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. A final judgment (in respect of which time for all appeals has elapsed) in any such suit, action or proceeding shall be conclusive and may be enforced in any court to the jurisdiction of which the Company is or may be subject, by suit upon judgment.

(f) **Titles and Subtitles.** The titles and subtitles used in this Warrant are used for convenience only and are not to be considered in construing or interpreting this Warrant. All references in this Warrant to sections, paragraphs and exhibits shall, unless otherwise provided, refer to sections and paragraphs hereof and exhibits attached hereto.

(g) **Severability.** If any provision of this Warrant becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, portions of such provision, or such provision in its entirety, to the extent necessary, shall be severed from this Warrant, and such illegal, unenforceable or void provision shall be replaced with a valid and enforceable provision that will achieve, to the extent possible, the same economic, business and other purposes of the illegal, unenforceable or void provision. The balance of this Warrant shall be enforceable in accordance with its terms.

(h) **Waiver of Jury Trial.** EACH OF THE HOLDER AND THE COMPANY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATED TO THIS WARRANT.

(i) **California Corporate Securities Law.** THE SALE OF THE SECURITIES THAT ARE THE SUBJECT OF THIS WARRANT HAS NOT BEEN QUALIFIED WITH THE COMMISSIONER OF CORPORATIONS OF THE STATE OF CALIFORNIA AND THE ISSUANCE OF SUCH SECURITIES OR THE PAYMENT OR RECEIPT OF ANY PART OF THE CONSIDERATION THEREFOR PRIOR TO SUCH QUALIFICATION IS UNLAWFUL, UNLESS THE SALE OF SECURITIES IS EXEMPT FROM QUALIFICATION BY SECTION 25100, 25102, OR 25105 OF THE CALIFORNIA CORPORATIONS CODE. THE RIGHTS OF ALL PARTIES TO THIS WARRANT ARE EXPRESSLY CONDITIONED UPON THE QUALIFICATION BEING OBTAINED, UNLESS THE SALE IS SO EXEMPT.

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(j) ***Saturdays, Sundays and Holidays.*** If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall be a Saturday, Sunday or U.S. federal holiday, then such action may be taken or such right may be exercised on the next succeeding day that is not a Saturday, Sunday or U.S. federal holiday.

(k) ***Rights and Obligations Survive Exercise of the Warrant.*** Except as otherwise provided herein, the rights and obligations of the Company and the Holder under this Warrant shall survive exercise of this Warrant.

(l) ***Entire Agreement.*** Except as expressly set forth herein, this Warrant (including the exhibits attached hereto) constitutes the entire agreement and understanding of the Company and the Holder with respect to the subject matter hereof and supersedes all prior agreements and understandings relating to the subject matter hereof.

*(signature page follows)*

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The Company and the Holder sign this Warrant as of the date stated on the first page.

COMPANY:

**STRONGBRIDGE BIOPHARMA PLC**

By \_\_\_\_\_

Name:

Title:

Address for Notices:

900 Northbrook Drive  
Suite 200  
Trevose, PA 19053

Attn:

Tel.: (610) 254-9200

Fax:

Email:

With a copy (which shall not constitute notice) to:

Reed Smith LLP  
599 Lexington Avenue  
New York, New York 10022  
Attention: Aron Izower  
Tel.: (212) 549-0393  
Fax: (212) 521-5450  
Email: aizower@reedsmith.com

**AGREED AND ACKNOWLEDGED,**

HOLDER:

By \_\_\_\_\_

Name:

Title:

Address for Notices:

Attn:

Tel.:

Fax:

Email:

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**AMENDED AND RESTATED EMPLOYMENT AGREEMENT**

**THIS AMENDED AND RESTATED EMPLOYMENT AGREEMENT** (the “Agreement”) is made by and between Strongbridge U.S. Inc., a Delaware Corporation (the “Company”), and Matthew Pauls (“Executive”) as of October 13, 2017.

**WITNESSETH:**

**WHEREAS**, the Company and Executive are parties to an amended and restated employment agreement (such agreement, the “Prior Agreement”);

**WHEREAS**, the Company desires to continue to retain the services of Executive as set forth in this Agreement, and Executive desires to serve the Company in such capacity, subject to the terms and conditions of this Agreement; and

**WHEREAS**, the Company and Executive intend for this Agreement to replace the Prior Agreement except as otherwise set forth herein.

**NOW, THEREFORE**, for and in consideration of the mutual promises, covenants and obligations contained herein, Company and Executive agree as follows:

**ARTICLE I**

**EMPLOYMENT AND DUTIES**

**Section 1.01** **Employment and Term.** Subject to the provisions of Article III of this Agreement, the Executive shall be employed by the Company for the period commencing on the date hereof and continuing until terminated as described in Section 3.01 (the “Term”) on the terms and subject to the conditions set forth in this Agreement.

**Section 1.02** **Position and Duties.** Executive shall serve as Chief Executive Officer of the Company, or in such other positions as the parties may agree and shall report directly to the Board of Directors of the Company (the “Board”). Executive shall have the duties and responsibilities customarily associated with such position and will perform such other duties as reasonably directed by the Board consistent with such position(s).

**Section 1.03** **Scope.** Executive will devote substantially all of his business time, attention, skills and efforts to the performance of his duties. Executive acknowledges that his duties and responsibilities require Executive’s full-time business efforts and agrees to not engage in any other business activity or interests which materially interfere or conflict with the performance of Executive’s duties. Notwithstanding the foregoing, Executive may (a) without obtaining approval of the Board, serve on one for profit corporate board that does not compete with the Company, (b) upon receipt of prior written approval by the Board, serve on any other for profit corporate boards that do not compete with the Company, (c) serve on civic or charitable boards or committees of entities that do not compete with the Company, (d) deliver a reasonable number of lectures or fulfill speaking engagements or (e) manage personal investments, so long as

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such activities do not significantly interfere with the performance of Executive's duties and so long as Executive does not own more than five percent (5%) of the voting stock of any publicly held corporation.

## **ARTICLE II**

### **COMPENSATION AND BENEFITS**

**Section 2.01**      **Base Salary.** During the Term, the Company will pay Executive a base salary (the "Base Salary") at an initial rate of \$500,000 per year in accordance with the Company's standard payroll practices. Base Salary will be reviewed at least annually by the Board or a committee thereof and may be adjusted (in which case such adjusted amount shall be the "Base Salary").

**Section 2.02**      **Annual Incentive.** During Executive's employment with the Company, and as determined by the Board in its sole discretion, Executive shall be eligible for an annual cash incentive (the "Annual Incentive") with a target of 50% of Base Salary (such percentage, the "Target Annual Incentive"). The Annual Incentive shall be based on the achievement of predetermined performance goals as determined annually by Executive and the Board, which shall be provided to the Executive in writing no later than thirty (30) days following the beginning of the year to which they relate. The actual Annual Incentive earned in any particular year may be greater or lower than the Target Annual Incentive, depending on the level of achievement of the applicable performance goals and the discretion of the Board. The Annual Incentive shall be paid to Executive as soon as practicable, but in no event later than the date that is two-and-one-half months following the end of the taxable year (of Executive, or the Company, whichever is later) in which such incentive is earned.

**Section 2.03**      **Long-Term Incentive Plans.** Executive shall be eligible to receive grants under the Company's long-term incentive plans (including stock option, restricted stock and other equity compensation plans and any other long-term incentive plans) at the discretion of the Company's Board.

**Section 2.04**      **Business and Entertainment Expenses.** Subject to the Company's standard policies and procedures for expense reimbursement as applied to its executive employees generally, the Company shall reimburse Executive for, or pay on behalf of Executive, reasonable out-of-pocket business expenses incurred by Executive on behalf of the Company.

**Section 2.05**      **Other Company Benefits.** Executive shall be entitled to participate in all employee benefit plans, practices and programs maintained by the Company and made available to its similarly situated executives, including the Company's paid time-off policy. Executive shall also be entitled to paid time-off for all holidays in the U.S. in accordance with the applicable Company policy. Executive shall agree to comply with a reasonable application process to permit the Company to insure his life under a standard "key man" insurance policy upon request from the Board.

**ARTICLE III**  
**TERMINATION**

**Section 3.01**      **General.** The Company may terminate Executive's employment for any reason or no reason, and Executive may terminate his employment for any reason or no reason, in either case subject only to the terms of this Agreement. For purposes of this Agreement, the following terms have the following meanings:

(a)      "Accrued Obligations" shall mean: (i) Executive's earned but unpaid Base Salary through the Termination Date; (ii) payment of any annual, long-term, or other incentive award which relates to a completed fiscal year or performance period, as applicable, and is payable (but not yet paid) on or before the Termination Date; (iii) a lump-sum payment in respect of accrued but unused vacation days at Executive's per-business-day Base Salary rate in effect as of the Termination Date; and (iv) any unpaid expense or other reimbursements due pursuant to Section 2.04 hereof.

