



**2018 ANNUAL REPORT**

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-K**

(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, 2018

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 001-37558

**Nabriva Therapeutics plc**

(Exact name of registrant as specified in its charter)

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

**Not applicable**  
(I.R.S. Employer  
Identification No.)

**25-28 North Wall Quay**  
**IFSC, Dublin 1, Ireland**  
(Address of principal executive  
offices)

**Not applicable**  
(Zip Code)

**+353 1 649 2000**

(Registrant's telephone number, including area code)

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Ordinary Shares, nominal value \$0.01 per share	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

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 Section 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 every Interactive Data File required to be submitted 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 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 an

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

As of June 29, 2018 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's voting securities held by non-affiliates was approximately \$141.7 million based on the last reported sale price of the registrant's ordinary shares on June 29, 2018. As of February 28, 2019, the registrant had 69,699,722 ordinary shares outstanding.

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## FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements that involve substantial risks and uncertainties. All statements contained in this Annual Report, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "around," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The forward-looking statements in this report include, among other things, statements about:

- the timing of receiving marketing approval of lefamulin, CONTEPO and other product candidates, including the completion of any post-marketing requirements with respect to any marketing approval we may obtain;
  - our expectations regarding how far into the future our cash on hand will fund our ongoing operations;
  - our ability to satisfy interest and principal payments under our debt facility with Hercules Capital, Inc., or Hercules;
  - our ability to comply with the restrictive covenants under our debt facility with Hercules;
  - the potential receipt of revenues from future sales of lefamulin or CONTEPO;
  - our plans to pursue development of lefamulin for additional indications other than community-acquired bacterial pneumonia, or CABP, and of CONTEPO for additional indications other than in complicated urinary tract infections, or cUTIs;
  - our plans to pursue development of other product candidates;
  - our expectations with respect to the potential financial impact, synergies, growth prospects and benefits of our acquisition of Zavante Therapeutics, Inc., or Zavante, which was completed on July 24, 2018, or the Acquisition, pursuant to the Agreement and Plan of Merger dated July 23, 2018, or the Merger Agreement, by and among Nabriva, Zuperbug Merger Sub I, Inc., or Merger Sub I, Zuperbug Merger Sub II, Inc., or Merger Sub II, Zavante and the Zavante stockholder representative, including the potential realization of the expected benefits from the Acquisition;
  - our expectations with respect to milestone payments pursuant to the Merger Agreement and expectations with respect to potential advantages of CONTEPO or any other product candidate that we acquired in connection with the Acquisition;
  - our ability to successfully integrate Zavante's operations into our business;
  - our ability to establish and maintain arrangements for manufacture of our product candidates;
  - our sales, marketing and distribution capabilities and strategy;
  - our ability to successfully commercialize lefamulin, CONTEPO and our other product candidates;
  - the potential advantages of lefamulin, CONTEPO and our other product candidates;
  - our estimates regarding the market opportunities for lefamulin, CONTEPO and our other product candidates;
  - the rate and degree of market acceptance and clinical benefit of lefamulin for CABP, CONTEPO for cUTI and our other product candidates;
  - our ability to establish and maintain collaborations in the U.S. our outside the U.S;
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- the future development or commercialization of lefamulin in the greater China region;
- the potential benefits under our license agreement with Sinovant Sciences, Ltd., or the Sinovant License Agreement;
- our ability to acquire or in-license additional products, product candidates and technologies;
- our future intellectual property position;
- our estimates regarding future expense, capital requirements and needs for additional financing;
- our ability to effectively manage our anticipated growth;
- our ability to maintain the level of our expenses consistent with our internal budgets and forecasts;
- the demand for securities of pharmaceutical and biotechnology companies in general and our ordinary shares in particular;
- competitive factors;
- compliance with current or prospective governmental regulation;
- general economic and market conditions;
- our ability to attract and retain qualified employees and key personnel;
- our business and business relationships, including with employees and suppliers, following the Acquisition;
- our ability to satisfy milestone, royalty and transaction revenue payments pursuant to the Stock Purchase Agreement between Zavante and SG Pharmaceuticals, Inc.; and
- other risks and uncertainties, including those described in the "Risk Factors" section of this Form 10-K.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report, particularly in the "Risk Factors" section of this Annual Report, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report and the documents that we have filed as exhibits to this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, except as required by applicable law.

This Annual Report includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

### **SPECIAL NOTE REGARDING THE REDOMICILIATION**

On June 23, 2017, Nabriva Therapeutics plc, a public limited company organized under the laws of Ireland, or Nabriva Ireland, became the successor issuer to Nabriva Therapeutics AG, a stock corporation (*Aktiengesellschaft*) organized under the laws of Austria, or Nabriva Austria, for certain purposes under both the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, or the Exchange Act. Such succession occurred following the conclusion of a tender offer

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related to the exchange of American Depositary Shares and common shares of Nabriva Austria for ordinary shares of Nabriva Ireland, which resulted in Nabriva Ireland, a new Irish holding company, becoming the ultimate holding company of Nabriva Austria (the predecessor registrant and former ultimate holding company) and its subsidiaries, which we refer to as the Redomiciliation Transaction. On October 19, 2017, Nabriva Austria was converted into a limited liability company under Austrian law and renamed Nabriva Therapeutics GmbH.

Unless the context requires otherwise, all references in this Annual Report to "Nabriva," "the Nabriva Group," "the Company," "we," "ours," "us," or similar terms on or prior to June 23, 2017 (the effective date of the Redomiciliation Transaction), refer to our predecessor, Nabriva Therapeutics AG, together with its subsidiaries.

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## PART I

### ITEM 1. BUSINESS

#### Overview

We are a biopharmaceutical company engaged in the development of novel anti-infective agents to treat serious infections. We have two product candidates that have been submitted to the U.S. Food and Drug Administration, or the FDA, for approval: lefamulin, potentially the first pleuromutilin antibiotic available for oral and intravenous (or IV) administration in humans, for the treatment of community-acquired bacterial pneumonia, or CABP and CONTEPO, a potentially first-in-class epoxide antibiotic for IV use in the United States for complicated urinary tract infections, or cUTI. We may potentially develop lefamulin and CONTEPO for additional indications. Both lefamulin formulations and CONTEPO were granted Qualified Infectious Disease Product, or QIDP, and Fast Track designation by the FDA, enabling priority review of the New Drug Applications, or the NDAs by the FDA.

#### Lefamulin

Lefamulin is a semi-synthetic pleuromutilin antibiotic discovered and developed by our team with the potential to be first-in-class for IV and oral administration in humans. It inhibits the synthesis of bacterial protein, which is required for bacteria to grow by binding with high affinity and specificity at molecular targets that are different than other antibiotic classes. Based on results from two global, Phase 3 clinical trials, we believe lefamulin is well-positioned for use as first-line monotherapy for the treatment of CABP due to its novel mechanism of action, targeted spectrum of activity, resistance profile, achievement of substantial drug concentrations in lung tissue and fluid, availability of oral and IV formulations and a generally well-tolerated profile. We believe lefamulin represents a potentially important new treatment option for the five to six million adults in the United States diagnosed with CABP each year.

We submitted two NDAs to the FDA for the oral and IV formulations of lefamulin for the treatment of CABP in December 2018. The FDA has granted us a Prescription Drug User Fee Act, or PDUFA, target action date of August 19, 2019 for lefamulin. We plan to submit a marketing authorization application for lefamulin in Europe in the first half of 2019. The two NDAs for lefamulin are supported by two pivotal, Phase 3 clinical trials (known as LEAP 1 and LEAP 2) that evaluated the safety and efficacy of IV and oral lefamulin compared to moxifloxacin in the treatment of adults with CABP, including the option to switch from IV to oral administration and a short course oral treatment with lefamulin. In both LEAP 1 and LEAP 2, lefamulin was demonstrated to be non-inferior to moxifloxacin, and met both the FDA and European Medicines Agency, or EMA primary and secondary efficacy endpoints for the treatment of CABP. Lefamulin was also shown to be generally well-tolerated when administered both orally and intravenously.

We believe that pleuromutilin antibiotics can help address the major public health threat posed by bacterial resistance, which the World Health Organization, or WHO, characterized in 2017 as one of the biggest threats to human health. Increasing resistance to antibiotics used to treat CABP is a growing concern and has become an issue in selecting the appropriate initial antibiotic treatment prior to determining the specific microbiological cause of the infection, referred to as empiric treatment. For example, the U.S. Centers for Disease Control and Prevention, or CDC, has classified *Streptococcus pneumoniae*, the most common respiratory pathogen, as a serious threat to human health as a result of increasing resistance to currently available antibiotics. In addition, the CDC recently reported on the growing evidence of widespread resistance to macrolides, widely used antibiotics that disrupt bacterial protein synthesis, in *Mycoplasma pneumoniae*, a common cause of CABP that is associated with significant morbidity and mortality. Furthermore, *Staphylococcus aureus*, including methicillin-resistant *S. aureus*, or MRSA, which has also been designated as a serious threat to human health by the CDC,



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has emerged as a more common cause of CABP in some regions of the world, and a possible pathogen to be covered with empiric therapy.

As a result of increasing resistance to antibiotics and the wide array of potential pathogens that cause CABP, the current standard of care for hospitalized patients with CABP whose treatment is initiated in the hospital usually involves first-line empiric treatment with a combination of antibiotics (cephalosporins and macrolides) to address all likely bacterial pathogens or monotherapy with a respiratory fluoroquinolone. Combination therapy presents the logistical challenge of administering multiple drugs with different dosing regimens, with some drugs available only as IV, and increases the risk of drug-drug interactions and the potential for serious side effects. Fluoroquinolones are associated with safety and tolerability concerns, including a relatively high risk for developing *Clostridium difficile* infection and increasing rates of resistance for uropathogens. We believe these concerns have resulted in a decreasing use of fluoroquinolones and restriction of their use within a growing number of hospitals.

The FDA has communicated safety information about fluoroquinolones, advising that when used systemically, in the form of tablets, capsules and injectable, fluoroquinolones are associated with disabling and potentially permanent serious side effects. In December 2018, the FDA warned prescribers of an increase in the occurrence of rare but serious events of ruptures or tears in the main artery of the body, called the aorta. These tears, called aortic dissections, or ruptures of an aortic aneurysm can lead to dangerous bleeding or even death. Prior communications pertaining to the safety of fluoroquinolones occurred in July 2018 (significant decreases in blood sugar and certain mental health side effects), July 2016 (disabling side effects of the tendons, muscles, joints, nerves, and central nervous system), May 2016 (restricting use for certain uncomplicated infections), August 2013 (peripheral neuropathy), and July 2008 (tendinitis and tendon rupture). The European Medicines Agency has also reviewed this class and have modified prescribing information restricting use, as well as outlining some of the safety risks.

Fluoroquinolones are typically administered in combination with other antibiotics, if community-acquired MRSA is suspected. In addition, many currently available antibiotic therapies are only available for IV administration and are prescribed for seven to fourteen days, meaning continued treatment requires prolonged hospitalization or a switch to a different antibiotic administered orally, with the attendant risk that the patient might respond differently.

Effective January 1, 2017, the Joint Commission & Center for Medicare and Medicaid Services, or CMS, began requiring all U.S. hospitals to have Antibiotic Management guidelines, also known as "Stewardship" Committees, in place to identify antibiotics most appropriate and targeted to each individual patient's infection. Past efforts to "cast the widest net possible" with broad-spectrum antibiotics that affect many types of bacteria have caused problems, such as *C. difficile* infections, by killing good bacteria or increased antibiotic resistance in other bacteria in different areas of the body. Additionally, in 2016, the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America, or IDSA/SHEA, updated their Antibiotic Stewardship guidelines for antibiotic use. We believe that three key goals from these guidelines are applicable to the treatment of CABP:

- Reduce the risk of antibiotics associated with a high risk of *C. difficile* infections;
- Increase use of oral antibiotics as a strategy to improve outcomes or decrease costs; and
- Reduce antibiotic therapy to the shortest effective duration.

Consistent with the Antimicrobial Stewardship principles, we believe that lefamulin could be well suited as either a first-line or second-line empiric monotherapy for the treatment of CABP patients in the hospital setting, outpatient-transition of care or in the community setting, because of its novel mechanism of action, complete spectrum of activity for CABP pathogens, including against multidrug

resistant strains, achievement of substantial drug concentrations in lung fluids and lung immune cells, and flexibility as step down oral agent with both the IV and oral formulations and favorable safety and tolerability profile.

## CONTEPO

On July 24, 2018, we completed the acquisition of Zavante Therapeutics, Inc., or Zavante, a privately-held late clinical-stage biopharmaceutical company focused on developing novel therapies to improve the outcomes of hospitalized patients. Zavante's lead product candidate is CONTEPO™ (fosfomycin for injection, previously referred to as ZTI-01 and ZOLYD).

We submitted an NDA for marketing approval of CONTEPO for the treatment of cUTI including AP in adults in the United States, to the FDA in October 2018. The NDA submission is utilizing the 505(b)(2) regulatory pathway and is supported by a robust data package, including a pivotal Phase 2/3 clinical trial (known as ZEUS™), which met its primary endpoint of statistical non-inferiority to piperacillin/tazobactam in patients with cUTI, including AP. The FDA has granted us a Prescription Drug User Fee Act, or PDUFA target action date of April 30, 2019 for CONTEPO.

The prevalence of antibiotic-resistant bacteria is increasing and is considered a significant threat to global health. In particular, the CDC and the WHO consider antibiotic resistance to be an urgent and critical threat to human health. The prevalence of lactamase enzymes among Gram-negative pathogens threatens the usefulness of many beta -lactam antibiotics and has resulted in greater reliance on last line antibiotics, including carbapenems. Complicated urinary tract infections, or cUTIs, including acute pyelonephritis, or AP, are among the most common infections due to multi-drug resistant, or MDR bacteria, including carbapenem-resistant Enterobacteriaceae, or CRE, and are often healthcare-associated. Global mortality attributable to CRE infections has been estimated in some studies to be over 20% and reflects the need for safe, alternative, carbapenem-sparing options.

CONTEPO is a novel, potentially first-in-class investigational IV antibiotic in the United States with a broad spectrum of Gram-negative and Gram-positive activity, including activity against most MDR strains such as extended-spectrum beta-lactamase-, or ESBL-producing Enterobacteriaceae. Intravenous fosfomycin has been approved for a number of indications and utilized for over 45 years in Europe to treat a variety of serious bacterial infections, including cUTIs. CONTEPO utilizes a new dosing regimen that optimizes its pharmacokinetics and pharmacodynamics. We believe these attributes, the extensive clinical experience worldwide and the positive efficacy and safety results from the Phase 2/3 clinical trial support CONTEPO as a first-line treatment for cUTIs, including AP, suspected to be caused by MDR pathogens. At least 20% of cUTIs are caused by MDR bacteria and limited treatment options are available in the U.S. In addition, non-clinical data have shown that CONTEPO acts in combination with certain other antibiotics to improve bacterial killing.

## Our Strategy

Our goal is to become a biopharmaceutical company focused on the commercialization of novel anti-infective products. The key elements of our strategy to achieve this goal are:

- **Maximize the commercial potential of CONTEPO for cUTI's and lefamulin for CABP.** We own exclusive, worldwide rights to lefamulin and US rights to CONTEPO and we have out licensed the rights to lefamulin in China. We expect that our initial target patient population for lefamulin will consist of patients with moderate to severe CABP and the initial target population for CONTEPO will be hospitalized patients with complicated urinary tract infections. If either or both CONTEPO or lefamulin receives marketing approval from the FDA, we plan to commercialize them in the United States with our own targeted sales and marketing organization that we plan to expand beyond its current levels. We believe both CONTEPO and lefamulin have innovative profiles which, if approved, would support their adoption in the

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United States for adult cUTI patients treated in the hospital and CABP patients, respectively, treated as in-patients in a hospital setting. Lefamulin also has the opportunity to be adopted as outpatient transition of care from the hospital, which we believe represents a significant commercial opportunity. We believe that we will be able to effectively communicate CONTEPO's and lefamulin's differentiating characteristics and key attributes to clinicians, hospital pharmacies and payors with the goal of establishing favorable reimbursement as well as a favorable formulary status in targeted hospitals. Outside the United States we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize lefamulin in such markets. We currently have a team of regional business directors and medical science liaisons in the field performing educational and market development activities, respectively. We initially plan to use a targeted hospital-based sales force to promote both lefamulin formulations and CONTEPO, if approved.

- ***Pursue the continued development of lefamulin in additional indications.*** We are evaluating the cost and benefits of the continued development of lefamulin for indications in addition to CABP. Pediatric oral formulation development is ongoing, and we initiated a Phase 1 clinical trial in pediatric patients in mid-2018. We believe lefamulin has potential to treat acute bacterial skin and skin structure infection (ABSSSI), ventilator-associated bacterial pneumonia (VABP) or hospital-acquired bacterial pneumonia (HABP) and sexually transmitted infections (STIs). In addition, we may explore longer duration of treatment with lefamulin to support development of a treatment for osteomyelitis and prosthetic joint infections. We believe that lefamulin would be differentiated from other treatment options for these potential indications because of its novel mechanism of action, spectrum of activity, including activity against multi-drug resistant pathogens, achievement of substantial concentrations in relevant tissues, availability as both an IV and oral formulation and favorable safety and tolerability profile.
- ***Pursue the development of CONTEPO for a pediatric indication.*** We are evaluating the continued development of CONTEPO for use in pediatric patients with cUTIs. In June 2018, we initiated a Phase 1, non-comparative, open-label study of the pharmacokinetics and safety of a single dose of CONTEPO in pediatric subjects less than 12 years of age.
- ***Evaluate business development opportunities and potential collaborations.*** We may expand our product pipeline through opportunistically in-licensing or acquiring the rights to complementary products, product candidates and technologies for the treatment of a range of infectious diseases or other hospital-based products that could utilize our planned commercial infrastructure. We plan to evaluate the merits of entering into collaboration agreements with other pharmaceutical or biotechnology companies that may contribute to our ability to efficiently advance our product candidates, build our product pipeline, concurrently advance a range of research and development programs and leverage our commercial infrastructure. Potential collaborations may provide us with funding and access to the scientific, development, regulatory and commercial capabilities of the collaborators. We also plan to encourage local and international government entities and non-government organizations to provide additional funding and support for our development programs.

## **Background**

### ***Anti-Bacterial Market and Scientific Overview***

Bacteria are broadly classified as Gram-positive or Gram-negative. Gram-positive bacteria possess a single membrane and a thick cell wall and turn dark-blue or violet when subjected to a laboratory staining method known as Gram's method. Gram-negative bacteria have a thin cell wall layered between an inner cytoplasmic cell membrane and a bacterial outer membrane and, as a result, do not retain the violet stain used in Gram's method. Antibiotics that are active against both Gram-positive

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and Gram-negative bacteria are referred to as broad spectrum, while those that are active only against a select subset of Gram-positive or Gram-negative bacteria are referred to as narrow spectrum. Bacteria that cause infections are often referred to as bacterial pathogens. Because it often takes from 24 to 48 hours to definitively diagnose the particular bacterial pathogen causing an infection, the causative pathogen often remains unidentified and narrow spectrum antibiotics are not generally used as empiric monotherapy for first-line treatment of hospitalized patients with serious infections.

Since the introduction of antibiotics in the 1940s, numerous new antibiotic classes have been discovered and developed for therapeutic use. The development of new antibiotic classes and new antibiotics within a class is important because of the ability of bacteria to develop resistance to existing mechanisms of action of currently approved antibiotics. However, the pace of discovery and development of new antibiotic classes slowed considerably in the past few decades. The CDC estimates that the pathogens responsible for more than 70% of U.S. hospital infections are resistant to at least one of the antibiotics most commonly used to treat them. The CDC also estimated in 2013, based on data collected from evaluations performed between 2006 and 2011, that annually in the United States at least two million people become infected with bacteria that are resistant to antibiotics and at least 23,000 people die as a direct result of these infections.

Antibiotic resistance is primarily caused by genetic mutations in bacteria selected by exposure to antibiotics that do not kill all of the bacteria. In addition to mutated bacteria being resistant to the drug used for treatment, many bacterial strains can also become cross-resistant, meaning that they become resistant to multiple classes of antibiotics. As a result, the effectiveness of many antibiotics has declined, limiting physicians' options to treat serious infections and exacerbating a global health issue. For example, the WHO estimated in 2014 that people with infections caused by MRSA, a highly resistant form of bacteria, are 64% more likely to die than people with a non-resistant form of the infection. Resistance can increase the cost of healthcare because of the potential for lengthier hospital stays and more intensive care. Growing antibiotic resistance globally, together with the low level of investment in research and development, is considered one of the biggest global health threats. In 2010, the WHO stated that antibiotic resistance is one of the three greatest threats to human health. Partially in response to this threat, the U.S. Congress passed the GAIN Act in 2012, which provides incentives, including access to expedited FDA review for approval, fast track designation and five years of potential data exclusivity extension for the development of new QIDPs. Additional legislation is also being considered in the United States, including the Antibiotic Development to Advance Patient Treatment Act of 2013, which is intended to accelerate the development of anti-infective products, and the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms Act of 2014, which is intended to establish a new reimbursement framework to enable premium pricing of anti-infective products.

In 2017, sales of antibiotics totaled approximately \$42 billion globally. Although judicious use of antibiotics is important to reduce the rate of antibiotic resistance, this approach alone cannot fully address the threat from increasing antibiotic resistance. New antibiotics, and particularly new antibiotic classes, are needed to ensure the availability of effective antibiotic therapy in the future.

### ***Community-Acquired Bacterial Pneumonia (CABP)***

#### *Market Overview*

The U.S. National Center for Health Statistics estimated that between 1988 and 1994 there were approximately 5.6 million cases of pneumonia per year in the United States. More recently, based on our combined analysis of the CDC's 2007 National Ambulatory Medical Care Survey, the National Hospital Ambulatory Medical Care Survey and 2013 data from the Healthcare Cost and Utilization Project we estimate that over 5.0 million adults are treated annually for CABP in the United States and that the majority of these adult CABP patients have their treatment initiated in a hospital, including

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emergency departments. According to the Healthcare Cost and Utilization Project, or HCUP, in 2013, approximately 3.1 million adults sought treatment in a U.S. hospital for CABP. In addition, in 2013, approximately 2.4 million adults were admitted to U.S. hospitals for in-patient care with a diagnosis of CABP and approximately 700,000 adults were seen in an emergency department at U.S. hospitals for treatment of CABP and then released.

Additionally, in 2014, based on CDC data approximately 50,000 patients died from CABP in the United States. Based on data collected from July 1, 2012 through June 30, 2015, on the Medicare.gov Hospital Compare website, the current national rate of readmissions for Medicare pneumonia patients is 17.1%, which is the percentage of patients who have had a recent hospital stay that must return to a hospital for unplanned care within 30 days of being discharged. The national average death rate for Medicare pneumonia patients, excluding Medicare Advantage plan data, is 16.3%, which is the percentage of patients who die, for any reason, within 30 days of admission to a hospital.

Based on data from LexisNexis® Risk Solutions, a leading provider of healthcare data and analytics solutions, as well as analysis of data from US hospitals and other healthcare facilities, we determined that the number of adult CABP patients who were treated with antibiotic therapy in hospitals in the United States exceeded 3.8 million for full-year 2016. Our analysis of the LexisNexis data also indicates that approximately 2.4 million of these adult CABP patients were treated as inpatients with IV/injectable antibiotics, and we find that the majority of CABP patients enter the hospital inpatient setting following the initiation of antibiotic therapy during an Emergency Department (ED) visit. Additionally, our analyses show that approximately 1.4 million adult CABP patients were treated with antibiotic courses (IV or oral) in the ED or as hospital outpatients and subsequently released without hospital admission.

Additionally, approximately 1.4 million adult CABP patients were treated with antibiotic courses (IV or oral) in the ED or as hospital outpatients and subsequently released without hospital admission. Furthermore, as a result of our market research in 2017-18, we believe that once adult CABP patients are released from ED stays or are discharged from U.S. hospitals, approximately 60-70%, receive antibiotic oral outpatient prescriptions as continuation of their antibiotic treatment. As hospitals look to minimize the total cost of care and duration of hospital stay for CABP patients toward improved outcomes, efficient transition of adult CABP inpatients to an oral antibiotic treatment as outpatient therapy can significantly reduce days of hospitalization and overall treatment cost.

IQIVA estimated that in 2017 approximately 2 million adult CABP patients were actively treated with antibiotics from prescribers in community clinics, e.g. primary care offices and at other non-hospital based sites of urgent care. As a result, we believe that approximately 6 million CABP patients are treated with antibiotics in the United States on an annual basis and 6 out of every 10 adult CABP patients have treatment initiated in a hospital setting versus the community setting.

### *Causes of CABP*

Pneumonia can be caused by a variety of micro-organisms, with bacteria being the most common identifiable cause. CABP refers to bacterial pneumonia that is acquired outside of a hospital setting. Signs and symptoms of CABP include cough, fever, sputum production and chest pain. A number of different types of bacteria can cause CABP, including both Gram-positive and Gram-negative bacteria. Pneumonia that is caused by atypical bacterial pathogens often has different symptoms and responds to different antibiotics than pneumonia caused by pathogens referred to as typical bacteria. However, atypical bacteria are not uncommon. The most common bacterial pathogens noted in current treatment guidelines from the Infectious Diseases Society of America, or IDSA, for hospitalized CABP patients who are not in the intensive care unit are *Streptococcus pneumoniae*, *Mycoplasma pneumoniae*, *Haemophilus influenzae*, *Chlamydia pneumoniae*, and *Legionella* species. In addition, IDSA notes the emergence of resistance to commonly utilized antibiotics for CABP, specifically drug-resistant

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*S. pneumoniae* and community-acquired MRSA, or CA-MRSA, as a major consideration in choosing empiric therapy. However, a majority of patients do not have a pathogen identified using routine diagnostic tests available to physicians.

### *Currently Available Treatment Options*

In 2007, based on the most likely bacteria to cause CABP, IDSA and the American Thoracic Society, or ATS, recommend empiric treatment of hospitalized patients with CABP who do not require treatment in an intensive care unit with either:

- a combination of a cephalosporin, an antibiotic that disrupts the cell wall of bacteria, plus a macrolide, an antibiotic that disrupts bacterial protein synthesis; or
- monotherapy with a respiratory fluoroquinolone, an antibiotic that disrupts bacterial protein synthesis.

In the event CA-MRSA is suspected, these guidelines recommend that vancomycin, an antibiotic that disrupts the cell wall of bacteria, or linezolid, an antibiotic that disrupts bacterial protein synthesis, be used or added to the current regimen.

In addition, physicians need to be aware of the local susceptibility profiles of the common bacterial pathogens associated with CABP because of increasing resistance to first-line antibiotics. For example, rates of pneumococcal resistance to recommended first-line macrolides exceed 40% in some areas, while resistance in *M. pneumoniae* associated with severe disease has been recently reported by the CDC in the United States.

### *Limitations of Currently Available Treatment Options*

When confronted with a new patient suffering from a serious infection caused by an unknown pathogen, a physician may be required to quickly initiate first-line empiric antibiotic treatment, often with a combination of antibiotics, to stabilize the patient prior to definitively diagnosing the particular bacterial infection. However, currently available antibiotic therapies for first-line empiric treatment of CABP suffer from significant limitations.

### *Bacterial Resistance and Spectrum of Activity*

As a result of bacterial resistance, the effectiveness of many antibiotics has declined. For example, the CDC estimates that in 30% of severe *S. pneumoniae* cases, the bacterial pathogen is fully resistant to one or more clinically relevant antibiotics, with 44% of strains resistant to a macrolide in the United States. In addition, fluoroquinolone resistance in *S. pneumoniae* has increased from less than 0.5% to more than 3% of cases in some regions of North America, which parallels increased total fluoroquinolone prescriptions. Antibiotic resistance has a significant impact on mortality and contributes heavily to healthcare system costs worldwide. According to the CDC, cases of resistant pneumococcal pneumonia result in 32,000 additional doctor visits, approximately 19,000 additional hospitalizations and 7,000 deaths each year. None of the currently available treatment options provides a spectrum of antibacterial coverage as a monotherapy that sufficiently covers all of the most common bacterial causes of CABP, including multi-drug resistant strains.

### *Difficult, Inconvenient and Costly Regimens*

Currently available antibiotics used to treat CABP and other serious infections can be difficult, inconvenient and costly to administer. Physicians typically prefer IV administration for patients hospitalized with more serious illness to ensure adequate delivery of the drug rapidly. Many IV antibiotics are prescribed for seven to 14 days or more and patients can be hospitalized for much or all of this period or require in-home IV therapy. The diagnosis related group, or DRG, reimbursement

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system often used in the U.S. hospital setting pays a fixed fee for an episode of CABP that may not fully compensate hospitals for the duration of hospitalized care. Prolonged IV treatment that extends the period of hospitalization may cause hospital costs to increase in excess of the fixed reimbursement fee, resulting in significant negative impact on healthcare institutions. In addition, to address all likely bacterial pathogens in a patient with a more serious illness, IDSA guidelines recommend using a combination of antibiotics. Combination therapy presents the logistical challenge of administering multiple drugs with different dosing regimens and increases the risk of drug-drug interactions. While IV treatment delivers the drug more rapidly than is possible orally, once a patient is stabilized, oral treatment with the same drug would allow for more convenient and cost-effective out-patient treatment. Because many commonly used antibiotics are only available in IV form, a switch to an oral therapy requires changing to a different antibiotic, which may be less effective for the patient.

### *Adverse Effects*

Currently available antibiotic therapies can have serious side effects. These side effects may include severe allergic reaction, decreased blood pressure, nausea and vomiting, suppression of platelets, pain and inflammation at the site of injection, muscle, renal and oto-toxicity, optic and peripheral neuropathies and headaches. At times, these side effects may be significant and require discontinuation of therapy. As a result, some treatments require clinicians to closely monitor patients' blood levels and other parameters, increasing the expense and inconvenience of treatment. This risk may be increased with combination therapy, which exposes patients to potential adverse effects from each of the antibiotics used in treatment. For example, fluoroquinolones are associated with tendon rupture and peripheral neuropathy. In addition, fluoroquinolones have been associated with an increased frequency of *C. difficile* colitis, an overgrowth of a bacteria in the colon that produces a toxin that results in inflammation of the colon and repeated bouts of watery diarrhea. This has resulted in limitations on the use of fluoroquinolones in several countries. In November 2015, the FDA convened an Advisory Committee meeting to review the benefits and risks of fluoroquinolones in less severe indications, such as uncomplicated UTI, acute bacterial sinusitis and acute bacterial exacerbations of chronic bronchitis. Based on the committee's recommendation, in July 2016, the FDA approved changes to the labels of fluoroquinolones to indicate that fluoroquinolones should be reserved for use in patients who have no other treatment options for the indications mentioned above, because the risk of these serious side effects generally outweighs the benefits in these patients. These changes included a requirement that a separate patient Medication Guide be given with each prescription that describes the safety issues associated with this class of drugs. In December 2018, an FDA review found that fluoroquinolone antibiotics can increase the occurrence of rare but serious events of ruptures or tears in the main artery of the body, called the aorta. These tears, called aortic dissections, or ruptures of an aortic aneurysm can lead to dangerous bleeding or even death. They can occur with fluoroquinolones for systemic use given by mouth or through an injection.

### **cUTIs**

#### *Market Overview*

Infections due to a bacterial pathogen that is resistant to three or more antibiotic classes have become increasingly common and present a risk to our fight against infectious diseases and the management of complications in vulnerable patients. According to the CDC, more than two million hospital infections caused by bacteria resistant to one or more antibiotics occur every year in the United States, and over 23,000 patients with an antibiotic-resistant pathogen die each year.

The prevalence of antibiotic-resistant bacteria is increasing and is considered a significant threat to global health. In particular, the CDC and the WHO consider antibiotic resistance to be an urgent and critical threat to human health. The prevalence of Beta-lactamase enzymes among Gram-negative

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pathogens threatens the usefulness of many Beta-lactam antibiotics and has resulted in greater reliance on last line antibiotics, including carbapenems.

CUTIs, including AP, are among the most common infections due to MDR bacteria, including CRE, and are often healthcare-associated. Global mortality attributable to CRE infections has been estimated in some studies to be over 20% and reflects the need for safe, alternative, carbapenem-sparing

Surveillance and epidemiological studies suggest that some traditional, first-line antibiotics may no longer be acceptable choices for early therapy. In one large-scale surveillance study, approximately one out of three patients hospitalized in the United States with cUTI, a complicated intra-abdominal infection, hospital-associated pneumonia, or a bloodstream infection did not receive timely effective antibiotic therapy, and this delay was associated with increased morbidity and mortality. The rate of antibiotic resistance appears to be two to four times higher in patients who were admitted to the hospital from a nursing home or were recently hospitalized. Antibiotic therapy within the past six months has also been identified as a risk factor for antibiotic resistance.

New classes of antibiotics that are effective against drug-resistant pathogens are needed for early, appropriate treatment of serious infections in hospitalized patients and to treat patients who have failed to respond to standard, first-line antibiotics due to acquired drug resistance.

For over 45 years, oral and IV formulations of fosfomycin have been used in the European Union, Africa, Asia, and South America, and an oral formulation of fosfomycin has been used in the United States and Canada for the treatment of a variety of indications. Oral fosfomycin is available in the United States as single-dose therapy for cystitis and is noted as an appropriate treatment option for cystitis in treatment guidelines by the Infectious Diseases Society of America and the CDC. However, oral administration of fosfomycin provides inadequate concentrations required for treatment of more serious infections due to its limited bioavailability and dose-limiting gastrointestinal tolerability.

Outside of the United States, IV fosfomycin is approved for patients with a variety of infections, often severe, including cUTI, bacteremia, osteomyelitis, nosocomial lower respiratory tract infections, surgical site infections, bone and joint infections, endocarditis, skin infections and bacterial meningitis. The efficacy and safety profile of IV fosfomycin has been established by more than 45 years of clinical use outside of the United States and has been evaluated in more than 60 clinical studies. Fosfomycin has retained high *in vitro* activity with a low and stable resistance profile, and continues to be suitable for use as a monotherapy for cUTI despite long term use.

### *Causes of cUTIs*

cUTI is defined as a clinical syndrome characterized by pyuria and a documented microbial pathogen on culture of urine or blood, accompanied by local and systemic signs and symptoms, including fever, chills, malaise, flank pain, back pain or costo-vertebral angle pain or tenderness that occur in the presence of a functional or anatomical abnormality of the urinary tract, or in the presence of catheterization. Indwelling urethral catheters account for 70% to 80% of cUTIs, or 1 million cases per year in the United States. Catheter-associated UTI is the most common cause of secondary bloodstream infections and is linked to increased morbidity and mortality. Patients with pyelonephritis, regardless of underlying abnormalities of the urinary tract, are considered a subset of patients with cUTI.

cUTI are usually caused by a greater variety of pathogens, with a greater likelihood of associated antimicrobial resistance, than uncomplicated UTIs, or uUTIs. *Escherichia coli*, or *E. coli*, is isolated in approximately 75% to 95% of uUTIs and approximately 50% of cUTIs and is the most common etiologic agent of cUTIs. Additional commonly-identified Gram-negative uropathogens include other Enterobacteriaceae (such as *Klebsiella* spp., *Proteus* spp., *Enterobacter cloacae*) and non-fermenting



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Gram-negative bacilli (such as *Pseudomonas aeruginosa*, or *P. aeruginosa*, and *Acinetobacter* spp.). Gram-positive organisms, such as Enterococci and coagulase-negative Staphylococci, may also be contributing pathogens.

### *Limitations of Currently Available Treatment Options*

We believe bacterial resistance against antimicrobials has created the need for more antibiotic treatment options, particularly among MDR, Gram-negative bacilli (including CRE, ESBL, producers, and MDR *P. aeruginosa*). Gram-negative antimicrobial resistance is particularly common among urinary tract pathogens. Enterobacteriaceae, including *E. coli* and *Klebsiella pneumoniae*, or *K. pneumoniae*, may acquire plasmids that encode ESBLs and confer resistance to third-generation cephalosporins and other broad-spectrum antibiotics. Third-generation cephalosporins and Beta-lactamase inhibitors, or BLIs, are also commonly ineffective against Enterobacteriaceae that generate AmpC enzymes.

The recent spread into hospitals of Enterobacteriaceae expressing emergent Beta-lactamases, including members of the serine carbapenemases and metallo-Beta-lactamases, endanger antibiotic options. The lack of available and effective antibiotic classes for these organisms has created an unmet medical need. For example, infections with CRE are difficult to treat, as there are limited treatment choices available. Mortality rates as high as 40% to 50% have been associated with CRE infections, making them a serious threat to public health. The available treatment choices are associated with serious potential toxicity, in the case of colistin and aminoglycosides, or concerns of allergy or hypersensitivity, in the case of Beta-lactams or penicillin derivatives.

### *Our Solution: CONTEPO for the Treatment of cUTI*

- CONTEPO is an IV formulation of fosfomycin and the sole member of the epoxide antibiotic class.
- CONTEPO has a different mechanism of action than other IV antibiotics in the United States.
- CONTEPO has a broad spectrum of *in vitro* activity against a variety of clinically important MDR Gram-negative pathogens, including ESBL-producing Enterobacteriaceae, CRE, and Gram-positive pathogens, including methicillin-resistant *Staphylococcus aureus*, or MRSA, and vancomycin-resistant enterococci.
- CONTEPO has demonstrated in *in vitro* studies additivity or synergy when used in combination with other classes of antibiotic agents in pre-clinical trials.
- CONTEPO has a small molecular size, which may enable high levels of tissue penetration and facilitates renal elimination, both of which are important for treatment of cUTIs.
- CONTEPO is supported by a long history of IV fosfomycin use outside the United States in a variety of indications, including cUTI.
- CONTEPO has completed the ZEUS Study, a pivotal registrational Phase <sup>2/3</sup> clinical trial in cUTI, achieving non-inferiority to an active comparator.

CONTEPO is a potentially first-in-class epoxide IV antibiotic in the United States with a broad spectrum of bactericidal Gram-negative and Gram-positive activity, including activity against many contemporary MDR strains that threaten hospitalized patients. IV fosfomycin has an extensive commercial history in markets outside the United States, where it has been used broadly for over 45 years to treat a variety of indications, including complicated urinary tract infections, bacteremia, pneumonia and skin infections.

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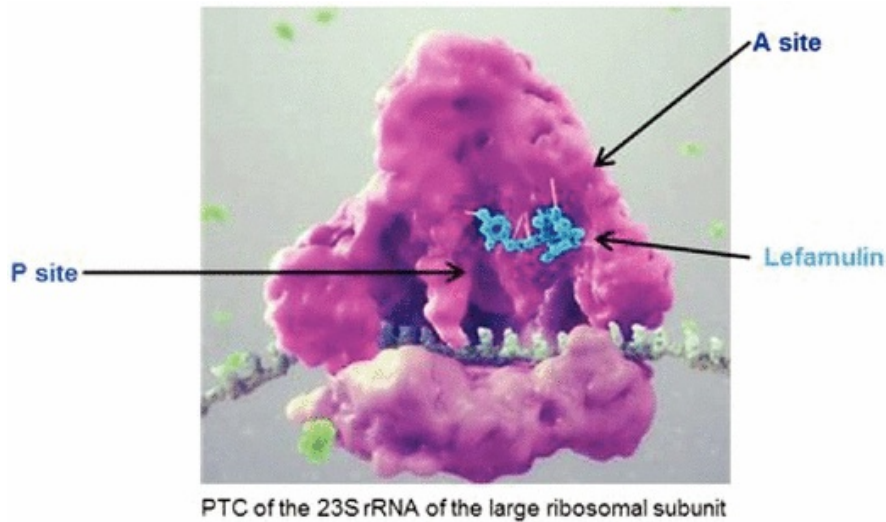
CONTEPO works differently than other IV antibiotics approved in the United States. CONTEPO inhibits an early step in bacterial cell wall synthesis, so the cell wall lacks integrity and the bacteria die quickly. We believe that because of its different mechanism of action, we have not observed any cross resistance to date between CONTEPO and any of the existing classes of intravenous antibiotics. In addition, CONTEPO has demonstrated in *in vitro* studies an additive or synergistic antibacterial effect with other classes of antibiotics when used in combination therapy, and has been shown to restore susceptibility in resistant strains.

**Our Product Development Pipeline**

***Lefamulin***

*Overview*

Lefamulin is a semi-synthetic derivative of the naturally occurring antibiotic, pleuromutilin, which was originally identified from a fungus called *Pleurotus mutilius*. Lefamulin inhibits the synthesis of bacterial protein, which is required for bacteria to grow. Lefamulin acts by binding to the peptidyl transferase center, or PTC, on the bacterial ribosome in such a way that it interferes with the interaction of protein production at two key sites known as the "A" site and the "P" site, resulting in the inhibition of bacterial proteins and the cessation of bacterial growth. Lefamulin's binding occurs with high affinity, high specificity and at molecular sites that are different than other antibiotic classes. We believe that lefamulin's novel mechanism of action is responsible for the lack of cross-resistance with other antibiotic classes that we have observed in our preclinical studies and clinical trials and a low propensity for development of bacterial resistance to lefamulin. The binding of lefamulin to the PTC on the bacterial ribosome is depicted in the graphic below.



We believe that lefamulin is well suited to be used empirically as monotherapy for the treatment of respiratory tract infections, such as CABP, because of its spectrum of antibacterial activity against both the typical and atypical pathogens causing CABP, including multi-drug resistant pathogens such as MRSA. In addition, in preclinical studies, lefamulin showed potent antibacterial activity against a variety of Gram-positive bacteria, Gram-negative bacteria and atypical bacteria, including multi-drug resistant strains. In preclinical studies and in Phase 1 clinical trials, lefamulin achieved substantial concentrations in the epithelial lining fluid, or ELF, of the lung, the site infected during pneumonia. Lefamulin also provides the ability to switch from IV to oral therapy and maintain therapy with the same antibacterial treatment. The efficacy of lefamulin in humans has been shown in a

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proof-of-concept clinical Phase 3 trial with 207 patients with ABSSSI (acute bacterial skin and skin structure infections) comparing two lefamulin doses (100 mg and 150 mg i.v. q12 h) with vancomycin (□ 1 000 mg) over 5-14 days. This trial enrolled patients with severe skin and skin structure infections, excluding any patients with minor and uncomplicated infections. In total, 90.8 % of patients in the Modified Intent to Treat, or mITT population had *S. aureus* infection; 69.1 % of patients had MRSA. There were consistent high response rates seen across all three treatment arms, across a wide range of clinical and microbiological outcomes. Furthermore, no development of resistance was observed for lefamulin or for vancomycin during the trial. Lefamulin treatment administered intravenously over 5 to 14 days was well tolerated. The types of treatment-emergent adverse events were consistent with a patient population under treatment for ABSSSI. Lefamulin prolonged the cardiac de- and repolarization duration but otherwise had a similar cardiac safety profile as vancomycin as assessed with standard 12-lead ECGs. The results of the clinical Phase 2 trial in ABSSSI provided the first proof of concept for the systemic use of a pleuromutilin antibiotic for the treatment of serious bacterial infections in humans. Thereafter, the clinical program for lefamulin progressed with completion of two Phase 3 clinical trials in CABP (LEAP 1, LEAP 2). These trials demonstrated that lefamulin treatment, administered as IV only, IV to oral, and oral only regimens, was non-inferior to the standard of care moxifloxacin for the treatment of adults with CABP. Each trial provided independent evidence of the treatment effect and safety in this population with unmet medical need.

The FDA has designated each of the IV and oral formulations of lefamulin as a QIDP which provides for the extension of statutory exclusivity periods in the United States for an additional five years upon FDA approval of the product for the treatment of CABP and granted fast track designation to these formulations of lefamulin. Fast track designation is granted by the FDA to facilitate the development and expedite the review of drugs that treat serious conditions and fill an unmet medical need. The fast track designation for the IV and oral formulations of lefamulin will allow for more frequent interactions with the FDA, the opportunity for a rolling review of any NDAs, we submit and eligibility for priority review and a shortening of the FDA's goal for taking action on a marketing application from ten months to six months. Two NDAs for IV and oral formulations of lefamulin for treatment of CABP were submitted to the FDA December 19, 2018. We plan to submit a marketing authorization application for lefamulin in Europe in the first half of 2019.

We own exclusive, worldwide rights to lefamulin, other than our rights in China which were licensed to Sinovant. Lefamulin is protected by issued patents in the United States, Europe and Japan covering composition of matter, which are scheduled to expire no earlier than 2028. We also have been granted patents for lefamulin relating to process and pharmaceutical crystalline salt forms in the United States, which are scheduled to expire no earlier than 2031. In addition, we own a family of pending patent applications directed to pharmaceutical compositions of lefamulin, which if issued would be scheduled to expire no earlier than 2036.

### *Key Attributes of Lefamulin*

We believe that the combination of the following key attributes of lefamulin, observed in clinical trials and preclinical studies, differentiates lefamulin from currently available antibiotics and make lefamulin well suited for use as a first-line or second-line empiric monotherapy for the treatment of CABP.

The preclinical studies and clinical trials we have conducted to date suggest that lefamulin's novel mechanism of action is responsible for the low risk of cross resistance observed with other antibiotic classes and a low propensity for development of bacterial resistance to lefamulin. As a result of the favorable safety and tolerability profile we have observed in our clinical trials to date, we believe lefamulin has the potential to present fewer complications relative to the use of current therapies. Based on our research, we also believe that the availability of both IV and oral formulations of

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lefamulin, and an option to switch to oral treatment, could reduce the length of a patient's hospital stay and the overall cost of care.