(b)      "Cause" shall mean (i) Executive's conviction of, or plea of guilty or nolo contendere to, any felony or any crime involving theft, embezzlement, dishonesty or moral turpitude; (ii) any act by Executive constituting willful misconduct, deliberate malfeasance, dishonesty, unethical conduct or gross negligence in the performance of his duties; (iii) Executive's willful and continued failure to perform any of the duties of his position (which has not been cured within thirty (30) days following the first written notice from the Company describing such failure in reasonable detail); or (iv) any material breach (which has not been cured within 30 days following the first written notice from the Company describing such breach in reasonable detail) by Executive of this Agreement or any other agreement between Executive and the Company or any of its affiliates.

(c)      "Change in Control" shall mean the occurrence of any of the following:

(i)      any person or group of persons becomes the beneficial owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities (a "Majority of the Securities"); provided that if the person or group of persons is already deemed to own more than 50% of the total fair market value or total voting power, then the acquisition of additional stock by such person or group of persons shall not constitute an additional Change in Control;

(ii)      the stockholders of the Company approve a plan of complete liquidation of the Company;

(iii)      the sale or disposition of all or substantially all of the Company's assets;

(iv)      a merger, consolidation or reorganization of the Company with or involving any other entity, other than a merger, consolidation or reorganization that would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting

securities of the surviving entity) at least a 50% of the combined voting power of the Company (or such surviving entity) outstanding immediately after such merger, consolidation or reorganization owned in approximately the same proportion of such ownership by each of the prior shareholders as prior to the transaction.

(v) Notwithstanding the foregoing, the following acquisitions shall not constitute a Change in Control: (A) an acquisition by the Company or entity controlled by the Company, or (B) an acquisition by an employee benefit plan (or related trust) sponsored or maintained by the Company.

(d) “Disability” shall mean Executive’s becoming incapacitated for a period of at least 180 days by accident, sickness or other circumstance that renders Executive mentally or physically incapable of performing the material duties and services required of Executive hereunder on a full-time basis during such period. A termination of Executive’s employment due to a Disability shall be effective only if the party terminating Executive’s employment first gives at least 15 days’ written notice of such termination to the other party.

(e) “Good Reason” shall mean, without Executive’s express written consent, the occurrence of any one or more of the following: (i) a material diminution by the Company of Executive’s Base Salary, other than any diminution that is also applicable in a substantially similar manner and proportion to the other senior executives of the Company; (ii) the assignment to Executive of duties or responsibilities which are materially inconsistent with Executive’s position; (iii) a change in the principal location at which Executive performs his duties for the Company to a new location that is more than fifty (50) miles from the prior location; or (iv) an action or inaction that constitutes a material breach of this Agreement by the Company.

A termination of employment by Executive for Good Reason shall be effectuated by giving the Company written notice (“Notice of Termination for Good Reason”), not later than 30 days following the occurrence of the circumstance that constitutes Good Reason, setting forth in reasonable detail the specific conduct of the Company that constitutes Good Reason and the specific provision(s) of this Agreement on which Executive relied. The Company shall be entitled, during the 45-day period following receipt of a Notice of Termination for Good Reason, to cure the circumstances that gave rise to Good Reason, provided that the Company shall be entitled to waive its right to cure or reduce the cure period by delivery of written notice to that effect to Executive (such 45-day or shorter period, the “Cure Period”). If, during the Cure Period, such circumstance is remedied, Executive will not be permitted to terminate employment for Good Reason as a result of such circumstance. If, at the end of the Cure Period, the circumstance that constitutes Good Reason has not been remedied, Executive will be entitled to terminate employment for Good Reason during the 30-day period that follows the end of the Cure Period. If Executive does not terminate employment during such 30-day period, Executive will not be permitted to terminate employment for Good Reason as a result of such event.

(f) “Pro-Rata Annual Incentive” shall mean an amount equal to (i) the Annual Incentive that Executive would have been entitled to receive for the calendar year that includes the Termination Date if his employment hereunder had continued (as determined by the Board of Directors based upon the actual achievement of the applicable performance goals), multiplied by

(ii) a fraction, the numerator of which is the number of days he was employed hereunder during such year and the denominator of which is the number of days in such year.

(g) “Termination Date” shall mean the date on which Executive’s employment hereunder terminates.

**Section 3.02      Termination Without Cause or by Executive with Good Reason or Due to Executive’s Death.** If the Company terminates Executive’s employment without Cause, or the Executive terminates for Good Reason, or Executive’s employment is terminated due to Executive’s death, the Term shall expire on the Termination Date and Executive shall be entitled to: (a) the Accrued Obligations; (b) an amount equal to the sum of (i) 18 months of the annual Base Salary as in effect immediately prior to the Termination Date and (ii) the Target Annual Incentive, paid in equal installments on the normal payroll cycle over the 18-month period that begins on the sixtieth (60<sup>th</sup>) day following the Termination Date; (c) the Pro-Rata Annual Incentive, payable in a cash lump sum to Executive on the date Company pays its annual incentive compensation bonuses for the year that includes the Termination Date if Executive’s employment continued; and (d) medical, dental benefits provided by the Company to Executive and Executive’s spouse and dependents (in each case, as provided in any applicable plan) at least equal to the levels of benefits provided to other similarly situated active employees of the Company and its subsidiaries until the earlier of (i) the 18-month anniversary of the Termination Date or (ii) the date that Executive becomes covered under a subsequent employer’s medical and dental plans.

**Section 3.03      Reserved.**

**Section 3.04      Termination Without Cause, by Executive with Good Reason, or Due to Executive’s Death following a Change in Control of the Company.** If the Company terminates Executive’s employment without Cause, or the Executive terminates for Good Reason, or Executive’s employment is terminated due to Executive’s death, in any case, within twenty-four (24) months following the occurrence of Change in Control, the Term shall expire on the Termination Date and, in lieu of the benefits set forth in Section 3.02 or 3.03, Executive shall be entitled to: (a) the Accrued Obligations; (b) an amount equal to the sum of (i) 24 months of the annual Base Salary as in effect immediately prior to the Termination Date and (ii) one (1) times the Target Annual Incentive, paid in equal installments on the normal payroll cycle over the 24-month period that begins on the sixtieth (60<sup>th</sup>) day following the Termination Date; (c) the Pro-Rata Annual Incentive, payable in a cash lump sum to Executive on the date Company pays its annual incentive compensation bonuses for the year that includes the Termination Date if Executive’s employment continued; (d) medical, dental benefits provided by the Company to Executive and Executive’s spouse and dependents (in each case, as provided in any applicable plan) at least equal to the levels of benefits provided to other similarly situated active employees of the Company and its subsidiaries until the earlier of (i) the 18-month anniversary of the Termination Date or (ii) the date that Executive becomes covered under a subsequent employer’s medical and dental plans; and (e) the acceleration of vesting of all unvested equity or equity-based awards held by Executive as of the Termination Date.

**Section 3.05      Other Terminations.** If Executive’s employment hereunder is terminated (a) by Executive without Good Reason, (b) by the Company for Cause; or (c) due to Executive’s

Disability, the Term shall expire as of the Termination Date and Executive shall be entitled to the Accrued Obligations.

**Section 3.06 Release.** Executive's entitlement to the payments (other than the Accrued Obligations) and benefits described in this Article III is expressly contingent upon Executive providing the Company with a signed release that is attached hereto as Attachment A (the "Release"). To be effective, such Release must be delivered by Executive to the Company no later than 45 days following the Termination Date and must not be revoked during the seven (7) days following such delivery. If such Release is not executed in a timely manner or is revoked, all such payments and benefits shall immediately cease and the Executive shall be required to repay to the Company any such payments that have already been paid to the Executive.

**Section 3.07 Resignation from Positions.** Upon the termination of Executive's employment for any reason, Executive shall immediately resign from each position held with the Company and its affiliates as of the Termination Date, including any position on the board of directors, if requested to do so by the Company.

## ARTICLE IV

### RESTRICTIVE COVENANTS

**Section 4.01 Confidentiality.**

(a) Company Information. Executive agrees at all times during the Term of this Agreement and thereafter, to hold in strictest confidence, and not to use, except in connection with the performance of Executive's duties, and not to disclose to any person or entity without written authorization of the Company, any Confidential Information of the Company. As used herein, "Confidential Information" means any Company proprietary or confidential information, technical data, trade secrets or know-how, including, but not limited to, research, product plans, products, services, customer lists and customers, markets, software, developments, inventions, processes, formulas, technology, designs, drawings, engineering, marketing, distribution and sales methods and systems, sales and profit figures, finances and other business information disclosed to Executive by the Company, either directly or indirectly in writing, orally or by drawings or inspection of documents or other tangible property. However, Confidential Information does not include any of the foregoing items which has become publicly known and made generally available through no wrongful act of Executive.