### *Targeted Spectrum of Activity for CABP Pathogens and Low Propensity for the Development of Bacterial Resistance*

We expect lefamulin's spectrum of antibacterial activity against typical and atypical pathogens could eliminate the need to use a combination of antibiotics for the treatment of CABP. In our completed Phase 2 clinical trial, IV lefamulin achieved a high cure rate against multi-drug resistant Gram-positive bacteria, including MRSA. In addition, in preclinical studies, lefamulin showed activity against a variety of Gram-positive bacteria, including *S. pneumoniae* and *S. aureus*, that are resistant to other classes of antibiotics, Gram-negative bacteria, including *H. influenzae* and *M. catarrhalis*, and atypical bacteria, including *C. pneumoniae*, *M. pneumoniae* and *L. pneumophila*. Included in lefamulin's spectrum of activity are all bacterial pathogens identified by IDSA as the most common causes of CABP for hospitalized patients who are not in the intensive care unit, as well as strains of the above listed bacteria that are resistant to other classes of antibiotics, including penicillins, cephalosporins, fluoroquinolones and macrolides.

Based on observations from our preclinical studies and clinical trials of lefamulin, as well as industry experience with pleuromutilins used in veterinary medicine over the last 39 years, we believe that lefamulin's novel mechanism of action is responsible for the low risk of cross-resistance observed with other antibiotic classes and a low propensity for development of bacterial resistance to lefamulin.

### *Convenient Dosing Regimen; Potential for Switching from IV to Oral Treatment*

We have developed both an IV and oral formulation of lefamulin, which we utilized in our clinical trials of lefamulin for the treatment of CABP. The administration of lefamulin as a monotherapy avoids the need for the complicated dosing regimens typical of multi-drug cocktails. We believe the availability of both IV and oral administration, and an option to switch to oral treatment, would be more convenient for patients and could reduce the length of a patient's hospital stay and the overall cost of care. The potential reduction in the overall cost of care could be particularly meaningful to healthcare institutions, as the DRG reimbursement system pays a fixed fee for the treatment of CABP regardless of the length of hospital stay.

The efficacy and safety of lefamulin in adult patients with CABP was shown in two pivotal Phase 3 clinical trials (LEAP 1 and LEAP 2). The two trials were designed in accordance with US and EU regulatory guidelines and conducted in parallel from 2016 to 2018. Design elements of the Phase 3 clinical trials were broadly comparable. Both were global, multicenter, randomized, double-blind, active-controlled, non-inferiority studies to establish the efficacy and safety of lefamulin against the standard-of-care moxifloxacin in the treatment of adult subjects with CABP. In LEAP 1, subjects were treated with IV study drug and could be switched to oral study drug at the discretion of the Investigator after 3 full days (6 doses) of IV treatment if, in the opinion of the Investigator, pre-defined criteria were met. In LEAP 2, subjects were treated with lefamulin for five days (ten doses) compared to seven days of moxifloxacin (seven doses).

### ***LEAP 1 (IV to Oral) Phase 3 Clinical Trial***

In LEAP 1, a total of 551 subjects with Pneumonia Outcomes Research Team (PORT) Risk Class III to V who required IV antibiotic therapy as initial treatment for the current episode of CABP were randomized 1:1 to treatment with lefamulin 150 mg IV every 12 hours (n=276) or moxifloxacin 400 mg IV every 24 hours (n=275). Subjects could be switched from IV to oral study drug (lefamulin 600 mg orally every 12 hours or moxifloxacin 400 mg orally every 24 hours) at the discretion of the Investigator after three full days (six doses) of IV treatment if pre-defined criteria were met. If the

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investigator determined that MRSA was a probable pathogen at Screening, adjunctive linezolid 600 mg IV every 12 hours was to be added to the moxifloxacin group and linezolid placebo was to be added to the lefamulin group.

The protocol defined different primary endpoints for the FDA and EMA to address regional differences in regulatory requirements for the development of antibacterial drugs to treat CABP. The FDA primary endpoint (EMA secondary endpoint) was the percentage of subjects with an Early Clinical Response, or ECR, of responder at 96 ± 24-hours after the first dose of study drug in the Intent-to-treat, or ITT, Analysis Set. The EMA co-primary endpoints (FDA secondary endpoints) were the percentages of subjects with an Investigator's Assessment of Clinical Response (IACR) of success at Test of Cure (TOC) Visit (5 to 10 days after the last dose of study drug) in the mITT and Clinically Evaluable at Test of Cure, or CE-TOC Analysis Sets.

Of the 551 subjects randomized, 546 received any amount of study drug (Safety Analysis Set: 273 lefamulin, 273 moxifloxacin). The mean total duration of study drug treatment (IV and oral combined) was approximately seven days in each treatment group. The two treatment groups were generally well balanced with respect to demographics and baseline characteristics. Overall, 59.9% of subjects were male. The overall mean age was 60.3 years; 43.6% were ≤65 years and 18.1% were ≥75 years. Overall, 72.1% of subjects were classified as PORT Risk Class III, 26.5% were PORT Risk Class IV, and 1.3% were PORT Risk Class V.

LEAP 1 met its primary objective and demonstrated that lefamulin is non-inferior to moxifloxacin with or without adjunctive linezolid for the treatment of adult subjects with CABP based on the FDA and EMA primary endpoints. The ECR responder rate (FDA primary endpoint) was 87.3% in the lefamulin group and 90.2% in the moxifloxacin group (treatment difference -2.9%; 95% CI: -8.5, 2.8). The lower limit of the 95% CI for the difference in ECR responder rates was greater than the non-inferiority margin of -12.5%. Success rates for IACR at TOC (EMA co-primary endpoints) were 81.7% in the lefamulin group and 84.2% in the moxifloxacin group (treatment difference -2.6%; 95% CI: -8.9, 3.9) in the mITT group, and 86.9% in the lefamulin group and 89.4% in the moxifloxacin group (treatment difference -2.5%; 95% CI: -8.4, 3.4) in the CE-TOC group. The lower limit of the 95% CI for the difference in IACR success rates was greater than the non-inferiority margin of -10% for both groups.

Early Clinical Response rates for the most frequently identified baseline pathogens in the Microbiological Intent-to-treat, or microITT, group were: *S. pneumoniae* (88.2% lefamulin vs 93.8% moxifloxacin), *H. influenzae* (92.2% lefamulin vs 94.7% moxifloxacin), *M. catarrhalis* (92.0% lefamulin vs 100.0% moxifloxacin), *M. pneumoniae* (84.2% lefamulin vs 90.0% moxifloxacin), *L. pneumophila* (88.9% lefamulin vs 85.7% moxifloxacin), and *C. pneumoniae* (90.9% lefamulin vs 94.7% moxifloxacin). ECR responder rates for *S. aureus* were 100.0% in both treatment groups. Responder rates among resistant pathogens were high in the lefamulin group (eg, 100.0% for penicillin-intermediate *S. pneumoniae* [PISP], penicillin-resistant *S. pneumoniae* [PRSP], multi-drug resistant *S. pneumoniae*, or MDRSP, and macrolide-resistant *S. pneumoniae*), although the number of resistant pathogens was low.

Both lefamulin and moxifloxacin were well tolerated in the IV ± oral treatment regimens administered in the study. A similar rate of treatment-emergent adverse events, or TEAEs, was observed (38.1% vs 37.7% in the lefamulin and moxifloxacin groups, respectively). Gastrointestinal events were the most frequently reported TEAEs in both treatment groups (6.6% lefamulin, 13.6% moxifloxacin), with the difference between groups driven by an imbalance in TEAEs of diarrhea (0.7% lefamulin, 7.7% moxifloxacin). No gastrointestinal TEAEs led to discontinuation of study drug in either treatment group.

Administration site reactions of any type occurred more frequently for lefamulin (7.7%) than moxifloxacin (3.7%). The most common individual TEAE was infusion site pain, affecting eight (2.9%)

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subjects in the lefamulin group, and no subjects in the moxifloxacin group. One subject in each treatment group had an infusion site reaction that led to discontinuation of study drug.

The incidence of TEAEs leading to discontinuation of study drug was 2.9% and 4.4% for the lefamulin and moxifloxacin groups, respectively. The only TEAE preferred terms leading to discontinuation for more than 1 subject per treatment group were electrocardiogram (ECG) QT prolonged (one lefamulin-treated subject and three moxifloxacin-treated subjects) and infectious pleural effusion (one lefamulin-treated subject and two moxifloxacin-treated subjects).

Serious TEAEs occurred in 7.0% of subjects in the lefamulin group and 4.8% of subjects in the moxifloxacin group and were most frequently reported in the Infections and Infestations System Organ Class, or SOC (2.9% lefamulin, 1.5% moxifloxacin).

Nine deaths (five in the lefamulin group and, four in the moxifloxacin group) occurred by Day 28. Two additional deaths were reported after Day 28 (i.e., after the intended Late Follow-up [LFU] Visit): one lefamulin-treated subject on Day 32 and one moxifloxacin-treated subject on Day 48. None of the deaths was assessed as related to study drug by the Investigators.

There were no clinically meaningful trends or pattern of changes identified in hematology or chemistry laboratory parameters. No subjects met Hy's Law criteria.

### **LEAP 2 (Oral Only) Phase 3 Clinical Trial**

In LEAP 2, a total of 738 subjects with PORT Risk Class II to IV who were appropriate candidates for oral antibiotic therapy for the current episode of CABP were randomized 1:1 to treatment with lefamulin (n=370) or moxifloxacin (n=368). Subjects received either lefamulin 600 mg orally every 12 hours for 5 days (10 doses) or moxifloxacin 400 mg orally every 24 hours for seven days (seven doses). The primary and secondary objectives were identical to those in LEAP 1.

Of the 738 subjects randomized, 736 received any amount of study drug (Safety Analysis Set: 368 lefamulin, 368 moxifloxacin). The mean duration of exposure to active lefamulin was 5.0 days, compared with 6.7 days of active moxifloxacin, which reflects the intended duration of active treatment for each drug as per the study design. The two treatment groups were generally well balanced with respect to demographics and baseline characteristics. Overall, 52.4% of subjects were male. The overall mean age was 57.5 years; 37.5% were  $\leq$  65 years and 16.3% were  $\leq$  75 years. Overall, 50.4% of subjects were classified as PORT Risk Class II, 37.7% were PORT Risk Class III, and 11.1% were PORT Risk Class IV.

LEAP 2 met its primary objective and demonstrated that lefamulin is non-inferior to moxifloxacin for the treatment of adult subjects with CABP based on the FDA and EMA primary endpoints. The ECR responder rate (FDA primary endpoint) was 90.8% in the lefamulin group and 90.8% in the moxifloxacin group (treatment difference 0.1%; 95% CI: -4.4, 4.5). The lower limit of the 95% CI for the difference in ECR responder rates was greater than the non-inferiority margin of -10%. Success rates for IACR at TOC (EMA co-primary endpoints) were 87.5% in the lefamulin group and 89.1% in the moxifloxacin group (treatment difference -1.6%; 95% CI: -6.3, 3.1) in the mITT group, and 89.7% in the lefamulin group and 93.6% in the moxifloxacin group (treatment difference -3.9%; 95% CI: -8.2, 0.5) in the CE-TOC group. The lower limit of the 95% CI for the difference in IACR success rates was greater than the non-inferiority margin of -10% for both groups.

Early Clinical Response rates for the most frequently identified baseline pathogens in the microITT group were: *S. pneumoniae* (89.4% lefamulin vs 91.3% moxifloxacin), *H. influenzae* (89.3% lefamulin vs 91.7% moxifloxacin), *M. pneumoniae* (100.0% in both groups), *M. catarrhalis* (85.7% lefamulin vs 100.0% moxifloxacin), *L. pneumophila* (81.3% lefamulin vs 94.1% moxifloxacin), and *C. pneumoniae* (93.8% lefamulin vs 100.0% moxifloxacin). ECR responder rates for *S. aureus* were 100.0% in both treatment groups. Responder rates among resistant pathogens were high in the

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lefamulin group (eg, 100.0% for PISP, PRSP, MDRSP, and MRSA), although the number of resistant pathogens was low.

Both lefamulin and moxifloxacin were well tolerated in the oral treatment regimens administered in the study. The overall incidence of TEAEs was higher in the lefamulin group (32.6%) than in the moxifloxacin group (25.0%), which was driven by a difference in the incidence of mild/moderate Gastrointestinal Disorders. For lefamulin and moxifloxacin, respectively, the most frequently reported individual TEAEs in this category (and for the study overall) were diarrhea (12.2% vs 1.1%), nausea (5.2% vs 1.9%), and vomiting (3.3% vs 0.8%). Among the lefamulin-treated subjects reporting each of these TEAEs, approximately 75% had mild events and the remainder had moderate events. The only severe gastrointestinal adverse event, which was also serious, was a case of inguinal hernia strangulated in a moxifloxacin-treated subject. There were no severe or serious gastrointestinal adverse events among lefamulin-treated subjects. Furthermore, gastrointestinal events led to study drug discontinuation for 3 lefamulin-treated subjects (due to vomiting or abdominal pain) and one moxifloxacin-treated subject (due to vomiting). One patient who had a positive clinical response to lefamulin was later diagnosed with a *C. difficile* infection during an extended hospital stay.

The incidence of TEAEs leading to discontinuation of study drug was 3.3% for the lefamulin group and 2.4% for the moxifloxacin group.

Serious TEAEs occurred in 4.6% of lefamulin-treated subjects and 4.9% of moxifloxacin-treated subjects, most frequently in the Infections and Infestations category (2.4% and 1.4%, respectively).

In each treatment group, three (0.8%) subjects died by Day 28. Deaths of two additional lefamulin-treated subjects were reported after Day 28 (i.e., after the intended LFU Visit): one subject on Day 57 and one subject on Day 271. None of the deaths was assessed as related to study drug by the Investigators.

No clinically meaningful trends or pattern of changes were identified in hematology or chemistry laboratory parameters. Two unique lefamulin-treated subjects had either an ALT or an aspartate aminotransferase (AST) value  $>10 \times$  the upper limit of normal, or ULN; in both cases the transaminase increases were transient with no associated increase in serum bilirubin. No subjects met Hy's Law criteria.

Electrocardiogram analyses demonstrated increases from baseline in the QTcF interval in both treatment groups, but the magnitude of the change in the lefamulin treatment group was smaller than that caused by moxifloxacin. In this study the mean change from baseline in QTcF interval at the steady state assessment was 9.5 msec for lefamulin and 11.6 msec for moxifloxacin. Post-baseline QTcF increases of  $>60$  msec occurred in 1.1% of lefamulin-treated subjects and 1.9% of moxifloxacin-treated subjects. No associated cardiac arrhythmias of concern were observed. No adverse trends in vital signs in either treatment group were observed.

### *Phase 1 Pediatric Clinical Trial*

Not unlike treatment of infectious diseases in adults, the management of pediatric infections has become more difficult due to the continuing rise in resistance in bacteria. Further complicating antimicrobial selection in the pediatric population is the need for agents to be very well tolerated and available in a final dosage form that can be easily administered to children. Based upon the *in vitro* antimicrobial spectrum of activity, along with the safety profile observed to date, we believe lefamulin is appropriate for evaluation for the treatment of a variety of pediatric infections, including those affecting the respiratory tract and skin and skin structure. We have an agreed Pediatric Investigation Plan, or PiP, and Pediatric Study Plan, or PSP, with the EMA and FDA, respectively. Pediatric oral formulation development is ongoing and we initiated a Phase 1 clinical trial in pediatric patients in mid-2018.

***Additional Potential Indications for Lefamulin***

*STIs*

Urethritis and cervicitis caused by *N. gonorrhoeae*, *C. trachomatis* or *M. genitalium* are frequently occurring sexually transmitted infections in the United States and Europe. Left untreated, these infections can cause serious health problems, particularly in women, including chronic pelvic pain, life-threatening ectopic pregnancy and infertility. Resistance in these organisms to the most commonly prescribed antibacterial treatments poses a serious public health threat. For example, the CDC estimates that 30% of the clinical isolates of *N. gonorrhoeae* are resistant to at least one currently available antibiotic.

In preclinical studies, lefamulin has shown high potency against *N. gonorrhoeae*, *C. trachomatis* and *M. genitalium*, including strains resistant to currently available antibacterial agents. As a result, we are actively assessing a non-clinical and clinical development plan to support the development of lefamulin as a first-line treatment for urethritis, cervicitis and pelvic inflammatory disease.

*Osteomyelitis*

The incidence of osteomyelitis, which is an infection of the bone, is increasing. The most common causative organism is *S. aureus*. In the United States, the prevalence of MRSA in these cases ranges from 33% to 55%. Up to 90% of cases of hematogenous osteomyelitis, most frequently in children, are caused by *S. aureus*. We believe that lefamulin has the potential to be an effective treatment option for osteomyelitis. Lefamulin has shown substantial tissue penetration and activity against the most common causative organism in all forms of osteomyelitis. We believe that based on the safety profile observed to date, lefamulin will be well tolerated for the long term use necessary for the treatment of both adult and pediatric patients with osteomyelitis. The current standard of care for these infections is treatment with vancomycin. We believe the ability to administer lefamulin by either the IV or oral route would provide a significant advantage over agents, such as vancomycin, that can only be administered by IV.

*Prosthetic Joint Infections*

Infection occurs in approximately 1% of joint replacement surgeries. Although the incidence of infection has been decreasing, the total number of replacement operations has been rising, such that, overall, there is increasing morbidity. The majority of these infections are caused by three organisms: coagulase negative staphylococci, *S. aureus* (including MRSA) and streptococci, all organisms that are susceptible to lefamulin. The preferred treatment for joint infections with MRSA is vancomycin, with daptomycin and linezolid as alternatives. Vancomycin and daptomycin are administered only by IV for this indication, and linezolid has side effects that affect long term use. We believe that lefamulin could provide an alternative for both IV and oral therapy for these infections cases.

Although we have no current plans to develop lefamulin for indications other than CABP, we may advance these programs in the clinic based on available funding.

***CONTEPO Clinical Development Program***

*Overview*

CONTEPO is under development in the United States for the treatment of cUTI, including AP. The clinical development plan for CONTEPO utilized a modernized dosing regimen to optimize coverage of the predominant pathogens in hospital infections, including strains recognized by the CDC as an urgent or serious antibiotic resistant threat to public health in the United States. We submitted an NDA for marketing approval of CONTEPO for the treatment of cUTI in adults in the United States, to the FDA in October 2018. The NDA submission is utilizing the 505(b)(2) regulatory pathway and is supported by a robust data package, including a pivotal Phase 2/3 clinical trial (known as



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ZEUS™), which met its primary endpoint of statistical non-inferiority to piperacillin/tazobactam in patients with cUTI, including acute pyelonephritis. The FDA has granted us a PDUFA target action date of April 30, 2019 for CONTEPO.

### *Phase 2/3 Clinical Trial*

The ZEUS Study was a multicenter, randomized, parallel-group, double-blind, pivotal Phase 2/3 clinical trial designed to evaluate safety, tolerability, efficacy and pharmacokinetics of CONTEPO compared to PIP-TAZ in the treatment of hospitalized adults with cUTI or AP. PIP-TAZ is a combination antibiotic consisting of a broad-spectrum antibiotic, piperacillin, plus a Beta-lactamase inhibitor, tazobactam, which extends the antibiotic spectrum of piperacillin to include many Beta-lactamase-producing bacteria that have acquired resistance to piperacillin alone. PIP-TAZ is widely used to treat serious Gram-negative infections. The primary objective of the ZEUS Study was to demonstrate that CONTEPO was non-inferior to PIP-TAZ in overall success based on clinical cure and microbiologic eradication in the microbiologic modified intent-to-treat, or m-MITT, population at the test-of-cure visit, or TOC, which occurred on the 19<sup>th</sup> to 21<sup>st</sup> day after completion of seven days of treatment with the study drug, or after up to 14 days of treatment for patients with concurrent bacteremia. The m-MITT population consisted of 362 patients, each of whom met the study's inclusion criteria, was randomized, received any amount of study drug, and had one or more baseline Gram-negative pathogens growing at greater than or equal to 10(5) CFU/mL from an appropriately collected, pre-treatment baseline urine or blood sample. The primary endpoint was a composite of the investigator's determination of clinical cure, meaning complete resolution or significant improvement of signs and symptoms that were present at baseline and no new symptoms, such that no further antimicrobial therapy is warranted, plus microbiologic eradication, meaning that the baseline bacterial pathogen was reduced to less than 10(4) CFU/mL on urine culture and, if applicable, negative on repeat blood culture, both in the m-MITT population at TOC. Any missing or presumed eradications were classified as indeterminates, and conservatively counted as failures in the overall success analysis.

All pathogens isolated from patients who had a baseline and TOC pathogen underwent blinded, post-hoc, pulsed-field gel electrophoresis, or PFGE, typing analysis. Microbiologic outcome was also defined utilizing the PFGE results, whereby microbiologic persistence required the same genus and species of baseline and post-baseline pathogens, as well as PFGE-confirmed genetic identity.

Patients eligible for the trial were required to be 18 years of age or older and have cUTI or AP that was considered by the clinical investigator to be serious enough to require hospitalization and IV antibiotic therapy. The diagnosis was based on pyuria, or the presence of pus or white blood cells in the urine, and cUTI or AP with at least two additional symptoms such as chills, rigors, or warmth associated with fever, nausea or vomiting, painful, difficult or frequent urination, lower abdominal or pelvic pain, or acute flank pain. Patients with cUTI were also required to have at least one risk factor, such as use of intermittent or indwelling bladder catheterization; functional or anatomical abnormality of the urogenital tract; complete or partial hindrance of normal urine flow; blood urea nitrogen greater than 20 mg/dL, blood urea greater than 42.8 mg/dL, or serum creatinine greater than 1.4 mg/dL, due to known prior renal disease; or, in male patients, chronic urinary retention. A baseline urine culture specimen was obtained within 48 hours prior to randomization, and any indwelling bladder catheters were required to be removed or replaced, unless such removal was considered unsafe or contraindicated, before or within 24 hours after randomization.

Eligible patients were randomly assigned to receive either CONTEPO (6 grams IV fosfomycin) or PIP-TAZ (4 grams piperacillin/0.5 grams tazobactam) as one-hour infusions three times daily for seven days, except patients with concurrent bacteremia, who could have received treatment for up to 14 days at the clinical investigator's discretion. Oral step down therapy was prohibited. Throughout the study, all patients were monitored for signs and symptoms of cUTI or AP and the occurrence of adverse events. Laboratory data, including chemistry panels, complete blood counts, electrocardiograms, and

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samples for urine and blood cultures were collected from all patients at specified times throughout the study.

Of the total of 465 patients randomized across 92 sites in 16 countries, with studies conducted at 74 sites in 15 countries, 464 (99.8%) received at least one dose of the study drug. Of the 464 patients who received at least one dose of study drug, 233 patients were in the CONTEPO treatment group, and 231 patients were in the PIP-TAZ treatment group. The incidence of premature discontinuation from study drug was low and similar between treatment groups (6.0% in the CONTEPO treatment group compared to 3.9% in the PIP-TAZ treatment group), and the incidence of not completing the study through the last follow-up visit, or LFU, which occurred on the 24<sup>th</sup> through 28<sup>th</sup> day after completion of seven days of treatment with the study drug, or after up to 14 days of treatment for patients with concurrent bacteremia, was 5.2% in the CONTEPO group compared to 0.9% in the PIP-TAZ group.

In the ZEUS Study, CONTEPO was non-inferior to PIP-TAZ for the primary efficacy outcome of overall success, which was defined as clinical cure and microbiologic eradication at TOC. Overall success occurred in 64.7% of CONTEPO patients and 54.5% of PIP-TAZ patients. The treatment difference between the CONTEPO and PIP-TAZ groups was 10.2%, with a 95% confidence interval (-0.4, 20.8). Additionally, the lower bound of the 95% confidence interval met the pre-specified non-inferiority margin of -15%, demonstrating that CONTEPO was non-inferior to PIP-TAZ in the study. In a post-hoc primary efficacy analysis using results of blinded PFGE molecular typing of urinary tract pathogens, this difference was even greater (69.0% CONTEPO patients compared to 57.3% PIP-TAZ patients, with a treatment difference of 11.7%, with a 95% confidence interval (1.3, 22.1). Overall success rates were driven by microbiologic eradication rates, as clinical cure rates were greater than 90% and treatment differences were small at TOC. Using the PFGE molecular typing, the microbiologic eradication rates in the m-MITT population at the TOC were 70.7% for patients receiving CONTEPO compared to 60.1% for patients receiving PIP-TAZ. These rates were consistent with those observed in some contemporary cUTI studies, and most patients with microbiologic persistence at TOC had identifiable reasons or risk factors for persistence, such as functional or anatomical abnormalities of the urogenital tract, recent or indwelling urinary tract catheterization, elevated minimum inhibitory concentration, or MIC, to the study drug received, abbreviated study drug therapy, or other underlying co-morbidities. Of note, a majority of patients with microbiologic persistence at TOC were clinical cures at TOC, did not require rescue antimicrobial therapy, and remained sustained cures at LFU.

The identity and frequency of pathogens recovered at baseline from patients in the ZEUS Study were similar in both the CONTEPO and PIP-TAZ treatment groups. The most common pathogens identified were Enterobacteriaceae, identified in 96.2% of the CONTEPO patients and 94.9% of the PIP-TAZ patients, including *E. coli*, identified in 72.3% of the CONTEPO patients and 74.7% of the PIP-TAZ patients; *K. pneumoniae*, identified in 14.7% of the CONTEPO patients and 14.0% of the PIP-TAZ patients; *Enterobacter cloacae* species complex, identified in 4.9% of the CONTEPO patients and 1.7% of the PIP-TAZ patients; and *Proteus mirabilis*, identified in 4.9% of the CONTEPO patients and 2.8% of the PIP-TAZ patients. Gram-negative aerobes other than Enterobacteriaceae included *Pseudomonas aeruginosa*, which was identified in 4.3% of the CONTEPO patients and 5.1% of the PIP-TAZ patients, and *Acinetobacter baumannii-calcoaceticus* species complex, identified in 1.1% of the CONTEPO patients and no PIP-TAZ patients. These pathogens are representative of the pathogens that have been recovered in other studies of patients with cUTI or AP. For the predominant pathogens *E. coli* and *K. pneumoniae*, the clinical cure rates at TOC for CONTEPO were greater than 90% for both pathogens, and microbiologic eradication rates were 68.4%, or 72.9% with PFGE analysis, for *E. coli*, and 66.7% for *K. pneumoniae* on both a non-PFGE analysis and PFGE analysis-basis.

A total of 42.1% of CONTEPO patients and 32.0% of PIP-TAZ patients experienced at least one TEAE. Most TEAEs were mild or moderate in severity, and severe TEAEs were uncommon (2.1% of

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CONTEPO patients and 1.7% of PIP-TAZ patients). The most common TEAEs in both treatment groups were transient, asymptomatic laboratory abnormalities and gastrointestinal events. Treatment-emergent serious adverse events, or SAEs, were uncommon in both treatment groups (2.1% of CONTEPO patients and 2.6% of PIP-TAZ patients). There were no deaths in the study and one SAE in each treatment group was deemed related to the study drug (hypokalemia in a CONTEPO patient and renal impairment in a PIP-TAZ patient), leading to study drug discontinuation in the PIP-TAZ patient. Study drug discontinuations due to TEAEs were infrequent and similar between treatment groups (3.0% of CONTEPO patients and 2.6% of PIP-TAZ patients).

The most common laboratory abnormality TEAEs were increases in the levels of alanine aminotransferase (8.6% of CONTEPO patients and 2.6% of PIP-TAZ patients) and aspartate transaminase (7.3% of CONTEPO patients and 2.6% of PIP-TAZ patients). None of the aminotransferase elevations were symptomatic or treatment-limiting, and none of the patients met the criteria for Hy's Law. Outside of the United States, elevated liver aminotransferases are listed among undesirable effects in labeling for IV fosfomycin.

Hypokalemia occurred in 71 of 232 (30.6%) CONTEPO patients and 29 of 230 (12.6%) PIP-TAZ patients. Most decreases in potassium levels were mild to moderate in severity. Shifts in potassium levels from normal at baseline to hypokalemia, as determined by worst post-baseline hypokalemia values, were more frequent in the CONTEPO group than the PIP-TAZ group for mild (17.7% compared to 11.3%), moderate (11.2% compared to 0.9%), and severe (1.7% compared to 0.4%) categories of hypokalemia. Hypokalemia was deemed a TEAE in 6.4% of patients receiving CONTEPO and 1.3% of patients receiving PIP-TAZ, and all cases were transient and asymptomatic. While no significant cardiac adverse events were observed in the ZEUS Study, post-baseline QT intervals calculated using Fridericia's formula, or QTcF, of greater than 450 to less than or equal to 480 msec (baseline QTcF of less than or equal to 450 msec) occurred at a higher frequency in CONTEPO patients (7.3%) compared to PIP-TAZ patients (2.5%). In the CONTEPO arm, these results appear to be associated with the hypokalemia associated with the salt load of the IV formulation.

### *Phase 1 Pediatric Clinical Trial*

In June 2018, we initiated a Phase 1, non-comparative, open-label study of the pharmacokinetics and safety of a single dose of CONTEPO in pediatric subjects less than 12 years of age receiving standard-of-care antibiotic therapy for proven or suspected infection or peri-operative prophylaxis. A total of 24 patients are expected to be enrolled at up to ten clinical sites in the United States. We anticipate completing enrollment in this trial in late 2020.

### *Potential Additional Indications for CONTEPO*

Fosfomycin has a long history of use outside the United States in a variety of indications beyond cUTI. The FDA has granted both Fast Track and QIDP designations for the investigation of CONTEPO for the following indications in addition to cUTI:

- Complicated intra-abdominal infections (cIAI)
- Hospital-acquired bacterial pneumonia (HABP)
- Ventilator-associated bacterial pneumonia (VABP)
- Acute bacterial skin and skin structure infections (ABSSSI)

Although we have no current plans to develop CONTEPO for indications other than cUTI, including AP, these designations make CONTEPO eligible for Fast Track and GAIN incentives. We may advance these programs in the clinic based on available non-dilutive funding.

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In August 2017, Zavante entered into an agreement with the United States National Institute of Allergy and Infectious Diseases, or NIAID, under which NIAID will conduct a clinical trial to assess CONTEPO's intrapulmonary penetration and pharmacokinetics in support of the product candidate's potential future development as a treatment for HABP and VABP. This bronchoalveolar lavage study, or the BAL study, will measure CONTEPO's pulmonary penetration by assessing drug concentrations in the lining of study subjects' bronchial pathways. Diffusion and saturation of antibiotics in patients' airways are considered important factors in assessing a drug's ability to effectively treat lower-respiratory tract infections. Prior preclinical and clinical investigations of IV fosfomycin have demonstrated that the product candidate penetrates rapidly into tissues and achieves clinically relevant concentrations in urine, soft tissues, lungs and other organs, supporting CONTEPO's potential versatility as an antibiotic treatment option. The protocol for the BAL study is currently under development in conjunction with NIAID, and we anticipate that the study will be initiated in mid-2019.

### **License Agreement with Sinovant Sciences**

In March 2018, we entered into a license agreement, or the License Agreement, with Sinovant Sciences, Ltd. or Sinovant, an affiliate of Roivant Sciences, Ltd., to develop and commercialize lefamulin in the greater China region. As part of the License Agreement, Nabriva Therapeutics Ireland DAC and Nabriva Therapeutics GmbH, our wholly owned subsidiaries, granted Sinovant an exclusive license to develop and commercialize, and a non-exclusive license to manufacture, certain products containing lefamulin, or the Licensed Products, in the People's Republic of China, Hong Kong, Macau, and Taiwan (together the "Territory"). We retain development and commercialization rights in the rest of the world.

Under the License Agreement, Sinovant and our subsidiaries established a joint development committee, or the JDC, to review and oversee development and commercialization plans in the Territory. We received a \$5.0 million upfront payment pursuant to the terms of the License Agreement and are eligible for up to an additional \$91.5 million in milestone payments upon the achievement of certain regulatory and commercial milestone events related to lefamulin for CABP, plus an additional \$4.0 million in milestone payments if any Licensed Product receives a second or any subsequent regulatory approval in the People's Republic of China. The first milestone was a \$1.5 million payment for the submission of a clinical trial application by Sinovant to the Chinese Food and Drug Administration that was received in February 2019. The remaining milestone payments are tied to additional regulatory approvals and annual sales targets. In addition, we will be eligible to receive low double-digit royalties on sales, if any, of Licensed Products in the Territory.

Sinovant will be solely responsible for all costs related to developing, obtaining regulatory approval of and commercializing Licensed Products in the Territory and is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize Licensed Product in the Territory. We are obligated to use commercially reasonable efforts to supply, pursuant to supply agreements to be negotiated by the parties, to Sinovant sufficient supply of lefamulin for Sinovant to manufacture finished drug products for development and commercialization of the Licensed Products in the Territory.

Unless earlier terminated, the License Agreement will expire upon the expiration of the last royalty term for the last Licensed Product in the Territory, which we expect will occur in 2033. Following the expiration of the last royalty term, the license granted to Sinovant will become non-exclusive, fully-paid, royalty-free and irrevocable. The License Agreement may be terminated in its entirety by Sinovant upon 180 days' prior written notice at any time. Either party may, subject to specified cure periods, terminate the License Agreement in the event of the other party's uncured material breach. Either party may also terminate the License Agreement under specified circumstances relating to the other party's insolvency. We have the right to terminate the License Agreement immediately if Sinovant does not reach certain development milestones by certain specified dates

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(subject to specified cure periods). The License Agreement contemplates that we will enter into ancillary agreements with Sinovant, including clinical and commercial supply agreements and a pharmacovigilance agreement.

**Commercialization Strategy**

Other than in greater China where we have licensed development and commercialization rights to lefamulin, we own exclusive, worldwide rights to lefamulin and U.S. rights to CONTEPO. We expect that our initial target population for lefamulin will consist of patients with moderate to severe CABP whose antibiotic treatment is hospital-initiated. If lefamulin receives marketing approval from the FDA for the treatment of CABP, we plan to pursue commercialization strategies that maximize the value of lefamulin in the United States with our own targeted hospital sales and marketing organization that we plan to expand beyond its current levels. Based on our market research, we believe lefamulin has an innovative profile supporting adoption in the United States for adult hospital-initiated CABP patients, treated both as in-patients as well as outpatient-transition of care from the hospital to the community, which we believe represents a significant commercial opportunity. We believe that we will be able to effectively communicate lefamulin's differentiating characteristics and key attributes to clinicians, hospital pharmacies and payors with the goal of establishing favorable reimbursement for outpatients as well as a favorable formulary status in targeted hospitals. Additionally, we believe that our plans for an initial targeted hospital-focused sales force should allow us to address—on our own—the hospital-initiated treatment market for CABP in the United States in an efficient and effective way. There is also a significant opportunity for lefamulin to be used in the community for CABP patients, given its versatile profile, and this may represent a future expanded use. We plan to continue our pre-commercialization activities to prepare for a potential commercial launch of lefamulin, subject to receiving marketing approval in the United States. Outside of the United States, we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize lefamulin.

Along with additional market research, we believe that medical education will be a key component of our commercialization efforts and, following potential commercial launch, plan to invest in these activities to optimize the commercial potential of lefamulin. With a targeted initial prescribing base predominantly in the hospital setting, we expect that a targeted hospital sales and marketing organization would be relatively smaller than competitors who are focused on both the hospital and community prescribing base. We believe that lefamulin's novel mechanism of action, status as the only member of a new class of systemically administered pleuromutilins and anticipated clinical profile will support its potential favorable reimbursement, its potential inclusion on formularies and in local and national treatment guidelines, subject to and following marketing approval.

We plan to evaluate the merits of entering into collaboration agreements with other pharmaceutical or biotechnology companies that may contribute to our ability to efficiently advance our product candidates, build our product pipeline and concurrently advance a range of research and development programs for a variety of indications outside the United States.

We own exclusive U.S. rights to CONTEPO. Our strategic intention, supported by CONTEPO's differentiated profile, is to establish CONTEPO as the standard of care in the United States for hospitalized patients with serious infections caused by suspected or confirmed MDR bacteria. We plan to use a targeted sales force to promote CONTEPO to hospital-based healthcare professionals in key locations within the United States where MDR infections, including CRE, are concentrated. These include roughly 900 hospitals in high resistance locations such as New York City, Los Angeles and Chicago, and other major population centers.

We currently have a team of regional business directors and medical science liaisons in the field performing educational and market development activities, respectively, for lefamulin and CONTEPO.

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We initially plan to use a targeted hospital-based sales force to promote both lefamulin formulations and CONTEPO, if approved.

### **Manufacturing**

We do not own or operate, and currently have no plans to establish, manufacturing facilities for the production of clinical or commercial quantities of lefamulin, CONTEPO, or any of the other compounds that we are evaluating in our discovery program. We currently rely, and expect to continue to rely, on third parties for the manufacture of lefamulin, CONTEPO and any further products that we may develop. We have significant in-house knowledge and experience in (i) the relevant chemistry associated with our product candidates; and (ii) the relevant manufacturing and supply chain processes associated with the commercial supply of our product candidates. In addition to these internal resources, we engage third-party consultants, to assist in the management of our third-party manufacturers.

We have engaged a limited number of third-party manufacturers to provide all of our starting materials, drug substance and finished product for use in clinical trials. The active pharmaceutical ingredients, or API, and drug products have been produced under master service contracts and specific work orders from these manufacturers pursuant to agreements that include specific supply timelines and volume and quality expectations. We choose the third-party manufacturers of the drug substance based on the volume required and the regulatory requirements at the relevant stage of development. All lots of drug substance and drug products used in clinical trials are manufactured under current good manufacturing practices. Separate third-party manufacturers have been responsible for fill and finish services, and for labeling and shipment of the final drug product to the clinical trial sites.

#### *Lefamulin*

We have entered into a long-term commercial supply agreement with SEL Biochem Xinjiang Co., Ltd, or SEL, and Fountain International Development Holding Limited for the supply of pleuromutilin, which is the key intermediate for lefamulin API production. Under this agreement, SEL is required to manufacture and supply and we are required to purchase from SEL a specified percentage of our commercial requirements of pleuromutilin. The agreement expires on August 28, 2022, subject to automatic renewal for successive three-year periods. Either party may elect not to renew the agreement by providing two-year prior written notice before the end of the initial term or the then-current renewal term. Either party may terminate the agreement for the other party's uncured material breach or upon the occurrence of specified bankruptcy events.

The agreement includes customary supply terms, including product specifications, price, payment terms, requirements forecasting, delivery mechanics and quality assurance. Under the agreement, we have also negotiated a quality technical agreement pursuant to which SEL will conduct all quality control and release testing for the pleuromutilin produced under the agreement.

In November 2018 we entered into a long-term commercial supply agreement with Arran Chemical Company Limited, or Arran, for the supply of the chiral acid starting material required in the synthesis of lefamulin API. Under this agreement Arran is required to manufacture and supply, and we are required to purchase from Arran the amount forecast for the first six months of a twelve-month rolling forecast provided monthly by us. The agreement term expires on November 12, 2023 and continues thereafter unless terminated by either party with not less than twelve months written notice. Either party may terminate the agreement for the other party's uncured material breach or upon the occurrence of insolvency or bankruptcy events. The agreement includes customary supply terms including material specifications, price, payment terms, demand forecasting, delivery mechanics, and quality assurance.

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We have entered into a long-term commercial supply agreement with Hovione Limited, or Hovione, for the supply of lefamulin API. Under this agreement, Hovione is required to manufacture and supply and we are required to purchase from Hovione a specified percentage of our commercial requirements of lefamulin API. The agreement expires on November 22, 2025, subject to automatic renewal for successive two-year periods. Either party may elect not to renew the agreement by providing two-year prior written notice before the end of the initial term or the then-current renewal term. Either party may terminate the agreement for the other party's uncured material breach or upon the occurrence of specified bankruptcy events.

The agreement includes customary supply terms, including product specifications, price, payment terms, requirements forecasting, delivery mechanics and quality assurance. We are required to purchase a minimum of 750 kg to 1,500 kg per year of lefamulin API dependent on potential regulatory approval timing. Under the agreement, we have also negotiated a quality technical agreement pursuant to which Hovione will conduct all quality control and release testing for the pleuromutilin produced under the agreement.

We have also entered into a long-term commercial supply agreement with Patheon UK Limited, or Patheon, for the supply of IV vials of lefamulin. Under this agreement, Patheon is required to supply and we are required to purchase a specified percentage of our commercial requirements of IV vials of lefamulin. The agreement expires on December 31, 2023, subject to automatic renewal for successive two-year periods. Either party may elect not to renew the agreement by providing two-year prior written notice before the end of the initial term, and after the initial term, either party may terminate the agreement with 24-months prior written notice at any time. Either party may also terminate the agreement for the other party's uncured material breach or upon the occurrence of specified bankruptcy events. We may also terminate the agreement if a governmental authority takes action that prevents us from importing, exporting, purchasing or selling the IV vials of lefamulin. Finally, Patheon may terminate the agreement if we assign any of our rights under the agreement to an assignee that it does not consider to be a creditworthy substitute or is a competitor of Patheon.

The agreement includes customary supply terms, including product specifications, batch size requirements, price, payment terms, requirements forecasting, delivery mechanics and quality assurance. Under the agreement, we have also negotiated a quality agreement pursuant to which Patheon will conduct all quality control testing for the IV vials of lefamulin.

In addition, we have entered into a long-term commercial supply agreement with Almac Pharma Services Limited, or Almac, for the commercial supply of lefamulin tablets. Under this agreement, Almac is required to supply and we are required to purchase services relating to the manufactured tablets equaling a specified minimum annual spend. The initial term of the agreement expires on August 7, 2022, but it will remain in force until it is terminated by either party with 24-months prior written notice, expiring on or at any time after the expiry of the initial term. Either party may also terminate the agreement for the other party's uncured material breach or upon the occurrence of specified bankruptcy events. The agreement includes customary supply terms, including payment terms, requirements forecasting, delivery mechanics and quality assurance. Under the agreement, we have also negotiated a quality technical agreement pursuant to which Almac will conduct all quality control testing for the tablets.

In August 2018, we entered into a commercial packaging and supply agreement, or the Packaging Agreement with Sharp Corporation, or Sharp, for the commercial packaging of lefamulin acetate for oral and intravenous administration. Under the Packaging Agreement, Sharp has agreed to provide certain packaging services to us, including labeling, serialization and final packaging of the packaged products.

The Packaging Agreement has an initial five-year term ending December 31, 2023 and will automatically renew after the initial term for additional one-year terms unless either party gives notice

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of its intention to terminate the Packaging Agreement at least 90 days prior to the end of the then-current term. In addition, either party may terminate the Packaging Agreement for the other party's uncured material breach, in addition to other specified events, including with respect to bankruptcy proceedings and governmental actions, in each case subject to notice, cure periods and other conditions set forth in the Packaging Agreement.

The Packaging Agreement includes customary supply terms, including product specifications, batch size requirements, price, payment terms, requirements forecasting, delivery mechanics and quality assurance. Under the agreement, we have also negotiated a quality agreement pursuant to which Sharp will conduct quality control testing for the packaged products.

These six commercial supply agreements relating to lefamulin are filed as exhibits to this Form 10-K. Other than these six agreements, we do not have long-term agreements with any other third parties for the manufacture of commercial supplies of lefamulin, but we intend to enter into additional agreements with third-party contract manufacturers for additional commercial supplies of lefamulin pending potential regulatory approval.

Lefamulin is a semi-synthetic organic compound of low molecular weight. The pleuromutilin core of the molecule is produced by fermentation and is manufactured on a significant scale by various manufacturers. The second part of the molecule is established from a readily accessible chiral starting material. We have selected the lefamulin based on its efficacy and safety profile, although it is also associated with reasonable cost of goods, ready availability of starting materials and ease of synthesis. The development stage production of lefamulin was carried out at a significant scale and we believe, if required, the synthetic route to lefamulin is amenable to further scale-up. The synthetic route does not require unusual, or specialized, equipment in the manufacturing process. Therefore, if any of our current or future drug substance manufacturers were to become unavailable for any reason, we believe there are a number of potential replacements, although delays may be incurred in identifying and qualifying such replacements.

### **CONTEPO**

Effective July 28, 2016, Zavante, Laboratorios ERN, S.A. ("ERN") and Ercros, S.A. ("Ercros") entered into an amended and restated three-way agreement (the "Three-Way Agreement"), which established the basis for related supply agreements with ERN and Ercros in anticipation of FDA approval of fosfomycin disodium and succinic acid injection for intravenous use filled, finished and packaged into containers for use by end users ("Product") in the United States. Pursuant to the Three-Way Agreement, Zavante has the direct responsibility for the manufacture and supply of the commercial Product in the United States.

Under the Three-Way Agreement, (i) ERN has agreed to provide Zavante with certain technical documentation (Technical Documentation") and data required for submission of an NDA or Abbreviated New Drug Application ("ANDA"), as applicable, for the Product, and other assistance in connection with the submission of an NDA or ANDA, pursuant to the ERN Supply Agreement (as defined below); (ii) Ercros has agreed to provide Zavante with certain Technical Documentation and the manufacture and supply of a blend of fosfomycin disodium and succinic acid (the "API Mixture") for the manufacture of the Product, pursuant to the terms of the Ercros Supply Agreement (as defined below); and (iii) Zavante has agreed to obtain the commercial supply of the Product, under one or more separate agreements with third party manufacturers. The rights and obligations of each of the parties are set forth in each of the ERN Supply Agreement and the Ercros Supply Agreement.

In addition, pursuant to the Three-Way Agreement, Zavante is required to (i) contract with one or more third party manufacturers to provide quantities of the Product required by Zavante for commercial sale in the United States, perform validation activities as required by the FDA, and obtain FDA approval of such third party manufacturer's facilities and quality systems; (ii) use commercially



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reasonable efforts to file an NDA within one year of its receipt of all Technical Documentation for the NDA from ERN and Ercros; (iii) obtain and own all trademarks to be used for the Product in the United States and (iv) bear the cost and manage all clinical trials necessary for obtaining FDA approval of the Product and keep ERN and Ercros updated regarding the progress of such clinical trials.

The Three-Way-Agreement will continue in force and effect until the Ercros Supply Agreement and the ERN Supply Agreement have both been terminated or expired in accordance with the respective terms therein, or if the Three-Way Agreement is terminated upon mutual written agreement of all of the parties. The Three-Way Agreement contains, among other provisions, customary provisions relating to legal compliance and publicity.