(b) Executive-Restricted Information. Executive agrees that during the Term of this Agreement Executive will not improperly use or disclose any proprietary or confidential information or trade secrets of any person or entity with whom Executive has an agreement or duty to keep such information or secrets confidential.

(c) Third Party Information. Executive recognizes that the Company has received and in the future will receive from third parties their confidential or proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. Executive agrees at all times during the Term of this Agreement and thereafter, to hold in strictest confidence, and not to use, except



in connection with the performance of Executive's duties, and not to disclose to any person or entity, or to use it except as necessary in performing the Executive's duties, consistent with the Company's agreement with such third party.

**Section 4.02      Non-Competition.**

(a) Executive acknowledges that, during the Term, Executive has had access to information concerning the Company's critical business strategies, engineering and technology development plans, competitive analyses, organizational structure. Accordingly, in consideration of the compensation provided under this Agreement, Executive agrees that during the Term and for the one (1) year period thereafter, Executive will not directly or indirectly, own, manage, operate, control (including indirectly through a debt or equity investment), provide services to, or be employed by, any person or entity engaged in any business that is (i) located in or provides services or products to a region in which the Company does business, and (ii) competitive with the business activities of the Company as they existed during the period that Executive provided services to the Company.

(b) Executive acknowledges that the restrictions contained under this Section 4.02 are reasonable and necessary to protect the legitimate interests of the Company, that the Company would not have executed this Agreement in the absence of such restrictions, and that any violation of any provision of this paragraph will result in irreparable injury to the Company. In the event the provisions under this Section 4.02 shall ever be deemed to exceed the time, scope or geographic limitations permitted by applicable laws, then such provisions shall be reformed to the maximum time, scope or geographic limitations, as the case may be, permitted by applicable laws.

**Section 4.03      Injunctive Relief.** Executive agrees that it is impossible to measure in money the damages which will accrue to the Company by reason of a failure by Executive to perform any of Executive's obligations under this Article IV. Accordingly, if Company or any of its affiliates institutes any action or proceeding to enforce its rights under this Article IV, to the extent permitted by applicable law, Executive hereby waives the claim or defense that the Company or its affiliates has an adequate remedy at law, and Executive shall not claim that any such remedy at law exists.

**ARTICLE V**

**MISCELLANEOUS**

**Section 5.01      Withholding.** The Company shall withhold all applicable federal, state and local taxes, social security and workers' compensation contributions and other amounts as may be required by law with respect to compensation payable to Executive.

**Section 5.02      Modification of Payments.**

(a) In the event it shall be determined that any payment, right or distribution by the Company or any other person or entity to or for the benefit of Executive pursuant to the terms of this Agreement or otherwise, in connection with, or arising out of, his employment with the Company or a change in ownership or effective control of the Company or a substantial portion of

its assets (a “Payment”) is a “parachute payment” within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the “Code”) on account of the aggregate value of the Payments due to Executive being equal to or greater than three times the “base amount,” as defined in Section 280G(b)(3) of the Code, (the “Parachute Threshold”) so that Executive would be subject to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”) and the net after-tax benefit that Executive would receive by reducing the Payments to the Parachute Threshold is greater than the net after-tax benefit Executive would receive if the full amount of the Payments were paid to Executive, then the Payments payable to Executive shall be reduced (but not below zero) so that the Payments due to Executive do not exceed the amount of the Parachute Threshold, reducing first any Payments under Section 3.02(b) hereof.

(b) The Company hereby agrees that, for purposes of determining whether any payment and benefits set forth in Section 3.04 above would be subject to the Excise Tax, the non-compete set forth in in Section 4.02 above shall be treated as an agreement for the performance of personal services. The Company hereby agrees to indemnify, defend, and hold harmless Executive from and against any adverse impact, tax, penalty, or excise tax resulting from the Company or accountant’s attribution of a value to the non-compete set forth in in Section 4.02 above that is less than the total compensation amount that would be disclosed under Item 402(c) of Securities and Exchange Commission Regulation S-K in the year prior to year of the event that triggers the Excise Tax, to the extent the use of such lesser amount results in a larger Excise Tax than Executive would have been subject to had the Company or accountant attributed a value to the non-compete set forth in in Section 4.02 above that is at least equal to the total compensation amount disclosed under Item 402(c) of Securities and Exchange Commission Regulation S-K for such year.

**Section 5.03      Section 409A.**

(a) Notwithstanding anything herein to the contrary, this Agreement is intended to be interpreted and applied so that the payment of the benefits set forth herein either shall either be exempt from the requirements of Section 409A of the Code (“Section 409A”) or shall comply with the requirements of such provision.

(b) Notwithstanding any provision of this Agreement to the contrary, if Executive is a “specified employee” within the meaning of Section 409A, any payments or arrangements due upon a termination of Executive’s employment under any arrangement that constitutes a “nonqualified deferral of compensation” within the meaning of Section 409A and which do not otherwise qualify under the exemptions under Treas. Regs. Section 1.409A-1 (including without limitation, the short-term deferral exemption or the permitted payments under Treas. Regs. Section 1.409A-1(b)(9)(iii)(A)), shall be delayed and paid or provided, without interest, on the earlier of (i) the date which is six months after Executive’s “separation from service” (as such term is defined in Section 409A and the regulations and other published guidance thereunder) for any reason other than death, and (ii) the date of Executive’s death.

(c) After any Termination Date, Executive shall have no duties or responsibilities that are inconsistent with having a “separation from service” within the meaning of Section 409A and, notwithstanding anything in the Agreement to the contrary, distributions upon termination of employment of nonqualified deferred compensation may only be made upon a “separation from service” as determined under Section 409A and such date shall be the

Termination Date for purposes of this Agreement. Each payment under this Agreement or otherwise shall be treated as a separate payment for purposes of Section 409A. In no event may Executive, directly or indirectly, designate the calendar year of any payment to be made under this Agreement which constitutes a “nonqualified deferral of compensation” within the meaning of Section 409A and to the extent an amount is payable within a time period, the time during which such amount is paid shall be in the discretion of the Company.

**Section 5.04      Merger Clause.** Effective as of the date hereof, this Agreement contains the complete, full, and exclusive understanding of Executive and the Company as to its subject matter and shall, on such date, and supersede any prior employment agreement between Executive and the Company (and its affiliates), including the Prior Agreement. Any amendments to this Agreement shall be effective and binding on Executive and the Company only if any such amendments are in writing and signed by both Parties.

**Section 5.05      Assignment.**

(a) This Agreement is personal to Executive and, without the prior written consent of the Company, shall not be assigned by Executive otherwise than by will or the laws of descent and distribution, and any assignment in violation of this Agreement shall be void.

(b) Notwithstanding the foregoing Section 5.05(a), this Agreement and all rights of Executive hereunder shall inure to the benefit of, and be enforceable by, Executive’s personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees. If Executive should die while any amounts would still be payable to him or her hereunder if he or she had continued to live, all such amounts, unless otherwise provided herein, shall be paid in accordance with the terms of this Agreement to Executive’s devisee, legatee or other designee or, should there be no such designee, to Executive’s estate.

(c) The Company may assign this Agreement to any affiliate or subsidiary of the Company without the consent of Executive and shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company (a “Successor”) to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would have been required to perform it if no such succession had taken place. As used in this Agreement, (i) the term “Company” shall mean the Company as hereinbefore defined and any Successor and any permitted assignee to which this Agreement is assigned and (ii) the term “Board” shall mean the Board as hereinbefore defined and the board of directors or equivalent governing body of any Successor and any permitted assignee to which this Agreement is assigned.

**Section 5.06      Dispute Resolution.** Except for any proceeding brought pursuant to Section 5.05 above, the parties agree that any dispute arising out of or relating to this Agreement or the formation, breach, termination or validity thereof, will be settled by binding arbitration by a panel of three arbitrators in accordance with the commercial arbitration rules of the American Arbitration Association. The arbitration proceedings will be located in Philadelphia, Pennsylvania. The arbitrators are not empowered to award damages in excess of compensatory damages and each party irrevocably waives any damages in excess of compensatory damages. Judgment upon any arbitration award may be entered into any court having jurisdiction thereof

and the parties consent to the jurisdiction of any court of competent jurisdiction located in the Eastern District of Pennsylvania.

**Section 5.07**      **GOVERNING LAW.** THIS AGREEMENT SHALL BE DEEMED TO BE MADE IN THE COMMONWEALTH OF PENNSYLVANIA, INTERPRETATION, CONSTRUCTION AND PERFORMANCE OF THIS AGREEMENT IN ALL RESPECT SHALL BE GOVERNED BY THE LAWS OF THE COMMONWEALTH OF PENNSYLVANIA WITHOUT REGARD TO ITS PRINCIPLES OF CONFLICTS OF LAW.

**Section 5.08**      **Amendment; No Waiver.** No provision of this Agreement may be amended, modified, waived or discharged except by a written document signed by Executive and duly authorized officer of the Company. The failure of a party to insist upon strict adherence to any term of this Agreement on any occasion shall not be considered as a waiver of such party's rights or deprive such party of the right thereafter to insist upon strict adherence to that term or any other term of this Agreement. No failure or delay by any party in exercising any right or power hereunder will operate as a waiver thereof, nor will any single or partial exercise of any other right or power. No agreements or representations, oral or otherwise, express or implied, with respect to the subject matter hereof have been made by any party, which are not set forth expressly in this Agreement.

**Section 5.09**      **Severability.** If any term or provision of this Agreement is invalid, illegal or incapable of being enforced by any applicable law or public policy, all other conditions and provisions of this Agreement shall nonetheless remain in full force and effect so long as the economic and legal substance of the transactions contemplated by this Agreement is not affected in any manner materially adverse to any party. Upon any such determination that any term or other provision is invalid, illegal or incapable of being enforced, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the fullest extent possible.

**Section 5.10**      **Survival.** The rights and obligations of the parties under the provisions of this Agreement that relate to post-termination obligations shall survive and remain binding and enforceable, notwithstanding the expiration of the term of this Agreement, the termination of Executive's employment with the Company for any reason or any settlement of the financial rights and obligations arising from Executive's employment hereunder, to the extent necessary to preserve the intended benefits of such provisions.

**Section 5.11**      **Notices.** All notices and other communications required or permitted by this Agreement will be made in writing and all such notices and communications will be deemed to have been duly given when delivered or (unless otherwise specified) mailed by United States certified or registered mail, return receipt requested, postage prepaid, addressed, if to the Company, at its principal office, and if to Executive, at Executive's last address on file with the Company. Either party may change such address from time to time by notice to the other.

**Section 5.12**      **Headings and References.** The headings of this Agreement are inserted for convenience only and neither constitute a part of this Agreement nor affect in any way the

meaning or interpretation of this Agreement. When a reference in this Agreement is made to a Section, such reference shall be to a Section of this Agreement unless otherwise indicated.

**Section 5.13**      **Counterparts.**      This Agreement may be executed in one or more counterparts (including via facsimile), each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

*[signature page follows]*

**IN WITNESS WHEREOF**, this Agreement has been executed by the parties as of the date first written above.

**STRONGBRIDGE U.S. INC.**

By:  
Name: A. Brian Davis  
Title: Chief Financial Officer

**EXECUTIVE**

Matthew Pauls

## ATTACHMENT A

### GENERAL RELEASE

1. Matthew Pauls (“Executive”), for and in consideration of the commitments of Strongbridge U.S. Inc. (the “Company”) as set forth in Article III of the Amended and Restated Employment Agreement dated as of October 13, 2017 (the “Employment Agreement”), and intending to be legally bound, does hereby REMISE, RELEASE AND FOREVER DISCHARGE the Company and its present and former divisions, subsidiaries, parents, predecessor and successor corporations, officers, directors, and their respective successors, predecessors, assigns, heirs, executors, and administrators (collectively, “Releasees”) from all causes of action, suits, debts, claims and demands whatsoever in law or in equity, which Executive ever had, now has, or hereafter may have, whether known or unknown, or which Executive’s heirs, executors, or administrators may have, by reason of any matter, cause or thing whatsoever, up to the date of Executive’s execution of this General Release, particularly, but without limitation of the foregoing general terms, any claims arising from or relating in any way to Executive’s employment relationship with the Company and Releasees, the terms and conditions of that relationship, and the termination of that relationship, including, but not limited to, any claims arising under any applicable Company employee benefit plan(s), the Age Discrimination in Employment Act, the Older Workers’ Benefit Protection Act, Title VII of The Civil Rights Act of 1964, the Civil Rights Act of 1991, Sections 1981 through 1988 of Title 42 of the United States Code, the Americans with Disabilities Act, the Employee Retirement Income Security Act of 1974, the Family and Medical Leave Act, the Worker Adjustment and Retraining Notification Act, Pennsylvania employment laws, and any other federal, state and local employment laws, as amended, and any other claims under any federal, state or local common law, statutory, or regulatory provision, now or hereafter recognized, and any claims for attorneys’ fees and costs. This General Release is effective without regard to the legal nature of the claims raised and without regard to whether any such claims are based upon tort, equity, implied or express contract or discrimination of any sort.

2. To the fullest extent permitted by law, and subject to the provisions of Paragraph 3 below, Executive represents and affirms that (i) Executive has not filed or caused to be filed on Executive’s behalf any claim for relief against the Company or any Releasee and, to the best of Executive’s knowledge and belief, no outstanding claims for relief have been filed or asserted against the Company or any Releasee on Executive’s behalf; and (ii) Executive has no knowledge of any improper, unethical or illegal conduct or activities that Executive has not already reported to any supervisor, manager, department head, human resources representative, agent or other representative of the Company, to any member of the Company’s legal or compliance departments, or to the ethics hotline; and (iii) Executive will not file, commence, prosecute or participate in any judicial or arbitral action or proceeding against the Company or any Releasee based upon or arising out of any act, omission, transaction, occurrence, contract, claim or event existing or occurring on or before the date of execution of this General Release.

3. The release of claims described in Paragraph 1 of this General Release does not preclude Executive from filing a charge with the U.S. Equal Employment Opportunity Commission. However, Executive agrees and hereby waives any and all rights to any monetary relief or other personal recovery from any such charge, including costs and attorneys’ fees.

4. Subject to the provisions of Paragraph 3 of this General Release, in further consideration of the commitments of the Company as described in the Employment Agreement, Executive agrees that Executive will not file, claim, sue or cause or permit to be filed, any civil action,

suit or legal proceeding seeking equitable or monetary relief (including damages, injunctive, declaratory, monetary or other relief) for himself involving any matter released in Paragraph 1. In the event that suit is filed in breach of this release of claims, it is expressly understood and agreed that this release of claims shall constitute a complete defense to any such suit. In the event any Releasee is required to institute litigation to enforce the terms of this paragraph, Releasees shall be entitled to recover reasonable costs and attorneys' fees incurred in such enforcement. Executive further agrees and covenants that should any person, organization, or other entity file, claim, sue, or cause or permit to be filed any civil action, suit or legal proceeding involving any matter occurring at any time in the past, Executive will not seek or accept personal equitable or monetary relief in such civil action, suit or legal proceeding. Nothing in this General Release shall prohibit or restrict Executive from: (i) making any disclosure of information required by law; (ii) providing information to, or testifying or otherwise assisting in any investigation or proceeding brought by any federal regulatory or law enforcement agency or legislative body, any self-regulatory organization, or the Company's designated legal, compliance or human resources officers; or (iii) filing, testifying, participating in or otherwise assisting in a proceeding relating to an alleged violation of any federal, state or municipal law relating to fraud, or any rule or regulation of the Securities and Exchange Commission or any self-regulatory organization.

5. Executive understands and agrees that the payments, benefits and agreements provided in the Employment Agreement are being provided to Executive in consideration for Executive's acceptance and execution of, and in reliance upon Executive's representations in, the Employment Agreement and this General Release, and that they are greater than the payments, benefits and agreements, if any, to which Executive would have received if Executive had not executed the Employment Agreement and this General Release. In addition, Executive acknowledges and agrees that Executive has been paid all amounts owed to Executive as of the date of Executive's signing of this General Release.

6. Executive and the Company agree and acknowledge that the agreement by the Company described in the Employment Agreement, and the settlement and termination of any asserted or unasserted claims against the Releasees, are not and shall not be construed to be an admission of any violation of any federal, state or local statute or regulation, or of any duty owed by any of the Releasees to Executive.

7. This General Release and the obligations of the parties hereunder shall be construed, interpreted and enforced in accordance with and be governed by the laws of Pennsylvania without reference to its conflicts of laws principles.

8. Executive certifies and acknowledges as follows:

- a. that Executive has read the terms of this General Release, and that Executive understands its terms and effects, including the fact that Executive has agreed to **RELEASE AND FOREVER DISCHARGE** the Company and each and every one of its affiliated entities from any legal action arising out of Executive's relationship with the Company and the termination of that relationship;
- b. that Executive has signed this Release voluntarily and knowingly in exchange for the consideration described herein and in the Employment Agreement,



which Executive acknowledges is adequate and satisfactory to Executive and to which Executive acknowledges that Executive would not otherwise be entitled;

- c. that Executive has been and is hereby advised in writing to consult with an attorney prior to signing this General Release;
- d. that Executive does not waive rights or claims that may arise after the date this General Release is executed;
- e. that the Company has provided Executive with at least 21 (twenty-one) days within which to consider this General Release, that any modifications, material or otherwise, made to this General Release have not restarted or affected in any manner the original 21 (twenty-one) day consideration period, and that Executive has signed on the date indicated below after concluding that this General Release is satisfactory to Executive;
- f. that Executive acknowledges that this General Release may be revoked by Executive within seven (7) days after Executive's execution, and it shall not become effective until the expiration of such seven-day revocation period. If the last day of the revocation period is a Saturday, Sunday, or legal holiday in the state in which Executive resides, then the revocation period shall not expire until the next following day which is not a Saturday, Sunday, or legal holiday. In the event of a timely revocation by Executive, this General Release and the Employment Agreement will be deemed null and void and the Company will have no obligations hereunder; and
- g. that this General Release may not be signed prior to the third calendar day before the last day of the Term of the Employment Agreement. If this General Release is signed prior to the last day of the Term of the Employment Agreement, the Company reserves the right to have Executive ratify the General Release on or after the last day of the Term.