Effective July 28, 2016, Zavante and Ercros entered into a manufacturing and supply agreement (the "Ercros Supply Agreement") pursuant to the Three-Way Agreement. Under the Ercros Supply Agreement, Ercros has agreed, pursuant to purchase orders entered into under the Ercros Supply Agreement, to manufacture (i) the exclusive supply of the API Mixture for Zavante in support of filing an NDA or an ANDA, as applicable, and (ii) the commercial supply of fosfomycin disodium and succinic acid injection for intravenous use in the United States. In addition, Ercros has agreed to provide access to certain technical documentation as may be requested by Zavante in connection with the filing of an NDA.

The Ercros Supply Agreement has an initial ten-year term ending July 28, 2026 and will automatically renew after the initial term for additional two-year terms unless either party gives notice of its intention to terminate the Ercros Supply Agreement at least 18 months prior to the end of the then-current term. Either party may terminate the Ercros Supply Agreement for the other party's uncured material breach, in addition to other specified events, including with respect to bankruptcy proceedings, governmental actions and legal proceedings, in each case subject to notice, cure periods and other conditions set forth in the Ercros Supply Agreement.

The Ercros Supply Agreement contains customary supply terms, including requirements forecasting, purchase orders, product specifications, price, payment terms, delivery mechanics and quality insurance. In addition, the Ercros Supply Agreement contains, among other provisions, customary representations and warranties by the parties, a grant by Ercros to Zavante of certain limited license rights to Ercros' intellectual property in connection with Zavante's performance under the Ercros Supply Agreement, certain indemnification rights in favor of both parties and customary confidentiality provisions.

Under the Ercros Supply Agreement, Zavante and Ercros have also entered into a quality agreement, pursuant to which Ercros will conduct all quality control and release testing for the API Mixture produced under the Ercros Supply Agreement.

Effective July 28, 2016, Zavante and ERN entered into an amended and restated pharmaceutical manufacturing and exclusive supply agreement, as amended on December 1, 2016, March 1, 2017, May 1, 2017 and December 20, 2017, pursuant to the Three-Way Agreement (the ERN Supply Agreement). Under the ERN Supply Agreement, each party is required to use commercially reasonable efforts to complete certain development activities required for submission of an NDA or an ANDA for fosfomycin sodium and succinic acid (the bulk formulation of CONTEPO). In addition, ERN has agreed to provide to Zavante (i) certain technical documentation and data as required by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's guidelines and the FDA for submission of an NDA or an ANDA for the bulk formulation of CONTEPO, and (ii) certain regulatory support in connection with the bulk formulation of CONTEPO sold or intended for commercial sale and human use.

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Upon the first commercial sale of the bulk formulation of CONTEPO, Zavante is obligated to make a one-time cash payment to ERN and subsequent quarterly payments thereafter based on the number of vials of the bulk formulation of CONTEPO sold during each calendar quarter.

The ERN Supply Agreement has an initial ten-year term ending July 28, 2026 and will automatically renew after the initial term for additional two-year terms unless either party gives notice of its intention to terminate the ERN Supply Agreement at least 18 months prior to the end of the then-current term. Either party may terminate the ERN Supply Agreement by mutual written agreement and for the other party's uncured material breach, in addition to other specified events, including with respect to bankruptcy proceedings and governmental actions, in each case subject to notice, cure periods and other conditions set forth in the ERN Supply Agreement.

The ERN Supply Agreement contains, among other provisions, customary representations and warranties by the parties, a grant to each party by the other party of certain limited license rights to such other party's intellectual property in connection with the parties' performance of the services under the ERN Supply Agreement, certain indemnification rights in favor of both parties and customary confidentiality provisions.

On April 25, 2017, Zavante and Fisiopharma, S.r.l. ("Fisiopharma") entered into a manufacturing and supply agreement, as amended on May 8, 2017 (the "Fisiopharma Supply Agreement"). Under the Fisiopharma Supply Agreement, Fisiopharma has agreed, pursuant to purchase orders entered into under the Fisiopharma Supply Agreement, to manufacture and supply fosfomycin disodium for intravenous injection in bulk drug vials (the "Bulk Drug Vials") to Zavante in support of filing an NDA or an ANDA, as applicable, and a specified percentage of Zavante's commercial requirements of Bulk Drug Vials for the United States.

The Fisiopharma Supply Agreement has an initial ten-year term ending April 25, 2027 and will automatically renew after the initial term for additional one-year terms unless Zavante gives notice of its intention to terminate the Fisiopharma Supply Agreement at least six months prior to the end of the then-current term. Either party may terminate the Fisiopharma Supply Agreement for the other party's uncured material breach or upon the occurrence of specified bankruptcy events, and Zavante may terminate the Fisiopharma Supply Agreement upon the occurrence of other specified events, including with respect to governmental actions and legal proceedings instituted against Fisiopharma, in each case subject to notice, cure periods and other conditions set forth in the Fisiopharma Supply Agreement.

The Fisiopharma Supply Agreement contains customary supply terms, including requirements forecasting, purchase orders, product specifications, price, payment terms, delivery mechanics and quality insurance. In addition, it contains, among other provisions, customary representations and warranties by the parties, a grant to Fisiopharma of certain limited license rights of Zavante's intellectual property in connection with Fisiopharma's performance of services under the Fisiopharma Supply Agreement, certain indemnification rights in favor of both parties, limitations of liability and customary confidentiality provisions.

Under the Fisiopharma Supply Agreement, Zavante and Fisiopharma have also entered into a quality control agreement, pursuant to which Fisiopharma will conduct all quality control and release testing for the bulk drug vials produced under the Fisiopharma Supply Agreement. Any default under the quality control agreement constitutes a default under the Ercros Supply Agreement.

On December 26, 2017, Zavante entered into a commercial packaging agreement (the "PCI Packaging Agreement") with AndersonBrecon Inc., doing business as PCI of Illinois ("PCI") for the commercial packaging of fosfomycin disodium for intravenous injection in bulk drug vials (the "Packaged Product"). Under the PCI Packaging Agreement, PCI has agreed to provide certain packaging services to Zavante, including labeling, serialization and final packaging of the PCI Packaged Product.

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The PCI Packaging Agreement has an initial three-year term ending December 26, 2020 and will automatically renew after the initial term for additional one-year terms unless either party gives notice of its intention to terminate the PCI Packaging Agreement at least 120 days prior to the end of the then-current term. In addition, either party may terminate the PCI Packaging Agreement for the other party's uncured material breach, in addition to other specified events, including with respect to bankruptcy proceedings and governmental actions, in each case subject to notice, cure periods and other conditions set forth in the PCI Packaging Agreement.

The PCI Packaging Agreement contains customary supply terms, including product specifications, price, payment terms, delivery mechanics and quality insurance. In addition, it contains, among other provisions, customary representations and warranties by the parties, a grant to PCI of certain limited license rights of Zavante's intellectual property in connection with PCI's performance of services under the PCI Packaging Agreement certain indemnification rights in favor of both parties, limitations of liability and customary confidentiality provisions.

Under the PCI Packaging Agreement, Zavante and PCI have also entered into a contract services quality agreement, which governs the responsibilities of each party regarding the quality aspects of packaging and release of PCI Packaged Product.

These five commercial supply agreements relating to CONTEPO are filed as exhibits to this Form 10-K. Other than these five agreements, we do not have long-term agreements with any other third parties for the manufacture of commercial supplies of CONTEPO, but we intend to enter into additional agreements with third-party contract manufacturers for additional commercial supplies of CONTEPO pending potential regulatory approval.

### **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 technologies, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, government agencies and private and public research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our 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. Our competitors also may obtain marketing approvals for their products more rapidly than we obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected because in some cases insurers or other third-party payors seek to encourage the use of generic products. This may have the effect of making branded products less attractive, from a cost perspective, to buyers. We expect that if lefamulin is

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approved for CABP, it will be priced at a significant premium over competitive generic products. This may make it difficult for us to replace existing therapies with lefamulin.

The key competitive factors affecting the success of our product candidates are likely to be their efficacy, safety, convenience, price and the availability of coverage and reimbursement from government and other third-party payors.

There are a variety of available therapies marketed for the treatment of CABP. Currently, the treatment of CABP is dominated by generic products. For hospitalized patients, combination therapy is frequently used. Many currently approved drugs are well-established therapies and are widely accepted by physicians, patients and third-party payors. We also are aware of various drugs under development for the treatment of CABP, including omadacycline which was launched in February 2019 by Paratek Pharmaceuticals Inc., delafloxacin which was approved by the FDA in June 2017 for ABSSSI, and is marketed by Melinta Therapeutics Inc. which also have an ongoing Phase 3 clinical trial of delafloxacin for CABP and oral nafithromycin which is in Phase 2 clinical development by Wockhardt Ltd.

If approved, we expect CONTEPO will face competition from commercially available antibiotics such as ceftazidime-avibactam, meropenem-vaborbactam, tigecycline, plazomicin, from other product candidates currently in development for the treatment of cUTI, including AP, such as imipenem-relebactam (under Phase 3 clinical development by Merck), cefiderocol (under Phase 3 clinical development by Shionogi), ETX0282-cefpodoxime proxetil (under development by Entasis Therapeutics), and LYS228 (under development by Boston Pharma), as well as generically available agents including carbapenems, aminoglycosides, and polymyxins.

### **Intellectual Property**

Our success depends in large part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. We strive to protect the proprietary technology that we believe is important to our business by, among other methods, seeking and maintaining patents, where available, that are intended to cover our product candidates, compositions and formulations, their methods of use and processes for their manufacture and any other inventions that are commercially important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary and competitive position.

As of January 31, 2019, we owned 22 different families of patents and patent applications, including 21 families directed to the various pleuromutilin derivatives as compositions of matter, processes for their manufacture, and their use in pharmaceutical compositions and methods of treating disease. The remaining family is directed to  $\beta$ -lactamase inhibitors. Our patent portfolio includes 23 issued U.S. patents, 23 granted European patents and 18 granted Japanese patents, as well as patents in other jurisdictions. We also have pending patent applications in the United States, Europe, Japan and other countries and regions, including Asia, Australia, Eastern Europe, and South America, including notably Canada, Brazil, China, Israel, India and Taiwan among others.

All of these patents and patent applications are assigned solely to us and were either originally filed by us or originally filed by Sandoz and subsequently assigned to us.

As of January 31, 2019, our lead product candidate, lefamulin, was protected by the following seven patent families:

- The first patent family includes patents and applications with claims directed to generic classes of compounds that include lefamulin and/or their use in the treatment of microbial infections. This family includes issued patents in the United States, Europe and Japan, as well as issued patents in 11 other jurisdictions. The standard term for patents in this family expires in 2021.

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- The second patent family includes patents and applications with claims that specifically recite lefamulin and/or its use in the treatment of microbial infections. This family includes two issued patents in each of the United States, Europe and Japan, as well as issued patents in 21 other jurisdictions and 5 pending patent applications in other jurisdictions, including one divisional application in the United States. The standard term for patents in this family expires in 2028. A patent term adjustment of 303 days has already been obtained in the United States for one patent.
- The third patent family includes patents and applications with claims directed to the processes for the manufacture of lefamulin, crystalline intermediates useful in the processes, and the resulting crystalline salts. This family includes 16 granted patents including issued patents in the United States, Europe and Japan and 13 pending patent applications one each in Europe and Japan and 13 in other jurisdictions. The standard term for patents in this family expires in 2031.
- The fourth patent family includes patents and applications with claims directed to processes for the synthetic manufacture of crystalline intermediates useful in the manufacture of lefamulin. This family includes granted patents in Europe, the United States and Japan and granted patents in other jurisdictions and further pending applications. The standard term for patents in this family expires in 2031.
- The fifth patent family includes patents and applications with claims directed to pharmaceuticals and treatments for *Helicobacter* infection, including pleuromutilins, such as lefamulin. This family includes issued patents in the United States, Europe and one other jurisdiction. The standard term for patents in this family expires in 2023. A patent term adjustment of 921 days has already been obtained for the U.S. patent.
- A further patent family is directed to pharmaceutical compositions of lefamulin and covers 17 pending patent applications in various jurisdictions.
- The seventh patent family covers methods for purification of pleuromutilins and the PCT-application was recently published.

Our second most advanced product candidate, BC-7013, is covered specifically in one patent family with patents granted in the United States, Europe and Japan, as well as nine other jurisdictions, and pending patent applications in other jurisdictions. The standard term for patents in this family expires in 2027.

The remaining 13 pleuromutilin patent families are directed to either molecules in the intellectual property landscape surrounding our product candidates in development or molecules which can be potentially further developed by us but have not yet been pursued. All patent applications in these families have been filed at least in the United States and Europe, and most have been filed in other countries. The majority of these patent applications have already resulted in granted patents.

Finally, we own one patent family directed to  $\beta$ -lactamase inhibitor compounds. Patent applications in this family have been filed and granted in the United States and Europe. The standard term for patents in this family expires in 2030.

Zavante holds one issued United States patent (U.S. 9,345,717) directed to methods for identifying dosing regimens that decrease the potential for on-therapy drug resistance. Additionally, Zavante has filed a patent application based on results from the ZEUS Study that relates to methods for treating patients with resistant bacterial infections and, specifically, Gram-negative bacterial infections. However, this patent may not ensure exclusivity through the patent term and we may not be able to secure any additional patent protection. We plan to rely on regulatory protection afforded to CONTEPO through orphan drug designations, data exclusivity, and market exclusivity where available.

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The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the filing date of a non-provisional patent application. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or the USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a U.S. patent that covers a drug, biological product or medical device approved pursuant to a pre-market approval, or PMA, may also be eligible for patent term extension when FDA approval is granted, provided that certain statutory and regulatory requirements are met. The length of the patent term extension is related to the length of time the drug is under regulatory review while the patent is in force. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date set for the patent. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be granted an extension and only those claims reading on the approved drug may be extended. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug, provided that statutory and regulatory requirements are met. Thus, in the future, if and when our product candidates receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those products, depending upon the length of the clinical trials for each drug and other factors. The expiration dates of our patents and patent applications referred to above are without regard to potential patent term extension or other market exclusivity that may be available to us.

In addition to patents, we may rely, in some circumstances, on trade secrets to protect our technology and maintain our competitive position. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, corporate and scientific collaborators, consultants, scientific advisors, contractors and other third parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

### **Government Regulation**

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, pricing, reimbursement, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

### ***Review and Approval of Drugs in the United States***

In the United States, the FDA reviews, approves and regulates drugs under the federal Food, Drug, and Cosmetic Act, or FDCA, and associated implementing regulations. The failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-approval may result in delays to the conduct of study, regulatory review and subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, adverse publicity, injunctions, fines, refusals of government

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contracts, restitution, disgorgement of profits, and civil or criminal investigations and penalties brought by the FDA and the U.S. Department of Justice, or DOJ, or other governmental entities, including state agencies.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following before a product candidate will be approved by the FDA:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of a new drug application, or NDA, summarizing available data to support the proposed approval of the new drug product for the proposed use;
- review of the product application by an FDA advisory committee, where appropriate or if applicable and as may be requested by the FDA;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of PDUFA fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, where applicable, and the potential to conduct post-approval studies required by the FDA.

### *Preclinical Studies*

Before an applicant begins testing a compound with potential therapeutic value in humans, the drug candidate enters the preclinical testing stage. Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, are submitted to the FDA as part of an IND. Additional long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

Companies usually must complete some long-term preclinical testing, such as animal tests of long term exposure and reproductive adverse events, and must also develop additional information about the chemistry and physical characteristics of the investigational product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The

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manufacturing process must be capable of consistently producing quality batches of the candidate product and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the candidate product does not undergo unacceptable deterioration over its shelf life.

### *The IND and IRB Processes*

An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved NDA. In support of a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold or partial clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that trial. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with FDA certain regulatory requirements in order to use the study as support for an IND or application for marketing approval. Specifically, on April 28, 2008, the FDA amended its regulations governing the acceptance of foreign clinical studies not conducted under an investigational new drug application as support for an IND or a new drug application. The final rule provides that such studies must be conducted in accordance with good clinical practice, or GCP, including review and approval by an independent ethics committee, or IEC, and informed consent from subjects. The GCP requirements in the final rule encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The



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IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee, or DSMB. This group provides authorization as to whether or not a trial may move forward at designated check points based on unblinded safety data from the study to which only the DSMB has access. Suspension or termination of development during any phase of clinical trials may occur if it is determined that the participants or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by us based on evolving business objectives and/or competitive climate.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on its ClinicalTrials.gov website.

### *Human Clinical Studies in Support of an NDA*

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in the following four sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.
- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.
- Phase 4: Post-approval studies, which are conducted following initial approval, are typically conducted to gain additional experience and data from treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or

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the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, purity, and potency of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product 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. With enactment of the Food and Drug Safety and Innovation Act, or the FDASIA, in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time. For drugs intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of an applicant, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

### *Expanded Access to an Investigational Drug for Treatment Use*

Expanded access, sometimes called "compassionate use," is the use of investigational new drug products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. The rules and regulations related to expanded access are intended to improve access to investigational drugs for patients who may benefit from investigational therapies. FDA regulations allow access to investigational drugs under an IND by the company or the treating physician for treatment purposes on a case-by-case basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the drug under a treatment protocol or Treatment IND Application.

When considering an IND application for expanded access to an investigational product with the purpose of treating a patient or a group of patients, the sponsor and treating physicians or investigators will determine suitability when all of the following criteria apply: patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative

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therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational drug for the requested treatment will not interfere initiation, conduct, or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

On December 13, 2016, the 21st Century Cures Act established (and the 2017 Food and Drug Administration Reauthorization Act later amended) a requirement that sponsors of one or more investigational drugs for the treatment of a serious disease(s) or condition(s) make publicly available their policy for evaluating and responding to requests for expanded access for individual patients. Although these requirements were rolled out over time, they have now come into full effect. This provision requires drug and biologic companies to make publicly available their policies for expanded access for individual patient access to products intended for serious diseases. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 study; or 15 days after the drug or biologic receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

In addition, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

### *Special Protocol Assessment Agreements*

A Special Protocol Assessment, or SPA, agreement is an agreement between a drug manufacturer and the FDA on the design and size of studies and clinical trials that can be used for approval of a drug or biological product. The FDA's guidance on such agreements states that an agreement may not be changed by the manufacturer or the agency unless through a written agreement of the two entities or if FDA determines a substantial scientific issue essential to determining the safety or effectiveness of the drug. The protocols that are eligible for SPA agreements are: animal carcinogenicity protocols, final product stability protocols and clinical protocols for Phase 3 trials whose data will form the primary basis for an efficacy claim.

Specifically, under the FDCA, the FDA may meet with sponsors, provided certain conditions are met, for the purpose of reaching a SPA agreement on the design and size of clinical trials intended to form the primary basis of an efficacy claim in a marketing application. If a sponsor makes a reasonable written request to meet with the FDA for the purpose of reaching agreement on the design and size of a clinical trial, then the FDA will meet with the sponsor. If an agreement is reached, the FDA will reduce the agreement to writing and make it part of the administrative record. An agreement may not be changed by the sponsor or FDA after the trial begins, except with the written agreement of the sponsor and FDA, or if the director of the FDA reviewing division determines that "a substantial scientific issue essential to determining the safety or effectiveness of the drug" was identified after the testing began. If a sponsor and the FDA meet regarding the design and size of a clinical trial and the parties cannot agree that the trial design is adequate to meet the goals of the sponsor, the FDA will clearly state the reasons for the disagreement in a letter to the sponsor. We reached agreement with the FDA in September 2015 on a SPA regarding the study design of our first Phase 3 clinical trial of lefamulin for the treatment of CABP.

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### *Submission of an NDA to the FDA*

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is subject to an application user fee, which for federal fiscal year 2019 is \$2,588,478 for an application requiring clinical data. The sponsor of an approved NDA is also subject to an annual program fee, which for fiscal year 2019 is \$309,154. Exceptions or waivers for these fees exist for a small company (fewer than 500 employees, including employees and affiliates) satisfying certain requirements and products with orphan drug designation for a particular indication are not subject to a fee provided there are no other intended uses in the NDA.

Following submission of an NDA, the FDA conducts a preliminary review of an NDA generally within 60 calendar days of its receipt and strives to inform the sponsor by the 74th day after the FDA's receipt of the submission whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to certain performance goals in the review process of NDAs. Standard review, representing most such applications are meant to be reviewed within ten months from the date of filing. Priority review applications are meant to be reviewed within six months of filing. The review process and the Prescription Drug User Fee Act goal date may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission. Under the FDA Reauthorization Act of 2017, the FDA must implement a protocol to expedite review of responses to inspection reports pertaining to certain applications, including applications for products in shortage or those for which approval is dependent on remediation of conditions identified in the inspection report.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA submission, including drug component manufacturing (such as active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

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The FDA may refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions relating to approval of a new drug product.

### *Fast Track, Breakthrough Therapy, Priority Review and Regenerative Advanced Therapy Designations*

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as fast track designation, breakthrough therapy designation, priority review designation and regenerative advanced therapy designation.

Specifically, the FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the application is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, a product may be designated as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to Breakthrough Therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

With passage of the 21st Century Cures Act, or the Cures Act, in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product has the potential to address unmet medical

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needs for such disease or condition. The benefits of a regenerative advanced therapy designation include early interactions with FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

### *Accelerated Approval Pathway*

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit. The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

### *Limited Population Antibacterial Drug Pathway*

With passage of the CURES Act, Congress authorized FDA to approve an antibacterial or antifungal drug, alone or in combination with one or more other drugs, as a "limited population drug." To qualify for this approval pathway, the drug must be intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs; the standards for approval of drugs and biologics under the FDCA and PHSA must be satisfied; and FDA must receive a written request from the sponsor to approve the drug as a limited population drug pursuant to this provision. The FDA's determination of safety and effectiveness for such a product must reflect the benefit-risk profile of such

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drug in the intended limited population, taking into account the severity, rarity, or prevalence of the infection the drug is intended to treat and the availability or lack of alternative treatment in such a limited population.

Any drug or biologic approved under this pathway must be labeled with the statement "Limited Population" in a prominent manner and adjacent to the proprietary name of the drug or biological product. The prescribing information must also state that the drug is indicated for use in a limited and specific population of patients and copies of all promotional materials relating to the drug must be submitted to FDA at least 30 days prior to dissemination of the materials. If FDA subsequently approves the drug for a broader indication, the agency may remove any post-marketing conditions, including requirements with respect to labeling and review of promotional materials applicable to the product. Nothing in this pathway to approval of a limited population drug prevents sponsors of such products from seeking designation or approval under other provisions of the FDCA, such as accelerated approval.

### *The FDA's Decision on an NDA*

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require additional, sometimes substantial, testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a new product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

### *Post-Approval Regulation*

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 sampling and 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. 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 or without 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

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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, or 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, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, or 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 the marketing, labeling, advertising and promotion of prescription drug products placed on the market. This regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved. After approval, a drug product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information. In the United States, health care professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, FDA regulations impose rigorous restrictions on manufacturers' communications and prohibit the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in non-promotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.



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In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, and its implementing regulations, as well as the Drug Supply Chain Security Act, or DSCA, which regulate the distribution and tracing of prescription drug samples at the federal level, and set minimum standards for the regulation of drug distributors by the states. The PDMA, its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples and the DSCA imposes requirements to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market.

*Section 505(b)(2) NDAs*

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product for the proposed use. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the applicant for approval of the application "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Thus, Section 505(b)(2) authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the Section 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

*Abbreviated New Drug Applications for Generic Drugs*

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD.

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug."

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often

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results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. For the purposes of this provision, a new chemical entity, or NCE, is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

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The FDA must establish a priority review track for certain generic drugs, requiring the FDA to review a drug application within eight (8) months for a drug that has three (3) or fewer approved drugs listed in the Orange Book and is no longer protected by any patent or regulatory exclusivities, or is on the FDA's drug shortage list. The new legislation also authorizes FDA to expedite review of "competitor generic therapies" or drugs with inadequate generic competition, including holding meetings with or providing advice to the drug sponsor prior to submission of the application.

*Hatch-Waxman Patent Certification and the 30-Month Stay*

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;

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- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the ANDA applicant is not seeking approval).

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. As a result, approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

### *Pediatric Studies and Exclusivity*

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

### *GAIN Exclusivity for Antibiotics*

In 2012, Congress passed legislation known as the Generating Antibiotic Incentives Now Act, or GAIN Act. This legislation is designed to encourage the development of antibacterial and antifungal drug products that treat pathogens that cause serious and life-threatening infections. To that end, the law grants an additional five years of exclusivity upon the approval of an NDA for a drug product designated by FDA as a QIDP. Thus, for a QIDP, the periods of five-year new chemical entity exclusivity, three-year new clinical investigation exclusivity, and seven-year orphan drug exclusivity, would become ten years, eight years, and twelve years, respectively.

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A QIDP is defined in the GAIN Act to mean "an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by (1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens" or (2) certain "qualifying pathogens." A "qualifying pathogen" is a pathogen that has the potential to pose a serious threat to public health (such as resistant Gram-positive pathogens, multi-drug resistant Gram-negative bacteria, multi-drug resistant tuberculosis, and *C. difficile*) and that is included in a list established and maintained by FDA. A drug sponsor may request the FDA to designate its product as a QIDP any time before the submission of an NDA. The FDA must make a QIDP determination within 60 days of the designation request. A product designated as a QIDP will be granted priority review by the FDA and can qualify for "fast track" status.

The additional five years of exclusivity under the GAIN Act for drug products designated by the FDA as QIDPs applies only to a drug that is first approved on or after July 9, 2012. Additionally, the five year exclusivity extension does not apply to: a supplement to an application under FDCA Section 505(b) for any QIDP for which an extension is in effect or has expired; a subsequent application filed with respect to a product approved by the FDA for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength; or a product that does not meet the definition of a QIDP under Section 505(g) based upon its approved uses. The FDA has designated IV fosfomycin, and each of the IV and oral formulations of lefamulin as a QIDP and also granted fast track designations.

### *Patent Term Restoration and Extension*

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of a clinical investigation involving human beings is begun and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The United States Patent and Trademark Offices reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

### *Regulation Outside the United States*

In order to market any product outside of the United States, a company must also 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 drug products. Whether or not we obtain FDA approval for lefamulin, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately 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.

***Regulation and Marketing Authorization in the European Union***

The process governing approval of medicinal products in the European Union follows essentially the same lines as in the United States and, likewise, generally involves satisfactorily completing each of the following:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable E.U. Good Laboratory Practice regulations;
- submission to the relevant national authorities of a clinical trial application, or CTA, which must be approved before human clinical trials may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the relevant competent authorities of a marketing authorization application, or MAA, which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced cGMP;
- potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and
- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

*Preclinical Studies*

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animal studies, in order to assess the potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of the compounds for testing must comply with the relevant E.U. regulations and requirements. The results of the preclinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA.

*Clinical Trial Approval*

Requirements for the conduct of clinical trials in the European Union including Good Clinical Practice, or GCP, are set forth in the Clinical Trials Directive 2001/20/EC and the GCP Directive 2005/28/EC. Pursuant to Directive 2001/20/EC and Directive 2005/28/EC, as amended, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the E.U. member states. Under this system, approval must be obtained from the competent national authority of each E.U. member state in which a study is planned to be conducted. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier, or IMPD, and further supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

In April 2014, the E.U. passed the new Clinical Trials Regulation, (EU) No 536/2014, which will replace the current Clinical Trials Directive 2001/20/EC. The Regulation was published on June 16, 2014 but is not expected to apply until later in 2019. To ensure that the rules for clinical trials are identical throughout the European Union, the new E.U. clinical trials legislation was passed as a

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regulation that is directly applicable in all E.U. member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation (EU) No 536/2014 becomes applicable. The Clinical Trials Directive 2001/20/EC will, however, still apply three years from the date of entry into application of the Clinical Trials Regulation to (i) clinical trials applications submitted before the entry into application and (ii) clinical trials applications submitted within one year after the entry into application if the sponsor opts for the old system.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trial in the European Union. The main characteristics of the regulation include:

- a streamlined application procedure via a single entry point, the E.U. portal;
- a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures that will spare sponsors from submitting broadly identical information separately to various bodies and different member states;
- a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed jointly by all member states concerned. Part II is assessed separately by each member state concerned;
- strictly defined deadlines for the assessment of clinical trial applications; and
- the involvement of the ethics committees in the assessment procedure in accordance with the national law of the member state concerned but within the overall timelines defined by the Clinical Trials Regulation.

### *Marketing Authorization*

Authorization to market a product in the member states of the European Union proceeds under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure or a national procedure.

#### *Centralized Authorization Procedure*

The centralized procedure enables applicants to obtain a marketing authorization that is valid in all E.U. member states based on a single application. Certain medicinal products, including products developed by means of biotechnological processes must undergo the centralized authorization procedure for marketing authorization, which, if granted by the European Commission, is automatically valid in all 28 E.U. member states. The EMA and the European Commission administer this centralized authorization procedure pursuant to Regulation (EC) No 726/2004.

Pursuant to Regulation (EC) No 726/2004, this procedure is mandatory for:

- medicinal products developed by means of one of the following biotechnological processes:
  - recombinant DNA technology;
  - controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells; and
  - hybridoma and monoclonal antibody methods;
- advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No 1394/2007 on advanced therapy medicinal products;

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- medicinal products for human use containing a new active substance that, on the date of effectiveness of this regulation, was not authorized in the European Union, and for which the therapeutic indication is the treatment of any of the following diseases:
  - acquired immune deficiency syndrome;
  - cancer;
  - neurodegenerative disorder;
  - diabetes;
  - auto-immune diseases and other immune dysfunctions; and
  - viral diseases; and
  
- medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

The centralized authorization procedure is optional for other medicinal products if they contain a new active substance or if the applicant shows that the medicinal product concerned constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization is in the interest of patients in the European Union.

### *Administrative Procedure*

Under the centralized authorization procedure, the EMA's Committee for Medicinal Products for Human Use, or CHMP serves as the scientific committee that renders opinions about the safety, efficacy and quality of medicinal products for human use on behalf of the EMA. The CHMP is composed of experts nominated by each member state's national authority for medicinal products, with one of them appointed to act as Rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the Committee acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle. The CHMP has 210 days, to adopt an opinion as to whether a marketing authorization should be granted. The process usually takes longer in case additional information is requested, which triggers clock-stops in the procedural timelines. The process is complex and involves extensive consultation with the regulatory authorities of member states and a number of experts. When an application is submitted for a marketing authorization in respect of a drug that is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may pursuant to Article 14(9) Regulation (EC) No 726/2004 request an accelerated assessment procedure. If the CHMP accepts such request, the time-limit of 210 days will be reduced to 150 days but it is possible that the CHMP can revert to the standard time-limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. Once the procedure is completed, a European Public Assessment Report, or EPAR, is produced. If the opinion is negative, information is given as to the grounds on which this conclusion was reached. After the adoption of the CHMP opinion, a decision on the MAA must be adopted by the European Commission, after consulting the E.U. member states, which in total can take more than 60 days.

### *Conditional Approval*

In specific circumstances, E.U. legislation (Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products), if (1) the risk-benefit balance of the product candidate is positive, (2) it is likely that the applicant will be

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in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

### *Marketing Authorization Under Exceptional Circumstances*

Under Regulation (EC) No 726/2004, products for which the applicant can demonstrate that comprehensive data (in line with the requirements laid down in Annex I of Directive 2001/83/EC, as amended) cannot be provided (due to specific reasons foreseen in the legislation) might be eligible for marketing authorization under exceptional circumstances. This type of authorization is reviewed annually to reassess the risk-benefit balance. The fulfillment of any specific procedures/obligations imposed as part of the marketing authorization under exceptional circumstances is aimed at the provision of information on the safe and effective use of the product and will normally not lead to the completion of a full dossier/approval.

### *Market Authorizations Granted by Authorities of E.U. Member States*

In general, if the centralized procedure is not followed, there are three alternative procedures to obtain a marketing authorization in (one or several) E.U. member states as prescribed in Directive 2001/83/EC:

- The decentralized procedure allows applicants to file identical applications to several E.U. member states and receive simultaneous national approvals based on the recognition by E.U. member states of an assessment by a reference member state.
- The national procedure is only available for products intended to be authorized in a single E.U. member state.
- A mutual recognition procedure similar to the decentralized procedure is available when a marketing authorization has already been obtained in at least one E.U. member state.

A marketing authorization may be granted only to an applicant established in the European Union.

### *Pediatric Studies*

Prior to obtaining a marketing authorization in the E.U., applicants have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant



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waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

### *Period of Authorization and Renewals*

A marketing authorization, other than a conditional marketing authorization, is initially valid for five years and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the E.U. market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

### *Regulatory Data Protection*

European Union legislation also provides for a system of regulatory data and market exclusivity. According to Article 14(11) of Regulation (EC) No 726/2004, as amended, and Article 10(1) of Directive 2001/83/EC, as amended, upon receiving marketing authorization, new chemical entities approved on the basis of complete independent data package benefit from eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application. During the additional two-year period of market exclusivity, a generic marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic medicinal product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder, or MAH, obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the innovator is able to gain the period of data exclusivity, another company nevertheless could also market another version of the drug if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical test, preclinical tests and clinical trials.

### *Transparency*

There is an increasing trend in the E.U. towards greater transparency and, while the manufacturing or quality information in marketing authorization dossiers is currently generally protected as confidential information, the EMA and national regulatory authorities are now liable to disclose much of the non-clinical and clinical information, including the full clinical study reports, in response to freedom of information requests after the marketing authorization has been granted. In October 2014, the EMA adopted a policy under which clinical study reports would be posted on the agency's website following the grant, denial or withdrawal of a marketing authorization application, subject to procedures for limited redactions and protection against unfair commercial use. Additional

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transparency provisions are contained in the new Clinical Trials Regulation (EU) No 536/2014 that will take effect in May 2016 at the earliest.

### *Regulatory Requirements After a Marketing Authorization has been Obtained*

If we obtain authorization for a medicinal product in the European Union, we will be required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products:

#### *Pharmacovigilance and Other Requirements*

We will, for example, have to comply with the E.U.'s stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. E.U. regulators may conduct inspections to verify our compliance with applicable requirements, and we will have to continue to expend time, money and effort to remain compliant. Non-compliance with E.U. requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties in the European Union. Similarly, failure to comply with the European Union's requirements regarding the protection of individual personal data can also lead to significant penalties and sanctions. Individual E.U. member states may also impose various sanctions and penalties in case we do not comply with locally applicable requirements.

#### *Manufacturing*

The manufacturing of authorized drugs, for which a separate manufacturer's license is mandatory, must be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. The EMA enforces its GMP requirements through mandatory registration of facilities and inspections of those facilities. The EMA may have a coordinating role for these inspections while the responsibility for carrying them out rests with the member states competent authority under whose responsibility the manufacturer falls. Failure to comply with these requirements could interrupt supply and result in delays, unanticipated costs and lost revenues, and could subject the applicant to potential legal or regulatory action, including but not limited to warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil and criminal penalties.

#### *Marketing and Promotion*

The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union under Directive 2001/83EC, as amended. The applicable regulations aim to ensure that information provided by holders of marketing authorizations regarding their products is truthful, balanced and accurately reflects the safety and efficacy claims authorized by the EMA or by the competent authority of the authorizing member state. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

#### *Patent Term Extension*

To compensate the patentee for delays in obtaining a marketing authorization for a patented product, a supplementary certificate, or SPC, may be granted extending the exclusivity period for that specific product by up to five years. Applications for SPCs must be made to the relevant patent office in each E.U. member state and the granted certificates are valid only in the member state of grant. An

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application has to be made by the patent owner within six months of the first marketing authorization being granted in the European Union (assuming the patent in question has not expired, lapsed or been revoked) or within six months of the grant of the patent (if the marketing authorization is granted first). In the context of SPCs, the term "product" means the active ingredient or combination of active ingredients for a medicinal product and the term "patent" means a patent protecting such a product or a new manufacturing process or application for it. The duration of an SPC is calculated as the difference between the patent's filing date and the date of the first marketing authorization, minus five years, subject to a maximum term of five years.

A six-month pediatric extension of an SPC may be obtained where the patentee has carried out an agreed pediatric investigation plan, the authorized product information includes information on the results of the studies and the product is authorized in all member states of the European Union.

### *Brexit and the Regulatory Framework in the United Kingdom*

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the E.U. (commonly referred to as "Brexit"). Thereafter, on March 29, 2017, the country formally notified the E.U. of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the U.K. from the European Union will take effect either on the effective date of the withdrawal agreement or, in the absence of agreement, two years after the U.K. provides a notice of withdrawal pursuant to the E.U. Treaty. Since the regulatory framework for pharmaceutical products in the U.K. covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from E.U. directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the U.K. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the U.K.

The United Kingdom has a period of a maximum of two years from the date of its formal notification to negotiate the terms of its withdrawal from, and future relationship with, the E.U. If no formal withdrawal agreement is reached between the United Kingdom and the E.U., then it is expected the United Kingdom's membership of the E.U. will automatically terminate two years after the submission of the notification of the United Kingdom's intention to withdraw from the E.U. Discussions between the United Kingdom and the E.U. focused on finalizing withdrawal issues and transition agreements are ongoing. However, limited progress to date in these negotiations and ongoing uncertainty within the UK Government and Parliament sustains the possibility of the United Kingdom leaving the E.U. on March 29, 2019 without a withdrawal agreement and associated transition period in place, which is likely to cause significant market and economic disruption.

### *General Data Protection Regulation*

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the E.U., including personal health data, is subject to the E.U. General Data Protection Regulation, or the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the E.U., including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for

damages resulting from violations of the GDPR. Compliance with the GDPR will be a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance.

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

In the United States and markets in other countries, 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. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

To secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product candidate could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the United States, ensuring adequate coverage and payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require a clinical trial that compares the cost effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been

agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies or so called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. E.U. European Union member states may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states, and parallel trade, *i.e.*, arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

### ***Healthcare Law and Regulation***

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with providers, consultants, third party payors and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, reporting of payments to physicians and teaching physicians and patient privacy laws and regulations and other healthcare laws and regulations that may constrain business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act and civil monetary penalty laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

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- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the Foreign Corrupt Practices Act, or FCPA, which prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the United States Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

### ***Healthcare Reform***

A primary trend in the United States healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States.

In March 2010, the United States Congress enacted the Affordable Care Act, or the ACA, which, among other things, includes changes to the coverage and payment for products under government health care programs. Among the provisions of the Affordable Care Act of importance to potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

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- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;
- 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;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- the Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs. However, the IPAB implementation has been not been clearly defined. PPACA provided that under certain circumstances, IPAB recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings; and
- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation from 2011 to 2019.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and will stay in effect through 2024 unless additional Congressional action is taken, and the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers 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 healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain

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ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole".

The Trump Administration has also taken executive actions to undermine or delay implementation of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than \$12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

Further, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. For example, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on May 11, 2018, the Administration issued a plan to lower drug prices. Under this blueprint for action, the Administration indicated that the Department of Health and Human Services (HHS) will: take steps to end the gaming of regulatory and patent processes by drug makers to unfairly protect monopolies; advance biosimilars and generics to boost price competition; evaluate the inclusion of prices in drug makers' ads to enhance price competition; speed access to and lower the cost of new drugs by clarifying policies for sharing information between insurers and drug makers; avoid excessive pricing by relying more on value-based pricing by expanding outcome-based payments in Medicare and Medicaid; work to give Part D plan sponsors more negotiation power with drug makers; examine which Medicare Part B drugs could be negotiated for a lower price by Part D plans, and improving the design of the Part B Competitive Acquisition Program; update Medicare's drug-pricing dashboard to increase transparency; prohibit Part D contracts that include "gag rules" that prevent pharmacists from informing patients when they could pay less out-of-pocket by not using insurance; and require that Part D plan members be provided with an annual statement of plan payments, out-of-pocket spending, and drug price increases.



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At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

### **Employees**

As of January 31, 2019, we had 110 employees, 1 employee was based in Dublin, Ireland, 39 of our employees are located in Vienna, Austria and 70 of our employees located in the U.S., with 47 located in King of Prussia, Pennsylvania and the remaining 23 employees in the field.

Our employees in Austria are subject to the collective bargaining agreement of the chemical industry. This is an annual agreement between the employer representatives and the trade union of an industry. It defines conditions of employment, such as minimum wages, working hours and conditions, overtime payments, vacations and other matters.

We consider our relations with our employees to be good.

### **Our Corporate Information**

On March 1, 2017, Nabriva Ireland was incorporated in Ireland under the name Hyacintho 2 plc, and was renamed to Nabriva Therapeutics plc on April 10, 2017, in order to effectuate the change of the jurisdiction of incorporation of the ultimate parent company of the Nabriva Group from Austria to Ireland. Nabriva Ireland replaced Nabriva Austria as the ultimate parent company on June 23, 2017, following the conclusion of a tender offer in which holders of the outstanding share capital of Nabriva Austria exchanged their holdings for ordinary shares, \$0.01 nominal value per share, of Nabriva Ireland. The ordinary shares of Nabriva Ireland were issued on a one-for-ten basis to the holders of the Nabriva Austria common shares and on a one-for-one basis to the holders of the Nabriva Austria American Depositary Shares, or Nabriva Austria ADSs. On June 26, 2017, the ordinary shares of Nabriva Ireland began trading on the Nasdaq Global Market under the symbol "NBRV," the same symbol under which the Nabriva Austria ADSs were previously traded. This transaction was accounted for as a merger between entities under common control; accordingly, the historical financial statements of Nabriva Austria for periods prior to this transaction are considered to be the historical financial statements of Nabriva Ireland. Our executive offices are located at 25-28 North Wall Quay IFSC, Dublin 1, Ireland, and our telephone number is +353 1 649 2000.

The predecessor of Nabriva Ireland, Nabriva Austria, was incorporated in Austria as a spin-off from Sandoz GmbH in October 2005 under the name Nabriva Therapeutics Forschungs GmbH, a limited liability company organized under Austrian law and commenced operations in February 2006. In 2007, Nabriva Austria transformed into a stock corporation (*Aktiengesellschaft*) under the name Nabriva Therapeutics AG. On October 19, 2017, Nabriva Austria was converted into a private limited liability company under Austrian law and renamed Nabriva Therapeutics GmbH.

Our U.S. operations are conducted by our wholly-owned subsidiary Nabriva Therapeutics US, Inc., a Delaware corporation established in August 2014 and located at 1000 Continental Drive, Suite 600, King of Prussia, PA 19406.

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Our website address is [www.nabriva.com](http://www.nabriva.com). The information contained on, or that can be accessed from, our website does not form part of this Annual Report. Our agent for service of process in the United States is CT Corporation System, 111 Eighth Avenue, New York, New York 10011.

**Available Information**

We make available free of charge through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the SEC. Previously, as a foreign private issuer, we filed our Annual Report on Form 20-F and furnished information on Form 6-K. You can review our electronically filed reports and other information that we file with the SEC on the SEC's web site at <http://www.sec.gov>. We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% shareholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. The information contained on, or that can be accessed through, our website is not a part of or incorporated by reference in this Annual Report on Form 10-K.

**ITEM 1A. RISK FACTORS**

*You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. The risks described below are not the only risks facing us. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and/or prospects.*

**Risks Related to Our Financial Position and Need for Additional Capital**

*We have incurred significant losses since our inception. We expect to incur losses for at least the next several years and may never generate profits from operations or maintain profitability.*

Since inception, we have incurred significant operating losses. Our net losses were \$114.8 million for the year ended December 31, 2018, \$74.4 million for the year ended December 31, 2017 and \$54.9 million for the year ended December 31, 2016. As of December 31, 2018, we had an accumulated deficit of \$394.0 million. To date, we have financed our operations primarily through the sale of our equity securities, loans, including convertible loans, and research and development support from governmental grants and loans. We have devoted most of our efforts to research and development, including clinical trials. We have not completed development of any drugs. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years, including in connection with our regulatory approval efforts and commercialization of lefamulin and CONTEPO. The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year.

We expect to continue to invest in critical pre-commercialization activities prior to potentially receiving marketing approval and making lefamulin and CONTEPO available to patients.

We initiated our first Phase 3 global, pivotal clinical trial of lefamulin, which we refer to as Lefamulin Evaluation Against Pneumonia 1, or LEAP 1, in September 2015, and we initiated our second Phase 3 global, pivotal clinical trial of lefamulin, which we refer to as Lefamulin Evaluation Against Pneumonia 2, or LEAP 2, in April 2016. In September 2017, we announced positive topline results for LEAP 1. In May 2018, we announced positive topline results from LEAP 2. LEAP 2 evaluated the safety and efficacy of five days of oral lefamulin compared to 7 days of oral moxifloxacin in adult patients with moderate community-acquired bacterial pneumonia, or CABP. We submitted two

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NDA for marketing approval of lefamulin for the treatment of CABP in adults in the United States in December 2018. We also expect to submit a marketing authorization application, or MAA, for lefamulin for the treatment of CABP in adults in Europe in the first half of 2019. We also continue to characterize the clinical pharmacology of lefamulin. If we obtain marketing approval of lefamulin for CABP or another indication, we also expect to incur significant additional sales, marketing, distribution and manufacturing expenses.

In June 2016, the first patient was enrolled by Zavante in its pivotal ZTI-01 Efficacy and Safety Study of CONTEPO, which we refer to as the ZEUS Study. In April 2017, Zavante announced positive topline results of the ZEUS Study. The ZEUS Study was a multicenter, randomized, parallel-group, double-blind Phase 2/3, pivotal clinical trial designed to evaluate safety, tolerability, efficacy and pharmacokinetics of seven days of treatment, or up to 14 days of treatment for patients with concurrent bacteremia, with CONTEPO compared to piperacillin-tazobactam, or PIP-TAZ, in the treatment of hospitalized adults with cUTI or acute pyelonephritis, or AP. We submitted an NDA for marketing approval of CONTEPO for the treatment of cUTI in adults in the United States, utilizing the FDA's 505(b)(2) pathway, in October 2018. In June 2018, Zavante initiated a Phase 1, non-comparative, open-label study of the pharmacokinetics and safety of a single dose of CONTEPO in pediatric subjects less than 12 years of age receiving standard-of-care antibiotic therapy for proven or suspected infection or peri-operative prophylaxis. We anticipate completing enrollment in this study in late 2020. We also intend to continue to characterize the clinical pharmacology of CONTEPO. If we obtain marketing approval of CONTEPO for cUTI, including AP, or another indication, we also expect to incur significant additional sales, marketing, distribution and manufacturing expenses.

On July 24, 2018, we completed our Acquisition of Zavante. Upfront consideration in connection with the Acquisition was 8,152,092 of our ordinary shares, including the 815,186 ordinary shares that are issuable upon release of the Holdback Shares subject to the terms of the Merger Agreement. Pursuant to the Merger Agreement, former Zavante stockholders are also entitled to receive from us up to \$97.5 million in contingent consideration, consisting of the Approval Milestone Payment and the Net Sales Milestone Payment, subject to the terms and conditions of the Merger Agreement. In connection with the Acquisition, we assumed certain payment obligations under the Stock Purchase Agreement and Zavante manufacturing agreements acquired in the Acquisition. See "*Risks Related to Our Acquisition of Zavante—We may fail to realize the anticipated benefits of our Acquisition of Zavante, those benefits may take longer to realize than expected, and we may encounter significant integration difficulties.*"

In addition, our expenses will increase if and as we:

- initiate or continue the research and development of lefamulin and CONTEPO for additional indications and of our other product candidates;
- seek to develop additional product candidates;
- seek marketing approval for any product candidates that successfully complete clinical development;
- are required by the FDA, EMA or other regulators to conduct additional clinical trials prior to or after approval;
- continue to build a medical affairs, sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize any product candidates for which we receive marketing approval;
- in-license or acquire other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;

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- expand our physical presence in the United States and Ireland;
- incur additional debt;
- establish and expand manufacturing arrangements with third parties; and
- add operational, financial and management information systems and personnel, including personnel to support our product development, our operations as a larger company following the Acquisition and our operations as a public company in addition to our planned future commercialization efforts.

Our ability to generate profits from operations, and to become and remain profitable, depends on our ability to successfully develop and commercialize drugs that generate significant revenue. Based on our current plans, we do not expect to generate significant revenue unless and until we obtain marketing approval for, and commercialize, lefamulin and CONTEPO. We do not expect to obtain marketing approval for CONTEPO before April 2019 or for lefamulin before August 2019, if at all. This will require us to be successful in a range of challenging activities, including:

- obtaining marketing approval for lefamulin and CONTEPO;
- expanding medical affairs, sales, marketing and distribution capabilities to effectively market and sell lefamulin and CONTEPO in the United States;
- establishing and maintaining collaboration, distribution or other marketing arrangements with third parties to commercialize lefamulin in markets outside the United States;
- protecting our rights to our intellectual property portfolio related to lefamulin and CONTEPO;
- establishing and maintaining arrangements for the manufacture of and obtaining commercial quantities of lefamulin and CONTEPO; and
- negotiating and securing adequate reimbursement from third-party payors for lefamulin and CONTEPO.

We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to generate profits from operations. Even if we do generate profits from operations, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to generate profits from operations, and to become and remain profitable, would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or continue our operations. A decline in the value of our company could also cause our shareholders to lose all or part of their investment.

***We will need substantial additional funding. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or future commercialization efforts.***

We expect to continue to incur substantial costs in connection with our ongoing activities, particularly as we seek marketing approval for lefamulin, CONTEPO and, possibly, other product candidates and continue our research activities. Our expenses will increase if we suffer any regulatory delays or are required to conduct additional clinical trials to satisfy regulatory requirements. If we obtain marketing approval for lefamulin, CONTEPO or any other product candidate that we develop, in-license or acquire, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing.

Furthermore, we expect to continue to incur additional costs to service our current debt and any potential future draws on the Loan Agreement (as defined below) and costs associated with operating as a public company and as a company with a commercial rather than a research and development

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focus. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We expect that our cash, cash equivalents and short-term investments as of December 31, 2018, proceeds from the sale of ordinary shares under the our ATM Agreement (as defined below) of \$5.9 million in the first quarter of 2019, as well as a \$1.5 million milestone payment received in February 2019 under our license agreement with Sinovant Sciences, Ltd., and research premiums from the Austrian government for our qualified research and development expenditures, will be sufficient to enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into the second quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate assumes, among other things, that we do not obtain any additional funding through grants and clinical trial support, collaboration agreements, equity or debt financings, including additional advances under the Loan Agreement with Hercules. We may be eligible to borrow up an additional \$50.0 million under our Loan Agreement with Hercules if we achieve specified regulatory and product revenue milestones, including \$10.0 million that we will be eligible to borrow upon the approval by the FDA of an NDA for lefamulin and \$5.0 million that we will be eligible to borrow upon the approval by the FDA of an NDA for CONTEPO.

We expect to seek additional funding in future periods for purposes of investment in our commercial and medical affairs organization, as well as investing in our supply chain in an effort to enhance the potential commercial launch of lefamulin and CONTEPO.

Our future capital requirements will depend on many factors, including:

- the costs and timing of process development and manufacturing scale-up activities associated with lefamulin and CONTEPO;
- the costs, timing and outcome of regulatory review of lefamulin and CONTEPO;
- the costs of commercialization activities for lefamulin and CONTEPO if we receive, or expect to receive, marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities, including the costs of building finished product inventory and its components in preparation of initial marketing of lefamulin and CONTEPO;
- subject to receipt of marketing approval, revenue received from commercial sales of lefamulin and CONTEPO;
- the costs of developing lefamulin and CONTEPO for the treatment of additional indications;
- our ability to establish collaborations on favorable terms, if at all;
- the scope, progress, results and costs of product development of any other product candidates that we may develop;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property-related claims;
- the continued availability of Austrian governmental grants;
- the rate of the expansion of our physical presence in the United States and Ireland;

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- interest expense on our debt and the eventual repayment of our debt obligations;
- the costs of operating as a company with a commercial rather than a research and development focus; and
- the costs of operating as a public company in the United States.

Our commercial revenues, if any, will be derived from sales of lefamulin, CONTEPO or any other products that we successfully develop, in-license or acquire, none of which we expect to be commercially available before April 2019, if at all. In addition, if approved, lefamulin, CONTEPO or any other product candidate that we develop, in-license or acquire may not achieve commercial success. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives.

Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

***Raising additional capital may cause dilution to our security holders, restrict our operations or require us to relinquish certain rights to our technologies or product candidates.***

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, and funding from local and international government entities and non-government organizations in the disease areas addressed by our product candidates and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a security holder. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt service obligations under any debt financings may limit the availability of our cash for other purposes, and we may be unable to make interest payments or repay the principal of such debt financings when due.

On March 16, 2018, we entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement with Cantor Fitzgerald & Co., or Cantor Fitzgerald, as agent, pursuant to which we may offer and sell ordinary shares, nominal value \$0.01 per share, for aggregate gross sale proceeds of up to \$50,000,000 from time to time through Cantor Fitzgerald under an "at-the-market" offering program. As of December 31, 2018, \$25.8 million remained available for sale under our ATM Agreement. As of March 1, 2019, \$20.2 million remained available for sale under the ATM Agreement. If a large number of our ordinary shares is sold in the public market after they become eligible for sale or if we make additional sales under our "at-the-market" offering program, the sales could cause dilution to our security holders, reduce the trading price of our ordinary shares and impede our ability to raise future capital.

In addition, in connection with the closing of the Acquisition, we issued 7,336,906 of our ordinary shares to former Zavante stockholders as initial upfront consideration. An additional 815,186 of ordinary shares will be issued to former Zavante Stockholders upon release of the Holdback Shares, subject to reduction in respect of certain indemnification and other obligations pursuant to the Merger Agreement. The shares that were issued in connection with the closing of the Acquisition are able to be freely sold in the public market, subject to any requirements and restrictions, including any applicable volume limitations, imposed by Rule 144 under the Securities Act. While the Holdback Shares will be restricted as a result of securities laws at the time of issuance, following expiration of applicable holding periods, the Holdback Shares will also be able to be freely sold in the public market, subject to any requirements and restrictions, including any applicable volume limitations, imposed by Rule 144 under the Securities Act. In addition, the Merger Agreement provides that we may issue up

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to an additional \$97.5 million in our ordinary shares to former Zavante stockholders upon the achievement of specified regulatory and commercial milestones in the future and obligates us to provide registration rights with respect to the registration for resale of such additional ordinary shares that may become issuable upon the achievement of such milestones. The issuance of our ordinary shares to satisfy the milestone payments will cause dilution to our equity holders, and the sale or resale of these shares in the public market, or the market's expectation of such sales, may result in an immediate and substantial decline in our stock price. Such a decline would adversely affect our investors and also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

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 technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings 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.

***Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

Our operations to date have been limited to organizing and staffing our company, developing and securing our technology, raising capital, undertaking preclinical studies and clinical trials of our product candidates, and preparing and filing NDAs for our product candidates. We have not yet demonstrated our ability to obtain marketing approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. Also, we may encounter delays or difficulties in our efforts to, or fail to, successfully integrate the operations of Zavante into our business and CONTEPO into our business strategy. Moreover, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

***Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations.***

On December 20, 2018, we entered into a Loan and Security Agreement, or the Loan Agreement, with Hercules Capital, Inc., as administrative agent, collateral agent and lender, pursuant to which an aggregate principal amount of up to \$75.0 million is available to us. As of December 31, 2018, we have drawn down on the initial term loan advance under the Loan Agreement of \$25.0 million.

All obligations under the Loan Agreement are secured by substantially all of our personal property, intellectual property and other assets owned or later acquired. This indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including:

- the need to repay our indebtedness by making payment of interest only initially and then interest and principal, which will reduce the amount of funds available to finance our operations, our research and development efforts and our general corporate activities; and

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- our failure to comply with the restrictive covenants in the Loan Agreement or the occurrence of an event that has a material adverse effect on our business, operations, properties, assets, condition, our ability to pay any amounts due, the collateral securing our obligations under the Loan Agreement or the ability of Hercules to enforce any of its rights under the Loan Agreement could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and the lenders could seek to enforce its security interest in the assets securing such indebtedness.

To the extent additional debt is added to our current debt levels, the risks described above could increase.

***We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.***

Failure to satisfy our current and future debt obligations under the Loan Agreement could result in an event of default and, as a result, the lenders under the Loan Agreement could accelerate all of the amounts due. In the event of an acceleration of amounts due under the Loan Agreement as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness. In addition, the lenders could seek to enforce their security interests in the assets securing such indebtedness.

***We are subject to certain restrictive covenants which, if breached, could have a material adverse effect on our business and prospects.***

The Loan Agreement imposes operating and other restrictions on us. Such restrictions will affect, and in many respects limit or prohibit, our ability and the ability of any future subsidiary to, among other things:

- declare dividends or redeem or repurchase equity interests;
- incur additional indebtedness and liens;
- make loans and investments;
- engage in mergers, acquisitions and asset sales;
- certain transactions with affiliates
- undergo a change in control;
- add or change business locations; and
- settle in cash potential milestone payment obligations that may become payable by us in the future to former security holders of Zavante.

We are also required to satisfy certain financial covenants, including an obligation to maintain specified minimum amounts of cash and cash equivalents in accounts pledged to Hercules. These restrictive covenants may prevent us from undertaking an action that we feel is in the best interests of our business. In addition, if we were to breach any of these restrictive covenants, Hercules could accelerate our indebtedness under the Loan Agreement or enforce its security interest against our assets, either of which would materially adversely affect our ability to continue to operate our business.



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*We have relied on, and expect to continue to rely on, certain government grants and funding from the Austrian government. Should these funds cease to be available, or our eligibility be reduced, or if we are required to repay any of these funds, this could impact our ongoing need for funding and the timeframes within which we currently expect additional funding will be required.*

As a company that carried out extensive research and development activities, we have benefited from the Austrian research and development support regime, under which we were eligible to receive a research premium from the Austrian government equal to 14% (12% for the fiscal years 2016 and 2017 and 10%, in the case of fiscal years prior to 2016) of a specified research and development cost base. Qualifying expenditures largely comprised research and development activities conducted in Austria, however, the research premium was also available for certain related third-party expenses with additional limitations. We received research premiums of \$4.7 million for the year ended December 31, 2017 and \$5.9 million for the year ended December 31, 2016. We have not received any research premium for our qualified 2018 expenditures as of December 31, 2018. As we increase our personnel and expand our business outside of Austria, we may not be able to continue to claim research premiums to the same extent as we have in previous years or at all, as some research and development activities may no longer be considered to occur in Austria. As research premiums that have been paid out already may be audited by the tax authorities, there is a risk that parts of the submitted cost base may not be considered as eligible and therefore repayments may have to be made.

*The intended efficiency of our corporate structure depends on the application of the tax laws and regulations in the countries where we operate, and we may have exposure to additional tax liabilities or our effective tax rate could change, which could have a material impact on our results of operations and financial position.*

As a company with international operations, we are subject to income taxes, as well as non-income based taxes, in both the United States and various foreign jurisdictions. We have designed our corporate structure, the manner in which we develop and use our intellectual property, and our intercompany transactions between our subsidiaries in a way that is intended to enhance our operational and financial efficiency. The application of the tax laws and regulations of various countries in which we operate and to our global operations is subject to interpretation. We also must operate our business in a manner consistent with our corporate structure to realize such efficiencies. The tax authorities of the countries in which we operate may challenge our methodologies for valuing developed technology or for transfer pricing. If, for one or more of these reasons, tax authorities determine that the manner in which we operate results in our business not achieving the intended tax consequences, our effective tax rate could increase and harm our financial position and results of operations.

A change in the tax law in the jurisdictions in which we do business, including an increase in tax rates, an adverse change in the treatment of an item of income or expense, a decrease in tax rates in a jurisdiction in which we have significant deferred tax assets, or a new or different interpretation of applicable tax law, could result in a material increase in tax expense.

### **Risks Related to Product Development and Commercialization**

*We depend heavily on the success of, lefamulin, which we are developing for CABP and potentially other indications, and CONTEPO, which we are developing for cUTI, including AP. If we are unable to obtain marketing approvals for lefamulin or CONTEPO, or if thereafter we fail to commercialize lefamulin or CONTEPO or experience significant delays in doing so, our business will be materially harmed.*

We have invested a significant portion of our efforts and financial resources in the development of lefamulin and, more recently, in CONTEPO. There remains a significant risk that we will fail to

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successfully develop lefamulin for CABP or any other indication or CONTEPO for cUTI or any other indication.

In September 2017, we announced positive topline results for LEAP 1. In May 2018, we announced positive topline results from LEAP 2. We submitted two new drug applications, or NDAs, for marketing approval of lefamulin for the treatment of CABP in adults in the United States in December 2018. We also expect to submit a marketing authorization application, or MAA, for lefamulin for the treatment of CABP in adults in Europe in the first half of 2019. In mid-2018, we initiated a Phase 1, non-comparative, open-label study of the pharmacokinetics and safety of a single dose of IV lefamulin in pediatric subjects 12 to 18 years of age.

In June 2016, Zavante initiated the ZEUS Study. In April 2017, Zavante announced positive topline results of the ZEUS Study. We submitted an NDA for marketing approval of CONTEPO for the treatment of cUTI in adults in the United States, utilizing the FDA's 505(b)(2) pathway, in October 2018. In June 2018, Zavante initiated a phase 1, non-comparative, open-label study of the pharmacokinetics and safety of a single dose of CONTEPO in pediatric subjects less than 12 years of age receiving standard-of-care antibiotic therapy for proven or suspected infection or peri-operative prophylaxis. We anticipate completing enrollment in this study in late 2020. We also intend to continue to characterize the clinical pharmacology of CONTEPO.

If we obtain marketing approval of lefamulin for CABP, or any other indication, and CONTEPO for cUTI, including AP, or any other indication, we also expect to incur significant additional sales, marketing, distribution and manufacturing expenses.

Our ability to generate product revenues will depend heavily on our obtaining marketing approval for and commercializing lefamulin and CONTEPO when and as we expect, and our ability to successfully integrate Zavante into our business and CONTEPO into our business strategy. The success of lefamulin and CONTEPO will depend on a number of factors, including the following:

- establishing and maintaining arrangements with third-party manufacturers for commercial supply and receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities;
- receipt of marketing approvals from applicable regulatory authorities for lefamulin for the treatment of CABP and CONTEPO for the treatment of cUTI, including AP;
- launching commercial sales of lefamulin and CONTEPO, if and when approved, in collaboration with third parties;
- acceptance of lefamulin and CONTEPO, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- maintaining a continued acceptable safety profile of lefamulin and CONTEPO following approval;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and
- protecting our rights in our intellectual property portfolio.

Successful development of lefamulin and CONTEPO for the treatment of additional indications, if any, or for use in other patient populations and our ability, if it is approved, to broaden the labels for lefamulin and CONTEPO will depend on similar factors.

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 commercialize lefamulin for CABP or for

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any other indication or CONTEPO for cUTI, including AP or for any other indication, which would materially harm our business.

***If clinical trials of lefamulin, CONTEPO or any of our other product candidates fail to demonstrate safety and efficacy to the satisfaction of the U.S. Food and Drug Administration, or FDA, regulatory authorities in the European Union, or other regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of lefamulin, CONTEPO or any other product candidate.***

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and early clinical trials, including Phase 1 clinical trials, in addition to extensive later-stage Phase 3 clinical trials, to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. In connection with the ZEUS Study in which CONTEPO met the primary endpoint of statistical non-inferiority versus piperacillin/tazobactam, Zavante conducted a post-hoc primary efficacy analysis of CONTEPO using results of blinded pulsed-field gel electrophoresis molecular typing of urinary tract pathogens. Regulatory authorities typically give greater weight to results from pre-specified analyses and less weight to results from post-hoc, retrospective analyses. While we believe this post-hoc analysis is illustrative information, the FDA may ultimately have a different interpretation of any of our data that may be based on such post-hoc analysis.

If we are required to conduct additional clinical trials or other testing or studies of lefamulin, CONTEPO or any other product candidate that we develop beyond those that we contemplate; if we are unable to successfully complete our clinical trials or other testing or studies; if the results of these trials, tests or studies are not positive or are only modestly positive; if there are safety concerns; or if they are otherwise not acceptable to the FDA, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements or restrictions;
- have the product removed from the market after obtaining marketing approval; or
- need to raise capital before we otherwise would or on terms less favorable to us.

The occurrence of any of the developments listed above could materially harm our business, financial condition, results of operations and prospects.

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***If we experience any of a number of possible unforeseen events in connection with our clinical trials, the potential marketing approval or commercialization of lefamulin, CONTEPO or other product candidates could be delayed or prevented.***

We may experience numerous unforeseen events during, or as a result of, our clinical trials of lefamulin and CONTEPO or other product candidates that could delay or prevent our ability to receive marketing approval or commercialize lefamulin, CONTEPO or our other product candidates, including:

- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators, institutional review boards or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- we may experience delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health or safety risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, institutional review boards or independent ethics committees to suspend or terminate the trials.

Our product development costs will increase if we experience delays in enrollment in our clinical development program or our non-clinical development program or in obtaining marketing approvals. We do not know whether any additional non-clinical tests or clinical trials will be required, or if they will begin as planned, or if they will need to be restructured or will be completed on schedule, or at all. Significant non-clinical development program delays, including chemistry, manufacturing and control activities, or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

***If we experience delays or difficulties in the enrollment of patients in our clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials for our product candidates, including with respect to lefamulin, CONTEPO or any other product candidate that we develop, if we are unable to locate and enroll a sufficient number of eligible patients to participate in these clinical trials. Some of our competitors have ongoing clinical trials for product candidates that could be competitive with

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lefamulin and CONTEPO, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors including:

- severity of the disease under investigation;
- eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the product candidate under study;
- approval of other therapies to treat the disease under investigation;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the time of year in which the trial is initiated or conducted;
- the geographic distribution of global trial sites, given the timing of pneumonia season globally, and the seasonal variation in the number of patients suffering from pneumonia, including a decline in the number of patients with CABP during the summer months;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- delays in the receipt of required regulatory approvals, or the failure to receive required regulatory approvals, in the jurisdictions in which clinical trials are expected to be conducted; and
- delays in the receipt of approvals, or the failure to receive approvals, from the relevant institutional review board or ethics committee at clinical trial sites.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of the company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients in any of our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

***If serious adverse or undesirable side effects are identified during the development of lefamulin, CONTEPO or any other product candidate that we develop, we may need to abandon or limit our development of that product candidate.***

It is impossible to predict when or if the FDA, EMA or other regulators will view any of our product candidates as effective and safe in humans or if we will receive marketing approval for any of our product candidates. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause side effects or other safety issues that prevented further development of the compound.

In LEAP 1, lefamulin was generally well tolerated and exhibited a similar rate of treatment-emergent adverse events to the comparator drug. However, 104 patients in the lefamulin arm of the trial reported at least one treatment-emergent adverse event and eight patients withdrew from the trial following an adverse event. Furthermore, at least 2.0% of patients in LEAP 1 who were dosed with lefamulin reported the following adverse events: hypokalemia, nausea, insomnia, infusion site pain and infusion site phlebitis. Fewer than 2.0% of trial patients dosed with lefamulin also experienced

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hypertension and an increase in alanine aminotransaminase, although no patients met Hy's Law criteria, which is an indicator for severe liver damage.

In LEAP 2, lefamulin was again generally well tolerated. However, 120 patients in the lefamulin arm of the trial reported at least one treatment-emergent adverse event and eleven patients withdrew from the trial following an adverse event. Furthermore, at least 2.0% of patients in LEAP 2 who were dosed with lefamulin reported the following adverse events: diarrhea, nausea and vomiting. Fewer than 2.0% of trial patients dosed with lefamulin also experienced hypertension and an increase in alanine aminotransaminase, although no patients met Hy's Law criteria. In addition, one patient who had a positive clinical response to lefamulin in LEAP 2 was later diagnosed with a *C. difficile* infection during an extended hospital stay.

In addition, lefamulin was well tolerated in our Phase 2 clinical trial for acute bacterial skin and skin structure infection, or ABSSSI. No patient in the trial suffered any serious adverse events that were found to be related to lefamulin, and no patient in the trial died. Some patients experienced adverse events that were assessed by the investigator as possibly or probably related to study medication. The majority of their symptoms were mild in severity. Four patients discontinued study medication following a drug-related event, three of whom were in a lefamulin treatment group: one patient experienced events of hyperhidrosis, vomiting and headache; one patient experienced infusion site pain; and one patient experienced dyspnea.

Because the potential for mild effect on electrocardiogram, or ECG, measurements was observed in preclinical studies of lefamulin, we have continued to assess this potential in all human clinical trials of lefamulin we have conducted. In the Phase 2 clinical trial, no change in ECG measurements was considered to be of clinical significance, and no drug-related cardiovascular adverse event was reported. Both lefamulin and vancomycin treatment were associated with a small increase in the QT interval. The QT interval is a measure of the heart's electrical cycle, and a prolonged QT interval is a risk factor for a potential ventricular arrhythmia. In each of LEAP 1 and LEAP 2, while changes in QT that were of potential clinical concern were uncommon, two patients treated with lefamulin had an increase in absolute QT interval to greater than 500 msec, regardless of baseline value, which may indicate a higher risk for ventricular arrhythmias.

There were no systemic adverse events of clinical concern and no drug-related serious adverse events observed in any of our completed Phase 1 clinical trials of lefamulin. In these trials, the most commonly observed adverse effects with oral administration of lefamulin were related to the gastrointestinal tract, including nausea and abdominal discomfort, while the most commonly observed adverse effects related to IV administration were related to irritation at the infusion site. In addition, lefamulin produced a transient, predictable and reproducible prolongation of the QT interval based on the maximum concentration of the drug in the blood plasma. We did not observe any drug-related cardiac adverse events, such as increase in ectopic ventricular activity or other cardiac arrhythmia, or clinically relevant ECG findings during the conduct of any of our completed Phase 1 clinical trials.

In the ZEUS Study, the incidence of premature discontinuation from study drug was low and similar between treatment groups (6.0% in the CONTEPO treatment group compared to 3.9% in the PIP-TAZ treatment group), and the incidence of not completing the study through the last follow-up visit, which occurred on the 24th through 28th day after completion of seven days of treatment with the study drug, or after up to 14 days of treatment for patients with concurrent bacteremia, was 5.2% in the CONTEPO group compared to 0.9% in the PIP-TAZ group. A total of 42.1% CONTEPO patients and 32.0% PIP-TAZ patients experienced at least one treatment-emergent adverse event. Most treatment-emergent adverse events were mild or moderate in severity, and severe treatment-emergent adverse events were uncommon (2.1% of CONTEPO patients and 1.7% of PIP-TAZ patients). The most common treatment-emergent adverse events in both treatment groups were transient, asymptomatic laboratory abnormalities and gastrointestinal events. Treatment-emergent serious adverse

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events were uncommon in both treatment groups (2.1% of CONTEPO patients and 2.6% of PIP-TAZ patients). There were no deaths in the study and one treatment-emergent serious adverse event in each treatment group was deemed related to study drug (hypokalemia in a CONTEPO patient and renal impairment in a PIP-TAZ patient), leading to study drug discontinuation in the PIP-TAZ patient. Study drug discontinuations due to the treatment-emergent adverse events were infrequent and similar between treatment groups (3.0% of CONTEPO patients and 2.6% of PIP-TAZ patients).

The most common laboratory abnormality treatment-emergent adverse events in the ZEUS Study were increases in the levels of alanine aminotransferase, or ALT, (8.6% of CONTEPO patients and 2.6% of PIP-TAZ patients) and aspartate transaminase, or AST, (7.3% of CONTEPO patients and 2.6% of PIP-TAZ patients). None of the ALT or AST elevations were symptomatic or treatment-limiting, and none of the patients met the criteria for Hy's Law. Outside the United States, elevated liver aminotransferases are listed among undesirable effects in the labeling for IV fosfomicin.

In the ZEUS Study, hypokalemia occurred in 71 of 232 (30.6%) CONTEPO patients and 29 of 230 (12.6%) PIP-TAZ patients. Most decreases in potassium levels were mild to moderate in severity. Shifts in potassium levels from normal at baseline to hypokalemia, as determined by worst post-baseline hypokalemia values, were more frequent in the CONTEPO group than the PIP-TAZ group for mild (17.7% compared to 11.3%), moderate (11.2% compared to 0.9%), and severe (1.7% compared to 0.4%) categories of hypokalemia. Hypokalemia was deemed a treatment-emergent adverse event in 6.4% of patients receiving CONTEPO and 1.3% of patients receiving PIP-TAZ, and all cases were transient and asymptomatic.

While no significant cardiac adverse events were observed in the ZEUS Study, post-baseline QT intervals calculated using Fridericia's formula, or QTcF, of greater than 450 to less than or equal to 480 msec (baseline QTcF of less than or equal to 450 msec) occurred at a higher frequency in CONTEPO patients (7.3%) compared to PIP-TAZ patients (2.5%). In the CONTEPO arm, these results appeared to be associated with the hypokalemia associated with the salt load of the IV formulation. Only one patient in the PIP-TAZ arm had a baseline QTcF of less than or equal to 500 msec and a post-baseline QTcF of greater than 500 msec.

If we elect or are forced to suspend or terminate any clinical trial of lefamulin, CONTEPO or any other product candidates that we are developing, the commercial prospects of lefamulin, CONTEPO or such other product candidates will be harmed and our ability to generate product revenues, if at all, from lefamulin, CONTEPO or any of these other product candidates will be delayed or eliminated. In addition, a higher rate of adverse events in lefamulin or CONTEPO as compared to the standard of care, even if slight, could negatively impact commercial adoption of lefamulin or CONTEPO by physicians. Any of these occurrences could materially harm our business, financial condition, results of operations and prospects.

***Even if lefamulin, CONTEPO or any other product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for lefamulin, CONTEPO or any other product candidate may be smaller than we estimate.***

If lefamulin, CONTEPO or any of our other product candidates receive marketing approval, it or they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current treatments for pneumonia, including generic options, are well established in the medical community, and doctors may continue to rely on these treatments without lefamulin, CONTEPO or any of our other product candidates. In addition, our efforts to effectively communicate the differentiating characteristics and key attributes of lefamulin, CONTEPO or any of our other product candidates to clinicians and hospital pharmacies with the goal of establishing favorable formulary status for lefamulin, CONTEPO or any of our other product

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candidates may fail or may be less successful than we expect. If lefamulin, CONTEPO or any of our other product candidates 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 our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the ability of lefamulin, CONTEPO or any other anti-infective product candidate to limit the development of bacterial resistance in the pathogens it targets;
- the prevalence and severity of any side effects;
- the ability to offer our product candidates for sale at competitive prices, including in comparison to generic competition;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies, physicians to prescribe these therapies and hospitals to approve the cost and use by their physicians of these therapies;
- our investment in and the strength of marketing, patient access and distribution support;
- the availability of third-party coverage and adequate reimbursement; and
- the timing of any marketing approval in relation to other product approvals.

Bacteria might develop resistance to lefamulin, CONTEPO or any future product candidates more rapidly or to a greater degree than we anticipate. If bacteria develop resistance or if lefamulin, CONTEPO or any future product candidates is not effective against drug-resistant bacteria, the efficacy of these product candidates would decline, which would negatively affect our potential to generate revenues from these product candidates.

Our ability to negotiate, secure and maintain third-party coverage and reimbursement may be affected by political, economic and regulatory developments in the United States, the European Union and other jurisdictions. Governments continue to impose cost containment measures, and third-party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. If the level of reimbursement is below our expectations, our revenue and gross margins would be adversely affected. Obtaining formulary approval from third-party payors can be an expensive and time-consuming process. We cannot be certain if and when we will obtain formulary approval to allow us to sell lefamulin, CONTEPO or any future product candidates into our target markets. Even if we do obtain formulary approval, third-party payors, such as government or private health care insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, drugs. These and other similar developments could significantly limit the degree of market acceptance of lefamulin, CONTEPO or any of our other product candidates that receive marketing approval.

***If we are unable to establish or maintain sales, marketing and distribution capabilities or enter into or maintain sales, marketing and distribution agreements with third parties, we may not be successful in commercializing lefamulin, CONTEPO or any other product candidate if and when they are approved.***

We have only a very limited sales, marketing, patient access and distribution infrastructure, and as a company we have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either establish an adequate sales, marketing, patient access and distribution organization or outsource these functions to third parties. If lefamulin or CONTEPO receives marketing approval, we plan to commercialize it in the United States with our own targeted hospital sales and marketing organization that we plan to expand beyond its current levels, subject to our ability to access additional capital. In addition, we expect to utilize a



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variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize lefamulin in markets outside the United States. We do not intend to seek approval to commercialize CONTEPO in any markets outside the United States.

There are risks involved with establishing our own sales, marketing, patient access and distribution capabilities and entering into arrangements with third parties to perform these services. If we do not establish adequate sales, marketing, patient access and distribution capabilities prior to or in connection with the commercial launch of any of our products, such products may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community and may fail commercially or be less successful than we expect. If the commercial launch of a product candidate for which we establish marketing and distribution capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, patient access and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put our sales representatives at a competitive disadvantage relative to sales representatives from companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales, marketing, patient access and distribution organization.

If we enter into arrangements with third parties to perform sales, marketing, patient access and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market, sell and distribute ourselves any products that we develop. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

***We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.***

The development and commercialization of new drug products is highly competitive. We face competition with respect to lefamulin, CONTEPO and any other products we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

There are a variety of available therapies marketed for the treatment of CABP and cUTI. Currently the treatment of CABP and cUTI is dominated by generic products. For hospitalized patients, combination therapy is frequently used in both CABP and cUTI. Many currently approved drugs are well-established therapies and are widely accepted by physicians, patients and third-party

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payors for the treatment of CABP. We also are aware of various drugs under development or recently approved by the FDA for the treatment of CABP, including omadacycline (recently approved by the FDA on behalf of Paratek Pharmaceuticals Inc.), delafloxacin (recently approved by the FDA for ABSSSI on behalf of Melinta Therapeutics Inc. with a completed phase 3 clinical trial for CABP) and oral nafithromycin (under Phase 2 clinical development by Wockhardt Ltd.). If approved, we expect CONTEPO will face competition from commercially available branded antibiotics such as ceftazidime-avibactam, meropenem-vaborbactam, tigecycline and plazomicin, from other products currently in development for the treatment of cUTI, including AP, such as imipenem-relebactam (under Phase 3 clinical development by Merck), cefiderocol (under Phase 3 clinical development by Shionogi), ETX0282-cefpodoxime proxetil (under Phase 1 clinical development by Entasis Therapeutics), and LYS228 (under development by Novartis), as well as generically available agents including piperacillin-tazobactam, carbapenems, aminoglycosides, and polymyxins.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are approved for broader indications or patient populations, are more convenient or are less expensive than any products that we may develop. Our competitors may also obtain marketing approvals for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected because in some cases insurers or other third-party payors seek to encourage the use of generic products. This may have the effect of making branded products less attractive, from a cost perspective, to buyers. We expect that if lefamulin is approved for CABP and CONTEPO is approved for cUTI, including AP, they will be priced at a significant premium over competitive generic products. This pricing difference may make it difficult for us to replace existing therapies with lefamulin and CONTEPO. The key competitive factors affecting the success of our product candidates are likely to be their efficacy, safety, convenience, price and the availability of coverage and reimbursement from government and other third-party payors.

Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining approvals from regulatory authorities and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to or necessary for our programs.

***Even if we are able to commercialize lefamulin, CONTEPO or any other product candidate that we develop, the product may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.***

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing

limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize lefamulin, CONTEPO or any other product candidate successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A major trend in the healthcare industries in the European Union and the United States and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for lefamulin, CONTEPO or any other product that we commercialize and, if coverage and reimbursement are available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for lefamulin and CONTEPO may be particularly difficult because of the number of generic drugs, which are typically available at lower prices, that are available to treat CABP and cUTI. In addition, third-party payors are likely to impose strict requirements for reimbursement of a higher priced drug, such as lefamulin and CONTEPO. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize lefamulin, CONTEPO or other product candidates for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the applicable regulatory authority. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. In the European Union, reference pricing systems and other measures may lead to cost containment and reduced prices. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

***Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and to limit commercialization of any products that we may develop or in-license.***

We face an inherent risk of product liability exposure related to the testing of lefamulin, CONTEPO and any other product candidate that we develop in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop or in-license. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;

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- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We maintain clinical trial liability insurance that covers bodily injury to patients participating in our clinical trials up to a \$10.0 million annual aggregate limit and subject to a per event deductible. This amount of insurance may not be adequate to cover all liabilities that we may incur. We will need to increase our insurance coverage when and if we begin commercializing lefamulin, CONTEPO or any other product candidate that receives marketing approval. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

### **Risks Related to Our Dependence on Third Parties**

*Use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable quality or cost, which could delay, prevent or impair our development or commercialization efforts.*

We do not own or operate manufacturing facilities for the production of lefamulin or CONTEPO that could be used in product candidate development, including clinical trial supply, or for commercial supply, or for the supply of any other compound that we are developing or evaluating in our research program. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on third parties for supply of lefamulin and CONTEPO, and our strategy is to outsource all manufacturing, packaging, testing, serialization and distribution of our product candidates and products to third parties.

We have entered into agreements, and expect to enter into additional agreements, with third-party manufacturers for the long-term commercial supply of lefamulin and CONTEPO. We obtained the pleuromutilin starting material for the clinical trial supply of lefamulin from a single third-party manufacturer, Sandoz GmbH, or Sandoz, a division of Novartis AG, or Novartis. Novartis stopped manufacturing pleuromutilin for us in June 2015 and will not be a commercial supplier of pleuromutilin for us. We have identified and entered into a commercial supply agreement with an alternative supplier that we believe will be able to provide pleuromutilin starting material for the commercial supply of lefamulin.

Another third-party manufacturer synthesizes lefamulin starting from pleuromutilin and a readily accessible chiral building block, and provides our supply of the active pharmaceutical ingredient. We may engage a secondary supplier to synthesize lefamulin. However, our current operating plans do not include a secondary supplier unless we obtain additional funding. We engage separate manufacturers to provide tablets, sterile vials, and sterile diluent that we are using in our clinical trials of lefamulin. We have entered into commercial supply agreements with these same manufacturers to support the future commercialization of lefamulin, if approved. We also entered into a long-term commercial supply agreement with Arran Chemical Company Limited, or Arran, for the supply of the chiral acid starting material required in the synthesis of lefamulin API and a commercial packaging and supply agreement with Sharp Corporation for the commercial packaging and of lefamulin.

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In addition, we have entered into a manufacturing and supply agreement with Ercros, S.A., pursuant to which Ercros, S.A. supplies to us, on an exclusive basis, the API mixture for CONTEPO in support of our NDA filing and, if CONTEPO is approved, will supply the commercial API Mixture for CONTEPO in the United State. We have also entered into a manufacturing and exclusive supply agreement with Laboratorios ERN, S.A., pursuant to which Laboratorios ERN, S.A. has agreed to supply us with certain technical documentation and data as required for our NDA filing for CONTEPO and certain regulatory support in connection with the commercial sale and use of CONTEPO in the United States. We entered into a commercial packaging agreement with AndersonBrecon, Inc. for the commercial packaging and serialization of CONTEPO in addition to a manufacturing and supply agreement with Fisiopharma S.r.l. for the supply, on a minimum commitment basis, of a percentage of our commercial requirements of CONTEPO in bulk drug vials for the United States as well as the supply of bulk drug vials of CONTEPO in connection with the submission of an NDA.

We may be unable to maintain our current arrangements for commercial supply, or conclude agreements for commercial supply with additional third-party manufacturers, or we may be unable to do so on acceptable terms. Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- an event at one of our manufacturers or suppliers causing an unforeseen disruption of the manufacture or supply of our product candidates;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with current good manufacturing practice, or cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and products.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

If the third parties that we engage to supply any materials or manufacture product for our non-clinical testing and clinical trials should cease to continue to do so for any reason, we likely would experience delays in advancing these trials while we identify and qualify replacement suppliers, and we may be unable to obtain replacement supplies on terms that are favorable to us. For example, there are only a limited number of known manufacturers that produce the pleuromutilin starting material used in the synthesis of lefamulin. In early 2015, Novartis completed the sale of its animal health division, including its veterinary products, to a third party. As a result, we were required to identify an alternative supplier for pleuromutilin starting material for lefamulin. If we are not able to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

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Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize any products that receive marketing approval on a timely and competitive basis.

***We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.***

We do not independently conduct clinical trials for our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to perform this function. We expect to continue to rely on such third parties in conducting our clinical trials of lefamulin and CONTEPO, and expect to rely on these third parties to conduct clinical trials of any other product candidate that we develop. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, or GCP, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a U.S. government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Similar GCP and transparency requirements apply in the European Union. Failure to comply with such requirements, including with respect to clinical trials conducted outside the European Union, can also lead regulatory authorities to refuse to take into account clinical trial data submitted as part of an MAA.

Furthermore, third parties that we rely on for our clinical development activities may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Our product development costs will increase if we experience delays in testing or obtaining marketing approvals.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

***We have entered into and may enter into additional collaborations with third parties for the development or commercialization of lefamulin, CONTEPO and our other product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.***

If lefamulin and CONTEPO receive marketing approval, we plan to commercialize them in the United States with our own targeted hospital sales and marketing organization. Outside the United States, we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize lefamulin. For example, we have entered into a license agreement with Sinovant pursuant to which we granted Sinovant certain rights to manufacture and commercialize lefamulin in the People's Republic of China, Hong Kong, Macau and

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Taiwan. We also may seek third-party collaborators for development and commercialization of other product candidates or for lefamulin for indications other than CABP.

Our likely future collaborators for any sales, marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Under our license agreement with Sinovant, we have, and under any such arrangements we enter into with any third parties in the future we will likely have, limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Our current collaborations involving our product candidates pose, and any future collaborations likely will pose, numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, product and product candidate priorities, available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may need to conduct clinical trials, and these clinical trials may not be successful;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborator and us as to the ownership of intellectual property arising during the collaboration;
- we may grant exclusive rights to our collaborators, which would prevent us from collaborating with others;
- collaborators may be unable to enforce our intellectual property rights in territories where we have licensed, or may license, them such rights, which may expose us to material adverse tax and other consequences;

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- disputes may arise between the collaborators and us that result in the delay or termination of the development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

For example, under our license agreement with Sinovant, if any court, tribunal or governmental agency in the People's Republic of China, Hong Kong, Macau or Taiwan determines that the exclusive license granted to Sinovant pursuant to the license agreement is not sufficiently exclusive such that Sinovant does not have sufficient rights to enforce the licensed patent rights in such territories, we and our subsidiary, Nabriva Therapeutics GmbH, have agreed to take such commercially reasonable steps as Sinovant reasonably requests to grant Sinovant such rights. If a court in such jurisdictions were to determine that our license to Sinovant was not sufficiently exclusive and that Sinovant did not have the rights to enforce the licensed patent rights in the licensed territories, Sinovant may require us to take such actions that it deems reasonable but that we do not and which may have a material adverse effect on our business, including requiring us to make changes to our organizational structure that may result in adverse tax and other consequences, or to conduct other activities that may cause us to incur significant expenses.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

***If we are not able to establish additional collaborations, we may have to alter our development and commercialization plans.***

The potential commercialization of lefamulin and CONTEPO and the development and potential commercialization of other product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to further collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. For example, we intend to seek to commercialize lefamulin through a variety of types of additional collaboration arrangements outside the United States. These collaborations will help fund the potential commercialization of our product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for additional collaborations outside greater China will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.



If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into additional collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

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

***If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be adversely affected.***

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States, Europe and in certain additional foreign jurisdictions related to our novel technologies and product candidates 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 or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, if we license technology or product candidates from third parties in the future, these license agreements may not permit us to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering this intellectual property. These agreements could also give our licensors the right to enforce the licensed patents without our involvement, or to decide not to enforce the patents at all. Therefore, in these circumstances, 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, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. 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. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. We also may not pursue or obtain patent protection in all major markets or may not obtain protection that enables us to prevent the entry of third parties onto the market. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our U.S. patents or pending U.S. patent applications, or that we were the first to file for patent protection of such inventions.

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Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, reexamination, *inter partes* review, post grant review, interference proceedings or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, 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. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or any future licensed patents by developing similar or alternative technologies or products in a non-infringing manner. In addition, other companies may attempt to circumvent any regulatory data protection or market exclusivity that we obtain under applicable legislation, which may require us to allocate significant resources to preventing such circumvention. Legal and regulatory developments in the European Union and elsewhere may also result in clinical trial data submitted as part of an MAA becoming publicly available. Such developments could enable other companies to circumvent our intellectual property rights and use our clinical trial data to obtain marketing authorizations in the European Union and in other jurisdictions. Such developments may also require us to allocate significant resources to prevent other companies from circumventing or violating our intellectual property rights. Our attempts to prevent third parties from circumventing our intellectual property and other rights may ultimately be unsuccessful. We may also fail to take the required actions or pay the necessary fees to maintain our patents.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. 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 candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

***We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter such infringement or unauthorized use, we may be required to file claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

***Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.***

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference, derivation, *inter partes* review or post-grant review proceedings before the USPTO. The risks of being involved in such litigation and proceedings may increase as our product candidates approach commercialization, and as we gain greater visibility as a public company. Third parties may assert infringement claims against us based on existing or future intellectual property rights. We may not be aware of all such intellectual property rights potentially relating to our product candidates. Any freedom-to-operate search or analysis previously conducted may not have uncovered all relevant patents and patent applications, and there may be pending or future patent applications that, if issued, would block us from commercializing lefamulin or CONTEPO. Thus, we do not know with certainty whether lefamulin, CONTEPO or any other product candidate, or our commercialization thereof, does not and will not infringe any third party's intellectual property.

If we are found to infringe a third party's intellectual property rights, or to avoid or settle litigation, we could be required to obtain a license to continue developing and marketing our products and technology. However, we may not be able to obtain any required license 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, and could require us to make substantial payments. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

***We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.***

Many of our employees 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 do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while we typically require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our pleuromutilin business was founded as a spin-off from Sandoz. Although all patent applications are fully owned by us and were either filed by Sandoz with all rights fully transferred to us, or filed in our sole name, because we acquired certain of our patents from Sandoz, we must rely on their prior practices, with regard to the assignment of such intellectual property. Similarly, for any patent applications we acquired from Zavante in connection with the Acquisition, we must rely on Zavante's prior practices with regard to the assignment of

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intellectual property. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or 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 prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

***Intellectual property litigation could cause us to spend substantial resources and could distract our personnel from their normal responsibilities.***

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could 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 have a substantial adverse effect on the price of our ordinary shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets or that the agreements we have executed will provide adequate protection. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be obtained or independently developed by a competitor, our competitive position would be harmed.

***We have not yet registered our trademarks in all of our potential markets, and failure to secure those registrations could adversely affect our business.***

Our trademark applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to

overcome such rejections. 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. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

#### **Risks Related to Regulatory Approval and Marketing of Our Product Candidates and Other Legal Compliance Matters**

*Even if we complete the necessary non-clinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, in particular in the United States or the European Union, we will not be able to commercialize our product candidates in those markets, and our ability to generate revenue will be materially impaired.*

Our product candidates, including lefamulin and CONTEPO, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and, in the case of lefamulin, by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market lefamulin, CONTEPO or any of our other product candidates from regulatory authorities in any jurisdiction and we do not intend to seek approval to market CONTEPO outside the United States.

We have little experience in filing and supporting the applications necessary to obtain marketing approvals for product candidates and we have and expect to continue to rely on third-parties to assist us in this process. Securing marketing approval requires the submission of extensive non-clinical and clinical data and supporting information to various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Regulatory authorities may determine that lefamulin, CONTEPO or any of our other product candidates are not effective or only moderately effective, or have undesirable or unintended side effects, toxicities, safety profiles or other characteristics that preclude us from obtaining marketing approval or that prevent or limit commercial use.