Intending to be legally bound hereby, Executive executed the foregoing General Release on the date indicated below.

**Matthew Pauls**

\_\_\_\_\_  
Signature

Date: \_\_\_\_\_

**AMENDED AND RESTATED EMPLOYMENT AGREEMENT**

**THIS AMENDED AND RESTATED EMPLOYMENT AGREEMENT** (the "Agreement") is made by and between Strongbridge U.S. Inc., a Delaware corporation (the "Company"), and \_\_\_\_\_ ("Executive") as of October 13, 2017.

**WITNESSETH:**

**WHEREAS**, the Company and Executive are parties to an amended and restated employment agreement (such agreement, the "Prior Agreement");

**WHEREAS**, the Company desires to continue to retain the services of Executive as set forth in this Agreement, and Executive desires to serve the Company in such capacity, subject to the terms and conditions of this Agreement; and

**WHEREAS**, the Company and Executive intend for this Agreement to replace the Prior Agreement except as otherwise set forth herein.

**NOW, THEREFORE**, for and in consideration of the mutual promises, covenants and obligations contained herein, Company and Executive agree as follows:

**ARTICLE I****EMPLOYMENT AND DUTIES**

**Section 1.01 Employment and Term**. Subject to the provisions of Article III of this Agreement, Executive shall be employed by the Company for the period commencing on the date hereof and continuing until terminated as described in Section 3.01 (the "Term") on the terms and subject to the conditions set forth in this Agreement.

**Section 1.02 Position and Duties**. Executive shall serve as the \_\_\_\_\_ of the Company, or in such other positions as the parties may agree. Executive shall have the duties and responsibilities customarily associated with such position and will perform such other duties as reasonably directed by the Chief Executive Officer of the Company (the "CEO") consistent with such position(s).

**Section 1.03 Scope**. Executive will devote substantially all of his business time, attention, skills and efforts to the performance of his duties. Executive acknowledges that his duties and responsibilities require Executive's full-time business efforts and agrees to not engage in any other business activity or interests which materially interfere or conflict with the performance of Executive's duties. Notwithstanding the foregoing, Executive may (a) serve on corporate, civic or charitable boards or committees of entities that do not compete with the Company, with the approval of the CEO, (b) deliver a reasonable number of lectures or fulfill speaking engagements, with the approval of the CEO, or (c) manage personal investments, so long as such activities do not significantly interfere with the performance of Executive's duties.

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## ARTICLE II

### COMPENSATION AND BENEFITS

**Section 2.01 Base Salary.** During the Term, the Company will pay Executive a base salary (the “Base Salary”) at an initial rate of \$ \_\_\_\_\_ per year in accordance with the Company’s standard payroll practices. The Base Salary will be reviewed at least annually by the Board of Directors of the Company (the “Board”) or a committee thereof and may be adjusted (in which case such adjusted amount shall be the “Base Salary”).

**Section 2.02 Annual Incentive.** During Executive’s employment with the Company, and as determined by the Board in its sole discretion, Executive shall be eligible for an annual cash incentive (the “Annual Incentive”) with a target of forty percent (40%) of the Base Salary (such percentage, the “Target Annual Incentive”). The Annual Incentive shall be based on the achievement of predetermined performance goals as determined annually by the CEO and the Board, which shall be provided to Executive in writing no later than thirty (30) days following the beginning of the year to which they relate. The actual Annual Incentive earned in any particular year may be greater or lower than the Target Annual Incentive, depending on the level of achievement of the applicable performance goals and the discretion of the Board. The Annual Incentive shall be paid to Executive as soon as practicable, but in no event later than the date that is two-and-one-half months following the end of the taxable year (of Executive, or the Company, whichever is later) in which such incentive is earned. Notwithstanding anything herein to the contrary, Executive’s Annual Incentive for the 2015 fiscal year shall be based on a full year of employment and not pro-rated.

**Section 2.03 Long-Term Incentive Plans.** Executive shall be eligible to receive grants under the Company’s long-term incentive plans (including stock option, restricted stock and other equity compensation plans and any other long-term incentive plans) at the discretion of the CEO and the Board.

**Section 2.04 Business and Entertainment Expenses.** Subject to the Company’s standard policies and procedures for expense reimbursement as applied to its executive employees generally, the Company shall reimburse Executive for, or pay on behalf of Executive, reasonable out-of-pocket business expenses incurred by Executive on behalf of the Company.

**Section 2.05 Other Company Benefits.** Executive shall be entitled to participate in all employee benefit plans, practices and programs maintained by the Company and made available to its similarly situated executives, including the Company’s paid time-off policy. Executive shall also be entitled to paid time-off for all holidays in the U.S. in accordance with the applicable Company policy.

## ARTICLE III

### TERMINATION

**Section 3.01 General.** The Company may terminate Executive's employment for any reason or no reason, and Executive may terminate his employment for any reason or no reason, in either case subject only to the terms of this Agreement. For purposes of this Agreement, the following terms have the following meanings:

(a) "Accrued Obligations" shall mean (i) Executive's earned but unpaid Base Salary through the Termination Date; (ii) payment of any annual, long-term, or other incentive award which relates to a completed fiscal year or performance period, as applicable, and is payable (but not yet paid) on or before the Termination Date; (iii) a lump-sum payment in respect of accrued but unused vacation days at Executive's per-business-day Base Salary rate in effect as of the Termination Date; and (iv) any unpaid expense or other reimbursements due pursuant to Section 2.04 hereof.

(b) "Cause" shall mean (i) Executive's conviction of, or plea of guilty or nolo contendere to, any felony or any crime involving theft, embezzlement, dishonesty or moral turpitude; (ii) any act by Executive constituting willful misconduct, deliberate malfeasance, dishonesty, unethical conduct or gross negligence in the performance of his duties; (iii) Executive's willful and continued failure to perform any of the duties of his position (which has not been cured within thirty (30) days following the first written notice from the Company describing such failure in reasonable detail); or (iv) any material breach (which has not been cured within thirty (30) days following the first written notice from the Company describing such breach in reasonable detail) by Executive of this Agreement or any other agreement between Executive and the Company or any of its affiliates.

(c) "Change in Control" shall mean the occurrence of any of the following:

(i) any person or group of persons becomes the beneficial owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities (a "Majority of the Securities"); provided that if the person or group of persons is already deemed to own more than 50% of the total fair market value or total voting power, then the acquisition of additional stock by such person or group of persons shall not constitute an additional Change in Control;

(ii) the stockholders of the Company approve a plan of complete liquidation of the Company;

(iii) the sale or disposition of all or substantially all of the Company's assets;

(iv) a merger, consolidation or reorganization of the Company with or involving any other entity, other than a merger, consolidation or reorganization that would result in the voting securities of the Company outstanding immediately prior thereto

continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) at least a 50% of the combined voting power of the Company (or such surviving entity) outstanding immediately after such merger, consolidation or reorganization owned in approximately the same proportion of such ownership by each of the prior shareholders as prior to the transaction.

(v) Notwithstanding the foregoing, the following acquisitions shall not constitute a Change in Control: (A) an acquisition by the Company or entity controlled by the Company, or (B) an acquisition by an employee benefit plan (or related trust) sponsored or maintained by the Company.

(d) “Disability” shall mean Executive’s becoming incapacitated for a period of at least one hundred eighty (180) days by accident, sickness or other circumstance that renders Executive mentally or physically incapable of performing the material duties and services required of Executive hereunder on a full-time basis during such period. A termination of Executive’s employment due to a Disability shall be effective only if the party terminating Executive’s employment first gives at least fifteen (15) days’ written notice of such termination to the other party.

(e) “Good Reason” shall mean, without Executive’s express written consent, the occurrence of any one or more of the following: (i) a material diminution by the Company of Executive’s Base Salary, other than any diminution that is also applicable in a substantially similar manner and proportion to the other senior executives of the Company; (ii) the assignment to Executive of duties or responsibilities which are materially inconsistent with Executive’s position; (iii) a change in the principal location at which Executive performs his duties for the Company to a new location that is more than fifty (50) miles from the prior location; or (iv) an action or inaction that constitutes a material breach of this Agreement by the Company.