The process of obtaining marketing approvals is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. For example, on June 23, 2016, eligible members of the electorate in the United Kingdom decided by referendum to leave the European Union, commonly referred to as Brexit. On March 29, 2017, the United Kingdom formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Because a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the referendum could materially change the regulatory regime applicable to the approval of any of our product candidates in the United Kingdom. In addition, because the European Medicines Agency, or EMA, is currently located in the United Kingdom but expected to move to the Netherlands as a result of the Brexit, the implications for the regulatory review process in the European Union has not been fully clarified and could result in disruption to the EMA review process.

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The United Kingdom has a period of a maximum of two years from the date of its formal notification to negotiate the terms of its withdrawal from, and future relationship with, the E.U. If no formal withdrawal agreement is reached between the United Kingdom and the E.U., then it is expected the United Kingdom's membership of the E.U. will automatically terminate two years after the submission of the notification of the United Kingdom's intention to withdraw from the E.U. Discussions between the United Kingdom and the E.U. focused on finalizing withdrawal issues and transition agreements are ongoing. However, limited progress to date in these negotiations and ongoing uncertainty within the UK Government and Parliament sustains the possibility of the United Kingdom leaving the E.U. on March 29, 2019 without a withdrawal agreement and associated transition period in place, which is likely to cause significant market and economic disruption.

The FDA and comparable regulatory authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from non-clinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Accordingly, if we or our collaborators experience delays in obtaining approval or if we or they fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

***Our failure to obtain marketing approval in jurisdictions other than the United States and Europe would prevent our product candidates from being marketed in these other jurisdictions, and any approval we are granted for our product candidates in the United States and Europe would not assure approval of product candidates in other jurisdictions.***

In order to market and sell lefamulin and our other product candidates in jurisdictions other than the United States and Europe, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval process varies among countries and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval or approvals from regulatory authorities in the European Union. The regulatory approval process outside the United States and Europe generally includes all of the risks associated with obtaining FDA approval or approvals from regulatory authorities in the European Union. In addition, some countries outside the United States and Europe require approval of the sales price of a drug before it can be marketed. In many countries, separate procedures must be followed to obtain reimbursement and a product may not be approved for sale in the country until it is also approved for reimbursement. We may not obtain marketing, pricing or reimbursement approvals outside the United States and Europe on a timely basis, if at all. Approval by the FDA or regulatory authorities in the European Union does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States and Europe does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA or regulatory authorities in the European Union. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. Marketing approvals in countries outside the United States and Europe do not ensure pricing approvals in those countries or in any other countries, and marketing approvals and pricing approvals do not ensure that reimbursement will be obtained.

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***Even if we obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.***

Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, including the potential requirements to implement a risk evaluation and mitigation strategy or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements including ensuring that quality control and manufacturing procedures conform to cGMP, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMP.

Accordingly, assuming we receive marketing approval for one or more of our product candidates, we and our contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

***Any product candidate for which we obtain marketing approval will be subject to strict enforcement of post-marketing requirements and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.***

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. In addition, even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval.

The FDA and other federal and state agencies, including the U.S. Department of Justice, or DOJ, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of such requirements may lead to investigations alleging violations of

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the Food, Drug and Cosmetic Act and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws.

Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure;
- exclusion from participation in federal healthcare reimbursement programs or debarment or the imposition of Corporate Integrity Agreements; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, also can result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

***Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the



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payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

***Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.***

In some countries, particularly the member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. Also, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidate to other available therapies to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

***The FDA's agreement to a Special Protocol Assessment, or SPA, with respect to the study design of our first Phase 3 clinical trial of lefamulin for CABP does not guarantee any particular outcome from regulatory review, including ultimate approval, and may not lead to a faster development or regulatory review or approval process.***

We reached agreement with the FDA in September 2015 on a SPA, which was later amended in April 2016, regarding the study design of our first Phase 3 clinical trial of lefamulin for the treatment of CABP. The SPA process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase 3 clinical trials that are intended to form the primary basis for determining a product candidate's efficacy and safety. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis, within 45 days of receipt of the request. The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the product candidate with respect to the effectiveness in the indication studied.

Our agreement with the FDA regarding the SPA may not lead to faster development, regulatory review or approval for lefamulin. Once the FDA and an applicant reach an agreement under the special protocol assessment process regarding the design and size of a clinical trial, the agreement generally cannot be changed after the clinical trial begins. Nevertheless, the FDA may revoke or alter a

SPA under defined circumstances, such as changes in the relevant data or assumptions provided by the sponsor or the emergence of new public health concerns. A revocation or alteration in our SPA could significantly delay or prevent approval of any marketing applications we submit for lefamulin.

***Fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process and does not assure FDA approval of our product candidate.***

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical need for this condition, the drug sponsor may apply for FDA fast track designation. The FDA has designated each of the IV and oral formulations of lefamulin and the IV formulation of CONTEPO as a qualified infectious disease product, or QIDP, and granted fast track designations to each of these formulations of lefamulin and CONTEPO. However, neither the QIDP nor the fast track designation ensures that lefamulin or CONTEPO will receive marketing approval or that approval will be granted within any particular timeframe. We have sought fast track designation for oral and IV lefamulin, as well as IV CONTEPO. We may, however, not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

***Priority review designation by the FDA may not lead to a faster regulatory review or approval process and, in any event, does not assure FDA approval of our product candidate.***

If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the FDA's goal to review an application is six months, rather than the standard review period of ten months. We were notified by the FDA that CONTEPO IV and the IV and oral formulations of lefamulin were granted priority review and have been given a Prescription Drug User Fee Act, or PDUFA, target action date of April 30, 2019 and August 19, 2019, respectively. Because the FDA designated each of the IV and oral formulations of lefamulin as a QIDP, lefamulin also will receive priority review. We may also request priority review for other product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or thereafter.

***Designation of each of lefamulin and CONTEPO as a Qualified Infectious Disease Product does not assure FDA approval of these product candidates.***

A QIDP is an antibacterial or antifungal drug intended to treat serious or life-threatening infections, including those caused by an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens or certain "qualifying pathogens." Upon the approval of an NDA for a drug product designated by the FDA as a QIDP, the product is granted an additional period of five years of regulatory exclusivity. Even though we have received QIDP designation for the IV and oral formulations of lefamulin and IV formulation of CONTEPO, there is no assurance that these product candidates will be approved by the FDA.

***If the FDA does not conclude that our product candidates satisfy the requirements under Section 505(b)(2) of the Federal Food Drug and Cosmetics Act, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates may take longer, cost more and entail greater complications and risks than anticipated, and may not be successful.***

We submitted an NDA for marketing approval of CONTEPO for the treatment of cUTI in adults in the United States in October 2018 utilizing Section 505(b)(2) of the Food, Drug and Cosmetic Act, or the FDCA, which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as Paragraph IV certifications, that certify any patents listed in the Orange Book publication in respect to any product referenced in the 505(b)(2) application are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) application. Under the Hatch-Waxman Act, the holder of the NDA which the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the Paragraph IV certification. Filing of a patent infringement lawsuit triggers a one-time automatic 30-month stay of the FDA's ability to approve the 505(b)(2) application. We have not conducted a comprehensive freedom-to-operate review with regard to CONTEPO.

Accordingly, we may invest a significant amount of time and expense in the development of CONTEPO or any other product candidate we may develop and experience significant delays and patent litigation before such products may be commercialized, if at all. A Section 505(b)(2) application also may not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the approved product. The FDA may then approve the new formulation for all or only some of the indications sought by us. The FDA may also reject our future Section 505(b)(2) submissions and may require us to file such submissions under Section 501(b)(1) of the FDCA, which could be considerably more expensive and time consuming.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. Thus, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to faster product development or earlier approval.

If the FDA does not conclude that CONTEPO, or any of our other product candidates for which we may utilize the 505(b)(2) pathway, satisfies the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates, including CONTEPO, under Section 505(b)(2) are not as we expect, the approval pathway for CONTEPO and any of our other product candidates for which we may utilize the 505(b)(2) pathway will likely take significantly

longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

***Under the CURES Act and the Trump Administration's regulatory reform initiatives, the FDA's policies, regulations and guidance may be revised or revoked and that could prevent, limit or delay regulatory approval of our product candidates, which would impact our ability to generate revenue.***

In December 2016, the Cures Act was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. 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 marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. An under-staffed FDA could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management and Budget on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a "Regulatory Reform Officer" and establish a "Regulatory Reform Task Force" to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations, however it is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

***Our relationships with healthcare providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which in the event of a violation could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates, including lefamulin and CONTEPO, for which we obtain marketing approval. Our future arrangements with healthcare providers, physicians and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through

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which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at \$5,500 to \$11,000 per false claim;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians and teaching hospitals, with data collection beginning in August 2013; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require product manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our financial results. We are developing and implementing a corporate compliance program designed to ensure that we will market and sell any future products that we successfully develop from our product candidates in compliance with all applicable laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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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 or case law involving applicable fraud and abuse or other 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 significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

***Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of lefamulin, CONTEPO or any of our other product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any collaborators, to profitably sell any product candidates, including lefamulin and CONTEPO, for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved products.

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, or collectively the ACA. Among the provisions of the ACA of potential importance to our business and our product candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report product samples that manufacturers and distributors provide to physicians; and

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- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in April 2013 and, due to subsequent legislative amendments to the statutes, will stay in effect through 2027 unless additional Congressional action is taken, and the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers 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 healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law.

Congress has repeatedly tried to repeal, replace and amend the ACA in recent years. With enactment of the legislation commonly referred to as the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the "individual mandate" for the ACA. The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Further, each chamber of the Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA.

The Trump Administration has also taken executive actions to undermine or delay implementation of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on

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states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys Generals filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than \$12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business. It is possible that repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. While the timing and scope of any potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects, it is also possible that some of the ACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with ACA coverage expansion provisions. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop commercialize product candidates.

Further, there have been several recent U.S. congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

In addition, on May 11, 2018, the Administration issued a plan to lower drug prices. Under this blueprint for action, the Administration indicated that the Department of Health and Human Services, or HHS, will take steps to end the gaming of regulatory and patent processes by drug makers to unfairly protect monopolies; advance biosimilars and generics to boost price competition; evaluate the inclusion of prices in drug makers' advertisements to enhance price competition; speed access to and lower the cost of new drugs by clarifying policies for sharing information between insurers and drug makers; avoid excessive pricing by relying more on value-based pricing by expanding outcome-based



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payments in Medicare and Medicaid; work to give Part D plan sponsors more negotiation power with drug makers; examine which Medicare Part B drugs could be negotiated for a lower price by Part D plans, and improving the design of the Part B Competitive Acquisition Program; update Medicare's drug-pricing dashboard to increase transparency; prohibit Part D contracts that include "gag rules" that prevent pharmacists from informing patients when they could pay less out-of-pocket by not using insurance; and require that Part D plan members be provided with an annual statement of plan payments, out-of-pocket spending, and drug price increases.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

Moreover, legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any future collaborators to more stringent drug labeling and post-marketing testing and other requirements.

***We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition.***

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act, or FCPA, the Irish Criminal Justice (Corruption Offenses) Act, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in that existing laws might be administered or interpreted.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States, and authorities in the European

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Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the trade control laws.

There is no assurance that we will be effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA or other legal requirements, including trade control laws. If we are not in compliance with the FCPA and other anti-corruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the FCPA, other anti-corruption laws or trade control laws by U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations currently, and may in the future, involve the use of hazardous and flammable materials, including chemicals and medical and biological materials, and produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and wastes, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials or disposal of hazardous wastes, we could be held liable for any resulting damages, and any liability could exceed our resources.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We also maintain a general liability program for some of the risks, but our insurance program includes limited environmental damage coverage, which has an annual aggregate coverage limit of \$2.0 million. Although we maintain an umbrella policy with an annual aggregate coverage limit of \$10.0 million, which may provide some environmental coverage, we do not maintain a separate policy covering environmental damages.

In addition, we may incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***Our employees may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.***

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, provide accurate information to the FDA or comparable non-U.S. regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

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Employee misconduct could also involve the improper use of information obtained during clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

***We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively.***

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our drug development programs and commercialization activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data 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 confidential or proprietary information, we could incur liability and our product research, development and commercialization efforts could be delayed.

***We are subject to various laws protecting the confidentiality of certain patient health information, and our failure to comply could result in penalties and reputational damage.***

Certain countries in which we operate have, or are developing, laws protecting the confidentiality of certain patient health information. European Union member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations.

For example, the European Union General Data Protection Regulation, or the GDPR, which came into force on May 25, 2018, introduced new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. The GDPR imposes strict obligations and restrictions on controllers and processors of personal data including, for example, expanded disclosures about how personal data is to be used, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data, mandatory data breach notification requirements and expanded rights for individuals over their personal data. This could affect our ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting, or could cause our costs to increase, and harm our business and financial condition.

While the GDPR, as a directly effective regulation, was designed to harmonize data protection law across the European Union, it does permit member states to legislate in many areas (particularly with regard to the processing of genetic, biometric or health data), meaning that inconsistencies between different member states will still arise. European Union member states have their own regimes on medical confidentiality and national and European Union-level guidance on implementation and compliance practices is often updated or otherwise revised, which adds to the complexity of processing personal data in the European Union.

## Risks Related to Our Acquisition of Zavante

*We may fail to realize the anticipated benefits of our Acquisition of Zavante, those benefits may take longer to realize than expected, and we may encounter significant integration difficulties.*

On July 24, 2018, we completed our acquisition, or the Acquisition, of Zavante Therapeutics, Inc., or Zavante, pursuant to an Agreement and Plan of Merger, or the Merger Agreement, dated July 23, 2018. Our ability to realize the anticipated benefits of the Acquisition will depend, to a large extent, on our ability to integrate Zavante and CONTEPO into our business and business strategy and realize anticipated growth opportunities and synergies. We expect that the integration process will be complex, costly and time-consuming. As a result, we will be required to devote significant management attention and resources to integrating Zavante into our business and CONTEPO into our business strategy. The integration process may be disruptive to our business and the expected benefits may not be achieved within the anticipated time frame, or at all. The failure to meet the challenges involved and to realize the anticipated benefits of the Acquisition could cause an interruption of, or a loss of momentum in, our development and commercialization efforts, including with respect to lefamulin and CONTEPO, and could adversely affect our business, financial condition and results of operations.

Our ability to realize the anticipated benefits of the Acquisition is expected to entail numerous additional material potential difficulties, including, among others:

- any delay or failure in obtaining marketing approvals for CONTEPO, or any delay or failure to commercialize CONTEPO in the United States thereafter;
- increased scrutiny from third parties, including regulators, legislative bodies and enforcement agencies, including with respect to product pricing and commercialization matters;
- changes in laws or regulations that adversely impact the anticipated benefits of the Acquisition;
- challenges related to the perception by patients, the medical community and third-party payors of CONTEPO for the treatment of complicated urinary tract infections, or cUTIs;
- disruptions to our manufacturing arrangements with third-party manufacturers, including our manufacturing and supply arrangements with respect to CONTEPO and disruptions to our third-party distribution channel;
- difficulties in managing the expanded operations of a larger and more complex company following the Acquisition;
- the diversion of management attention to integration matters;
- difficulties in achieving the anticipated business opportunities and growth prospects from the Acquisition;
- the size of the treatable patient population for CONTEPO may be smaller than we believe it is;
- difficulties in assimilating Zavante employees and in attracting and retaining key personnel; and
- potential unknown liabilities, adverse consequences, unforeseen increased expenses or other unanticipated problems associated with the Acquisition.

Many of these factors are outside of our control, and any one of them could result in increased costs, decreased expected revenues and further diversion of management time and energy, which could materially adversely impact our business, financial condition and results of operations.

Upfront consideration for the Acquisition was comprised of 8,152,092 of our ordinary shares, including the 815,186 ordinary shares that are issuable upon release of the Holdback Shares subject to the terms of the Merger Agreement. Pursuant to the Merger Agreement, former Zavante stockholders are also entitled to receive from us, subject to the terms and conditions of the Merger Agreement, up

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to \$97.5 million in contingent consideration, of which \$25.0 million would become payable upon the first approval of a new drug application from the U.S. Food and Drug Administration, or the FDA, for CONTEPO for injection for any indication, or the Approval Milestone Payment, and an aggregate of up to \$72.5 million would become payable upon the achievement of specified net sales milestones, or the Net Sales Milestone Payments. At our Extraordinary General Meeting of Shareholders held in October 2018, our shareholders approved the issuance of ordinary shares in settlement of potential milestone payment obligations that may become payable in the future to former Zavante stockholders, including the Approval Milestone Payment which will be settled in our ordinary shares. We also now have the right to settle the Net Sales Milestone Payments in ordinary shares, except as otherwise provided in the Merger Agreement. The issuance of our ordinary shares in connection with the closing of the Acquisition was dilutive to our existing shareholders, and the future issuance of our ordinary shares to satisfy our milestone payment obligations would be further dilutive to our then existing shareholders.

Also, following the Acquisition, we now possess certain liabilities and obligations, including contractual liabilities and obligations, that were assumed by us upon closing of the Acquisition. Prior to the Acquisition, former Zavante stockholders and SG Pharmaceuticals, Inc. entered into a stock purchase agreement, dated as of May 5, 2015, or the Stock Purchase Agreement, pursuant to which SG Pharmaceuticals, Inc. acquired all of the outstanding capital stock of Zavante from the Zavante selling stockholders and SG Pharmaceuticals, Inc., subsequently merged with and into Zavante, with Zavante as the surviving entity. Pursuant to the Stock Purchase Agreement, Zavante (as successor to SG Pharmaceuticals, Inc.) is obligated to make milestone payments to the selling stockholders of \$3.0 million upon marketing approval by the FDA with respect to any oral, intravenous or other form of fosfomycin, or the Zavante Products, and milestone payments of up to \$26.0 million in the aggregate upon the occurrence of various specified levels of net sales with respect to the Zavante Products. In addition, Zavante is obligated to make annual royalty payments to the selling stockholders of a mid-single-digit percentage of net sales of Zavante Products, subject to adjustment based on net sales thresholds and with such percentage reduced to low single-digits if generic fosfomycin products account for half of the applicable market on a product-by-product and country-by-country basis. The Stock Purchase Agreement also provides that Zavante will pay to the selling stockholders a mid-single-digit percentage of transaction revenue in connection with the consummation of the grant, sale, license or transfer of market exclusivity rights for a qualified infectious disease product (within the meaning of the 21st Century Cures Act, or the Cures Act) related to a Zavante Product.

In addition, we expect to incur expenses related to the continued development, regulatory approval process and commercialization with respect to CONTEPO. Zavante has entered into a manufacturing and supply agreement with Fisiopharma, S.r.l. pursuant to which Zavante has an obligation to purchase a minimum percentage of its commercial requirements of CONTEPO in the United States. Zavante has also entered into a manufacturing and exclusive supply agreement with Laboratorios ERN, S.A., pursuant to which Laboratorios ERN, S.A. has agreed to supply Zavante with certain technical documentation and data as required for submission of an NDA, or ANDA for CONTEPO and certain regulatory support in connection with the commercial sale and use of CONTEPO in the United States, and which provides for payments to Laboratorios ERN, S.A. of a one-time cash payment upon the first commercial sale of CONTEPO and subsequent quarterly payments thereafter based on the number of vials of CONTEPO sold in the United States during each quarter.

Because we have limited financial resources, by investing in the Acquisition, we may forgo or delay pursuit of other opportunities that may have proven to have greater commercial potential. Further, it is possible that undisclosed, contingent, or other liabilities or problems may arise in the future of which we were previously unaware. These undisclosed liabilities could have an adverse effect on our business, financial condition and results of operations.

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All of these factors could decrease or delay the expected accretive effect of the Acquisition and negatively impact our stock price. As a result, it cannot be assured that the Acquisition will result in the full realization of the benefits anticipated from the Acquisition or in the anticipated time frames or at all.

**Risks Related to Employee Matters and Managing Growth**

*Our future success depends on our ability to attract, retain and motivate key executives and qualified personnel.*

We are highly dependent on the principal members of our management and commercial teams. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain "key person" insurance on any of our executive officers. The unplanned loss of the services of any of these persons might impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel, including in the United States and Ireland where we plan to expand our physical presence, will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we cannot recruit and retain qualified personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

*We expect to expand the number of our employees and the scope of our operations in the certain areas, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.*

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of regulatory affairs, technical operations, supply chain, medical affairs and, subject to obtaining marketing approval of lefamulin and CONTEPO, sales and marketing. 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. In addition, our growth in connection with the Acquisition, including expansion of our business operations and employees who joined us in connection with the Acquisition, has imposed added responsibilities on members of our management, including the need to recruit, hire, retain, motivate and integrate additional employees and business operations.

Due to our limited financial resources and the limited experience of our management team in managing a company of our current size, and with such anticipated growth, we may not be able to manage the future expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

**Risks Related to Ownership of Our Ordinary Shares**

*An active trading market for our ordinary shares may not be sustained.*

Our ordinary shares began trading on the Nasdaq Global Market on June 26, 2017. Given the limited trading history of our ordinary shares, there is a risk that an active trading market for our

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ordinary shares will not be sustained, which could put downward pressure on the market price of our ordinary shares and thereby affect the ability of our security holders to sell their shares.

***The price of our ordinary shares may be volatile and fluctuate substantially.***

The trading price of our ordinary shares has been and is likely to continue to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced significant volatility that has often been unrelated to the operating performance of particular companies. The market price for our ordinary shares may be influenced by many factors, including:

- our ability to successfully implement our proposed business strategy;
- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- regulatory delays and greater government regulation of potential products due to adverse events;
- regulatory or legal developments in the United States, the European Union and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- one of our manufacturers or suppliers could have an event which causes an unforeseen disruption of the manufacture or supply of our product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- perception and market performance of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. We also may face securities class-action litigation if we cannot obtain regulatory approvals for or if we otherwise fail to commercialize lefamulin, CONTEPO or any of our other product candidates or if our securities experience volatility for any reason. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources.

***Our executive officers, directors and principal shareholders, if they choose to act together, have the ability to significantly influence most matters submitted to shareholders for approval.***

Our executive officers and directors, combined with our shareholders, and their respective affiliates who owned more than 5% of our outstanding ordinary shares as of January 31, 2019 in the aggregate,

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beneficially owned approximately 38.4% of our share capital, assuming the issuance of all Holdback Shares under the Merger Agreement. As a result, if these shareholders were to choose to act together, they would be able to significantly influence most matters submitted to our shareholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would significantly influence the election of directors and could, depending on the structure of the particular transaction, significantly influence the approval of a merger, consolidation or sale of all or substantially all of our assets.

***Our ordinary shares do not trade on any exchange outside of the United States.***

Our ordinary shares are listed only in the United States on The Nasdaq Global Market, and we have no plans to list our ordinary shares in any other jurisdiction. As a result, a holder of ordinary shares outside of the United States may not be able to effect transactions in our ordinary shares as readily as the holder may if our ordinary shares were listed on an exchange in that holder's home jurisdiction.

***Substantial future sales of our ordinary shares in the public market, or the perception that these sales could occur, could cause the price of our ordinary shares to decline significantly, even if our business is doing well.***

Sales of a substantial number of our ordinary shares, or the perception in the market that these sales could occur, could reduce the market price of our ordinary shares. We had 67,019,094 ordinary shares outstanding as of December 31, 2018. To the extent any of these shares are sold into the market, particularly in substantial quantities, the market price of our ordinary shares could decline.

Future issuances of ordinary shares pursuant to our equity incentive plans could also result in a reduction in the market price of our ordinary shares. We have filed registration statements on Form S-8 registering all of the ordinary shares that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance and once vested, subject to volume, notice and manner of sale limitations applicable to affiliates. The majority of ordinary shares that may be issued under our equity compensation plans remain subject to vesting in tranches over a four-year period. As of December 31, 2018, an aggregate of 1,963,877 options to purchase our ordinary shares had vested and become exercisable. No restricted stock units have vested as of December 31, 2018.

In addition, in March 2018, we entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement, or the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, pursuant to which, from time to time, we may offer and sell our ordinary shares having an aggregate offering price of up to \$50.0 million through Cantor. As of December 31, 2018, we had issued and sold an aggregate of 4,778,031 ordinary shares under the ATM Agreement. From December 31, 2018 through March 1, 2019, we issued and sold an aggregate of 2,748,048 ordinary shares under the ATM Agreement.

If a large number of 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.

Upfront consideration for the Acquisition is comprised of 8,152,092 of our ordinary shares, including 815,186 ordinary shares that are issuable upon release of the Holdback Shares subject to the terms of the Merger Agreement. The shares that were issued in connection with the closing of the Acquisition are able to be freely sold in the public market, subject to any requirements and restrictions, including any applicable volume limitations, imposed by Rule 144 under the Securities Act. While the Holdback Shares will be restricted as a result of securities laws at the time of issuance, following expiration of applicable holding periods, the Holdback Shares will also be able to be freely sold in the public market, subject to any requirements and restrictions, including any applicable volume limitations, imposed by Rule 144 under the Securities Act. In addition, the Merger Agreement provides that we



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may issue up to an additional \$97.5 million in our ordinary shares to former Zavante stockholders upon the achievement of specified regulatory and commercial milestones in the future and obligates us to provide registration rights with respect to the registration for resale of such additional ordinary shares that may become issuable upon the achievement of such milestones.

The sale or resale of these shares in the public market, or the market's expectation of such sales, may result in an immediate and substantial decline in our stock price. Such a decline will adversely affect our investors and also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

***We are an "emerging growth company", and the reduced disclosure requirements applicable to emerging growth companies may make our ordinary shares less attractive to investors.***

We are an "emerging growth company," as that term is used in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until December 31, 2020 or such earlier time that we are no longer an emerging growth company. For so long as we remain an emerging growth company, we are permitted and may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

- an exemption from compliance with the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, on the design and effectiveness of our internal controls over financial reporting;
- an exemption from compliance with any requirement that the Public Company Accounting Oversight Board may adopt regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure about the company's executive compensation arrangements; and
- exemptions from the requirements to obtain a non-binding advisory vote on executive compensation or a shareholder approval of any golden parachute arrangements.

We may choose to take advantage of some, but not all, of the available exemptions. We may take advantage of these provisions until December 31, 2020 or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earlier to occur of: the last day of the fiscal year in which we have more than \$1 billion (as may be inflation-adjusted by the SEC from time-to-time) in annual revenues; the date we qualify as a "large accelerated filer," with more than \$700 million in market value of our share capital held by non-affiliates; or the issuance by us of more than \$1 billion of non-convertible debt over a three-year period.

We may choose to take advantage of some, but not all, of the available benefits under the JOBS Act. We cannot predict whether investors will find our ordinary shares less attractive if we rely on such 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 market price of our ordinary shares may be more volatile.

In addition, the JOBS Act also provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies that are not emerging growth companies.

***We have broad discretion in the use of our funds and may not use them effectively.***

We have broad discretion in the application of our available funds and could spend the funds in ways that do not improve our results of operations or enhance the value of our ordinary shares. Our failure to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our ordinary shares to decline and delay the development of our product candidates. Pending their use, we may invest funds in a manner that does not produce income or that loses value.

***We incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.***

As a public company we incur, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations have made it more expensive for us to obtain director and officer liability insurance, and if such insurance becomes prohibitively expensive, this could make it more difficult for us to attract and retain qualified members of our board.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, security holders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ordinary shares.***

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us, as and when required, conducted in connection with Section 404 of the Sarbanes-Oxley Act, or Section 404, or any subsequent testing by our independent registered public accounting firm, as and when required, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. As a growing company, implementing and maintaining effective controls may require more resources, and we may encounter internal control integration difficulties. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ordinary shares.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, as an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm until we are no longer an emerging growth company. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate

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through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

***United States investors may have difficulty enforcing judgments against us, our directors and executive officers.***

We are incorporated under the laws of Ireland, and our registered offices and a substantial portion of our assets are located outside of the United States. As a result, it may not be possible to effect service of process on such person or us in the United States or to enforce judgments obtained in courts in the United States against such person or us based on civil liability provisions of the securities laws of the United States.

There is no treaty between Ireland and the United States providing for the reciprocal enforcement of judgments obtained in the other jurisdiction and Irish common law rules govern the process by which a U.S. judgment may be enforced in Ireland. The following requirements must be met as a precondition before a U.S. judgment will be eligible for enforcement in Ireland:

- the judgment must be for a definite sum;
- the judgment must be final and conclusive, and the decree must be final and enforceable in the court which pronounces it;
- the judgment must be provided by a court of competent jurisdiction, and the procedural rules of the court giving the foreign judgment must have been observed;
- the U.S. court must have had jurisdiction in relation to the particular defendant according to Irish conflict of law rules; and
- jurisdiction must be obtained by the Irish courts over judgment debtors in enforcement proceedings by service in Ireland or outside Ireland in accordance with the applicable court rules in Ireland.

Even if the above requirements have been met, an Irish court may exercise its right to refuse to enforce the U.S. judgment if the Irish court is satisfied that the judgment (1) was obtained by fraud; (2) is in contravention of Irish public policy; (3) is in breach of natural justice; or (4) is irreconcilable with an earlier judgment. By way of example, a judgment of a U.S. court of liabilities predicated upon U.S. federal securities laws may not be enforced by Irish courts on the grounds of public policy if that U.S. judgment includes an award of punitive damages. Further, an Irish court may stay proceedings if concurrent proceedings are being brought elsewhere.

***We do not expect to pay dividends in the foreseeable future.***

We have not paid any dividends on our ordinary shares since our incorporation. Even if future operations lead to significant levels of distributable profits, we currently intend that earnings, if any, will be reinvested in our business and that dividends will not be paid until we have an established revenue stream to support continuing dividends. If we propose to pay dividends in the future, we must do so in accordance with Irish law, which provides that distributions including dividend payments, share repurchases and redemptions be funded from "distributable reserves." In addition, the terms of the Loan Agreement with Hercules currently, and the terms of any future debt agreements may in the future, preclude us from paying dividends. Payment of future dividends to security holders will be at the discretion of our board, after taking into account various factors including our business prospects, cash requirements, financial performance, debt covenant limitations and new product development. As

a result, capital appreciation, if any, of our ordinary shares will be the sole source of gain for holders of our ordinary shares for the foreseeable future.

***We are exposed to risks related to currency exchange rates.***

A portion of our expenses are denominated in currencies other than the U.S. dollar. Because our consolidated financial statements are presented in U.S. dollars, changes in currency exchange rates have had and could have a significant effect on our operating results. Exchange rate fluctuations between foreign currencies and the U.S. dollar create risk in several ways, including the following:

- weakening of the U.S. dollar may increase the U.S. dollar cost of overseas research and development expenses;
- strengthening of the U.S. dollar may decrease the value of our revenues denominated in other currencies;
- the exchange rates on non-U.S. dollar transactions and cash deposits can distort our financial results; and

***As a holding company, our operating results, financial condition and ability to pay dividends or other distributions are entirely dependent on funding, dividends and other distributions received from our subsidiaries, which may be subject to restrictions.***

Our ability to pay dividends or other distributions and to pay our obligations in the future will depend on the level of funding, dividends and other distributions, if any, received from our subsidiaries and any new subsidiaries we establish in the future. The ability of our subsidiaries to make loans or distributions (directly or indirectly) to us may be restricted as a result of several factors, including restrictions in financing agreements and the requirements of applicable law and regulatory and fiscal or other restrictions. In particular, our subsidiaries and any new subsidiaries may be subject to laws that restrict dividend payments, authorize regulatory bodies to block or reduce the flow of funds from those subsidiaries to us, or limit or prohibit transactions with affiliates. Restrictions and regulatory action of this kind could impede access to funds that we may need to make dividend payments or to fund our own obligations.

Furthermore, we may guarantee some of the payment obligations of certain of our subsidiaries from time to time. These guarantees may require us to provide substantial funds or assets to our subsidiaries or their creditors or counterparties at a time when we are in need of liquidity to fund our own obligations.

***The ownership percentage of our shareholders may be diluted in the future which could dilute the voting power or reduce the value our outstanding ordinary shares.***

As with any publicly traded company, the ownership percentage of our shareholders may be diluted in the future because of equity issuances for acquisitions, capital market transactions or otherwise, including equity awards that we intend to continue to grant to our directors, officers and employees. From time to time, we may issue additional options or other share awards to our directors, officers and employees under our benefits plans. Our employees are also entitled, subject to certain conditions, to purchase our ordinary shares at a discount pursuant to our Employee Share Purchase Plan.

In addition, our articles of association authorize us to issue, without the approval of our shareholders, one or more classes or series of preferred shares having such designation, powers, preferences and relative, participating, optional and other special rights, including preferences over our ordinary shares respecting dividends and distributions, as our board of directors generally may determine. The terms of one or more classes or series of preferred shares could dilute the voting power

or reduce the value of our ordinary shares. Similarly, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred shares could affect the residual value of the ordinary shares. Additionally, we may issue and sell our ordinary shares under our ATM Agreement from time to time, and we may issue additional ordinary shares as contingent consideration upon the achievement of certain regulatory and commercialization milestones, subject to the terms and conditions of the Merger Agreement. See "*Risks Related to Ownership of our Ordinary Shares—Substantial future sales of our ordinary shares in the public market, or the perception that these sales could occur, could cause the price of our ordinary shares to decline significantly, even if our business is doing well.*".

***The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation. We are incorporated as a public limited company under Irish law.***

The rights of our shareholders are governed by our memorandum and articles of association and Irish law. The rights associated with our ordinary shares are different to the rights generally associated with shares held in a U.S. corporation. Material differences between the rights of shareholders of a U.S. corporation and the rights of our shareholders include differences with respect to, among other things, distributions, dividends, repurchases and redemptions, bonus issues, the election of directors, the removal of directors, the fiduciary and statutory duties of directors, conflicts of interests of directors, the indemnification of directors and officers, limitations on director liability, the convening of annual meetings of shareholders and special shareholder meetings, notice provisions for meetings, the quorum for shareholder meetings, the adjournment of shareholder meetings, the exercise of voting rights, shareholder suits, rights of dissenting shareholders, anti-takeover measures and provisions relating to the ability to amend the articles of association.

***As an Irish public limited company, certain capital structure decisions require shareholder approval, which may limit our flexibility to manage our capital structure.***

Under Irish law, our board of directors may increase our authorized share capital and issue new ordinary or preferred shares up to a maximum amount equal to the authorized but unissued share capital, without shareholder approval, once authorized to do so by our articles of association or by an ordinary resolution of our shareholders. Additionally, subject to specified exceptions, Irish law grants statutory preemption rights to existing shareholders where shares are being issued for cash consideration but allows shareholders to disapply such statutory preemption rights either in our articles of association or by way of special resolution. Such disapplication can either be generally applicable or be in respect of a particular allotment of shares. Accordingly, our articles of association contain, as permitted by Irish company law, provisions authorizing our board of directors to issue new shares, and to disapply statutory preemption rights. The authorization of our board of directors to issue shares and the disapplication of statutory preemption rights must both be renewed by the shareholders at least every five years, and we cannot provide any assurance that these authorizations will always be approved, which could limit our ability to issue equity and thereby adversely affect the holders of our ordinary shares.

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

We are subject to the Irish Takeover Panel Act, 1997, Takeover Rules, 2013. Under those Irish Takeover Rules, the board is not permitted to take any action that might frustrate an offer for our ordinary shares once the board 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 (i) the issue of ordinary shares, options or convertible securities, (ii) material acquisitions or disposals, (iii) entering into contracts other than in the ordinary course of business or

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(iv) 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 the board has reason to believe an offer is or may be imminent. These provisions may give the board less ability to control negotiations with hostile offerors and protect the interests of holders of ordinary shares than would be the case for a corporation incorporated in a jurisdiction of the United States.

***The operation of the Irish Takeover Rules may affect the ability of certain parties to acquire our ordinary shares.***

Under the Irish Takeover Rules, if an acquisition of ordinary shares were to increase the aggregate holding of the acquirer and its concert parties to ordinary shares that represent 30% or more of the voting rights of a company, the acquirer and, in certain circumstances, its concert parties would be required (except with the consent of the Irish Takeover Panel) to make an offer for the outstanding ordinary shares at a price not less than the highest price paid for the ordinary shares by the acquirer or its concert parties during the previous 12 months. This requirement would also be triggered by an acquisition of ordinary shares by a person holding (together with its concert parties) ordinary shares that represent between 30% and 50% of the voting rights in the company if the effect of such acquisition were to increase that person's percentage of the voting rights by 0.05% within a 12-month period. The Irish Takeover Rules could therefore discourage an investor from acquiring 30% or more of our outstanding ordinary shares, unless such investor was prepared to make a bid to acquire all outstanding ordinary shares.

Certain separate concert parties will also be presumed to be acting in concert. Our board of directors and their relevant family members, related trusts and "controlled companies" are presumed to be acting in concert with any corporate shareholder who holds 20% or more of the company. The application of these presumptions may result in restrictions upon the ability of any of the concert parties and members of our board of directors to acquire more of our securities, including under the terms of any executive incentive arrangements. We may consult with the Irish Takeover Panel with respect to the application of this presumption and the restrictions on the ability to acquire further securities if necessary, although we are unable to provide any assurance as to whether the Irish Takeover Panel would overrule this presumption.

***We will be exposed to the risk of future changes in law, which could materially adversely affect us.***

We are subject to Irish law. As a result, we are subject to the risk of future adverse changes in Irish law (including Irish corporate and tax law). In addition, we and our subsidiaries are also subject to the risk of future adverse changes in Austrian and U.S. law, as well as changes of law in other countries in which we and our subsidiaries operate.

***Future adverse changes in law could result in our not being able to maintain a worldwide effective corporate tax rate that is competitive in our industry.***

While we believe that being incorporated in Ireland should not affect our ability to maintain a worldwide effective corporate tax rate that is competitive in our industry, we cannot give any assurance as to what our effective tax rate will be because of, among other things, uncertainty regarding the tax policies of the jurisdictions where we will operate. The tax laws of Ireland, Austria, the United States, and other jurisdictions could change in the future, and such changes could cause a material change in our worldwide effective corporate tax rate. In particular, legislative action could be taken by Ireland, Austria, the United States or other jurisdictions which could override tax treaties upon which we expect to rely and adversely affect our effective tax rate. As a result, our actual effective tax rate may be materially different from our expectation.

***Comprehensive tax reform legislation could adversely affect our business and financial condition.***

The Tax Cuts and Jobs Act of 2017, or the Tax Act, introduced significant changes to the United States Internal Revenue Code of 1986, as amended, or Code.

The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense, limitation of the deduction for net operating losses, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, and modifying or repealing many business deductions and credits.

We continue to examine the impact the Tax Act may have on our business. Notwithstanding the reduction in the federal corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected.

***After tax reform, U.S. persons who own 10 percent or more of our shares may be subject to U.S. federal income taxation on certain of our foreign subsidiaries' income even if such income is not distributed to such U.S. persons.***

A foreign corporation is treated as a "controlled foreign corporation", or CFC, for U.S. federal income tax purposes if, on any day during a taxable year, "United States shareholders" (as defined below) own (directly, indirectly or constructively within the meaning of Section 958 of the Code) more than 50% of the total combined voting power of all classes of our voting shares or more than 50% of the total value of all of our shares. A "United States shareholder" of a foreign corporation is a U.S. person who owns (directly, indirectly or constructively within the meaning of Section 958 of the Code) at least 10% of the total combined voting power of voting shares of such non-U.S. corporation or at least 10% of the total value of shares of all classes of stock of such non-U.S. corporation.

As a result of the Tax Act, all of our non-U.S. subsidiaries will be treated as CFCs. The legislative history under the Tax Act indicates that this change was not intended to cause these non-U.S. subsidiaries to be treated as CFCs with respect to a United States shareholder that is not related to the U.S. subsidiary of the Company. However, it is not clear whether the IRS or a court would interpret the change made by the Tax Act in a manner consistent with such indicated intent.

Any United States shareholder who owns our shares (directly or indirectly within the meaning of Section 958(a) of the Code) on the last day in such taxable year must include in its gross income for U.S. federal income tax purposes its pro rata share (based on direct or indirect ownership of value) of the non-U.S. subsidiaries' "subpart F income," regardless of whether that income was actually distributed to such U.S. person (with certain adjustments). "Subpart F income" of a CFC generally includes among other items passive income, such as dividends, interest, annuities, net gains from sales of property that do not generate active income, net commodities gains, net foreign currency gains, passive rents and royalties.

The Tax Act also requires such United States shareholders to include in their gross income for U.S. federal income tax purposes their pro rata share of a CFC's "global intangible low tax income", or GILTI." In general terms, GILTI is the net income of the CFCs (other than income already included in United States shareholders' taxable income) that exceeds 10% of the CFCs' bases in depreciable tangible assets. GILTI is treated in a manner similar to subpart F income.

In addition, if a U.S. person disposes of shares in a non-U.S. corporation and the U.S. person was a United States shareholder at any time when the corporation was a CFC during the five-year period ending on the date of disposition, any gain from the disposition will generally be treated as a dividend to the extent of the U.S. person's share of the corporation's undistributed earnings and profits that were accumulated during the period or periods that the U.S. person owned the shares while the

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corporation was a CFC (with certain adjustments). Also, a U.S. person may be required to comply with specified reporting requirements, regardless of the number of shares owned.

***A transfer of our ordinary shares, other than a transfer effected by means of the transfer of book-entry interests in the Depository Trust Company, may be subject to Irish stamp duty.***

Transfers of our ordinary shares effected by means of the transfer of book entry interests in the Depository Trust Company, or DTC, will not be subject to Irish stamp duty. However, if you hold our ordinary shares directly rather than beneficially through DTC, any transfer of your ordinary shares could be subject to Irish stamp duty (currently at the rate of 1% of the higher of the price paid or the market value of the shares acquired). Payment of Irish stamp duty is generally a legal obligation of the transferee. The potential for stamp duty could adversely affect the price of our ordinary shares.

***Our ordinary shares received by means of a gift or inheritance could be subject to Irish capital acquisitions tax.***

Irish capital acquisitions tax, or CAT, could apply to a gift or inheritance of our ordinary shares irrespective of the place of residence, ordinary residence or domicile of the parties. This is because our ordinary shares will be regarded as property situated in Ireland. The person who receives the gift or inheritance has primary liability for CAT. Gifts and inheritances passing between spouses are exempt from CAT. Children have a tax-free threshold of €320,000 in respect of taxable gifts or inheritances received from their parents.

***We may be classified as a passive foreign investment company for our tax year ending December 31, 2018, which may result in adverse U.S. federal income tax consequence to U.S. holders.***

Based on our estimated gross income and average value of our gross assets and the nature of our business, we do not believe that we were a "passive foreign investment company," or PFIC, for U.S. federal income tax purposes for any tax years from our initial public offering through the year ended December 31, 2018. A corporation organized outside the United States generally will be classified as a PFIC for U.S. federal income tax purposes (1) in any taxable year in which at least 75% of its gross income is passive income or on average at least 50% of the gross value of its assets is attributable to assets that produce passive income or are held for the production of passive income and (2) as to a given holder who was a holder in such year and regardless of such corporation's income or asset composition, in any subsequent taxable year, unless certain elections are made by that holder that can discontinue that classification as to that holder, at the risk of imposing substantial tax costs to that holder. Passive income for this purpose generally includes dividends, interest, royalties, rents and gains from commodities and securities transactions. Our status in any taxable year will depend on our assets and activities in each year, and because this is a factual determination made annually after the end of each taxable year, there can be no assurance that we will not be considered a PFIC for the current taxable year or any future taxable year. The gross value of our assets may be determined in part by reference to the market price of our ordinary shares, which may fluctuate considerably given that market prices of biotechnology companies have been especially volatile. If we were to be treated as a PFIC for the tax year ending December 31, 2018, or any future taxable year during which a U.S. holder held our ordinary shares, however, certain adverse U.S. federal income tax consequences could apply to the U.S. holder. We currently intend to make available the information necessary to permit a U.S. holder to make a valid QEF election, which may mitigate some of the adverse U.S. federal income tax consequences that could apply to a U.S. holder of ordinary shares if we determine that we were a PFIC for any taxable year. However, we may choose not to provide such information at a future date.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.



**ITEM 2. PROPERTIES**

**Facilities**

Our facilities consist of approximately 3,100 square meters of leased laboratory and office space in Vienna, Austria. We lease approximately 15,000 square feet of office space in King of Prussia, Pennsylvania. We also lease office space in Dublin, Ireland and San Diego, California. We may seek to negotiate new leases or evaluate additional or alternate space as we plan for the growth of our commercial operations in the United States and Ireland. We believe that suitable additional or alternative space will be available in the future on commercially reasonable terms.

**ITEM 3. LEGAL PROCEEDINGS**

None

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

## PART II

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

#### Market Information

Our ordinary shares have been listed on the Nasdaq Global Market since June 26, 2017 following the Redomiciliation and trade on the Nasdaq Global Market under the symbol "NBRV". Prior to the Redomiciliation, the ADSs, representing the common shares of our predecessor, Nabriva Therapeutics AG, or Nabriva Austria, had traded on the NASDAQ Global Market under the same symbol since September 18, 2015. Each ADS represented one tenth (1/10) of a common share of Nabriva Austria.

#### Stockholders

As of January 31, 2019, there were sixty-eight holders of record of ordinary shares. The number of record holders may not be representative of the number of beneficial owners because many of our ordinary shares are held by depositories, brokers or other nominees.

#### Securities Authorized for Issuance Under Equity Compensation Plans

Information regarding securities authorized for issuance under our equity compensation plans is contained in Part III, Item 12 of this Annual Report on Form 10-K.

#### Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. In addition, the terms of the Loan Agreement with Hercules preclude us from paying dividends. We do not intend to pay cash dividends on our ordinary shares for the foreseeable future.