A termination of employment by Executive for Good Reason shall be effectuated by giving the Company written notice (“Notice of Termination for Good Reason”), not later than thirty (30) days following the occurrence of the circumstance that constitutes Good Reason, setting forth in reasonable detail the specific conduct of the Company that constitutes Good Reason and the specific provision(s) of this Agreement on which Executive relied. The Company shall be entitled, during the forty-five (45) day period following receipt of a Notice of Termination for Good Reason, to cure the circumstances that gave rise to Good Reason, provided that the Company shall be entitled to waive its right to cure or reduce the cure period by delivery of written notice to that effect to Executive (such forty-five (45) day or shorter period, the “Cure Period”). If, during the Cure Period, such circumstance is remedied, Executive will not be permitted to terminate employment for Good Reason as a result of such circumstance. If, at the end of the Cure Period, the circumstance that constitutes Good Reason has not been remedied, Executive will be entitled to terminate employment for Good Reason during the thirty (30) day period that follows the end of the Cure Period. If Executive does not terminate employment during such thirty (30) day period, Executive will not be permitted to terminate employment for Good Reason as a result of such event.

( f ) “Pro-Rata Annual Incentive” shall mean an amount equal to (i) the Annual Incentive that Executive would have been entitled to receive for the calendar year that includes the

Termination Date if his employment hereunder had continued (as determined by the Board based upon the actual achievement of the applicable performance goals), multiplied by (ii) a fraction, the numerator of which is the number of days he was employed hereunder during such year and the denominator of which is the number of days in such year.

( g ) “Termination Date” shall mean the date on which Executive’s employment hereunder terminates.

**Section 3.02 Termination Without Cause or by Executive with Good Reason or Due to Executive’s Death.** If the Company terminates Executive’s employment without Cause, or Executive terminates for Good Reason, or Executive’s employment is terminated due to Executive’s death, the Term shall expire on the Termination Date and Executive shall be entitled to: (a) the Accrued Obligations; (b) an amount equal to the sum of (i) twelve (12) months of the annual Base Salary as in effect immediately prior to the Termination Date and (ii) the Target Annual Incentive, paid in equal installments on the normal payroll cycle over the twelve (12) month period that begins on the sixtieth (60<sup>th</sup>) day following the Termination Date; (c) the Pro-Rata Annual Incentive, payable in a cash lump sum to Executive on the date Company pays its annual incentive compensation bonuses for the year that includes the Termination Date if Executive’s employment continued; and (d) medical, dental benefits provided by the Company to Executive and Executive’s spouse and dependents (in each case, as provided in any applicable plan) at least equal to the levels of benefits provided to other similarly situated active employees of the Company and its subsidiaries until the earlier of (i) the one-year anniversary of the Termination Date or (ii) the date that Executive becomes covered under a subsequent employer’s medical and dental plans.

**Section 3.03 Reserved.**

**Section 3.04 Termination Without Cause, by Executive with Good Reason, or Due to Executive’s Death following a Change in Control of the Company.** If the Company terminates Executive’s employment without Cause, Executive terminates for Good Reason, or Executive’s employment is terminated due to Executive’s death, in any case, within twenty four (24) months following the occurrence of Change in Control, the Term shall expire on the Termination Date and, in lieu of the benefits set forth in Section 3.02 or 3.03, Executive shall be entitled to: (a) the Accrued Obligations; (b) an amount equal to the sum of (i) eighteen (18) months of the annual Base Salary as in effect immediately prior to the Termination Date and (ii) the Target Annual Incentive, paid in equal installments on the normal payroll cycle over the eighteen (18) month period that begins on the sixtieth (60<sup>th</sup>) day following the Termination Date; (c) the Pro-Rata Annual Incentive, payable in a cash lump sum to Executive on the date Company pays its annual incentive compensation bonuses for the year that includes the Termination Date if Executive’s employment continued; (d) medical, dental benefits provided by the Company to Executive and Executive’s spouse and dependents (in each case, as provided in any applicable plan) at least equal to the levels of benefits provided to other similarly situated active employees of the Company and its subsidiaries until the earlier of (i) the one-year anniversary of the Termination Date or (ii) the date that Executive becomes covered under a subsequent employer’s medical and dental plans; and (e) the acceleration of vesting of all unvested equity or equity based awards held by Executive as of the Termination Date.

**Section 3.05 Other Terminations.** If Executive's employment hereunder is terminated (a) by Executive without Good Reason; (b) by the Company for Cause; or (c) due to Executive's Disability, the Term shall expire as of the Termination Date and Executive shall be entitled to the Accrued Obligations.

**Section 3.06 Release.** Executive's entitlement to the payments (other than the Accrued Obligations) and benefits described in this Article III is expressly contingent upon Executive providing the Company with a signed release that is attached hereto as **Attachment A** (the "Release"). To be effective, such Release must be delivered by Executive to the Company no later than forty-five (45) days following the Termination Date and must not be revoked during the seven (7) days following such delivery. If such Release is not executed in a timely manner or is revoked, all such payments and benefits shall immediately cease and Executive shall be required to repay to the Company any such payments that have already been paid to Executive.

## ARTICLE IV

### RESTRICTIVE COVENANTS

#### **Section 4.01 Confidentiality.**

( a ) Company Information. Executive agrees at all times during the Term of this Agreement and thereafter, to hold in strictest confidence, and not to use, except in connection with the performance of Executive's duties, and not to disclose to any person or entity without written authorization of the Company, any Confidential Information of the Company. As used herein, "Confidential Information" means any Company proprietary or confidential information, technical data, trade secrets or know-how, including, but not limited to, research, product plans, products, services, customer lists and customers, markets, software, developments, inventions, processes, formulas, technology, designs, drawings, engineering, marketing, distribution and sales methods and systems, sales and profit figures, finances and other business information disclosed to Executive by the Company, either directly or indirectly in writing, orally or by drawings or inspection of documents or other tangible property. However, Confidential Information does not include any of the foregoing items which has become publicly known and made generally available through no wrongful act of Executive.

( b ) Executive-Restricted Information. Executive agrees that during the Term of this Agreement Executive will not improperly use or disclose any proprietary or confidential information or trade secrets of any person or entity with whom Executive has an agreement or duty to keep such information or secrets confidential.

( c ) Third Party Information. Executive recognizes that the Company has received and in the future will receive from third parties their confidential or proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. Executive agrees at all times during the Term of this Agreement and thereafter, to hold in strictest confidence, and not to use, except in connection with the performance of Executive's duties, and not to disclose to any person or entity, or to use it except as necessary in performing Executive's duties, consistent with the Company's agreement with such third party.



**Section 4.02 Non-Competition.**

( a ) Executive acknowledges that, during the Term, Executive has had access to information concerning the Company's critical business strategies, engineering and technology development plans, competitive analyses, organizational structure. Accordingly, in consideration of the compensation provided under this Agreement, Executive agrees that during the Term and for the one (1) year period thereafter, Executive will not directly or indirectly, own, manage, operate, control (including indirectly through a debt or equity investment), provide services to, or be employed by, any person or entity engaged in any business that is (i) located in or provides services or products to a region in which the Company does business, and (ii) competitive with the business activities of the Company as they existed during the period that Executive provided services to the Company.

( b ) Executive acknowledges that the restrictions contained under this Section 4.02 are reasonable and necessary to protect the legitimate interests of the Company, that the Company would not have executed this Agreement in the absence of such restrictions, and that any violation of any provision of this paragraph will result in irreparable injury to the Company. In the event the provisions under this Section 4.02 shall ever be deemed to exceed the time, scope or geographic limitations permitted by applicable laws, then such provisions shall be reformed to the maximum time, scope or geographic limitations, as the case may be, permitted by applicable laws.

**Section 4.03 Injunctive Relief.** Executive agrees that it is impossible to measure in money the damages which will accrue to the Company by reason of a failure by Executive to perform any of Executive's obligations under this Article IV. Accordingly, if Company or any of its affiliates institutes any action or proceeding to enforce its rights under this Article IV, to the extent permitted by applicable law, Executive hereby waives the claim or defense that the Company or its affiliates has an adequate remedy at law, and Executive shall not claim that any such remedy at law exists.

**ARTICLE V**

**MISCELLANEOUS**

**Section 5.01 Withholding.** The Company shall withhold all applicable federal, state and local taxes, social security and workers' compensation contributions and other amounts as may be required by law with respect to compensation payable to Executive.

**Section 5.02 Modification of Payments.**

( a ) In the event it shall be determined that any payment, right or distribution by the Company or any other person or entity to or for the benefit of Executive pursuant to the terms of this Agreement or otherwise, in connection with, or arising out of, his employment with the Company or a change in ownership or effective control of the Company or a substantial portion of its assets (a "Payment") is a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "Code") on account of the aggregate value of the Payments due to Executive being equal to or greater than three times the "base amount," as defined

in Section 280G(b)(3) of the Code, (the “Parachute Threshold”) so that Executive would be subject to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”) and the net after-tax benefit that Executive would receive by reducing the Payments to the Parachute Threshold is greater than the net after-tax benefit Executive would receive if the full amount of the Payments were paid to Executive, then the Payments payable to Executive shall be reduced (but not below zero) so that the Payments due to Executive do not exceed the amount of the Parachute Threshold, reducing first any Payments under Section 3.02(b) hereof.

( b ) The Company hereby agrees that, for purposes of determining whether any payment and benefits set forth in Section 3.04 above would be subject to the Excise Tax, the non-compete set forth in in Section 4.02 above shall be treated as an agreement for the performance of personal services. The Company hereby agrees to indemnify, defend, and hold harmless Executive from and against any adverse impact, tax, penalty, or excise tax resulting from the Company or accountant’s attribution of a value to the non-compete set forth in in Section 4.02 above that is less than the total compensation amount that would be disclosed under Item 402(c) of Securities and Exchange Commission Regulation S-K if Executive had been a “named executive officer” of the Company in the year prior to year of the event that triggers the Excise Tax, to the extent the use of such lesser amount results in a larger Excise Tax than Executive would have been subject to had the Company or accountant attributed a value to the non-compete set forth in in Section 4.02 above that is at least equal to the total compensation amount disclosed under Item 402(c) of Securities and Exchange Commission Regulation S-K for such year..

**Section 5.03 Section 409A.**

( a ) Notwithstanding anything herein to the contrary, this Agreement is intended to be interpreted and applied so that the payment of the benefits set forth herein either shall either be exempt from the requirements of Section 409A of the Code (“Section 409A”) or shall comply with the requirements of such provision.

( b ) Notwithstanding any provision of this Agreement to the contrary, if Executive is a “specified employee” within the meaning of Section 409A, any payments or arrangements due upon a termination of Executive’s employment under any arrangement that constitutes a “nonqualified deferral of compensation” within the meaning of Section 409A and which do not otherwise qualify under the exemptions under Treas. Regs. Section 1.409A-1 (including without limitation, the short-term deferral exemption or the permitted payments under Treas. Regs. Section 1.409A-1(b)(9)(iii)(A)), shall be delayed and paid or provided, without interest, on the earlier of (i) the date which is six (6) months after Executive’s “separation from service” (as such term is defined in Section 409A and the regulations and other published guidance thereunder) for any reason other than death, and (ii) the date of Executive’s death.

( c ) After any Termination Date, Executive shall have no duties or responsibilities that are inconsistent with having a “separation from service” within the meaning of Section 409A and, notwithstanding anything in the Agreement to the contrary, distributions upon termination of employment of nonqualified deferred compensation may only be made upon a -separation from service” as determined under Section 409A and such date shall be the Termination Date for purposes of this Agreement. Each payment under this Agreement or otherwise shall be treated as a separate payment for purposes of Section 409A. In no event may

Executive, directly or indirectly, designate the calendar year of any payment to be made under this Agreement which constitutes a -nonqualified deferral of compensation” within the meaning of Section 409A and to the extent an amount is payable within a time period, the time during which such amount is paid shall be in the discretion of the Company.

**Section 5.04 Merger Clause.** Effective as of the date hereof, this Agreement contains the complete, full, and exclusive understanding of Executive and the Company as to its subject matter and shall, on such date, and supersede any prior employment agreement between Executive and the Company (and its affiliates), including the Prior Agreement. Any amendments to this Agreement shall be effective and binding on Executive and the Company only if any such amendments are in writing and signed by both Parties.

**Section 5.05 Assignment.**

( a ) This Agreement is personal to Executive and, without the prior written consent of the Company, shall not be assigned by Executive otherwise than by will or the laws of descent and distribution, and any assignment in violation of this Agreement shall be void.

( b ) Notwithstanding the foregoing Section 5.05(a), this Agreement and all rights of Executive hereunder shall inure to the benefit of, and be enforceable by, Executive’s personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees. If Executive should die while any amounts would still be payable to him or her hereunder if he or she had continued to live, all such amounts, unless otherwise provided herein, shall be paid in accordance with the terms of this Agreement to Executive’s devisee, legatee or other designee or, should there be no such designee, to Executive’s estate.

(c) The Company may assign this Agreement to any affiliate or subsidiary of the Company without the consent of Executive and shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company (a “Successor”) to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would have been required to perform it if no such succession had taken place. As used in this Agreement, (i) the term “Company” shall mean the Company as hereinbefore defined and any Successor and any permitted assignee to which this Agreement is assigned and (ii) the term “Board” shall mean the Board as hereinbefore defined and the board of directors or equivalent governing body of any Successor and any permitted assignee to which this Agreement is assigned.

**Section 5.06 Dispute Resolution.** Except for any proceeding brought pursuant to Section 5.05 above, the parties agree that any dispute arising out of or relating to this Agreement or the formation, breach, termination or validity thereof, will be settled by binding arbitration by a panel of three arbitrators in accordance with the commercial arbitration rules of the American Arbitration Association. The arbitration proceedings will be located in Philadelphia, Pennsylvania. The arbitrators are not empowered to award damages in excess of compensatory damages and each party irrevocably waives any damages in excess of compensatory damages. Judgment upon any arbitration award may be entered into any court having jurisdiction thereof and the parties consent to the jurisdiction of any court of competent jurisdiction located in the Eastern District of Pennsylvania.

**Section 5.07 GOVERNING LAW. THIS AGREEMENT SHALL BE DEEMED TO BE MADE IN THE COMMONWEALTH OF PENNSYLVANIA, INTERPRETATION, CONSTRUCTION AND PERFORMANCE OF THIS AGREEMENT IN ALL RESPECT SHALL BE GOVERNED BY THE LAWS OF THE COMMONWEALTH OF PENNSYLVANIA WITHOUT REGARD TO ITS PRINCIPLES OF CONFLICTS OF LAW.**

**Section 5.08 Amendment; No Waiver.** No provision of this Agreement may be amended, modified, waived or discharged except by a written document signed by Executive and duly authorized officer of the Company. The failure of a party to insist upon strict adherence to any term of this Agreement on any occasion shall not be considered as a waiver of such party's rights or deprive such party of the right thereafter to insist upon strict adherence to that term or any other term of this Agreement. No failure or delay by any party in exercising any right or power hereunder will operate as a waiver thereof, nor will any single or partial exercise of any other right or power. No agreements or representations, oral or otherwise, express or implied, with respect to the subject matter hereof have been made by any party, which are not set forth expressly in this Agreement.

**Section 5.09 Severability.** If any term or provision of this Agreement is invalid, illegal or incapable of being enforced by any applicable law or public policy, all other conditions and provisions of this Agreement shall nonetheless remain in full force and effect so long as the economic and legal substance of the transactions contemplated by this Agreement is not affected in any manner materially adverse to any party. Upon any such determination that any term or other provision is invalid, illegal or incapable of being enforced, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the fullest extent possible.

**Section 5.10 Survival.** The rights and obligations of the parties under the provisions of this Agreement that relate to post-termination obligations shall survive and remain binding and enforceable, notwithstanding the expiration of the term of this Agreement, the termination of Executive's employment with the Company for any reason or any settlement of the financial rights and obligations arising from Executive's employment hereunder, to the extent necessary to preserve the intended benefits of such provisions.

**Section 5.11 Notices.** All notices and other communications required or permitted by this Agreement will be made in writing and all such notices and communications will be deemed to have been duly given when delivered or (unless otherwise specified) mailed by United States certified or registered mail, return receipt requested, postage prepaid, addressed, if to the Company, at its principal office, and if to Executive, at Executive's last address on file with the Company. Either party may change such address from time to time by notice to the other.

**Section 5.12 Headings and References.** The headings of this Agreement are inserted for convenience only and neither constitute a part of this Agreement nor affect in any way the meaning or interpretation of this Agreement. When a reference in this Agreement is made to a Section, such reference shall be to a Section of this Agreement unless otherwise indicated.

**Section 5.13 Counterparts.** This Agreement may be executed in one or more counterparts (including via facsimile), each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

*[signature page follows]*

IN WITNESS WHEREOF, this Agreement has been executed by the parties as of the date first written above.