#### Recent Sales of Unregistered Securities

On July 25, 2018, we granted a non-statutory option to purchase 850,000 of our ordinary shares and 150,000 performance-based restricted share units to Theodore Schroeder, our newly appointed Chief Executive Officer, or the CEO. These equity awards were made as an inducement material to the CEO entering into employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4). The exercise price per share for the share option is \$3.53 per share, and the option award has a ten-year term and will vest over a four-year period, with 25% of the shares underlying the award vesting on the first anniversary of the grant date and the remaining 75% of the shares underlying the option award to vest monthly over the subsequent 36-month period. The performance-based restricted share units are subject to vesting as follows: 50% will vest upon certification by the board of directors of the receipt of approval by the FDA of an NDA for each of lefamulin and CONTEPO for any indication, and 50% will vest on the first anniversary of such certification by the board of directors, provided, in each case, the CEO is performing services to us on the applicable vesting dates. If the FDA does not approve an NDA for both lefamulin and CONTEPO by January 31, 2020, the performance-based restricted share units will terminate in full. The shares underlying these option awards and the performance-based restricted share units have been registered on a Form S-8 registration statement.

#### Purchase of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

**ITEM 6. SELECTED FINANCIAL DATA**

The selected financial data set forth below for the years ended December 31, 2016, 2017 and 2018 and as of December 31, 2017 and 2018 has been derived from our audited consolidated financial statements which have been prepared in accordance with generally accepted accounting practices in the United States and included elsewhere in this Annual Report. Financial data set forth below for the years ended December 31, 2014 and 2015 and as of December 31, 2014, 2015 and 2016 has been derived from the audited consolidated financial statements not included in this Annual Report. The following selected consolidated financial data should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and the notes thereto included elsewhere in this Annual Report on Form 10-K. The selected financial data in this section are not intended to replace our consolidated financial statements and the related notes. Our historical results are not necessarily indicative of the results that may be expected in the future.

(in thousands)	Year ended December 31,				
	2014	2015	2016	2017	2018(a)
<b>Consolidated Operations Data:</b>					
Revenues	\$ 2,398	\$ 3,767	\$ 6,482	\$ 5,319	\$ 9,656
<b>Operating Expenses:</b>					
Research and development	(9,355)	(23,604)	(47,994)	(49,615)	(82,288)
General and administrative	(3,739)	(7,921)	(13,535)	(29,472)	(41,743)
Total operating expenses	(13,094)	(31,525)	(61,529)	(79,087)	(124,031)
<b>Loss from operations</b>	<b>(10,696)</b>	<b>(27,758)</b>	<b>(55,047)</b>	<b>(73,768)</b>	<b>(114,375)</b>
<b>Other income (expense):</b>					
Other income (expense), net	(524)	2,427	(783)	492	(272)
Interest income	2	14	343	318	49
Interest expense	(2,910)	(22,092)	(75)	(43)	(133)
<b>Loss before income taxes</b>	<b>(14,128)</b>	<b>(47,409)</b>	<b>(55,562)</b>	<b>(73,001)</b>	<b>(114,731)</b>
Income tax (expense) benefit	(94)	445	672	(1,355)	(49)
<b>Net Loss</b>	<b>\$ (14,222)</b>	<b>\$ (46,964)</b>	<b>\$ (54,890)</b>	<b>\$ (74,356)</b>	<b>\$ (114,780)</b>
<b>Loss per share</b>					
Basic and Diluted	\$ (4.44)	\$ (4.80)	\$ (2.56)	\$ (2.49)	\$ (2.26)
<b>Weighted average number of shares:</b>					
Basic and Diluted	<u>3,247,030</u>	<u>10,583,950</u>	<u>21,478,320</u>	<u>29,830,669</u>	<u>50,795,768</u>

(in thousands)	As of December 31,				
	2014	2015	2016	2017	2018(a)
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents and short-term investments	\$ 2,150	\$ 111,440	\$ 83,884	\$ 86,879	\$ 102,228
Total assets	4,812	117,711	93,240	95,763	110,418
Long-term liabilities	5,741	84	107	435	23,982
Total liabilities	33,192	9,005	15,984	13,695	41,788
Mezzanine equity	634	—	—	—	—
Accumulated deficit	(120,587)	(171,426)	(204,842)	(279,198)	(393,978)
Total stockholder's equity (deficit)	(29,014)	108,706	77,256	82,068	68,630

- (a) On July 24, 2018, we completed the acquisition of Zavante Therapeutics, Inc., or Zavante, a privately-held late clinical-stage biopharmaceutical company. Upon the closing of the acquisition, we issued 7,336,906 of our ordinary shares to former Zavante stockholders, which together with the 815,186 ordinary shares that are issuable upon release of the Holdback Shares constitute approximately 19.9% of our ordinary shares outstanding as of immediately prior to the Closing. See Item 7 below for a further description of the transaction.

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

*You should read the following discussion and analysis of our financial condition and results of operations together with our historical consolidated financial statements and the related notes thereto appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### Overview

We are a biopharmaceutical company engaged in the development of novel anti-infective agents to treat serious infections. We have two product candidates that have been submitted to the U.S. Food and Drug Administration, or the FDA, for approval: lefamulin, potentially the first pleuromutilin antibiotic available for oral and intravenous (or IV) administration in humans, for the treatment of community-acquired bacterial pneumonia, or CABP and CONTEPO, a potentially first-in-class epoxide antibiotic for intravenous (or IV) use in the United States for complicated urinary tract infections, or cUTI. We may potentially develop lefamulin and CONTEPO for additional indications. Both lefamulin formulations and CONTEPO were granted Qualified Infectious Disease Product, or QIDP, and Fast Track designation by the FDA, enabling Priority Review of the New Drug Applications, or the NDAs by the FDA.

Lefamulin is a semi-synthetic pleuromutilin antibiotic discovered and developed by our team with the potential to be first-in-class for IV and oral in humans. It inhibits the synthesis of bacterial protein, which is required for bacteria to grow by binding with high affinity, high specificity and at molecular targets that are different than other antibiotic classes. Based on results from two global, Phase 3 clinical trials, we believe that lefamulin is well-positioned for use as a first-line monotherapy for the treatment of CABP due to its novel mechanism of action, targeted spectrum of activity, resistance profile, achievement of substantial drug concentration in lung tissue and fluid, availability of oral and IV formulations and a

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generally well-tolerated safety profile. We believe lefamulin represents a potentially important new treatment option for the five to six million adults in the United States diagnosed with CABP each year.

On July 24, 2018, we completed the acquisition of Zavante Therapeutics, Inc., or Zavante, a privately-held late clinical-stage biopharmaceutical company focused on developing novel therapies to improve the outcomes of hospitalized patients. Zavante's lead product candidate is CONTEPO™ (fosfomycin for injection, previously referred to as ZTI-01 and ZOLYD).

CONTEPO is a novel, potentially first-in-class investigational intravenous antibiotic in the United States with a broad spectrum of Gram-negative and Gram-positive activity, including activity against most contemporary multi-drug resistant, or MDR, strains such as extended-spectrum b-lactamase-, or ESBL, producing Enterobacteriaceae. IV fosfomycin has been approved for a number of indications and utilized for over 45 years in Europe to treat a variety of serious bacterial infections, including cUTIs. CONTEPO utilizes a new dosing regimen that optimize its pharmacokinetics and pharmacodynamics. We believe these attributes, the extensive clinical experience worldwide and the positive efficacy and safety results from the Phase 2/3 clinical trial support CONTEPO as a first-line treatment for cUTIs, including acute pyelonephritis, or AP, suspected to be caused by MDR pathogens. At least 20% of cUTIs are caused by MDR bacteria and limited treatment options are available in the U.S. In addition, non-clinical data have shown that CONTEPO acts in combination with certain other antibiotics to improve bacterial killing.

We submitted an NDA, for marketing approval of CONTEPO for the treatment of cUTI in adults in the United States, to the FDA in October 2018. The NDA submission is utilizing the 505(b)(2) regulatory pathway and is supported by a robust data package, including a pivotal Phase 2/3 clinical trial (known as ZEUS™), which met its primary endpoint of statistical non-inferiority to piperacillin/tazobactam in patients with cUTI, including AP. We submitted two NDAs to the FDA for the oral and IV formulations of lefamulin for the treatment of CABP in December 2018. The FDA has granted us a Prescription Drug User Fee Act, or PDUFA, target action date of April 30, 2019 for CONTEPO and a PDUFA target action date of August 19, 2019 for lefamulin. We plan to submit a marketing authorization application for lefamulin in Europe in the first half of 2019. The two NDAs are supported by two pivotal, Phase 3 clinical trials (known as LEAP 1 and LEAP 2) that evaluated the safety and efficacy of IV and oral lefamulin compared to moxifloxacin in the treatment of adults with CABP, including the option to switch from IV to oral administration and a short course oral treatment with lefamulin. In both LEAP 1 and LEAP 2, lefamulin was demonstrated to be non-inferior to moxifloxacin, and met both the FDA and European Medicines Agency, or EMA, primary and secondary efficacy endpoints for the treatment of CABP. Lefamulin was also shown to be generally well-tolerated when administered either orally or intravenously.

Both lefamulin formulations and CONTEPO were granted QIDP and Fast Track designation by the FDA, enabling potential Priority Review of the NDAs by the FDA. We were notified by the FDA that CONTEPO IV and both formulations of lefamulin were granted Priority Review following acceptance of the NDAs. We currently have a team of regional business directors and medical science liaisons in the field performing educational and market development activities. We plan to use a targeted hospital-based sales force to promote both lefamulin formulations and CONTEPO, if approved.

We believe that pleuromutilin antibiotics can help address the major public health threat posed by bacterial resistance, which the World Health Organization, or WHO, characterized in 2017 as one of the biggest threats to human health. Increasing resistance to antibiotics used to treat CABP is a growing concern and has become an issue in selecting the appropriate initial antibiotic treatment prior to determining the specific microbiological cause of the infection, referred to as empiric treatment. For example, the U.S. Centers for Disease Control and Prevention, or CDC, has classified *Streptococcus pneumoniae*, the most common respiratory pathogen, as a serious threat to human health as a result of

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increasing resistance to currently available antibiotics. In addition, the CDC recently reported on the growing evidence of widespread resistance to macrolides, widely used antibiotics that disrupt bacterial protein synthesis, in *Mycoplasma pneumoniae*, a common cause of CABP that is associated with significant morbidity and mortality. Furthermore, *Staphylococcus aureus*, including methicillin-resistant *S. aureus*, or MRSA, which has also been designated as a serious threat to human health by the CDC, has emerged as a more common cause of CABP in some regions of the world, and a possible pathogen to be covered with empiric therapy.

As a result of increasing resistance to antibiotics and the wide array of potential pathogens that cause CABP, the current standard of care for hospitalized patients with CABP whose treatment is initiated in the hospital usually involves first-line empiric treatment with a combination of antibiotics (beta-lactams and macrolides) to address all likely bacterial pathogens or monotherapy with a fluoroquinolone. Combination therapy presents the logistical challenge of administering multiple drugs with different dosing regimens, with some drugs available only as IV, and increases the risk of drug-drug interactions and the potential for serious side effects. Fluoroquinolones are associated with safety and tolerability concerns, including a relatively high risk for developing *Clostridium difficile* infection and increasing rates of resistance for uropathogens. We believe these concerns have resulted in a decreasing use of fluoroquinolones and restriction of their use within a growing number of hospitals. In addition, in May 2016, the FDA announced that an FDA safety review has shown that fluoroquinolones, when used systemically, in the form of tablets, capsules and injectable, are associated with disabling and potentially permanent serious side effects that can occur together. These side effects can involve the tendons, muscles, joints, nerves, and central nervous system. Fluoroquinolones are typically administered in combination with other antibiotics, if community-acquired MRSA is suspected. In addition, many currently available antibiotic therapies are only available for IV administration and are prescribed for seven to fourteen days, meaning continued treatment requires prolonged hospitalization or a switch to a different antibiotic administered orally, with the attendant risk that the patient might respond differently.

Effective January 1, 2017, the Joint Commission & Center for Medicare and Medicaid Services, or CMS, began requiring all U.S. hospitals to have Antibiotic Management guidelines, also known as "Stewardship" Committees, in place to identify antibiotics most appropriate and targeted to each individual patient's infection. Past efforts to "cast the widest net possible" with broad-spectrum antibiotics that affect many types of bacteria have caused problems, such as *C. difficile* infections, by killing good bacteria or increased antibiotic resistance in other bacteria in different areas of the body. Additionally, in 2016, the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America, or IDSA/SHEA, updated their Antibiotic Stewardship guidelines for antibiotic use. We believe that three key goals from these guidelines are applicable to the treatment of CABP:

- Reduce the risk of antibiotics associated with a high risk of *C. difficile* infections;
- Increase use of oral antibiotics as a strategy to improve outcomes or decrease costs; and
- Reduce antibiotic therapy to the shortest effective duration.

Consistent with the Antimicrobial Stewardship principles, we believe that lefamulin could be well suited as either a first-line or second-line empiric monotherapy for the treatment of CABP patients in the hospital setting, outpatient-transition of care or in the community setting, because of its novel mechanism of action, complete spectrum of activity for CABP pathogens, including against multidrug resistant strains, achievement of substantial drug concentrations in lung fluids and lung immune cells, and flexibility as step down oral agent with both the IV and oral formulations and favorable safety and tolerability profile.

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CONTEPO (fosfomycin for injection) is a novel, potentially first-in-class investigational intravenous antibiotic in the United States with a broad spectrum of Gram-negative and Gram-positive activity, including activity against most contemporary MDR strains such as ESBL-producing Enterobacteriaceae. CONTEPO inhibits the bacteria's ability to form a normal cell wall, which is critical for the cell's survival and growth. It works at an earlier and different stage of cell wall synthesis than other injectable antibiotics, differentiating its mechanism of action from approved injectable antibiotics. CONTEPO utilizes a dosing approach developed by Zavante for the United States that is designed to optimize its pharmacokinetics and pharmacodynamics in order to improve treatment outcomes.

The CONTEPO development program has focused on obtaining marketing approval in the United States for the treatment of cUTIs, including AP. In April 2017, Zavante announced the results of the pivotal ZEUS Study, in which CONTEPO met the primary endpoint of statistical non-inferiority versus PIP-TAZ. Zavante then met with the FDA in the second half of 2017 to discuss the filing of an NDA for CONTEPO. We submitted an NDA for marketing approval of CONTEPO for the treatment of cUTI in adults in the United States, to the FDA in October 2018. The FDA has granted us PDUFA target action date of April 30, 2019 for CONTEPO.

We believe that the ZEUS Study results, along with extensive clinical experience with IV fosfomycin for over 45 years outside the United States, support CONTEPO as a potential first-line treatment for cUTI suspected to be caused by MDR pathogens in the United States. A number of studies report that at least 20% of cUTIs are caused by MDR bacteria and limited treatment options are available in the United States. In addition, non-clinical data have shown that CONTEPO acts in combination with certain other antibiotics to improve bacterial killing.

The FDA has designated CONTEPO as a QIDP and granted Fast Track designations to CONTEPO under the GAIN Act for:

- complicated urinary tract infections, or cUTI
- complicated intra-abdominal infections, or cIAI
- hospital-acquired bacterial pneumonia, or HABP
- ventilator-associated bacterial pneumonia, or VABP
- acute bacterial skin and skin structure infections, or ABSSSI

Although we have no current plans to finance development of CONTEPO for indications other than cUTI, including AP, these designations make CONTEPO eligible for Fast Track and Generating Antibiotic Incentives Now Act, or the GAIN Act, incentives. We may in the future consider additional non-dilutive financing options to advance these programs in the clinic.

In recognition of the growing need for the development of new antibiotics, recent regulatory changes, including Priority Review and regulatory guidance enabling smaller clinical trials, have led to renewed interest from the pharmaceutical industry in anti-infective development. For example, the FDA Safety and Innovation Act became law in 2012 and included the GAIN Act, which provides incentives, including access to expedited FDA review for approval, Fast Track designation and five years of potential data exclusivity extension for the development of new QIDPs.

On March 1, 2017, Nabriva Therapeutics plc, or Nabriva Ireland, was incorporated in Ireland under the name Hyacintho 2 plc, and was renamed to Nabriva Therapeutics plc on April 10, 2017, in order to effectuate the change of the jurisdiction of incorporation of the ultimate company of the group from Austria to Ireland. Nabriva Ireland replaced Nabriva Therapeutics AG, or Nabriva Austria, as the ultimate parent company on June 23, 2017, following the conclusion of a tender offer, or the Exchange Offer, in which holders of 98.6% of the outstanding share capital of Nabriva Austria exchanged their holdings for ordinary shares, \$0.01 nominal value per share, of Nabriva Ireland, which

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we refer to as the Redomiciliation Transaction. The ordinary shares of Nabriva Ireland were issued on a one-for-ten basis to the holders of the Nabriva Austria common shares and on a one-for-one basis to the holders of the Nabriva Austria American Depositary Shares, or Nabriva Austria ADSs, participating in the Exchange Offer. On June 26, 2017, the ordinary shares of Nabriva Ireland began trading on the Nasdaq Global Market under the symbol "NBRV," the same symbol under which the Nabriva Austria ADSs were previously traded. This transaction was accounted for as a merger between entities under common control; accordingly, the historical financial statements of Nabriva Austria for periods prior to this transaction are considered to be the historical financial statements of Nabriva Ireland. As of August 18, 2017, 100% of Nabriva Austria share capital had been exchanged for ordinary shares of Nabriva Ireland.

Nabriva Austria was incorporated in October 2005 in Austria under the name Nabriva Therapeutics Forschungs GmbH, a limited liability company organized under Austrian law, as a spin-off from Sandoz GmbH and commenced operations in February 2006. In 2007, Nabriva Austria transformed into a stock corporation (*Aktiengesellschaft*) under the name Nabriva Therapeutics AG. On October 19, 2017, Nabriva Austria was converted into a limited liability company under Austrian law and renamed Nabriva Therapeutics GmbH. In 2014, we established our wholly owned U.S. subsidiary, which began operations in August 2014.

Since inception, we have incurred significant operating losses. As of December 31, 2018, we had an accumulated deficit of \$394.0 million. To date, we have financed our operations primarily through our 2018 equity offering, our term loan, our "at-the-market" offering facility, our 2017 equity offering, our 2016 rights offering, our 2015 initial public offering, private placements of our equity securities, convertible loans and research and development support from governmental grants and loans. We have devoted substantially all of our efforts to research and development, including clinical trials. Our ability to generate profits from operations and remain profitable depends on our ability to successfully develop and commercialize drugs that generate significant revenue.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect to continue to invest in critical pre-commercialization and supply chain activities prior to potentially receiving marketing approval for lefamulin and CONTEPO and making them available to patients.

Our expenses will increase if we suffer any regulatory delays or are required to conduct additional clinical trials to satisfy regulatory requirements. If we obtain marketing approval for lefamulin, CONTEPO or any other product candidate that we develop, in-license or acquire, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing.

In December 2018, we announced the closing of up to a \$75.0 million term loan with Hercules Capital, Inc., or Hercules, \$25.0 million of which was funded on the day of closing. Under the terms of the loan, in addition to the \$25.0 million received at closing, we are eligible to receive up to an aggregate of \$15.0 million in two tranches upon the approval by the FDA of the NDAs recently submitted for lefamulin and CONTEPO. We will also be eligible to receive an additional \$30.0 million of aggregate term loan advances in three separate tranches upon the achievement of specified product revenue milestones. These additional tranches are at our discretion and may only be drawn upon during specified periods of time. The final \$5.0 million tranche is available through December 31, 2021, subject to Hercules' sole discretion. We are entitled to make interest-only payments through July 1, 2020, with incremental extensions through January 1, 2022 upon the achievement of specified performance milestones. We are required to repay the term loan after the interest only period based on a monthly amortization schedule, with a final maturity date occurring on June 1, 2023.

Based on our current plans, we do not expect to generate significant revenue unless and until we obtain marketing approval for, and commercialize, lefamulin and CONTEPO. We do not expect to



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obtain marketing approval for CONTEPO before April 2019 or for lefamulin before August 2019, if at all. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization effort.

### *Acquisition of Zavante*

On July 24, 2018, we acquired Zavante, or the Acquisition, a biopharmaceutical company focused on developing CONTEPO (fosfomycin for injection) to improve the outcomes of hospitalized patients pursuant to the Agreement and Plan of Merger dated July 23, 2018, or the Merger Agreement.

Upon the closing of the Acquisition, or the Closing, we issued 7,336,906 of our ordinary shares to former Zavante stockholders, which together with the 815,186 ordinary shares that are issuable upon release of the Holdback Shares (as defined below) constitute approximately 19.9% of our ordinary shares outstanding as of immediately prior to the Closing, or the Upfront Shares.

Pursuant to the Merger Agreement, former Zavante stockholders and other equity holders, in the aggregate and subject to the terms and conditions of the Merger Agreement, will also be entitled to receive from us up to \$97.5 million in contingent consideration, of which \$25.0 million would become payable upon the first approval of an NDA from the the FDA for fosfomycin for injection for any indication, or the Approval Milestone Payment, and an aggregate of up to \$72.5 million would become payable upon the achievement of specified sales milestones, or the Net Sales Milestone Payments.

At our Extraordinary General Meeting of Shareholders held in October 2018, our shareholders approved the issuance of ordinary shares in settlement of potential milestone payment obligations that may become payable in the future to former Zavante stockholders, including the Approval Milestone Payment which will be settled in our ordinary shares. We also now have the right to settle the Net Sales Milestone Payments in our ordinary shares, except as otherwise provided in the Merger Agreement.

Subject to the terms of the Merger Agreement, 10% of the Upfront Shares, or the Holdback Shares, will serve as a source for the satisfaction of indemnification and other obligations of the former Zavante stockholders and, subject to reduction in respect of these obligations, will be issued to the former Zavante stockholders following the first anniversary of the Closing.

In addition, we assumed certain liabilities and obligations, including contractual liabilities and obligations, that were assumed by us upon the Closing. Prior to the Acquisition, Zavante was obligated to make milestone payments to the former stockholders of \$3.0 million upon marketing approval by the FDA with respect to any oral, intravenous or other form of fosfomycin, or the Zavante Products, and milestone payments of up to \$26.0 million in the aggregate upon the occurrence of various specified levels of net sales with respect to the Zavante Products. In addition, Zavante is obligated to make annual royalty payments of a mid-single-digit percentage of net sales of Zavante Products, subject to adjustment based on net sales thresholds and with such percentage reduced to low single-digits if generic fosfomycin products account for half of the applicable market on a product-by-product and country-by-country basis. Zavante will also pay a mid-single-digit percentage of transaction revenue in connection with the consummation of the grant, sale, license or transfer of market exclusivity rights for a qualified infectious disease product (within the meaning of the 21st Century Cures Act, or the Cures Act) related to a Zavante Product.

Zavante had entered into a manufacturing and supply agreement with Ercros, S.A., pursuant to which Ercros, S.A. supplies to Zavante, on an exclusive basis, a blend of fosfomycin disodium and succinic acid, or API Mixture, for CONTEPO and, if CONTEPO is approved, will supply the commercial API Mixture for CONTEPO in the United State. In addition, Zavante had entered into a

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manufacturing and supply agreement with Fisiopharma, S.r.l. pursuant to which Zavante has an obligation to purchase a minimum percentage of its commercial requirements of CONTEPO in the United States. Zavante had also entered into a manufacturing and exclusive supply agreement with Laboratorios ERN, S.A., pursuant to which Laboratorios ERN, S.A. has agreed to supply Zavante with certain technical documentation and data as required for submission of an NDA or an abbreviated new drug application for CONTEPO and certain regulatory support in connection with the commercial sale and use of CONTEPO in the United States, and which provides for payments by Zavante to Laboratorios ERN, S.A. of a one-time cash payment upon the first commercial sale of CONTEPO and subsequent quarterly payments thereafter based on the number of vials of CONTEPO sold in the United States during each quarter.

In connection with the closing of the Acquisition, we have assumed other agreements entered into by Zavante, including, among others, an R&D office lease, a collaboration agreement governing the supply and manufacturing agreements described above and a commercial packaging agreement.

We accounted for the Acquisition as an asset acquisition as the arrangement did not meet the definition of a business pursuant to the guidance prescribed in Accounting Standards Codification, or ASC, Topic 805, Business Combinations. We concluded the Acquisition did not meet the definition of a business because the transaction principally resulted in the acquisition of the exclusive rights to IV fosfomycin in the U.S. which is a single identifiable asset and represents substantially all the fair value of the assets acquired.

We expensed the acquired intellectual property as of the acquisition date as in-process research and development with no alternative future uses. We recorded an in-process research and development expense of \$32.0 million which represents \$26.9 million for the fair value of the Upfront Shares, \$4.9 million of transaction costs and \$0.2 million of net liabilities assumed.

### ***License Agreement with Sinovant Sciences, Ltd.***

In March 2018, we entered into a license agreement, or the Sinovant License Agreement, with Sinovant Sciences, Ltd. or Sinovant, an affiliate of Roivant Sciences, Ltd., to develop and commercialize lefamulin in the greater China region. As part of the Sinovant License Agreement, Nabriva Therapeutics Ireland DAC and Nabriva Therapeutics GmbH, our wholly owned subsidiaries, granted Sinovant an exclusive license to develop and commercialize, and a non-exclusive license to manufacture, certain products containing lefamulin, or the Licensed Products, in the People's Republic of China, Hong Kong, Macau, and Taiwan, which we refer to as the Territory. We retain development and commercialization rights in the rest of the world.

Under the Sinovant License Agreement, Sinovant and our subsidiaries have established a joint development committee, or the JDC, to review and oversee development and commercialization plans in the Territory. We received a \$5.0 million upfront payment pursuant to the terms of the Sinovant License Agreement and will be eligible for up to an additional \$91.5 million in milestone payments upon the achievement of certain regulatory and commercial milestone events related to lefamulin for CABP, plus an additional \$4.0 million in milestone payments if any Licensed Product receives a second or any subsequent regulatory approval in the People's Republic of China. The first milestone was a \$1.5 million payment for the submission of a Clinical Trial Application, or CTA, by Sinovant to the Chinese Food and Drug Administration that was received in February 2019. The remaining milestone payments are tied to additional regulatory approvals and annual sales targets. In addition, we will be eligible to receive low double-digit royalties on sales, if any, of Licensed Products in the Territory.

Sinovant will be solely responsible for all costs related to developing, obtaining regulatory approval of and commercializing Licensed Products in the Territory and is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize Licensed Product in the Territory. We are obligated to use commercially reasonable efforts to supply, pursuant to supply agreements to be negotiated by the parties, to Sinovant sufficient supply of lefamulin for Sinovant to

manufacture finished drug products for development and commercialization of the Licensed Products in the Territory.

Unless earlier terminated, the Sinovant License Agreement will expire upon the expiration of the last royalty term for the last Licensed Product in the Territory, which we expect will occur in 2033. Following the expiration of the last royalty term, the license granted to Sinovant will become non-exclusive, fully-paid, royalty-free and irrevocable. The Sinovant License Agreement may be terminated in its entirety by Sinovant upon 180 days' prior written notice at any time. Either party may, subject to specified cure periods, terminate the Sinovant License Agreement in the event of the other party's uncured material breach. Either party may also terminate the Sinovant License Agreement under specified circumstances relating to the other party's insolvency. We have the right to terminate the Sinovant License Agreement immediately if Sinovant does not reach certain development milestones by certain specified dates (subject to specified cure periods). The Sinovant License Agreement contemplates that we will enter into ancillary agreements with Sinovant, including clinical and commercial supply agreements and a pharmacovigilance agreement.

We have identified two performance obligations at inception: (1) the delivery of the licenses to Sinovant; and, (2) the participation in the JDC. The \$5.0 million non-refundable upfront payment was allocated entirely to the delivery of the licenses as the JDC deliverable was deemed to be de minimis. In addition, since the first \$1.5 million milestone payment is related to a submission of the CTA that is in the control of the parties', we recorded such milestone as variable consideration allocated to the licenses at the inception of the arrangement as we believe it is probable to be met and received. The future regulatory and commercial milestone payments will be recorded during the period the milestone is probable of achievement.

## **Financial Operations Overview**

### ***Revenue***

To date, we have not generated any revenues from product sales. Based on our current plans, we do not expect to generate significant revenue unless and until we obtain marketing approval for, and commercialize, lefamulin and CONTEPO. We do not expect to obtain marketing approval for CONTEPO before April 2019 or for lefamulin before August 2019, if at all. If our development efforts result in clinical success and regulatory approval, we may also enter into collaboration agreements with third parties and we may generate revenue from those agreements.

Our revenue consists principally of the collaboration revenues recorded from the Sinovant License Agreement, and includes a \$5.0 million non-refundable upfront payment received as consideration for entering into the Sinovant License Agreement, as well as \$1.5 million of variable consideration related to a milestone payment that we believe was probable to be met and was received in February of 2019. Revenue also includes governmental research premiums, non-refundable government grants and the benefit of government loans at below-market interest rates, which are more fully described below under "Critical Accounting Policies."

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

Research and development expenses represented 78.0%, 62.7% and 66.3% of our total operating expenses for the years ended December 31, 2016, 2017 and 2018, respectively.

For each of our research and development programs, we incur both direct and indirect expenses. Direct expenses include third party expenses related to these programs such as expenses for manufacturing services, non-clinical and clinical studies and other third party development services. Indirect expenses include salaries and related costs, including stock-based compensation, for personnel in research and development functions, infrastructure costs allocated to research and development

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operations, costs associated with obtaining and maintaining intellectual property associated with our research and development operations, laboratory consumables, consulting fees related to research and development activities and other overhead costs. We utilize our research and development staff and infrastructure resources across multiple programs, and many of our indirect costs historically have not been specifically attributable to a single program. Accordingly, we cannot state precisely our total indirect costs incurred on a program-by-program basis.

The following table summarizes our direct research and development expenses by program and our indirect costs.

(in thousands)	Year Ended December 31,		
	2016	2017	2018
<b>Direct costs</b>			
Lefamulin	\$ 36,003	\$ 34,538	\$ 20,685
CONTEPO	—	—	3,423
In-process research and development	—	—	32,048
Other programs and initiatives	71	223	53
<b>Indirect costs</b>	11,920	14,854	26,079
<b>Total</b>	<b>\$ 47,994</b>	<b>\$ 49,615</b>	<b>\$ 82,288</b>

We expect to continue to incur research and development expenses in connection with required regulatory activities, our activities related to our ongoing pediatric studies of lefamulin for the treatment of CABP and of CONTEPO for the treatment of cUTI, the pursuit of the clinical development of lefamulin and CONTEPO for additional indications and engagement in earlier stage research and development activities. It is difficult to estimate the duration and completion costs of our research and development programs.

The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the scope, progress, costs and results of clinical trials and other research and development activities;
- the costs, timing and outcome of regulatory review of our product candidates;
- the efficacy and potential advantages of our product candidates compared to alternative treatments, including any standard of care, and our ability to achieve market acceptance for any of our product candidates that receive marketing approval;
- the costs and timing of commercialization activities, including product sales, marketing, distribution and manufacturing, for any of our product candidates that receive marketing approval; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining, enforcing and protecting our intellectual property rights and defending against any intellectual property-related claims.

A change in the outcome of any of these variables with respect to the development of our product candidates could result in a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials or other testing beyond those that we have completed or currently contemplate will be required for the completion of clinical development of any product candidate, we could be required to expend significant additional resources and time on the completion of clinical development of that product candidate.

### ***General and Administrative Expenses***

General and administrative expenses represented 22.0%, 37.3% and 33.7% of our total operating expenses for the years ended December 31, 2016, 2017 and 2018, respectively.

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation not related to research and development activities for personnel in our finance, information technology, commercial, medical affairs and administrative functions. General and administrative expenses also include costs related to professional fees for auditors, lawyers and tax advisors and consulting fees not related to research and development operations, as well as functions that are partly or fully outsourced by us, such as accounting, payroll processing and information technology.

We expect general and general administrative expenses to increase with the expansion of our staff and management team in anticipation of the commercialization of lefamulin and CONTEPO, particularly commercial, medical affairs, technical operations and business development functions

### **Critical Accounting Policies**

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. The preparation of our 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 end of the reporting period, as well as the reported revenues and expenses during the reporting periods. We base our estimates on our limited historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing at the end of this filing. However, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

### ***Research Premium and Grant Revenue***

As a company that carries out research and development activities, we benefit from the Austrian research and development support regime, under which we are eligible to receive a research premium from the Austrian government equal to 12% of a specified research and development cost base. Qualifying expenditures largely comprise research and development activities conducted in Austria, however, the research premium is also available for certain related third-party expenses with additional limitations. We recorded research premiums of \$6.2 million, \$4.8 million and \$2.6 million for the years ended December 31, 2016, 2017, and 2018, respectively. We have not received any research premium for our qualified 2018 expenditures as of December 31, 2018. We recognize the research premium, as long as we have incurred research and development expenses. Significant judgment is required in determining which expenditures are eligible to be included in the research and development costs base and such costs are subject to review by the Austrian government.

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

Research expenses are defined as costs incurred for current or planned investigations undertaken with the prospect of gaining new scientific or technical knowledge and understanding. Development

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expenses are defined as costs incurred for the application of research findings or specialist knowledge to production, production methods, services or goods prior to the commencement of commercial production or use. We expense all research and development costs as incurred.

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with preclinical development activities;
- the production of preclinical and clinical trial materials;
- CROs in connection with clinical trials; and,
- investigative sites in connection with clinical trials.

### **Implications of Being an Emerging Growth Company**

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

- an exemption from compliance with the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002 on the design and effectiveness of our internal controls over financial reporting;
- an exemption from compliance with any requirement that the Public Company Accounting Oversight Board may adopt regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure about the company's executive compensation arrangements; and
- exemptions from the requirements to obtain a non-binding advisory vote on executive compensation or a shareholder approval of any golden parachute arrangements.

We may take advantage of these provisions until December 31, 2020 or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earlier to occur of: the last day of the fiscal year in which we have more than \$1 billion in annual revenues (as may be inflation adjusted by the SEC from time-to-time); the date we qualify as a "large accelerated filer," with at least more than \$700 million in market value of our share capital held by nonaffiliates; or the issuance by us of more than \$1 billion of non-convertible debt over a three-year period. We may choose to take advantage of some, but not all, of the available benefits under the JOBS Act. We have taken advantage of some reduced reporting burdens in this Annual Report. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of delayed adoption of new or revised accounting standards and, therefore, we will adopt new

or revised accounting standards on the relevant dates on which adoption of such standards is required by for non-emerging growth companies.

## Results of Operations

### Comparison of Years Ended December 31, 2017 and 2018

(in thousands)	Year ended December 31,		Change
	2017	2018	
<b>Consolidated Operations Data:</b>			
Revenues	\$ 5,319	\$ 9,656	\$ 4,337
<b>Operating Expenses:</b>			
Research and development	(49,615)	(82,288)	(32,673)
General and administrative	(29,472)	(41,743)	(12,271)
Total operating expenses	(79,087)	(124,031)	(44,944)
<b>Loss from operations</b>	<b>(73,768)</b>	<b>(114,375)</b>	<b>(40,607)</b>
<b>Other income (expense):</b>			
Other income (expense), net	492	(272)	(764)
Interest income (expense), net	275	(84)	(359)
<b>Loss before income taxes</b>	<b>(73,001)</b>	<b>(114,731)</b>	<b>(41,730)</b>
Income tax (expense) benefit	(1,355)	(49)	1,306
<b>Net loss</b>	<b>\$ (74,356)</b>	<b>\$ (114,780)</b>	<b>\$ (40,424)</b>

#### Revenues

Revenues increased by \$4.3 million from \$5.3 million for the year ended December 30, 2017 to \$9.7 million for the year ended December 31, 2018, primarily due to the \$5.0 million upfront payment received from our Sinovant License Agreement, as well as a \$1.5 million of variable consideration related to a future milestone payment pursuant to the Sinovant License Agreement that we believe is probable to be met. Grant revenue from research premiums provided to us by the Austrian government decreased by \$2.2 million as a result of a decrease in our research and development expenses for which we can receive grant revenue.

#### Research and Development Expenses

Research and development expenses increased by \$32.7 million from \$49.6 million for the year ended December 31, 2017 to \$82.3 million for the year ended December 31, 2018. The increase was primarily due to a \$32.0 million increase for in-process research and development expenses associated with the acquisition of Zavante assets, a \$6.5 million increase in research consulting fees, a \$6.5 million increase associated with the payment of the NDA fees to the FDA for lefamulin and CONTEPO, a \$1.9 million increase in staff costs due to the addition of employees, a \$0.3 million increase in travel and other research and development costs, partly offset by a \$13.9 million decrease in research materials and purchased services related to the development of lefamulin and a \$0.7 million decrease in stock-based compensation expense.

#### General and Administrative Expenses

General and administrative expense increased by \$12.3 million from \$29.5 million for the year ended December 31, 2017 to \$41.7 million for the year ended December 31, 2018. The increase was primarily due to a \$2.6 million increase of advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees, a \$9.6 million increase in staff costs

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due to the addition of employees, a \$0.1 million increase in stock-based compensation expense, a \$1.0 million increase in other corporate costs, a \$0.7 million increase in travel expenses, and a \$0.4 million increase in infrastructure costs, partly offset by a \$2.2 million decrease in legal fees.

*Other Income (Expense), net*

Other income (expense), net decreased by \$0.8 million from \$0.5 million income for the year ended December 31, 2017, to \$0.3 million expense for the year ended December 31, 2018 primarily due to re-measurements of our foreign currency account balances.

*Interest income (expense), net*

During the year ended December 31, 2018, net interest expense increased over the prior year due to lower interest earned on cash and cash equivalents.

*Income Tax Expense*

Our income tax expense was \$1.4 million for the year ended December 31, 2017 compared to \$49,000 for the year ended December 31, 2018. The change to income tax expense was primarily due to the recognition of a valuation allowance on deferred tax assets in 2017.

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

(in thousands)	Year ended December 31,		Change
	2016	2017	
<b>Consolidated Operations Data:</b>			
Revenues	\$ 6,482	\$ 5,319	\$ (1,163)
<b>Costs and Expenses:</b>			
Research and development	(47,994)	(49,615)	(1,621)
General and administrative	(13,535)	(29,472)	(15,937)
Total operating expenses	(61,529)	(79,087)	(17,558)
<b>Loss from operations</b>	<b>(55,047)</b>	<b>(73,768)</b>	<b>(18,721)</b>
<b>Other income (expense):</b>			
Other income (expense), net	(783)	492	1,275
Interest income (expense), net	268	275	7
<b>Loss before income taxes</b>	<b>(55,562)</b>	<b>(73,001)</b>	<b>(17,439)</b>
Income tax (expense) benefit	672	(1,355)	(2,027)
<b>Net loss</b>	<b>\$ (54,890)</b>	<b>\$ (74,356)</b>	<b>\$ (19,466)</b>

*Revenues*

Revenues, consisting primarily of research premium and grant revenue, decreased by \$1.2 million from \$6.5 million for the year ended December 31, 2016 to \$5.3 million for the year ended December 31, 2017. The change was primarily due to a \$1.4 million decrease in grant revenue from research premiums provided to us by the Austrian government as a result of lower applicable research and development expenses, which was offset by a \$0.2 million increase in grant income.

*Research and Development Expenses*

Research and development expenses increased by \$1.6 million from \$48.0 million for the year ended December 31, 2016 to \$49.6 million for the year ended December 31, 2017. The increase was



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primarily due to a \$2.1 million increase in staff costs due to the addition of employees and a \$1.2 million increase in share-based compensation expense also due to the inclusion of additional employees in our share-based compensation plan, partially offset by a \$1.5 million decrease in direct costs for purchased services related to the development of lefamulin and a \$0.2 million decrease of advisory and external consultancy, travel and other expenses.

### *General and Administrative Expenses*

General and administrative expense increased by \$16.0 million from \$13.5 million for the year ended December 31, 2016 to \$29.5 million for the year ended December 31, 2017. The increase was primarily due to a \$4.1 million increase in legal fees mainly related to the redomiciliation of our parent company from Austria to Ireland, a \$6.1 million increase of advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees, a \$2.0 million increase in share-based compensation expense due to the inclusion of additional employees in our share-based compensation plan, a \$2.8 million increase in staff costs due to the addition of employees, a \$0.7 million increase in VAT tax expenses, and a \$0.3 million increase in support, infrastructure and other corporate costs.

### *Other income (expense), net*

Other income (expense), net increased by \$1.3 million from a net expense of \$0.8 million for the year ended December 31, 2016 to net income of \$0.5 million for the year ended December 31, 2017. The increase was primarily due to re-measurements of our foreign currency account balances.

### *Interest expense, net*

During the year ended December 31, 2017, net interest income was relatively flat compared to the same period in 2016.

### *Income tax (Expense) Benefit*

Our income tax expense was \$1.4 million for the year ended December 31, 2017 compared to an income tax benefit of \$0.7 million for the year ended December 31, 2016. The year over year change was primarily due to the recognition of a valuation allowance against deferred tax assets in our foreign subsidiaries. Our income tax (expense) benefit includes Irish, Austrian and U.S. income taxes at statutory rates and the effects of various permanent differences.

## **Liquidity and Capital Resources**

Since our inception, we have incurred net losses and generated negative cash flows from our operations. To date, we have financed our operations through the sale of equity securities, including our initial public offering, public follow-on offerings and private placements of our equity securities, convertible and term debt financings, payments from a collaboration partner and research and development support from governmental grants and loans.

In December 2018, we announced the closing of up to a \$75.0 million term loan with Hercules, or the Loan Agreement, \$25.0 million of which was funded on the day of closing. Under the terms of the loan, in addition to the \$25.0 million received at closing, we are eligible to receive up to an aggregate of \$15.0 million in two tranches upon the approval by the FDA of the NDAs recently submitted for lefamulin and CONTEPO. We will also be eligible to receive an additional \$30.0 million of aggregate term loan advances in three separate tranches upon the achievement of specified product revenue milestones. These additional tranches are at our discretion and may only be drawn upon during specified periods of time. The final \$5.0 million tranche is available through December 31, 2021, subject to the lenders' sole discretion. We are entitled to make interest-only payments through July 1,

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2020, with incremental extensions through January 1, 2022 upon the achievement of specified performance milestones. We are required to repay the term loan after the interest only period based on a monthly amortization schedule, with a final maturity date occurring on June 1, 2023. The term loan bears interest at an annual rate equal to the greater of 9.80% and 9.80% plus the prime rate of interest minus 5.50%. The Loan Agreement provides for interest-only payments through July 1, 2020, which may be incrementally extended from time to time upon the occurrence of certain conditions through January 1, 2022, and repayment of the aggregate outstanding principal balance of the term loan thereafter in monthly installments through June 1, 2023. In addition, we are required to pay a fee of 6.95% of the aggregate amount of advances under the Loan Agreement at maturity. At our option, we may elect to prepay any portion of the outstanding term loan that is greater than or equal to \$5.0 million by paying such portion of the principal balance and all accrued and unpaid interest thereon plus a prepayment charge equal to the following percentage of the principal amount being prepaid: (i) 3.0% if the term loan is prepaid during the first 12 months following the initial closing, (ii) 2.0% if the term loan is prepaid after 12 months following the initial closing but before 24 months following the initial closing and (iii) 1.0% if the term loan is prepaid any time thereafter but prior to the final maturity date. We are also required to satisfy certain financial covenants, including an obligation to maintain specified minimum amounts of cash and cash equivalents in accounts pledged to Hercules.

In July 2018, we completed an underwritten public offering of 18,181,818 ordinary shares at a public offering price of \$2.75 per share, resulting in gross proceeds of \$50.0 million and net proceeds to us of \$46.3 million, after deducting underwriting discounts and commissions and offering expenses.

In March 2018, we entered into a sales agreement, or the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, pursuant to which, from time to time, we may offer and sell our ordinary shares having an aggregate offering price of up to \$50.0 million through Cantor pursuant to an effective universal shelf registration statement. Sales of our ordinary shares, if any, under the agreement with Cantor may be made in sales deemed to be an "at-the-market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended.

In September 2017 we completed an underwritten public offering of 9,411,765 ordinary shares at a public offering price of \$8.50 per share, resulting in gross proceeds of \$80.0 million and net proceeds to us of \$73.3 million, after deducting underwriting discounts and commissions and offering expenses.

In December 2016, we completed a rights offering and a related underwritten offering for the sale of an aggregate of 588,127 common shares resulting in aggregate gross proceeds of approximately \$24.8 million and net proceeds to us of \$20.6 million, after deducting underwriting fees and offering expenses.

## Cash Flows

### *Comparison of Years Ended December 31, 2017 and 2018*

The following table summarizes our cash flows for the years ended December 31, 2017 and 2018:

<u>(in thousands)</u>	<u>Year ended</u> <u>December 31,</u>	
	<u>2017</u>	<u>2018</u>
Net cash (used in) provided by:		
Operating activities	\$ (69,348)	\$ (72,723)
Investing activities	49,749	(4,604)
Financing activities	72,219	92,923
Effect of foreign currency translation on cash	1,371	(362)
Net increase (decrease) in cash and cash equivalents	<u>\$ 53,991</u>	<u>\$ 15,234</u>

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*Operating Activities*

Cash flow used in operating activities increased by \$3.4 million from \$69.3 million for the year ended December 31, 2017 to \$72.7 million for the year ended December 31, 2018 primarily due to a \$8.7 million increase in net loss, after adjustments for non-cash amounts included in net loss and higher working capital of \$5.3 million primarily due to changes in accrued expenses and other current liabilities.

*Investing Activities*

Cash flow provided by investing activities decreased by \$54.4 million from \$49.7 million of cash provided for the year ended December 31, 2017 to \$4.6 million cash used for the year ended December 31, 2018 primarily due to a \$51.0 million decrease in proceeds from sale of available-for-sale financial assets to fund operational cash outflows and \$4.3 million in transaction costs related to the acquisition of Zavante assets.

*Financing Activities*

Cash flow provided by financing activities increased by \$20.7 million from \$72.2 million for the year ended December 31, 2017 to \$92.9 million for the year ended December 31, 2018 primarily due to net proceeds of \$24.2 million related to sales of our ordinary shares under our ATM Agreement, net proceeds of \$46.3 million from our July 2018 public offering of ordinary shares and the \$25.0 million advance under our December 2018 Loan Agreement with Hercules.

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

The following table summarizes our cash flows for the years ended December 31, 2016 and 2017:

<u>(in thousands)</u>	<u>Year ended</u> <u>December 31,</u>	
	<u>2016</u>	<u>2017</u>
Net cash (used in) provided by:		
Operating activities	\$ (48,325)	\$ (69,348)
Investing activities	23,352	49,749
Financing activities	22,301	72,219
Effect of foreign currency translation on cash	(996)	1,371
Net increase (decrease) in cash and cash equivalents	<u>\$ (3,668)</u>	<u>\$ 53,991</u>

*Operating Activities*

Cash flow utilized by operating activities increased by \$21.0 million from \$48.3 million for the year ended December 31, 2016 to \$69.3 million for the year ended December 31, 2017 primarily due to a \$16.1 million increase in net loss, after adjustments for non-cash amounts included in net loss and higher working capital of \$4.9 million primarily due to changes in accrued expenses and other current liabilities.

*Investing Activities*

Cash flow provided by investing activities increased by \$26.4 million from \$23.4 million cash inflow in the year ended December 31, 2016 to \$49.7 million cash inflow in the year ended December 31, 2017 primarily due to an increase of \$15.0 million in proceeds from sale of available-for-sale securities to fund operational cash out flows and a decrease of \$57.0 million in purchases of available-for

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sale-securities in 2017. The year over year increase in investing activities was partially offset by a \$45.0 million decrease in proceeds from maturities of term deposits.

### *Financing Activities*

Cash flow provided by financing activities increased by \$49.9 million from \$22.3 million for the year ended December 31, 2016 to \$72.2 million for the year ended December 31, 2017 primarily due to the gross proceeds of \$80.0 million from our 2017 equity financing, compared to the proceeds of \$24.8 million from our rights offering and related underwritten offering in December 2016. The year-over-year increase in financing cash inflows was partially offset by a \$5.3 million increase in equity transaction costs.

### **Operating and Capital Expenditure Requirements**

We anticipate that our expenses will increase as we continue to invest in critical pre-commercialization activities prior to obtaining marketing approval for lefamulin and CONTEPO. If we obtain marketing approval for lefamulin, CONTEPO or any other product candidate that we develop, in-license or acquire, we expect to incur significant additional commercialization expenses related to product sales, marketing, distribution and manufacturing. In addition, our expenses will increase if we suffer any regulatory delays or are required to conduct additional clinical trials to satisfy regulatory requirements.

In addition, our expenses will increase if and as we:

- initiate or continue the research and development of lefamulin and CONTEPO for additional indications and of our other product candidates;
- seek to discover and develop additional product candidates;
- seek marketing approval for any product candidates that successfully complete clinical development;
- continue to establish a medical affairs, sales, marketing and distribution infrastructure and build up inventory of finished product and its components to commercialize any product candidates for which we receive marketing approval;
- in-license or acquire other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- establish and expand manufacturing arrangements with third parties;
- Draw additional funds under the Loan Agreement with Hercules;
- expand our physical presence in the United States and Ireland; and,
- add operational, financial and management information systems and personnel, including personnel to support our product development, our operations as a public company and our planned commercialization efforts.

We expect that our cash, cash equivalents and short-term investments as of December 31, 2018, proceeds from the sale of ordinary shares under the our ATM Agreement of \$5.9 million in the first quarter of 2019, as well as a \$1.5 million milestone payment received in February 2019 under our license agreement with Sinovant Sciences, Ltd., and research premiums from the Austrian government for our qualified research and development expenditures, will be sufficient to enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into the second quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate assumes, among other

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things, that we do not obtain any additional funding through grants and clinical trial support, collaboration agreements, equity or debt financings, including additional advances under the Loan Agreement with Hercules. We may be eligible to borrow up an additional \$50.0 million under our Loan Agreement with Hercules if we achieve specified regulatory and product revenue milestones, including \$10.0 million that we will be eligible to borrow upon the approval by the FDA of an NDA for lefamulin and \$5.0 million that we will be eligible to borrow upon the approval by the FDA of an NDA for CONTEPO.

We expect to seek additional funding in future periods for purposes of investment in our commercial and medical affairs organization, as well as investing in our supply chain, in an effort to enhance the potential commercial launch of lefamulin and CONTEPO.

Our future capital requirements will depend on many factors, including:

- the costs and timing of process development and manufacturing scale-up activities associated with lefamulin and CONTEPO;
- the costs, timing and outcome of regulatory review of lefamulin and CONTEPO;
- the costs of commercialization activities for lefamulin and CONTEPO if we receive, or expect to receive, marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities, including the costs of building finished product inventory and its components in preparation of initial marketing of lefamulin and CONTEPO;
- subject to receipt of marketing approval, revenue received from commercial sales of lefamulin and CONTEPO;
- the costs of developing lefamulin and CONTEPO for the treatment of additional indications;
- our ability to establish collaborations on favorable terms, if at all;
- the scope, progress, results and costs of product development of any other product candidates that we may develop;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property-related claims;
- the continued availability of Austrian governmental grants;
- the need to satisfy interest and principal obligations in our debt facility;
- the rate of the expansion of our physical presence in the United States and Ireland; and
- the costs of operating as a public company in the United States.

Conducting clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. Our commercial revenues, if any, will be derived from sales of lefamulin, CONTEPO or any other products that we successfully develop, in-license or acquire, none of which are yet commercially available. In addition, if approved, lefamulin, CONTEPO or any other product candidate that we develop, in-license or acquire may not achieve commercial success. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

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Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, and funding from local and international government entities and non-government organizations in the disease areas addressed by our product candidates and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our shareholders. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

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 technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings 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.

**Capital Expenditures**

Capital expenditures were \$1.2 million and \$0.2 million for the years ended December 31, 2017 and 2018, respectively. We made no significant investments in intangible assets during the years ended December 31, 2017 and 2018. Currently, there are no material capital projects planned in 2019.

**Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, other than our operating lease obligations for our facilities in Austria, Ireland and the United States.

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

We are exposed to a variety of financial risks in the ordinary course of our business: market risk, credit risk and liquidity risk. Our overall risk management program focuses on preservation of capital given the unpredictability of financial markets. These market risks are principally limited to interest rate and foreign currency fluctuations.

***Market Risk***

We do not have any significant credit risk exposure to any single counterparty or any group of counterparties having similar characteristics. The credit risk on liquid funds (bank accounts, cash balances, marketable securities and term deposits) is limited because the counterparties are banks with high credit ratings from international credit rating agencies. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes.

We are exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the euro and the British pound. Our functional currency is the U.S. dollar, but we receive payments and acquire materials, in each of these other currencies. We have not established any formal practice to manage the foreign exchange risk against our functional currency. However, we attempt to minimize our net exposure by buying or selling foreign currencies at spot rates upon receipt of new funds to facilitate committed or anticipated foreign currency transactions.

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Interest rate risk may arise from short-term or long-term debt. In December 2018, we announced the closing of up to a \$75.0 million term loan with Hercules, \$25.0 million of which was funded on the day of closing. This initial draw and subsequent draws will have interest rates set based on US Prime Interest Rate at the time of the draw. If the US Prime Interest Rate increases, our interest rate will increase.

Due to the short-term nature of our investment portfolio, we do not believe an immediate 10% increase in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

### ***Liquidity Risk***

Since our inception, we have incurred net losses and generated negative cash flows from our operations. Based on our current operating plans, we expect that our cash, cash equivalents and short-term investments as of December 31, 2018, proceeds from the sale of ordinary shares under the our ATM Agreement of \$5.9 million in the first quarter of 2019, as well as a \$1.5 million milestone payment received in February 2019 under our license agreement with Sinovant Sciences, Ltd., and research premiums from the Austrian government for our qualified research and development expenditures, will be sufficient to enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into the second quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate assumes, among other things, that we do not obtain any additional funding through grants and clinical trial support, collaboration agreements, equity or debt financings, including additional advances under the Loan Agreement with Hercules. We may be eligible to borrow up an additional \$50.0 million under our Loan Agreement with Hercules if we achieve specified regulatory and product revenue milestones, including \$10.0 million that we will be eligible to borrow upon the approval by the FDA of an NDA for lefamulin and \$5.0 million that we will be eligible to borrow upon the approval by the FDA of an NDA for CONTEPO.

We anticipate that our expenses will increase substantially as we continue to seek marketing approval for and prepare for the commercialization of lefamulin and CONTEPO, and, possibly, other product candidates. If we obtain marketing approval for lefamulin and CONTEPO or any other product candidate that we develop, in-license or acquire, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. We have developed plans to mitigate this risk, which primarily consist of raising additional capital through a combination of equity or debt financings, new collaborations, and reducing cash expenditures.

However, there can be no assurance that we will be successful in acquiring additional capital at level sufficient to fund our operations or on terms favorable to us.

If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce to eliminate our research and development programs or any future commercialization effort.

### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

Our consolidated financial statements, together with the report of our independent registered public accounting firm, appear on pages F-1 through F-31 of this Annual Report on Form 10-K.

### **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

**Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures**

We have carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) under the supervision and the participation of the company's management, which is responsible for the management of the internal controls, and which includes our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively). The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon our evaluation of our disclosure controls and procedures as of December 31, 2018, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable level of assurance.

**Management's Annual Report on Internal Control Over Financial Reporting**

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our 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: (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and board of directors; and (3) 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.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.



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Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(e) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled "*Internal Control—Integrated Framework (2013)*" published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2018, the end of our most recent fiscal year.

Our independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. For as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) that occurred during the three months ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

**PART III****ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE****Board of Directors**

Set forth below are the names and certain biographical information about each member of our board of directors as of March 1, 2019. The information presented includes each director's principal occupation and business experience for at least the past five years and the names of other public companies of which he or she has served as a director during the past five years.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Daniel Burgess(1)(3)	57	Director, Chairman of the Board
Theodore Schroeder	63	Director, Chief Executive Officer
Colin Broom, MD	63	Director
Carrie Bourdow(2)	56	Director
Mark Corrigan, MD(2)(3)	61	Director
Charles A. Rowland, Jr.(1)(2)	60	Director
George H. Talbot, MD(3)	70	Director
Stephen Webster(1)(3)	57	Director

- (1) Member of the audit committee.
- (2) Member of the compensation committee.
- (3) Member of the nominating and corporate governance committee.

**Daniel Burgess** has served on our board of directors since June 23, 2017. Mr. Burgess was a member of the supervisory board of Nabriva Austria and served as its chairman from October 2016 until the Redomiciliation. Mr. Burgess has been a venture partner at SV Life Sciences since 2014. He was previously president and chief executive officer of Rempex Pharmaceuticals, an antibiotics company he co-founded in 2011 and that was subsequently sold to The Medicines Company in 2013. Prior to this, Mr. Burgess was president and chief executive officer of Mpex Pharmaceuticals from 2007 until its acquisition by Aptalis Inc. in 2011. He also served as chief operating officer and chief financial officer of Hollis-Eden Pharmaceuticals from 1999 to 2007 and chief financial officer at Nanogen Inc. from 1998 to 1999. Prior to this, Mr. Burgess spent 10 years at Gensia Sicom, Inc. (acquired by Teva Pharmaceutical Industries Ltd), where he held a variety of executive-level positions with responsibility for overall finance for the company. He began his career at Castle & Cooke, and Smith Barney, Harris Upham and Company. Mr. Burgess also is chairman of the board of directors of Atox Bio, a private biotechnology company, and of Pulmocide Ltd., a private drug discovery company; and executive chairman of Qpex Biopharma, a drug discovery company. In addition, he serves as a member of the boards of directors of Cidara Therapeutics, Inc., a public biotechnology company; Arbutus Biopharma Corp., a public biotechnology company; and Leiter's Inc., a private compounding pharmacy. Mr. Burgess was a member of the board of directors of Santarus, Inc., from 2004 until its acquisition in 2014 by Salix Pharmaceuticals Inc. (now Valeant Pharmaceuticals International, Inc.). He received his B.A. in economics from Stanford University and an M.B.A. from Harvard University. We believe Mr. Burgess is qualified to serve as a director because of his expertise and experience as an executive in the pharmaceutical industry and his educational background.

**Theodore Schroeder** has served on our board of directors and as chief executive officer since July 24, 2018. During the last 30 years, Mr. Schroeder has been focused on drug development and commercialization in both large and small pharmaceutical companies. Most recently, he served as president, chief executive officer and director of Zavante Therapeutics from June 2015 until its acquisition by Nabriva Therapeutics in July 2018. Mr. Schroeder co-founded Cadence Pharmaceuticals

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in 2004 and previously held leadership roles at Elan Pharmaceuticals, Dura Pharmaceuticals and earlier in his career, Bristol-Myers Squibb. He currently serves on the board of Cidara Therapeutics, Otonomy and Collegium Pharmaceutical. He is a former chair of BIOCOM, the California life sciences trade association and in 2014, he was named the EY Entrepreneur of the Year for the San Diego region and was listed as a national finalist. He received a bachelor's degree in management from Rutgers University. We believe Mr. Shroeder is qualified to serve as a director because of his expertise and experience as an executive in the pharmaceutical industry, his service on other boards of directors and his educational background.

**Colin Broom** has served on our board of directors since June 23, 2017 and as our chief executive officer since April 12, 2017 until July 24, 2018. Dr. Broom was previously chief executive officer of Nabriva Austria from August 2014 until the Redomiciliation. Prior to joining Nabriva Austria, he served as chief scientific officer at ViroPharma Incorporated from 2004 until it was acquired by Shire plc in 2014. Dr. Broom served as vice president of clinical development and medical affairs in Europe for Amgen Inc. from 2000 to 2003 and previously held several leadership positions with Hoechst Marion Roussel (now Sanofi), SmithKline Beecham and Glaxo (now GlaxoSmithKline). Dr. Broom served as a member of the board of directors of NPS Pharmaceuticals, Inc. from 2009 until its acquisition by Shire in 2015. He is a member of the U.K. Royal College of Physicians and a fellow of the Faculty of Pharmaceutical Medicine. Dr. Broom received his B.Sc. from University College London and M.B.B.S. from St. George's Hospital Medical School. We believe that Dr. Broom is qualified to serve as a director due to his extensive experience in all stages of drug development and commercialization.

**Carrie Bourdow** has served on our board of directors since June 23, 2017. Ms. Bourdow has been the President, Chief Executive Officer, and member of the Trevena Board of Directors since October 2018. She has served in various senior positions at Trevena since May 2015. She joined Trevena as Chief Commercial Officer and was appointed Executive Vice President and Chief Operating Officer in January 2018. Prior to joining Trevena, Ms. Bourdow was Vice President of Marketing at Cubist Pharmaceuticals, Inc., from 2013 until its acquisition by Merck & Co., Inc. in January 2015. At Cubist, Ms. Bourdow led launch strategy, marketing, reimbursement, and operations for five acute care hospital pharmaceuticals. Prior to Cubist, Ms. Bourdow served for more than 20 years at Merck & Co., Inc., where she held positions of increasing responsibility across multiple therapeutic Ms. Bourdow holds a B.A. degree from Hendrix College and an M.B.A. from Southern Illinois University. We believe Ms. Bourdow is qualified to serve as a director due to her extensive experience in the biopharmaceutical industry, including her experience with anti-infectives and with the commercialization of new drugs.

**Mark Corrigan** has served on our board of directors since June 23, 2017. Dr. Corrigan previously served on the supervisory board of Nabriva Austria from October 2016 until the Redomiciliation. Since January 2015, Dr. Corrigan has been executive chairman of BlackThorn Therapeutics. Dr. Corrigan served as president and chief executive officer of Zalicus, Inc. from January 2010 until July 2014. Previously, Dr. Corrigan was executive vice president of research and development at the specialty pharmaceutical company Sepracor Inc., and prior to this, he spent 10 years with Pharmacia & Upjohn, most recently as Group Vice President of Global Clinical Research and Experimental Medicine. Before entering the healthcare industry, Dr. Corrigan was in academic research at the University of North Carolina at Chapel Hill School of Medicine, where he maintains a faculty appointment as Adjunct Professor in the Psychiatry Department. Dr. Corrigan currently serves on the boards of directors of BlackThorn Therapeutics, Inc., a private clinical-stage biopharmaceutical company, Novelin Therapeutics, Inc., a public biopharmaceutical company, Correvio Pharma Corporation (formerly Cardiome Pharma), a public biopharmaceutical company, Quartet Medicine, a private biotechnology company, and Accele BioPharma Inc., a private biopharmaceutical company, and previously served on the boards of directors of CoLucid Pharmaceuticals, Inc., Cubist Pharmaceuticals, Inc., Avanair Pharmaceuticals, Inc., and EPIRUS Biopharmaceuticals, Inc., where he served as chairman of the

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board of directors. Dr. Corrigan holds an M.D. from the University of Virginia and received specialty training in psychiatry at Maine Medical Center and Cornell University. We believe Dr. Corrigan is qualified to serve as a director due to his extensive experience in the biopharmaceutical industry as both an executive and a board member and because of his education and training.

**George H. Talbot** has served on our board of directors since June 23, 2017. Dr. Talbot previously served on the supervisory board of Nabriva Austria from 2009 until the Redomiciliation. Dr. Talbot has been the principal at Talbot Advisors LLC, a biopharmaceutical company consultancy, since 2007 and prior to that, from 2000 to 2006. From 2006 to 2007, he served as chief medical officer and executive vice president of Cerexa, Inc. prior to its acquisition by Forest Laboratories, Inc. Dr. Talbot also worked closely with Calixa Therapeutics, Inc. and Durata Therapeutics, Inc., prior to their acquisitions by Cubist Pharmaceuticals, Inc. and Actavis plc, respectively. He was an initial member of the Infectious Diseases Society of America's Antimicrobial Availability Task Force ("Bad Bugs, No Drugs") and recently completed a seven-year tenure as co-chair of the Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium Projects for Endpoint Development in Acute Bacterial Skin and Skin Structure Infections, Community-acquired Bacterial Pneumonia, and Hospital-acquired Bacterial Pneumonia/Ventilator-associated Bacterial Pneumonia, which made evidence-based recommendations to the Food and Drug Administration for its Guidance development in these indications. Dr. Talbot received his B.A. from Wesleyan University, his M.D. from the Yale University School of Medicine, and his Infectious Diseases fellowship training at the University of Pennsylvania. After serving as a faculty member of the Infectious Diseases Section at the University of Pennsylvania, he joined the anti-infectives group at Rhone-Poulenc-Rorer in 1990. We believe that Dr. Talbot is qualified to serve as a director due to his education, training and extensive experience in the biopharmaceutical industry.

**Charles A. Rowland, Jr.** has served on our board of directors since June 23, 2017. Mr. Rowland previously served on the supervisory board of Nabriva Austria from January 2015 until the Redomiciliation. Mr. Rowland served as chief executive officer of Aurinia Pharmaceuticals Inc. from April 2016 to January 2017. Mr. Rowland previously served as vice president and chief financial officer of ViroPharma Incorporated from 2008 until it was acquired by Shire plc in 2014. Prior to joining ViroPharma, Mr. Rowland served as executive vice president and chief financial officer, as well as interim co-chief executive officer, for Endo Pharmaceuticals Inc. from 2006 to 2008 and chief financial officer at Biovail Corporation from 2004 to 2006. He previously held finance and operational positions of increasing responsibility at Breakaway Technologies, Inc., Pharmacia, Novartis International AG and Bristol-Myers Squibb Company. Mr. Rowland currently serves as a member of the board of directors for Blueprint Medicines Corporation, a public biopharmaceutical company, Viking Therapeutics, a public, clinical-stage biopharmaceutical company, and Orchard Therapeutics, a public, clinical-stage biopharmaceutical company. In addition, Mr. Rowland serves as a member of the board of directors for Generation Bio and PsiOxus Therapeutics Ltd., both of which are privately held biopharmaceutical companies. Previously, he served on the board of directors at Idenix Pharmaceuticals, Inc., Vitae Pharmaceuticals, Inc., Bind Therapeutics Inc. and Aurinia Pharmaceuticals Inc. Mr. Rowland received his B.S. from Saint Joseph's University and M.B.A. from Rutgers University. We believe that Mr. Rowland is qualified to serve as a director due to his extensive experience in pharmaceutical operations and all areas of finance and accounting.

**Stephen Webster** has served on our board of directors since June 23, 2017. Mr. Webster previously served on the supervisory board of Nabriva Austria from October 2016 until the Redomiciliation. Mr. Webster has been chief financial officer of Spark Therapeutics since July 2014. He was previously senior vice president and chief financial officer of Optimer Pharmaceuticals, Inc. from June 2012 until its acquisition by Cubist Pharmaceuticals in November 2013. Prior to this, Mr. Webster served as senior vice president and chief financial officer of Adolor Corporation, also acquired by Cubist, from 2008 to 2011. Previously, Mr. Webster served as managing director, Investment Banking Division, Health Care

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Group for Broadpoint Capital Inc. (formerly First Albany Capital). He also was a co-founder and served as president and chief executive officer of Neuronix, Inc. Prior to this, Mr. Webster held positions of increasing responsibility, including as director, Investment Banking Division, Health Care Group, for PaineWebber Incorporated. Mr. Webster is currently a member of the board of directors of Viking Therapeutics, Inc. He holds an A.B. in economics from Dartmouth College and an M.B.A. from the University of Pennsylvania. We believe that Mr. Webster is qualified to serve as a director due to his extensive experience in the biopharmaceutical industry, particularly his service as a chief financial officer and in other executive management roles.

**Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates under a charter that has been approved by our board. Copies of the committee charters are posted under the heading "Corporate Governance" on the Investor section of our website, which is located at <http://investors.nabriva.com>.

*Audit Committee*

Our audit committee consists of Charles A. Rowland, Jr., Daniel Burgess and Stephen Webster. Charles A. Rowland, Jr. was the chair of the audit committee until August 1, 2018, and Stephen Webster has been chair since August 1, 2018. The audit committee oversees our accounting and financial reporting processes and the audits of our consolidated financial statements. The audit committee is responsible for, among other things:

- making recommendations to our board regarding the ratification by the annual general meeting of shareholders of our independent auditors;
- overseeing the work of the independent auditors, including resolving disagreements between management and the independent auditors relating to financial reporting;
- pre-approving all audit and non-audit services permitted to be performed by the independent auditors;
- reviewing the independence and quality control procedures of the independent auditors;
- reviewing and approving all proposed related-party transactions;
- discussing the annual audited consolidated and statutory financial statements with management;
- annually reviewing and reassessing the adequacy of our audit committee charter;
- meeting separately with the independent auditors to discuss critical accounting policies, recommendations on internal controls, the auditor's engagement letter and independence letter and other material written communications between the independent auditors and the management; and
- attending to such other matters as are specifically delegated to our audit committee by our board from time to time.

Our Board has determined that Charles A. Rowland, Jr. and Stephen Webster are "audit committee financial experts" as defined in the applicable SEC rules.

*Compensation Committee*

Our compensation committee consists of Charles A. Rowland, Jr., Mark Corrigan and Carrie Bourdow. Charles A. Rowland, Jr. is the chair of the compensation committee. The compensation committee assists the board in reviewing and approving or recommending our compensation structure,

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including all forms of compensation relating to our directors and management. The compensation committee is responsible for, among other things:

- reviewing and making recommendations to the board with respect to compensation of our board of directors and management;
- reviewing and approving the compensation, including equity compensation, change-of-control benefits and severance arrangements, of our chief executive officer, chief financial officer and such other members of our management as it deems appropriate;
- overseeing the evaluation of our management;
- reviewing periodically and making recommendations to our board with respect to any incentive compensation and equity plans, programs or similar arrangements;
- exercising the rights of our board under any equity plans, except for the right to amend any such plans unless otherwise expressly authorized to do so; and
- attending to such other matters as are specifically delegated to our compensation committee by our board from time to time.

***Nominating and Corporate Governance Committee***

Our nominating and corporate governance committee consists of Daniel Burgess, Mark Corrigan and Stephen Webster. Daniel Burgess is the chair of the nominating and corporate governance committee. The nominating and corporate governance committee assists the board in selecting individuals qualified to become our directors and in determining the composition of the board and its committees. The nominating and corporate governance committee is responsible for, among other things:

- recommending to the board persons to be nominated for election or re-election to the board at any meeting of shareholders;
- overseeing the board's annual review of its own performance and the performance of its committees; and
- considering, preparing and recommending to the board a set of corporate governance guidelines.

**Compensation Committee Interlocks and Insider Participation**

For the fiscal year ended December 31, 2018, the members of our compensation committee were Axel Bolte, Carrie Bourdow, Mark Corrigan and Charles Rowland, Jr. No member of our compensation committee is, or has been, an officer or employee of ours or any subsidiary of ours. None of our executive officers served as a director or a member of a compensation committee (or other committee serving an equivalent function) of any other entity that had one or more executive officers serving as a director or member of our compensation committee during the year ended December 31, 2018.

**Executive Officers**

The following table sets forth information regarding our executive officers as of March 1, 2019:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Theodore Schroeder	63	Chief Executive Officer
Robert Crotty	45	General Counsel and Secretary
Steven Gelone	51	President and Chief Operating Officer
Francesco Maria Lavino	45	Chief Commercial Officer
Jennifer Schranz	54	Chief Medical Officer
Gary Sender	56	Chief Financial Officer

In addition to the biographical information for Mr. Schroeder, which is set forth above under "Board of Directors," set forth below is certain biographical information about Drs. Gelone and Schranz, and Messrs. Crotty, Lavino and Sender:

**Robert Crotty** has served as our general counsel and secretary since June 23, 2017. Mr. Crotty joined Nabriva Austria as general counsel and secretary prior to the Redomiciliation on June 14, 2017. Previously, Mr. Crotty served as vice president, general counsel, chief compliance officer and secretary of Vernalis Therapeutics, Inc. from January 2016 to June 2017. Prior to joining Vernalis, Mr. Crotty held several positions at Dendreon Corporation from April 2012 to July 2015, including president, general counsel and secretary from February 2015 to July 2015, executive vice president, general counsel and secretary from March 2014 to February 2015, and vice president, assistant general counsel and assistant secretary from April 2012 to February 2014. Before Dendreon, Mr. Crotty was senior counsel at NPS Pharmaceuticals from 2009 until 2012 and at ImClone Systems, Inc. from 2006 to 2009. Prior to going in-house, Mr. Crotty was an associate at Morgan, Lewis & Bockius and Norton Rose Fulbright. Mr. Crotty received his B.A. from Princeton University and J.D. from University of Pennsylvania.

**Steven Gelone** has served as our president and chief operating officer since July 24, 2018. Dr. Gelone previously served as Nabriva Austria's chief development officer and head of business development from 2014 until the Redomiciliation, our chief development officer from the Redomiciliation until June 30, 2017 and our chief scientific officer from June 30, 2017 until July 24, 2018. Prior to joining Nabriva Austria, he served as head of clinical research and development at Spark Therapeutics, Inc. in 2014 and vice president of clinical and preclinical development at ViroPharma Incorporated from 2005 to 2014. Dr. Gelone also served as director of medical affairs at Vicuron Pharmaceuticals from 2002 to 2003 and director of clinical pharmacology and experimental medicine at GlaxoSmithKline Pharmaceuticals from 2000 to 2002. Dr. Gelone received his B.S. Pharm. and Pharm.D. from Temple University.

**Francesco Maria Lavino** has served as our chief commercial officer since July 10, 2017. Previously, Mr. Lavino served as associate vice president and global brand leader for the anti-infective portfolio at Merck & Co. from September 2015 to July 2017. Prior to Merck, Mr. Lavino was vice president of international marketing for Cubist Pharmaceuticals from December 2013 until September 2015. Before joining Cubist, Mr. Lavino spent 10 years with Merck & Co. in various roles, including serving as executive director and global brand leader for Merck's anti-fungal portfolio from January 2011 to November 2013. Mr. Lavino began his career in pharmaceutical sales at UCB S.A. and 3M Company in Italy. He has a B.A. in Pharmacy from the Federico II University of Napoli, Italy and an M.B.A. from SDA Bocconi School of Management in Milan, Italy.

**Jennifer Schranz** has served as our chief medical officer since March 21, 2018. Previously, Dr. Schranz served as vice president, clinical research and development, global development team lead, for hereditary angioedema at Shire plc from January 2014 until March 2018. Prior to Shire, Dr. Schranz served as vice president of clinical development for ViroPharma, Inc. from March 2011 until January

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2014. Before joining ViroPharma, Dr. Schranz was vice president, clinical research at Cempra, Inc., where she was responsible for clinical and regulatory strategy. Earlier in her career, Dr. Schranz worked in clinical development and medical affairs at several pharmaceutical companies, including Wyeth (now Pfizer), Vicuron Pharmaceuticals, Inc. (now Pfizer), GlaxoSmithKline plc, and Merck & Co. Inc. Dr. Schranz completed two years of biology and psychology at McMaster University prior to acceptance and subsequent completion of an M.D. from the University of Toronto, where she completed her internal medicine training and was a fellow in infectious diseases.

**Gary Sender** has served as our chief financial officer since April 12, 2017. Mr. Sender previously served as our chief financial officer from May 2016 until the Redomiciliation. Prior to joining Nabriva Austria, he served as chief financial officer and executive vice president at Synergy Pharmaceuticals from 2015 to 2016. From 2009 until 2015, Mr. Sender served as senior vice president, Finance at Shire plc., supporting its Specialty Pharmaceuticals business and subsequently its Global Commercial businesses. At Shire he was responsible for financial management and support of all commercial areas of Shire's Specialty Pharmaceutical and Rare Disease businesses, with an emphasis on resource allocation, financial forecasting, business cases and mergers and acquisitions. Prior to joining Shire, Mr. Sender was the founding CFO of Tengion, Inc. Mr. Sender also spent 15 years in a number of leadership roles within Merck. Mr. Sender received his B.S. from Boston University and an M.B.A from Carnegie-Mellon University.

***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 available on our website at <http://investors.nabriva.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.

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

Section 16(a) of the Exchange Act requires our directors, executive officers and holders of more than 10% of our ordinary shares to file with the SEC initial reports of ownership of our ordinary shares and other equity securities on a Form 3 and reports of changes in such ownership on a Form 4 or Form 5. Our directors, executive officers and holders of more than 10% of our ordinary shares are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. Based solely on a review of our records and representations made by the persons required to file these reports, we believe that, during the year ended December 31, 2018, our directors, executive officers and holders of more than 10% of any class of equity securities complied with all Section 16(a) filing requirements applicable to them.

**ITEM 11. EXECUTIVE COMPENSATION**

The following discussion provides the amount of compensation paid, and benefits in-kind granted, by us and our subsidiaries to the members of our board of directors and certain executives for services provided in all capacities to us and our subsidiaries for the year ended December 31, 2018.

**Executive and Director Compensation Processes**

Our executive compensation program is administered by the compensation committee of our board of directors, subject to the oversight and approval of our full board of directors. Our compensation



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committee reviews our executive compensation practices on an annual basis and based on this review approves, or, as appropriate, makes recommendations to our board of directors for approval of our executive compensation program.

In designing our executive compensation program, our compensation committee considers publicly available compensation data for national and regional companies in the biotechnology/pharmaceutical industry to help guide its executive compensation decisions at the time of hiring and for subsequent adjustments in compensation. Since 2016, our compensation committee has retained Radford, a part of Aon Hewitt, a business unit of Aon plc, as its independent compensation consultant, to provide comparative data on executive compensation practices in our industry and to advise on our executive compensation program generally. The committee also has retained Radford for guidelines and review of non-employee director compensation. Although our compensation committee considers the advice and guidelines of Radford as to our executive compensation program, our compensation committee ultimately makes its own decisions about these matters. In the future, we expect that our compensation committee will continue to engage independent compensation consultants to provide additional guidance on our executive compensation programs and to conduct further competitive benchmarking against a peer group of publicly traded companies.

Our director compensation program is administered by our board of directors with the assistance of the compensation committee. The compensation committee conducts an annual review of director compensation and makes recommendations to the board of directors with respect thereto.

**Summary Compensation Table**

Our "named executive officers" for the year ended December 31, 2018 were as follows: Dr. Broom, our former chief executive officer, Mr. Schroeder, our chief executive officer, Dr. Gelone, our president and chief operating officer, and Mr. Lavino, our chief commercial officer. The following table sets forth information regarding compensation awarded to, earned by or paid to our named executive officers for the periods presented.

<u>Name and principal position</u>	<u>Year</u>	<u>Salary(\$)</u>	<u>Bonus (\$)</u>	<u>Share Awards (\$)(1)</u>	<u>Option Awards (\$)(1)</u>	<u>Non-Equity Incentive Plan Compensation (\$)(2)</u>	<u>All Other Compensation (\$)(3)</u>	<u>Total (\$)</u>
<b>Colin Broom</b>	<b>2018</b>	<b>275,137</b>	<b>—</b>	<b>436,725</b>	<b>754,400</b>	<b>355,594</b>	<b>223,131</b>	<b>2,044,987</b>
<b>Chief Executive Officer(4)</b>	<b>2017</b>	<b>457,387</b>	<b>—</b>	<b>—</b>	<b>1,235,835</b>	<b>183,501</b>	<b>40,158</b>	<b>1,916,881</b>
	<b>2016</b>	<b>410,354</b>	<b>—</b>	<b>—</b>	<b>769,798</b>	<b>175,776</b>	<b>43,043</b>	<b>1,398,971</b>
<b>Theodore Schroeder</b>	<b>2018</b>	<b>220,360</b>	<b>—</b>	<b>529,500</b>	<b>1,739,100</b>	<b>—</b>	<b>20,380</b>	<b>2,509,340</b>
<b>Chief Executive Officer</b>								
<b>Francesco Maria Lavino</b>	<b>2018</b>	<b>360,298</b>	<b>50,000(5)</b>	<b>145,575</b>	<b>377,200</b>	<b>119,438</b>	<b>36,253</b>	<b>1,088,764</b>
<b>Chief Commercial Officer</b>								
<b>Steven Gelone</b>	<b>2018</b>	<b>426,104</b>	<b>—</b>	<b>225,255</b>	<b>546,738</b>	<b>126,822</b>	<b>15,116</b>	<b>1,340,035</b>
<b>President and Chief Operating Officer</b>	<b>2017</b>	<b>370,278</b>	<b>—</b>	<b>—</b>	<b>535,055</b>	<b>93,766</b>	<b>15,942</b>	<b>1,015,041</b>

- (1) The amounts reported in the "Share Awards" and "Option Awards" columns reflect the aggregate grant-date fair value of share-based compensation awarded during the year computed in accordance with the provisions of ASC Topic 718. See Note 11 to the consolidated financial statements regarding assumptions underlying the valuation of equity awards.
- (2) The amounts reported in the "Non-Equity Incentive Plan Compensation" column represent awards to our named executive officers under our annual cash bonus program.

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- (3) The compensation included in the "All Other Compensation" column consists of amounts we contributed to our 401(k) plan and medical insurance premiums paid by us on behalf of such individual. This column also includes severance benefits for Dr. Broom of \$195,868.
- (4) Dr. Broom resigned from his position as chief executive officer effective as of July 24, 2018.
- (5) During 2018, Mr. Lavino received a sign-on bonus of \$50,000 that became payable on the first anniversary of his start date.

**Narrative Disclosure to Summary Compensation Table**

*Base Salary*

In 2018, we paid annualized base salaries of \$471,534 to Dr. Broom; \$530,000 to Mr. Schroeder; \$360,500 to Mr. Lavino; and \$450,000 to Dr. Gelone. In 2017, we paid annualized base salaries of \$457,800 to Dr. Broom; \$350,000 to Mr. Lavino; and \$390,000 to Dr. Gelone.

In January 2019, our board of directors, following approval and recommendation from the compensation committee and consistent with the recommendations of the compensation committee's independent compensation consultant, approved an increase to the base salaries of our named executive officers for 2019 as follows: \$560,000 for Mr. Schroeder, \$371,800 for Mr. Lavino and \$472,100 for Dr. Gelone. The board also approved 2019 base salaries for Mr. Crotty, our general counsel and secretary, of \$371,100, Dr. Schranz, our chief medical officer, of \$436,200 and Mr. Sender, our chief financial officer, of \$382,500, which also were consistent with the recommendation of the compensation committee's independent consultant.

None of our named executive officers is currently party to an employment agreement or other agreement or arrangement that provides for automatic or scheduled increases in base salary.

*Annual Performance-Based Compensation*

Our executive officers, which include the named executive officers, participate in our performance-based bonus program. All annual cash bonuses for our executives under the performance-based bonus program are tied to the achievement of strategic and operational corporate goals for the company, which are set by the compensation committee and approved by the board. There are no discretionary individual goals under the bonus program. The 2018 strategic and operational goals for Nabriva related to the following objectives:

- corporate strategy;
- commercial launch readiness;
- finance, specifically fundraising;
- business development;
- clinical development, including topline data for LEAP 2 and filing the NDA for lefamulin in the fourth quarter of 2018; and,
- chemistry, manufacturing, and control (CMC), including completing manufacture of the active pharmaceutical ingredient validation and tablet optimization batches.

Under their respective employment agreements, the annual target bonus for Mr. Schroeder is 50% of his current base salary, the annual target bonus for Dr. Gelone is 40% of his current base salary and the annual target bonus for each of Dr. Schranz, Mr. Sender, Mr. Crotty and Mr. Lavino is 35% of their respective current base salaries. The annual target bonus for Dr. Broom was 50% of his then-current base salary. In October 2018, the compensation committee recommended, and the board of directors approved, an annual target bonus for each of Dr. Schranz, Mr. Sender, Mr. Crotty and Mr. Lavino at 40% of their respective salaries.

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At a meeting held in October 2018, our compensation committee reviewed the accomplishments of the named executive officers as measured against the aforementioned 2018 goals. The compensation committee reviewed whether each goal had been obtained and the weight such goals should be given in determining the bonus payout for 2018 performance. Based on its review, the compensation committee recommended an 108% payout of the target bonuses for 2018, which were paid in January 2019. Accordingly, the 2018 bonus payouts were \$119,250 for Mr. Schroeder, \$136,269 for Mr. Lavino and \$181,420 for Dr. Gelone. Dr. Broom received a lump sum cash payment of \$132,417 in full satisfaction of any bonus as part of his separation agreement.

### *Equity Incentive Awards*

We believe that equity grants provide our executive officers with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executive officers and our shareholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incents our executive officers to remain in our employment during the vesting period. Accordingly, our board of directors periodically reviews the equity incentive compensation of our executive officers, which includes the named executive officers, and from time to time may grant equity incentive awards to them in the form of stock options. We also generally make stock option grants to new executive officers in connection with the commencement of their employment.

We have historically granted stock options with exercise prices that are set at no less than the fair market value of the underlying award on the date of grant, as determined by contemporaneous valuations and reviewed, and approved by our compensation committee or our board.

On January 31, 2019, our board of directors granted stock options under the 2017 Share Incentive Plan to Mr. Schroeder, Mr. Lavino and Dr. Gelone. The options will vest over a four-year period beginning on January 31, 2019. Twenty-five percent (25%) of the option will vest on January 31, 2020, and the remaining seventy-five percent (75%) will vest on a monthly pro-rata basis over the remaining vesting period. Each of the option awards had an exercise price \$1.90 per share, which was the closing sale price of our ordinary shares on the Nasdaq Global Market on the grant date. Mr. Schroeder, Mr. Lavino and Dr. Gelone were also granted Restricted Stock Units, or RSUs. The RSUs will vest over a four-year period beginning on January 31, 2019. Twenty-five percent (25%) of the RSUs will vest on January 31, 2020, and the remaining seventy-five percent (75%) will vest on a monthly pro-rata basis over the remaining vesting period.

The following table sets forth the number of our ordinary shares issuable upon exercise of the share awards granted to our named executive officers in 2019:

<u>Name</u>	<u>Option Award (#)</u>	<u>RSU Award (#)</u>
Theodore Schroeder	429,800	163,250
Colin Broom	—	—
Steven Gelone	278,400	105,750
Francesco Maria Lavino	138,200	52,500

On July 23, 2018, Nabriva Therapeutics US, Inc. ("Nabriva US") entered into an Employment Agreement with Theodore Schroeder (the "Schroeder Agreement") providing for Mr. Schroeder, age 63, to serve as chief executive officer of the Company and president and chief executive officer of Nabriva US, contingent on and effective as of the Closing of the Zavante Acquisition (the "Commencement Date"). Pursuant to the Schroeder Agreement, the Board also approved the grant to Mr. Schroeder, effective as of the first business day immediately following the Commencement Date (the "Grant Date"), of a non-statutory stock option to purchase 850,000 ordinary shares of the Company at an exercise price per share equal to the closing price per share of the Company's ordinary

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shares on the Nasdaq Global Select Market on the Grant Date. The option award will have a ten-year term and will vest over a four-year period, with 25% of the shares underlying the award vesting on the first anniversary of the Commencement Date and the remaining 75% of the shares underlying the option award to vest monthly over the subsequent 36-month period. In addition, the Board approved the grant to Mr. Schroeder, effective as of the Grant Date, of 150,000 performance-based restricted share units (the "Schroeder PRSUs"). The Schroeder PRSUs will vest as follows: 50% of the Schroeder PRSUs will vest upon Board certification of the receipt of FDA approval of a new drug application for each of (x) lefamulin and (y) CONTEPO for any indication, and 50% of the Schroeder PRSUs will vest on the first anniversary of such Board certification, provided, in each case, that Mr. Schroeder is performing services to Nabriva US on the applicable vesting dates. If the FDA does not approve an NDA for both lefamulin and CONTEPO by January 31, 2020, the Schroeder PRSUs award will terminate in full.

On January 31, 2018, our board of directors granted stock options under the 2017 Share Incentive Plan to Dr. Broom, Mr. Sender and Dr. Gelone. The options will vest over a four-year period beginning on January 31, 2018. Twenty-five percent (25%) of the option will vest on January 31, 2019, and the remaining seventy-five percent (75%) will vest on a monthly pro-rata basis over the remaining vesting period. Each of the option awards had an exercise price \$6.47 per share, which was the equivalent of the closing sale price of our ordinary shares on the Nasdaq Global Market on the grant date. Dr. Broom, Mr. Lavino and Dr. Gelone were also granted Restricted Stock Units, or RSUs. Vesting of the RSUs is subject to FDA approval of an NDA, for lefamulin. Fifty percent (50%) of each RSU award will vest upon FDA approval of an NDA for lefamulin, and the remaining fifty percent (50%) will vest on the one-year anniversary of such approval. If the FDA does not approve an NDA for lefamulin within two years of the grant date, the RSU award will terminate in full.

The following table sets forth the number of our ordinary shares issuable upon exercise of the share awards granted to our named executive officers in 2018:

<u>Name</u>	<u>Option Award</u> <u>(#)</u>	<u>RSU Award</u> <u>(#)</u>
Theodore Schroeder	850,000	150,000
Colin Broom	200,000	67,500
Steven Gelone	185,000	54,500
Francesco Maria Lavino	100,000	22,500

**Outstanding Equity Awards as of December 31, 2018**

The following table sets forth information regarding outstanding stock options and RSUs held by our named executive officers as of December 31, 2018:

Name	Option Awards				Share Awards			
	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price (\$)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares of stock that have not vested (\$)	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested (\$)
Colin Broom	158,270	—(1)	7.21	7/5/2025	—	—	67,500(14)	98,550
	168,185	28,715(2)	7.21	7/5/2025	—	—	—	—
	106,958	44,042(3)	8.34	2/4/2026	—	—	—	—
	119,625	141,375(4)	8.50	2/7/2027	—	—	—	—
	—	200,000(5)	6.47	1/31/2028	—	—	—	—
Theodore Schroeder	—	850,000(6)	3.53	7/25/2028	150,000(15)	219,000	—	—
Francesco Maria Lavino	53,125	96,875(7)	10.48	7/31/2027	—	—	22,500(14)	32,850
Steven Gelone	—	100,000(8)	6.47	1/31/2028	—	—	—	—
	81,997	6,793(9)	7.21	7/5/2025	—	—	54,500(14)	79,570
	39,596	16,304(10)	8.34	2/4/2026	—	—	—	—
	51,792	61,208(11)	8.50	2/7/2027	—	—	—	—
	—	100,000(8)	6.47	1/31/2028	—	—	—	—
	—	77,500(12)	3.53	7/25/2028	—	—	—	—
	—	7,500(13)	2.49	2/8/2028	—	—	—	—

- (1) Dr. Broom's option to purchase 158,270 of our ordinary shares vests over four years, with 25% of the options vesting on August 31, 2015, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.
- (2) Dr. Broom's option to purchase 196,900 of our ordinary shares vests over four years, with 25% of the options vesting on July 31, 2016, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.
- (3) Dr. Broom's option to purchase 151,000 of our ordinary shares vests over four years, with 25% of the options vesting on February 28, 2017, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.
- (4) Dr. Broom's option to purchase 261,000 of our ordinary shares vests over four years, with 25% of the options vesting on February 28, 2018, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.
- (5) Dr. Broom's option to purchase 200,000 of our ordinary shares vests over four years, with 25% of the options vesting on January 31, 2019, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.
- (6) Mr. Schroeder's option to purchase 850,000 of our ordinary shares vests over four years, with 25% of the options vesting on July 25, 2019, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.
- (7) Mr. Lavino's option to purchase 150,000 of our ordinary shares vests over four years, with 25% of the options vesting on July 31, 2018, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.
- (8) Mr. Lavino's and Dr. Gelone's option to purchase 100,000 of our ordinary shares vests over four years, with 25% of the options vesting on January 31, 2019, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.
- (9) Dr. Gelone's option to purchase 88,790 of our ordinary shares vests over four years, with 25% of the options vesting on May 31, 2016, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.
- (10) Dr. Gelone's option to purchase 55,900 of our ordinary shares vests over four years, with 25% of the options vesting on February 28, 2017, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.
- (11) Dr. Gelone's option to purchase 113,000 of our ordinary shares vests over four years, with 25% of the options vesting on February 28, 2018, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.
- (12) Dr. Gelone's option to purchase 77,500 of our ordinary shares vests over four years, with 25% of the options vesting on July 25, 2019, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.
- (13) Dr. Gelone's option to purchase 7,500 of our ordinary shares vests over four years, with 25% of the options vesting on August 2, 2019, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.
- (14) Dr. Broom, Mr. Lavino and Dr. Gelone's vesting of the RSUs is subject to the FDA approval of an NDA for lefamulin. Fifty percent (50%) of each RSU award will vest upon FDA approval of an NDA for lefamulin, and the remaining fifty percent (50%) will vest on the one-year anniversary of such approval. If the FDA does not approve an NDA for lefamulin within two years of the grant date, the RSU award will terminate in full.
- (15) Mr. Schroeder's RSUs will vest as follows: 50% of the RSUs will vest upon Board certification of the receipt of FDA approval of a new drug application for each of (x) lefamulin and (y) CONTEPO for any indication, and 50% of his RSUs will vest on the first anniversary of such Board certification, provided, in each case, that Mr. Schroeder is performing services to Nabriva US on the applicable vesting dates. If the FDA does not approve an NDA for both lefamulin and CONTEPO by January 31, 2020, the RSUs will terminate in full.