**STRONGBRIDGE U.S. INC.**

By: \_\_\_\_\_

Name: Matthew Pauls

Title: President

**EXECUTIVE**

\_\_\_\_\_  
[NAME]

**ATTACHMENT A**

**GENERAL RELEASE**

\_\_\_\_\_ (“Executive”), for and in consideration of the commitments of Strongbridge U.S. Inc. (the “Company”) as set forth in Article III of the Amended and Restated Employment Agreement dated as of October 13, 2017 (the “Employment Agreement”), and intending to be legally bound, does hereby REMISE, RELEASE AND FOREVER DISCHARGE the Company and its present and former divisions, subsidiaries, parents, predecessor and successor corporations, officers, directors, and their respective successors, predecessors, assigns, heirs, executors, and administrators (collectively, “Releasees”) from all causes of action, suits, debts, claims and demands whatsoever in law or in equity, which Executive ever had, now has, or hereafter may have, whether known or unknown, or which Executive’s heirs, executors, or administrators may have, by reason of any matter, cause or thing whatsoever, up to the date of Executive’s execution of this General Release, particularly, but without limitation of the foregoing general terms, any claims arising from or relating in any way to Executive’s employment relationship with the Company and Releasees, the terms and conditions of that relationship, and the termination of that relationship, including, but not limited to, any claims arising under any applicable Company employee benefit plan(s), the Age Discrimination in Employment Act, the Older Workers’ Benefit Protection Act, Title VII of The Civil Rights Act of 1964, the Civil Rights Act of 1991, Sections 1981 through 1988 of Title 42 of the United States Code, the Americans with Disabilities Act, the Employee Retirement Income Security Act of 1974, the Family and Medical Leave Act, the Worker Adjustment and Retraining Notification Act, Pennsylvania employment laws, and any other federal, state and local employment laws, as amended, and any other claims under any federal, state or local common law, statutory, or regulatory provision, now or hereafter recognized, and any claims for attorneys’ fees and costs. This General Release is effective without regard to the legal nature of the claims raised and without regard to whether any such claims are based upon tort, equity, implied or express contract or discrimination of any sort.

To the fullest extent permitted by law, and subject to the provisions of Paragraph 3 below, Executive represents and affirms that (i) Executive has not filed or caused to be filed on Executive’s behalf any claim for relief against the Company or any Releasee and, to the best of Executive’s knowledge and belief, no outstanding claims for relief have been filed or asserted against the Company or any Releasee on Executive’s behalf; and (ii) Executive has no knowledge of any improper, unethical or illegal conduct or activities that Executive has not already reported to any supervisor, manager, department head, human resources representative, agent or other representative of the Company, to any member of the Company’s legal or compliance departments, or to the ethics hotline; and (iii) Executive will not file, commence, prosecute or participate in any judicial or arbitral action or proceeding against the Company or any Releasee based upon or arising out of any act, omission, transaction, occurrence, contract, claim or event existing or occurring on or before the date of execution of this General Release.

The release of claims described in Paragraph I of this General Release does not preclude Executive from filing a charge with the U.S. Equal Employment Opportunity Commission. However, Executive agrees and hereby waives any and all rights to any monetary relief or other personal recovery from any such charge, including costs and attorneys’ fees.

Subject to the provisions of Paragraph 3 of this General Release, in further consideration of the commitments of the Company as described in the Employment Agreement, Executive agrees that Executive will not file, claim, sue or cause or permit to be filed, any civil action, suit or legal proceeding seeking equitable or monetary relief (including damages, injunctive, declaratory, monetary or other relief) for himself involving any matter released in Paragraph 1. In the event that suit is filed in breach of this release of claims, it is expressly understood and agreed that this release of claims shall constitute a complete defense to any such suit. In the event any Releasee is required to institute litigation to enforce the terms of this paragraph, Releasees shall be entitled to recover reasonable costs and attorneys' fees incurred in such enforcement. Executive further agrees and covenants that should any person, organization, or other entity file, claim, sue, or cause or permit to be filed any civil action, suit or legal proceeding involving any matter occurring at any time in the past, Executive will not seek or accept personal equitable or monetary relief in such civil action, suit or legal proceeding. Nothing in this General Release shall prohibit or restrict Executive from: (i) making any disclosure of information required by law; (ii) providing information to, or testifying or otherwise assisting in any investigation or proceeding brought by any federal regulatory or law enforcement agency or legislative body, any self-regulatory organization, or the Company's designated legal, compliance or human resources officers; or (iii) filing, testifying, participating in or otherwise assisting in a proceeding relating to an alleged violation of any federal, state or municipal law relating to fraud, or any rule or regulation of the Securities and Exchange Commission or any self-regulatory organization.

Executive understands and agrees that the payments, benefits and agreements provided in the Employment Agreement are being provided to Executive in consideration for Executive's acceptance and execution of, and in reliance upon Executive's representations in, the Employment Agreement and this General Release, and that they are greater than the payments, benefits and agreements, if any, to which Executive would have received if Executive had not executed the Employment Agreement and this General Release. In addition, Executive acknowledges and agrees that Executive has been paid all amounts owed to Executive as of the date of Executive's signing of this General Release.

Executive and the Company agree and acknowledge that the agreement by the Company described in the Employment Agreement, and the settlement and termination of any asserted or unasserted claims against the Releasees, are not and shall not be construed to be an admission of any violation of any federal, state or local statute or regulation, or of any duty owed by any of the Releasees to Executive.

This General Release and the obligations of the parties hereunder shall be construed, interpreted and enforced in accordance with and be governed by the laws of Pennsylvania without reference to its conflicts of laws principles.

- a. Executive certifies and acknowledges as follows: that Executive has read the terms of this General Release, and that Executive understands its terms and effects, including the fact that Executive has agreed to RELEASE AND FOREVER DISCHARGE the Company and each and every one of its affiliated entities from any legal action arising out of Executive's relationship with the Company and the termination of that relationship;



- b. that Executive has signed this Release voluntarily and knowingly in exchange for the consideration described herein and in the Employment Agreement, which Executive acknowledges is adequate and satisfactory to Executive and to which Executive acknowledges that Executive would not otherwise be entitled;
- c. that Executive has been and is hereby advised in writing to consult with an attorney prior to signing this General Release;
- d. that Executive does not waive rights or claims that may arise after the date this General Release is executed;
- e. that the Company has provided Executive with at least 21 (twenty-one) days within which to consider this General Release, that any modifications, material or otherwise, made to this General Release have not restarted or affected in any manner the original 21 (twenty-one) day consideration period, and that Executive has signed on the date indicated below after concluding that this General Release is satisfactory to Executive;
- f. that Executive acknowledges that this General Release may be revoked by Executive within seven (7) days after Executive's execution, and it shall not become effective until the expiration of such seven-day revocation period. If the last day of the revocation period is a Saturday, Sunday, or legal holiday in the state in which Executive resides, then the revocation period shall not expire until the next following day which is not a Saturday, Sunday, or legal holiday. In the event of a timely revocation by Executive, this General Release and the Employment Agreement will be deemed null and void and the Company will have no obligations hereunder; and
- g. that this General Release may not be signed prior to the third calendar day before the last day of the Term of the Employment Agreement. If this General Release is signed prior to the last day of the Term of the Employment Agreement, the Company reserves the right to have Executive ratify the General Release on or after the last day of the Term.

Intending to be legally bound hereby, Executive executed the foregoing General Release on the date indicated below.

[NAME]

\_\_\_\_\_  
Signature

Date: \_\_\_\_\_

**Subsidiaries of the Company**

Strongbridge U.S. Inc. (a Delaware corporation)

Strongbridge Ireland Limited (a private limited company incorporated under the laws of Ireland)

Cortendo AB (publ) (a public limited liability company incorporated under the laws of Sweden)

Cortendo Cayman Ltd. (an exempted company incorporated in the Cayman Islands)

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**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-222818, 333-215532) of our report dated March 12, 2018, with respect to the consolidated financial statements of Strongbridge Biopharma plc included in this Annual Report (Form 10-K) for the year ended December 31, 2017.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania  
March 12, 2018

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**CERTIFICATIONS**

I, Matthew Pauls, certify that:

1. I have reviewed this Annual Report on Form 10-K of Strongbridge Biopharma plc;
2. Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Annual Report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2018

By: /s/ Matthew Pauls

Matthew Pauls  
Chief Executive Officer  
(Principal Executive Officer)

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**CERTIFICATIONS**

I, A. Brian Davis, certify that:

1. I have reviewed this Annual Report on Form 10-K of Strongbridge Biopharma plc;
2. Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Annual Report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2018

By: /s/ A. Brian Davis  
A. Brian Davis  
Chief Financial Officer  
(Principal Financial Officer)

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**CERTIFICATIONS PURSUANT TO 18 U.S.C. 1350**

Pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Matthew Pauls, the Chief Executive Officer (principal executive officer) of Strongbridge Biopharma plc (the “Company”), and A. Brian Davis, the Chief Financial Officer (principal financial officer) of the Company, each hereby certifies that, to his knowledge on the date hereof:

(a) The Annual Report on Form 10-K of the Company for the period ended December 31, 2017 filed on the date hereof with the Securities and Exchange Commission (the “Annual Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(b) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by the Annual Report.

These certifications accompanying the Annual Report to which they relate, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Annual Report), irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained and furnished to the Securities and Exchange Commission or its staff upon request.

By: /s/ Matthew Pauls

Matthew Pauls  
Chief Executive Officer  
(Principal Executive Officer)  
March 12, 2018

By: /s/ A. Brian Davis

A. Brian Davis  
Chief Financial Officer  
(Principal Financial Officer)  
March 12, 2018

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