## **Employment Agreements with Executive Officers**

### *Agreement with Theodore Schroeder, Chief Executive Officer and Director*

Mr. Schroeder was appointed our chief executive officer and entered into an employment agreement dated and effective as of July 23, 2018. He was appointed to our board on August 1, 2018. His employment agreement continues until terminated in accordance with its terms, as described below.

Pursuant to his employment agreement, Mr. Schroeder receives an annual base salary of \$530,000 and is eligible to receive an annual performance bonus targeted at 50% of his annual base salary, with the actual amount of such bonus, if any, to be determined by the Board. For 2018, Mr. Schroeder's bonus was pro-rated to reflect his 2018 service to us. Mr. Schroeder is also eligible to receive equity awards at such times and on such terms and conditions as the Board may determine and is also entitled to participate in any and all benefit programs that we make available to our executive officers, for which he may be eligible, under the plan documents governing such programs.

Pursuant to his employment agreement, the Board also approved the grant to Mr. Schroeder, effective as of the first business day immediately following his employment commencement date (the "Grant Date"), of a non-statutory stock option to purchase 850,000 ordinary shares at an exercise price per share equal to the closing price per share of the Company's ordinary shares on the Nasdaq Global Select Market on the Grant Date. The option award has a ten-year term and vests over a four-year period, with 25% of the shares underlying the award vesting on the first anniversary of his employment commencement date and the remaining 75% of the shares underlying the option award to vest monthly over the subsequent 36-month period. In addition, the Board approved the grant to Mr. Schroeder, effective as of the Grant Date, of 150,000 performance-based restricted share units (the "Schroeder PRSUs"). The Schroeder PRSUs vest as follows: 50% of the Schroeder PRSUs will vest upon Board certification of the receipt of FDA approval of a new drug application for each of (x) lefamulin and (y) CONTEPO for any indication, and 50% of the Schroeder PRSUs will vest on the first anniversary of such Board certification, provided, in each case, that Mr. Schroeder is performing services for us on the applicable vesting dates. If the FDA does not approve an NDA for both lefamulin and CONTEPO by January 31, 2020, the Schroeder PRSUs award will terminate in full. The option being granted to Mr. Schroeder and the Schroeder PRSUs were awarded outside of our 2017 Share Incentive Plan as an inducement material to Mr. Schroeder's entering into employment with us in accordance with Nasdaq Stock Market Listing Rule 5635(c)(4).

The employment agreement, and Mr. Schroeder's employment, may be terminated as follows: (1) upon Mr. Schroeder's death or "disability" (as disability is defined in his employment agreement); (2) at our election, with or without "cause" (as cause is defined in his employment agreement); and (3) at Mr. Schroeder's election, with or without "good reason" (as good reason is defined in his employment agreement).

In the event of the termination of Mr. Schroeder's employment by us without cause, including as a result of a termination of his employment for good reason prior to, or more than twelve months following, a "change in control" (as change in control is defined in his employment agreement), Mr. Schroeder will be entitled to his base salary that has accrued and to which he is entitled as of the termination date. In addition, subject to his execution and nonrevocation of a release of claims in our favor and his continued compliance with his proprietary rights, non-disclosure and developments agreement with us, he is entitled to (1) continued payment of his base salary, in accordance with our regular payroll procedures, for a period of 18 months (2) provided he is eligible for and timely elects to continue receiving group medical insurance under COBRA and the payments would not result in the violation of nondiscrimination requirements of applicable law, payment by us of the portion of health coverage premiums we pay for similarly-situated, active employees who receive the same type of coverage, for a period of up to 18 months following his date of termination, (3) a lump sum payment equal to any earned but unpaid annual bonus for a previously completed calendar year and (4) a lump

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sum payment equal to a prorated annual bonus for the year in which Mr. Schroeder's employment is terminated based on the number of days he provided services to us during the year in which his employment is terminated.

In the event of the termination of Mr. Schroeder's employment by us without cause, including as a result of a termination of his employment for good reason prior to, or by him for good reason within twelve months following a change in control, subject (as described above with respect to certain payments), to his execution and nonrevocation of a release of claims in our favor and his continued compliance with his proprietary rights, non-disclosure and developments agreement with us, Mr. Schroeder would be entitled to the same payments and benefits as described in the preceding paragraph, except that, in lieu of a pro-rated annual bonus payment, he would be entitled to receive a lump sum payment equal to 100% of his target bonus for the year in which his employment is terminated and he shall also be entitled to full vesting acceleration of his then-unvested equity awards, whether granted under the 2017 Share Incentive Plan or any successor equity incentive plan or as an inducement to his employment, such that his equity awards become fully exercisable and non-forfeitable as of the termination date.

If Mr. Schroeder's employment is terminated for any other reason, including as a result of his death or disability, for cause, or voluntarily by Mr. Schroeder without good reason, our obligations under the employment agreement cease immediately, and Mr. Schroeder is only entitled to his base salary that has accrued and to which he is entitled as of the termination date and solely if his employment is terminated as a result of his death or disability, subject to his execution and nonrevocation of a release of claims in our favor and his continued compliance with his proprietary rights, non-disclosure and developments agreement with us, he or his estate, as applicable, is entitled to any earned but unpaid annual bonus from a previously completed calendar year.

As a condition of his employment, Mr. Schroeder signed a proprietary rights, non-disclosure and developments agreement.

### *Agreements with other Executive Officers*

Mr. Sender was appointed chief financial officer of Nabriva Austria and entered into an employment agreement dated and effective as of May 2, 2016. He was appointed our chief financial officer on April 12, 2017. Dr. Gelone was appointed chief development officer and entered into an employment agreement dated and effective as of December 1, 2014, which was amended and restated as of May 26, 2016 and further amended on restated on July 24, 2018. Mr. Crotty was appointed general counsel and secretary of Nabriva Austria and entered into an employment agreement dated and effective as of June 14, 2017. Dr. Gelone was appointed as our chief development officer and Mr. Crotty was appointed our general counsel and secretary effective as of June 23, 2017. Dr. Gelone was subsequently appointed our chief scientific officer on June 30, 2017, and our president and chief operating officer on July 24, 2018. Dr. Schranz was appointed our chief medical officer and entered into an employment agreement dated and effective as of March 21, 2018. Mr. Lavino was appointed our chief commercial officer and entered into an employment agreement dated and effective as of July 10, 2017. Each of these employment agreements provides that such executive officer is an at-will employee, and his or her employment with us can be terminated by the respective executive officer or us at any time and for any reason.

The employment agreements and the employment of each of Mr. Sender, Dr. Gelone, Mr. Crotty, Dr. Schranz and Mr. Lavino may be terminated in one of three ways: (1) upon the death or "disability" (as disability is defined in the applicable employment agreement) of such executive officer; (2) at our election, with or without "cause" (as cause is defined in the applicable employment agreement); and (3) at such executive officer's election, with or without "good reason" (as good reason is defined in the applicable employment agreement).

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In the event of the termination of such executive officer's employment by us without cause or by him or her for good reason prior to, or more than twelve months following, a "change in control" (as change in control is defined in the applicable employment agreement), such executive officer will be entitled to his or her base salary that has accrued and to which he or she is entitled as of the termination date. In addition, subject to such executive officer's execution and nonrevocation of a release of claims in our favor and his or her continued compliance with his or her proprietary rights, non-disclosure and developments agreement with us, such executive officer is entitled to (1) continued payment of such executive officer's base salary, in accordance with our regular payroll procedures, for a period of 12 months, (2) provided he or she is eligible for and timely elects to continue receiving group medical insurance under COBRA and the payments would not result in the violation of nondiscrimination requirements of applicable law, payment by us of the portion of health coverage premiums we pay for similarly-situated, active employees, who receive the same type of coverage, for a period of up to 12 months following the date of termination, (3) a lump sum payment equal to any earned but unpaid annual bonus for a previously completed calendar year and (4) a lump sum payment equal to a prorated annual bonus for the year in which such executive officer's employment is terminated based on the number of days such executive officer provided services to us during the year in which such executive officer's employment is terminated.

In the event of the termination of the executive officer's employment by us without cause or by him or her for good reason within twelve months following a change in control, subject (as described above with respect to certain payments) to such executive officer's execution and nonrevocation of a release of claims in our favor and his or her continued compliance with his or her proprietary rights, non-disclosure and developments agreement with us, such executive officer will be entitled to the same payments and benefits as described in the preceding paragraph, except that, in lieu of a pro-rated annual bonus payment, such executive officer will be entitled to receive a lump sum payment equal to 100% of such executive officer's target bonus for the year in which his or her employment is terminated, and such executive officer shall also be entitled to full vesting acceleration of his or her then-unvested equity awards, whether granted under the 2017 Share Incentive Plan or any successor equity incentive plan, such that his or her equity awards become fully exercisable and non-forfeitable as of the termination date.

If such executive officer's employment is terminated for any other reason, including as a result of his or her death or disability, for cause, or voluntarily by such executive officer without good reason, our obligations under the applicable employment agreement cease immediately, and such executive officer is only entitled to his or her base salary that has accrued and to which he or she is entitled as of the termination date and, solely if such executive officer's employment is terminated as a result of his or her death or disability and subject to his or her execution and nonrevocation of a release of claims in our favor and his or her continued compliance with his or her proprietary rights, non-disclosure and developments agreement with us, such executive officer or the estate of such executive officer, as applicable, is entitled to any earned but unpaid annual bonus from a previously completed calendar year.

Pursuant to their respective employment agreements, each of these executive officers is entitled to an annual base salary, as follows: Mr. Sender: \$382,500; Dr. Gelone: \$472,100; Mr. Crotty; \$371,100; Dr. Schranz: \$436,200 and Mr. Lavino: \$371,800. Such base salary is reviewed by our compensation committee and the board of directors in the first quarter of each fiscal year and any adjustment to such base salary is retroactively effective to the first day of such fiscal year. In addition, such executive officers are eligible for an annual discretionary bonus of 35% of their current base salary. Each executive officer is also eligible to receive equity awards at such times and on such terms and conditions as the Board may determine and is also entitled to participate in any and all benefit programs that we make available to our executive officers, for which he or she may be eligible, under the plan documents governing such programs.



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As a condition to their employment, each of Mr. Sender, Dr. Gelone, Mr. Crotty, Dr. Schranz and Mr. Lavino signed a proprietary rights, non-disclosure and developments agreement.

### *Agreements with Colin Broom, Director and Former Chief Executive Officer*

Dr. Broom was appointed chief executive officer of Nabriva Austria and entered into an employment agreement dated and effective as of August 28, 2014, which was amended and restated as of June 17, 2016. He was appointed our chief executive officer on April 12, 2017. Dr. Broom resigned as chief executive officer, effective July 24, 2018 (the "Transition Date"). We entered into a Transition, Separation and Release of Claims Agreement, or the Transition Agreement, with Dr. Broom on July 23, 2018. We also entered into a Consulting Agreement with Dr. Broom, effective as of the Transition Date, pursuant to which Dr. Broom provides to us, upon the request of the Board, consulting and advisory services relating to the preparation and submission of a new drug application for the Company's lefamulin product candidate to the FDA (collectively, the "Services"). Dr. Broom continues to serve as a director on the Board.

Under the Transition Agreement, Dr. Broom will be entitled to compensation for such services consistent with the Company's Non-Employee Director Compensation Policy as in effect from time to time (the "Policy"). However, Dr. Broom was not eligible to receive an "initial grant" of share options under such Policy or an "annual grant" of share options under such Policy in 2018.

Pursuant to the Transition Agreement, in return for Dr. Broom's execution of the Transition Agreement and timely execution and nonrevocation of an additional release of claims at the time of the Transition Date, Dr. Broom received the "severance benefits" described in his amended and restated employment agreement dated as of June 17, 2016 that he would be entitled to receive upon a "qualifying termination" occurring prior to or more than 12 months following a "change in control" (as such terms are defined in the Employment Agreement). Specifically, he received continued payment of his current annual base salary of \$471,534 for a period of 18 months, or \$707,301 in the aggregate; subject to certain conditions, payment of a portion of health coverage premiums for a period of up to 18 months following the Transition Date; and a lump sum payment of \$132,417 which is equal to the prorated portion of Dr. Broom's 2018 annual target bonus of \$235,767, representing 50.0% of his 2018 annual base salary, based on the number of days of his employment in 2018.

In addition, pursuant to the Transition Agreement, Dr. Broom will continue to vest in any options he holds to purchase the Company's ordinary shares that were outstanding as of the Transition Date (the "Outstanding Options") for a period of 12 months following the Transition Date provided he remains on the Board during such 12-month period. In the event his service as a director on the Board terminates before the 12-month anniversary of the Transition Date, the portion of the Outstanding Options that would have vested had Dr. Broom remained on the Board through the 12-month anniversary of the Transition Date will be accelerated at that time. Any of Dr. Broom's options that are unvested at the 12-month anniversary of the Transition Date will terminate and Dr. Broom will no longer have any rights with respect to them. In addition, the post-termination exercise period of the vested Outstanding Options will be extended such that Dr. Broom is entitled to exercise any vested Outstanding Options until the later of the date that is 24 months following the Transition Date and the date that is three months following his cessation of service on the Board (but in no event later than the final exercise date applicable to such option). The Transition Agreement also provides that, if Dr. Broom continues to serve on the Board or to provide Services under the Consulting Agreement on the effective date of grant, he shall continue to be entitled to receive the grant of performance-based restricted share units (the "Broom PRSUs") previously approved by the Board, which will vest in accordance with, and otherwise be subject to the terms and conditions of, the previously-approved award agreement. However, if Dr. Broom ceases to serve on the Board and ceases to provide Services under the Consulting Agreement following achievement of the applicable performance metric under the Broom PRSUs but before the first anniversary of the achievement of the performance vesting metric,

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the award will accelerate and vest in full at the time he ceases to provide all services on the Board and as a consultant.

The Transition Agreement also provided for, among other things, a release of claims by Dr. Broom in favor of us and our affiliates, continuing confidentiality, non-solicitation and non-competition obligations applicable to Dr. Broom under his existing Proprietary Rights, Non-Disclosure and Developments Agreement, and a mutual non-disparagement obligation applicable to us and Dr. Broom.

Pursuant to the Consulting Agreement, Dr. Broom receives \$500.00 per hour in consulting fees for his performance of the Services under the Consulting Agreement. The term of the Consulting Agreement will be from the Transition Date until January 31, 2020, and may be extended for additional periods upon mutual written agreement of both us and Dr. Broom. In addition, the Consulting Agreement may be terminated by us if Dr. Broom materially breaches the Consulting Agreement or the Transition Agreement; by Dr. Broom, if we materially breach the Consulting Agreement or the Transition Agreement; at any time by either us or Dr. Broom upon not less than 15 days prior written notice to the other party; at any time upon the mutual written consent of the parties; or automatically upon the death, physical incapacitation or mental incompetence of Dr. Broom.

**Equity Incentive Plans**

In this section, we describe our 2017 Share Incentive Plan and Stock Option Plan 2015. Prior to the Redomiciliation, Nabriva Austria granted awards to eligible recipients under the Stock Option Plan 2015. In connection with the Redomiciliation, both plans were amended to take account of certain requirements under Irish law and assumed by us, with each option to acquire one Nabriva Austria common share becoming an option to acquire ten of our ordinary shares on the same terms and conditions. We currently make share awards to eligible recipients solely under our 2017 Share Incentive Plan.

*2017 Share Incentive Plan*

The 2017 Share Incentive Plan permits the award of share options, share appreciation rights, or SARs, restricted shares, restricted share units or RSUs, and other share-based awards to our employees, officers, directors, consultants and advisers. Our board of directors will administer the 2017 Share Incentive Plan. As of January 31, 2019, under our 2017 Share Incentive Plan, there were options to purchase an aggregate of 2,398,425 of our ordinary shares at a weighted average exercise price of \$5.41 per share, 1,222,100 restricted stock units outstanding with a weighted average grant date fair value of \$3.33 per share, and 1,443,853 ordinary shares available for future issuance under the plan. Shares covered by awards under the 2017 Share Incentive Plan that expire or are terminated, surrendered, or cancelled without having been fully exercised or are forfeited in whole or in part or that result in any shares not being issued will again be available for the grant of awards under the 2017 Share Incentive Plan (subject, in the case of incentive share options, to any limitations under the Internal Revenue Code, or the Code).

Options and SARs granted under the 2017 Share Incentive Plan may not have an exercise price or measurement price, respectively, that is less than 100% of the fair market value of our ordinary shares on the date of grant; provided, however, that if our board of directors approves the grant of an option or SAR with an exercise price or measurement price to be determined on a future date, such price may not be less than 100% of the fair market value of our ordinary shares on such future date. Such options and SARs will be exercisable at such times and subject to such terms and conditions as the board may specify in the applicable option or SAR agreement. No option or SAR will be granted with a term in excess of ten years.

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Restricted shares and RSUs granted under the 2017 Share Incentive Plan will determine the terms and conditions of restricted shares and RSUs, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

If, during the term of the 2017 Share Incentive Plan, there is a change in our capital or a restructuring measure which has an effect on our capital, such as a share split or reverse share split, which change or measure results in a change in the value of the share-based awards outstanding under the 2017 Share Incentive Plan, the board will make appropriate adjustments to the price or the amount of such outstanding awards.

The 2017 Share Incentive Plan also contains provisions addressing the consequences of any reorganization event. A reorganization event is defined as (a) any merger or consolidation of us with or into another entity as a result of which all of our ordinary shares are converted into or exchanged for the right to receive cash, securities or other property, or are cancelled, (b) any transfer or disposition of all of our ordinary shares for cash, securities or other property pursuant to a share exchange or other transaction or (c) our liquidation or dissolution; any one of which, (a), (b) or (c), may be effected pursuant to the laws of the Republic of Ireland.

The 2017 Share Incentive Plan provides that, if a reorganization event occurs, the board of directors may take one or more of the following actions to all or any outstanding awards other than restricted shares on such terms as the board of directors determines: (1) provide that such awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (2) upon written notice to a participant, provide that all of the participant's unvested awards will be forfeited immediately prior to the consummation of such reorganization event and/or that all of the participant's unexercised awards will terminate immediately prior to the consummation of such reorganization event unless exercised by the participant (to the extent then exercisable) within a specified period following the date of such notice, (3) provide that outstanding awards will become exercisable, realizable, or deliverable, or restrictions applicable to an award will lapse, in whole or in part prior to or upon such reorganization event, (4) in the event of a reorganization event under the terms of which holders of our ordinary shares will receive, upon consummation thereof, a cash payment for each share surrendered in the reorganization event, which we refer to as the Acquisition Price, make or provide for a cash payment to participants with respect to each award held by a participant equal to (A) the number of ordinary shares subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event) multiplied by (B) the excess, if any, of (I) the Acquisition Price over (II) the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award, (5) provide that, in connection with our liquidation or dissolution, awards will convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings) and (6) any combination of the foregoing. Our board is not obligated to treat all awards, all awards held by a participant, or all awards of the same type, identically.

No award may be granted under the 2017 Share Incentive Plan after September 14, 2027. The board of directors may, at any time, amend, suspend or terminate the 2017 Share Incentive Plan or any portion thereof. However, if shareholder approval is required, including by application of Irish law, the board may not effect such modification or amendment without such approval.

### *Stock Option Plan 2015*

The Stock Option Plan 2015 provided for the grant of options to purchase our ordinary shares to our employees, including executive officers, and to directors. As of January 31, 2019, under our Stock Option Plan 2015, there were options to purchase an aggregate of 2,842,913 of our ordinary shares at a weighted average exercise price of \$8.34 per share and no ordinary shares were available for issuance

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under the plan. Following the approval of the 2017 Share Incentive Plan by our shareholders on September 15, 2017, we ceased granting awards under the Stock Option Plan 2015. Unless the context specifically indicates otherwise, references to our Stock Option Plan 2015 in this Annual Report on Form 10-K refer to the Stock Option Plan 2015, as amended and adopted by us.

Options granted under the Stock Option Plan 2015 entitle beneficiaries thereof to purchase our ordinary shares at an exercise price equal to 100% of the fair market value per share on the beneficiary's date of participation, which following the Redomiciliation was derived from the closing sale price of our ordinary shares on the Nasdaq Global Market. Options granted under the Stock Option Plan 2015 generally vest over four years from the beneficiary's date of participation. Typically, 25% of the options subject to a particular grant vest on the last day of the last calendar month of the first year of the vesting period, and the remaining 75% vests on a monthly pro-rata basis over the second, third and fourth years of the vesting period (i.e., 2.083% per month). Any alternative vesting period determined by us is subject to approval by our executive officers, board of directors or shareholders, in accordance with any applicable voting requirements.

The Stock Option Plan 2015 provides that, if a liquidity event (as defined below) occurs, all options outstanding under the Stock Option Plan 2015 will be assumed (or substantially equivalent awards will be substituted by an acquiring or succeeding corporation (or an affiliate of the acquiring or succeeding corporation)), and any then-unvested options shall continue to vest in accordance with the beneficiary's original vesting schedule. If a beneficiary is terminated due to a good leaver event (within the meaning of the Stock Option Plan 2015), on or prior to the first anniversary of the date of the liquidity event, the beneficiary's options will be immediately exercisable in full as of the date of such termination. If the acquiring or succeeding corporation (or an affiliate of the acquiring or succeeding corporation) refuses to assume the options outstanding under the Stock Option Plan 2015 or to substitute substantially equivalent options therefor, all then-unvested options under the Stock Option Plan 2015 will automatically vest in full upon the liquidity event. For purposes of the Stock Option Plan 2015, a liquidity event generally refers to an exclusive license of or the sale, lease or other disposal of all or substantially all of our assets, a sale or other disposal (but not a pledge) of 50% or more of our shares, a merger or consolidation of us with or into any third party, or our liquidation, winding up or other form of dissolution of us.

Unless otherwise specifically permitted in an option agreement or resolved upon by the board of directors, the exercise of vested options is permitted under the Stock Option Plan 2015 only during specified periods and on specified terms in the case of a liquidity event or following an initial public offering occurring during the term of the option. A beneficiary is entitled to exercise vested options at any time during the remaining term of the option while the beneficiary is providing services to us, and within the three-month period following a termination of the beneficiary's services due to a good leaver event. Options granted under the Stock Option Plan 2015 will have a term of no more than ten years from the beneficiary's date of participation.

If, during the term of the Stock Option Plan 2015, there is a change in our capital or a restructuring measure which has an effect on our capital, such as a stock split or reverse stock split, which change or measure results in a change in the value of the options outstanding under the Stock Option Plan 2015, the board may make appropriate adjustments to the price or the amount of such outstanding options.

The board of directors may, at any time, amend, suspend or terminate the Stock Option Plan 2015 in whole or in part. However, if shareholder approval is required, including by application of Irish law, the board may not effect such modification or amendment without such approval.

**401(k) Plan**

We maintain a defined contribution employee retirement plan for our U.S.-based employees. Our 401(k) plan is intended to qualify as a tax-qualified plan under Section 401 of the Internal Revenue Code, so that contributions to our 401(k) plan, and income earned on such contributions, are not taxable to participants until withdrawn or distributed from the 401(k) plan. Our 401(k) plan provides that each participant may contribute up to 90% of his or her pre-tax compensation, up to a statutory limit, which is \$18,000 for 2017. Participants who are at least 50 years old can also make "catch-up" contributions, which in 2017 may be up to an additional \$6,000 above the statutory limit. Under our 401(k) plan, each employee is fully vested in his or her deferred salary contributions. Employee contributions are held and invested by the plan's trustee, subject to participants' ability to give investment directions by following certain procedures. We match 100.0% of the first 3.0% of the employee's voluntary contribution to the 401(k) plan and 50.0% of the next 2.0% contributed by the employee.

**Risk Considerations in Our Compensation Program**

Our compensation committee has reviewed and evaluated the philosophy and standards on which our compensation plans have been developed and implemented across our company. It is our belief that our compensation programs do not encourage inappropriate actions or risk taking by our executive officers. We do not believe that any risks arising from our employee compensation policies and practices are reasonably likely to have a material adverse effect on our company. In addition, we do not believe that the mix and design of the components of our executive compensation program encourage management to assume excessive risks.

**DIRECTOR COMPENSATION****Summary Compensation Table**

The following table sets forth a summary of the compensation earned by the non-employee members of the board of directors for the year ended December 31, 2018.

<u>Name</u>	<u>Fees Earned or Paid in Cash (S)(1)</u>	<u>Option Awards (S)(2)</u>	<u>Total (S)</u>
Daniel Burgess	82,500	101,113(4)	183,613
Axel Bolte(3)	—	—	—
Colin Broom	16,982	—	16,982
George Talbot	40,114	79,663(6)	119,777
Charles Rowland, Jr.	62,542	93,963(5)	156,505
Stephen Webster	54,058	79,663(6)	133,721
Mark Corrigan	44,630	79,663(6)	124,293
Carrie Bourdow	44,000	79,663(6)	123,663

- (1) Fees earned consist of gross director retainer fees which were subject to income tax withholdings in Ireland.
- (2) The amounts reported in the "Option Awards" column reflect the aggregate fair value of share-based compensation awarded during 2018 computed in accordance with the provisions of ASC Topic 718.
- (3) Mr. Bolte has declined to accept either cash or equity compensation for his services on our board of directors.

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- (4) Represents the grant of an option to purchase 44,000 of our ordinary shares vesting with respect to all of the shares on the last date of the month of the first anniversary of the grant date.
- (5) Represents the grant of an option to purchase 39,000 of our ordinary shares vesting with respect to all of the shares on the last date of the month of the first anniversary of the grant date.
- (6) Represents the grant of an option to purchase 10,100 of our ordinary shares vesting with respect to all of the shares on the last date of the month of the first anniversary of the grant date.

**Director Compensation Arrangements**

Following the Redomiciliation, we adopted a non-employee director compensation policy for our directors, which provided for the following:

- each new non-employee director receives an initial grant of an option to purchase 20,200 of our ordinary shares upon his or her initial election to the board of directors;
- each non-employee director receives an annual grant of an option to purchase 10,100 of our ordinary shares on the date of our annual general meeting of shareholders;
- each non-employee director receives an annual cash fee of \$38,500;
- the chairman of our board of directors receives an additional annual cash fee of \$27,500;
- each non-employee director who is a member of the audit committee receives an additional annual cash fee of \$8,250 (\$16,500 for the audit committee chair);
- each non-employee director who is a member of the compensation committee receives an additional annual cash fee of \$5,500 (\$11,000 for the compensation committee chair); and
- each non-employee director who is a member of the nominating and corporate governance committee receives an additional annual cash fee of \$3,850 (\$8,250 for the nominating and corporate governance committee chair).

On March 12, 2018, our board of directors approved an amendment to our non-employee director compensation policy. Effective as of March 12, 2018, the amendment increased the initial grant of an option to purchase our ordinary shares to new non-employee directors upon their initial election to the board of directors to 58,000 ordinary shares and increased the annual grant of an option to purchase our ordinary shares for each non-employee director to 29,000 ordinary shares. The board of directors approved the annual grants to non-employee directors for the 2018 fiscal year on May 2, 2018.

On October 31, 2018, our board of directors approved an amendment to our non-employee director compensation policy. Effective as of October 31, 2018, we adopted a non-employee director compensation policy for our directors, which provides for the following:

- each new non-employee director receives an initial grant of an option to purchase 70,000 of our ordinary shares upon his or her initial election to the board of directors;
- each non-employee director receives an annual grant of an option to purchase 35,000 of our ordinary shares on the date of our annual general meeting of shareholders;

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- each non-employee director receives an annual cash fee of \$40,000;
- the chairman of our board of directors receives an additional annual cash fee of \$30,000;
- each non-employee director who is a member of the audit committee receives an additional annual cash fee of \$10,000 (\$20,000 for the audit committee chair);
- each non-employee director who is a member of the compensation committee receives an additional annual cash fee of \$7,500 (\$15,000 for the compensation committee chair); and
- each non-employee director who is a member of the nominating and corporate governance committee receives an additional annual cash fee of \$5,000 (\$10,000 for the nominating and corporate governance committee chair).

The stock options to be granted to our non-employee directors under our non-employee director compensation policy have an exercise price equal to the fair market value of our ordinary shares on the date of grant and will expire ten years after the date of grant. The initial stock options granted to newly elected director vest, subject to such director's continued service on the board, over a three-year period on a monthly pro-rata basis at the end of each successive month following the date of the initial grant. The annual stock options granted to directors will vest, subject to such director's continued service on the board, fully on the last date of the month of the first anniversary of the grant date.

Under our non-employee director compensation policy, the annual cash fees are payable in arrears in four equal quarterly installments payable the week following the end of each quarter. Each non-employee director is also entitled to reimbursement for reasonable travel and other expenses incurred in connection with attending meetings of the board of directors and any committee on which he or she serves or otherwise in direct service of the company.

### **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 January 31, 2019 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
- 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 67,645,598 ordinary shares outstanding as of January 31, 2019.

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 January 31, 2019 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

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community property laws, where applicable. Except as otherwise set forth below, the address of the beneficial owner is c/o Nabriva Therapeutics plc, 25-28 North Wall Quay, Dublin 1, Ireland.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
<b>Directors, Director Nominees and Named Executive Officers:</b>		
Daniel Burgess(1)	73,594	*0%
George H. Talbot(2)	104,507	*0%
Mark Corrigan(3)	37,594	*0%
Stephen Webster(4)	45,594	*0%
Charles A. Rowland, Jr.(5)	87,867	*0%
Carrie Bourdow(6)	21,322	*0%
Colin Broom(7)	824,429	1.21%
Steven Gelone(8)	238,759	*0%
Theodore Schroeder(9)	60,741	*0%
Francesco Lavino(10)	95,386	*0%
All current directors and executive officers as a group (13 individuals)(11)	1,868,456	2.70%
<b>5% Shareholders:</b>		
Entities affiliated with Vivo(12)	6,619,190	9.79%
Novo Holdings A/S(13)	4,703,720	6.95%
Longitude Capital Management Co., LLC(14)	4,012,375	5.93%
Frazier Healthcare(15)	4,012,374	5.93%
OrbiMed Private Investments V, L.P.(16)	3,919,600	5.79%

\* Less than one percent.

- (1) Consists of (i) 36,000 ordinary shares and (ii) 37,594 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2019.
- (2) Consists of (i) 47,640 ordinary shares and (ii) 56,867 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2019.
- (3) Consists of 69,400 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2019.
- (4) Consists of (i) 8,000 ordinary shares and (ii) 69,400 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2019.
- (5) Consists of (i) 53,000 ordinary shares and (ii) 34,867 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2019.
- (6) Consists of 21,322 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2019.
- (7) Consists of (i) 175,000 ordinary shares directly owned by Dr. Broom and (ii) 649,429 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2019.
- (8) Consists of (i) 22,740 ordinary shares and (ii) 216,019 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2019.
- (9) Consists of 60,741 ordinary shares.
- (10) Consists of (i) 3,719 ordinary shares and (ii) 91,667 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2019.



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- (11) Consists of (i) 428,540 ordinary shares and (ii) 1,439,916 ordinary shares issuable upon exercise of stock options within 60 days of January 31, 2019.
- (12) Based solely upon Schedule 13G filed on February 14, 2019, which sets forth beneficial ownership as of December 31, 2018. Consists of (i) 4,218,777 ordinary shares and held by Vivo Hong Kong VIII Co., Limited, wholly owned subsidiary of Vivo Capital Fund VIII, L.P., (ii) 582,556 ordinary shares held by Vivo Hong Kong VIII Surplus Co., Limited, wholly owned subsidiary of Vivo Capital Surplus Fund VIII, L.P. and (iii) 1,817,857 ordinary shares and held by Vivo Opportunity, LLC. Vivo Capital VIII, LLC is the general partner of both Vivo Capital Fund VIII, L.P. and Vivo Capital Surplus Fund VIII, L.P. The voting members of Vivo Capital VIII, LLC are Frank Kung, Albert Cha, Edgar Engleman, Chen Yu and Shan Fu, none of whom has individual voting or investment power with respect to these shares and each of whom disclaims beneficial ownership of such shares of Vivo Hong Kong VIII Co., Limited and Vivo Hong Kong VIII Surplus Co., Limited. Vivo Opportunity, LLC is the general partner of Vivo Opportunity Fund, L.P. The voting members of Vivo Opportunity, LLC are Albert Cha, Gaurav Aggarwal, Shan Fu, Frank Kung and Michael Chang, none of whom has individual voting or investment power with respect to these shares of Vivo Opportunity, LLC and each of whom disclaims beneficial ownership of such shares. The address for Vivo Capital VIII, LLC and Vivo Opportunity, LLC is 505 Hamilton Avenue, Suite 207, Palo Alto, California 94301.
- (13) Based solely upon Schedule 13G filed on February 1, 2019, which sets forth beneficial ownership as of December 31, 2018. Novo Holdings A/S, a Danish limited liability company, is wholly owned by Novo Nordisk Fonden (the "Foundation"), a Danish commercial foundation. Novo Holdings A/S is the holding company in the group of Novo companies (currently comprised of Novo Nordisk A/S, Novozymes A/S and NNIT A/S) and is responsible for managing the Foundation's assets, including its financial assets. Based on the governance structure of Novo Holdings A/S and the Foundation, the Foundation disclaims any beneficial ownership of the shares held by Novo Holdings A/S. Novo Holdings A/S, through its board of directors (the "Novo Board"), has the sole power to vote and dispose of the shares. Lars Rebien Sorensen, Steen Riisgaard, Francis Cuss, Jean-Luc Butel, Jeppe Christiansen and Vivian Monges serve on the Novo Board and may exercise voting and dispositive control over the shares only with the support of a majority of the Novo Board. As such, no individual member of the Novo Board is deemed to hold any beneficial ownership or reportable pecuniary interest in the shares. The business address of Novo Holdings A/S is Tuborg Havnevej 19, 2900 Hellerup, Denmark.
- (14) Based solely upon Schedule 13G filed on August 7, 2018, which sets forth beneficial ownership as of July 31, 2018 for Longitude Venture Partners II, L.P. ("LVPII"), Longitude Capital Partners II, LLC ("LCPII"), Juliet Tammenoms Bakker and Patrick G. Enright. The ordinary shares are owned of record by LVPII. LCPII is the sole general partner of LVPII, and Ms. Bakker and Mr. Enright are managing members of LCPII. The address for these entities and persons is 2740 Sand Hill Road, Second Floor, Menlo Park, California 94025.
- (15) Based solely upon Schedule 13G filed on August 2, 2018, which sets forth beneficial ownership as of July 24, 2018 for Frazier Healthcare VII, L.P. and Frazier Healthcare VII-A, L.P. FHM VII, L.P. is the general partner of both Frazier Healthcare VII, L.P. and Frazier Healthcare VII-A, L.P., and FHM VII, L.L.C. is the general partner of FHM VII, L.P. Alan Frazier, Nader Naini, Patrick Heron, James Topper, Nathan Every and Brian Morfitt are the members of FHM VII, L.L.C. and therefore share voting and investment power over the ordinary shares. The address for these entities and persons is c/o Frazier Healthcare Partners, 601 Union Street, Suite 3200, Seattle, Washington 98101.
- (16) Based solely upon the Schedule 13D filed on January 26, 2018, which sets forth beneficial ownership as of January 24, 2018 for OrbiMed Private Investments V-NB B.V., or OPI V-NB and

OrbiMed Private Investments V, L.P., or OPI V. OrbiMed Private Investments V Cooperatief U.A., or Cooperatief, is the sole stockholder of OPI V-NB. OPI V is the majority member of Cooperatief, and OrbiMed Capital GP V LLC, or GP V, is the sole general partner of OPI V. OrbiMed Advisors LLC, or OrbiMed Advisors, is the managing member of GP V. GP V and OrbiMed Advisors may be deemed to have beneficial ownership of the shares held by OPI V and OPI V-NB. OrbiMed Advisors exercises its investment and voting power with respect to the shares held by OPI V-NB and OPI V through a management committee comprised of Carl L. Gordon, Sven H. Borho and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of such shares. Each of GP V and OrbiMed Advisors disclaims beneficial ownership of the shares held by OPI V and OPI V-NB except to the extent of its or his pecuniary interest therein, if any. The address for these entities is 601 Lexington Avenue, 54th floor, New York, New York 10022.

#### Securities Authorized for Issuance under Equity Compensation Plans

The following table contains information about our equity compensation plans as of December 31, 2018, as adjusted to reflect our assumption of the option granted under the Stock Option Plan 2015 in connection with the Redomiciliation. As of December 31, 2018, Nabriva had three equity compensation plans, the 2017 Share Incentive Plan, the Stock Option Plan 2015 and the 2018 Employee Share Purchase Plan, each of which were approved by our shareholders. In addition, from time to time, the compensation committee grants inducement equity awards to individuals as an inducement material to the individual's entry into employment with us within the meaning of Nasdaq Listing Rules.

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a))</u>
	(a)	(b)	(c)
Equity compensation plans approved by security holders	6,463,438(1)	\$ 6.52(2)	1,543,853(3)
Equity compensation plans not approved by security holders	1,000,000(4)	3.53(2)	—
<b>Total</b>	<b>7,463,438</b>	<b>\$ 6.52(2)</b>	<b>1,543,853</b>

- (1) Includes ordinary shares underlying awards outstanding under our 2017 Share Incentive Plan and our Stock Option Plan 2015.
- (2) Only share option awards were used in computing the weighted-average exercise price.
- (3) Includes ordinary shares available for issuance under our 2017 Share Incentive Plan and 2018 Employee Share Purchase Plan.
- (4) Represents an option award and a performance-based restricted share unit award granted to Mr. Schroeder on July 25, 2018, as an inducement material to Mr. Schroeder's acceptance of employment with the company in accordance with Nasdaq Listing Rule 5635(c)(4).

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

*Board Determination of Independence*

Applicable Nasdaq rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the Nasdaq rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under applicable Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. To be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of the director, including any consulting, advisory or other compensatory fee paid by such company to the director; and (2) whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In March 2019, our board of directors undertook a review of the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board has determined that each of our directors, with the exception of Colin Broom and Theodore Schroeder, is an "independent director" as defined under applicable Nasdaq rules, including, in the case of all the members of our audit committee, the independence criteria set forth in Rule 10A-3 under the Exchange Act, and in the case of all the members of our compensation committee, the independence criteria set forth in Rule 10C-1 under the Exchange Act. In making such determination, our board considered the relationships that each such director has with us, including each of the transactions described below in "[Board Policies—Related Person Transactions—Certain Relationships and Related Transactions](#)," and all other facts and circumstances that our board deemed relevant in make such independence determination.

**Board Policies**

*Related Person Transactions*

Our board of directors has adopted written policies and procedures for the review of any transaction, arrangement or relationship in which the company is a participant, the amount involved exceeds the lesser of \$120,000 and one percent of the average of the our total assets at year-end for the last two completed fiscal years and one of our executive officers, directors, director nominees or 5% shareholders, or their immediate family members, each of whom we refer to as a "related person," has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a "related person transaction," the related person must report the proposed related

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person transaction to our chief financial officer or general counsel. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by our audit committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the committee will review, and, in its discretion, may ratify the related person transaction. The policy also permits the chair of the audit committee to review and, if deemed appropriate, approve proposed related person transactions that arise between committee meetings, subject to ratification by the committee at its next meeting. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the audit committee after full disclosure of the related person's interest in the transaction. As appropriate for the circumstances, the audit committee will review and consider:

- the related person's interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person's interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of our business;
- whether the terms of the transaction are no less favorable to us than terms that could have been reached with an unrelated third party;
- the purpose of, and the potential benefits to us of, the transaction; and
- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of such transaction.

Our audit committee may approve or ratify the transaction only if it determines that, under all of the circumstances, the transaction is in our best interests. Our audit committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC's related person transaction disclosure rule, our board of directors has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- interests arising solely from the related person's position as an executive officer of another entity, whether or not the person is also a director of the entity, that is a participant in the transaction where the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity, the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction and the amount involved in the transaction is less than the greater of \$200,000 or 5% of the annual gross revenues of the company receiving payment under the transaction; and
- a transaction that is specifically contemplated by provisions of our memorandum and articles of association.

The policy provides that transactions involving compensation of our executive officers shall be reviewed and approved by our compensation committee in the manner specified in the compensation committee's charter.

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In addition, under our Code of Business Conduct and Ethics, our directors, executive officers and employees have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest.

***Certain Relationships and Related Transactions***

Since January 1, 2018, we have engaged in the following transactions with our executive officers, directors and holders of more than 5% of our voting securities, and affiliates of our executive officers, directors and 5% shareholders. We believe that all of the transactions described below were made on terms no less favorable to us than could have been obtained from unaffiliated third parties:

*July 2018 Financing*

In July 2018, we completed an underwritten offering for the sale of an aggregate of 18,181,818 ordinary shares. In connection with such offerings, our 5% shareholders, purchased an aggregate of 8,715,000 ordinary shares at a purchase price of \$2.75 per ordinary share.

<u>5% Shareholders:</u>	<u>Number of Shares Acquired</u>
Entities affiliated with Vivo Capital	2,545,000
Novo A/S	1,815,000
Longitude Ventures Partners	1,815,000
Frazier Healthcare Partners	1,815,000
OrbiMed Private Investments V, L.P.	725,000

*At-the-Market Offering*

In March 2018, Wellington Management Group LLP, purchased an aggregate of 3,414,100 of our ordinary shares at a purchase price of \$5.50 per share under our "at-the-market" offering program. Following such purchase, Wellington Management Group LLP beneficially owned more than 5% of our outstanding share capital.

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

The following table sets forth, for each of the years indicated, the aggregate fees billed or expected to be billed to us for services rendered by KPMG LLP, or KPMG, and PwC Wirtschaftsprüfung GmbH, or PwC, our independent registered public accounting firms during the periods indicated. Effective June 2017, we engaged KPMG as our independent registered public accounting firm replacing PwC, as further described in Part II, Item 9 "Changes in and Disagreements with Accountants on Accounting and Financial Disclosure".

<u>(in thousands)</u>	<u>Year Ended December 31,</u>	
	<u>2018</u>	<u>2017</u>
Audit Fees	\$ 654	\$ 467
Audit-Related Fees(1)	—	—
Tax Fees(2)	23	24
All Other Fees(3)	235	1,210
<b>Total</b>	<b>\$ 912</b>	<b>\$ 1,701</b>

(1) Fees for the performance of assurance reporting on historical information

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- (2) Fees related to services rendered on tax compliance, tax advice and tax planning.
- (3) Fees related to services associated with our 2017 public offering, at-the-market facility, July 2018 public offering and Zavante acquisition.

**Pre-Approval Policies and Procedures**

Our audit committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by our independent registered public accounting firm. This policy generally provides that we will not engage our independent registered public accounting firm to render audit or non-audit services unless the service is specifically approved in advance by our audit committee or the engagement is entered into pursuant to a de minimis exception in accordance with applicable SEC rules.

All of the services provided to us by KPMG and PwC Wirtschaftsprüfung GmbH during the last two fiscal years were approved by the audit committee.

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

- (a) (1) Financial Statements: See Index to Consolidated Financial Statements on page F-1.
- (2) No financial statement schedules have been filed as part of this Annual Report on Form 10-K because they are not applicable, not required or because the information is otherwise included in our financial statements or notes thereto.
- (3) The exhibits listed on the Exhibit Index set forth immediately following Item 16 are filed or furnished as part of this Annual Report. The Exhibit Index is incorporated herein by reference.

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

None

**EXHIBIT INDEX**

Exhibit Number	Description of Exhibit	Incorporated by Reference			Filed Herewith
		Form	File Number	Date of Filing	
2.1*	<a href="#">Agreement and Plan of Merger dated as of July 23, 2018, by and among Nabriva Therapeutics plc, Zuperbug Merger Sub I, Inc., Zuperbug Merger Sub II, Inc., Zavante Therapeutics, Inc. and Cam Gallagher, solely in his capacity as Stockholder Representative</a>	8-K	001-37558	07/25/2018	2.1
3.1	<a href="#">Memorandum and Articles of Association of Nabriva Therapeutics plc.</a>	8-K	001-38132	06/26/2017	3.1
10.1	<a href="#">Form of Indemnification Agreement.</a>	8-K	001-38132	06/26/2017	10.1
10.2#	<a href="#">2017 Share Incentive Plan, as Amended.</a>	10-Q	001-37558	11/09/2017	10.2
10.3#	<a href="#">Stock Option Plan 2007, as Amended.</a>	8-K	001-38132	06/26/2017	10.2
10.4#	<a href="#">Stock Option Plan 2015, as Amended.</a>	8-K	001-38132	6/26/2017	10.3
10.5	<a href="#">Lease Agreement, dated March 16, 2007, by and between Nabriva Therapeutics AG and CONTRA Liegenschaftsverwaltung GmbH</a>	F-1	333-205073	06/18/15	10.4

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Exhibit Number	Description of Exhibit	Incorporated by Reference			Filed Herewith
		Form	File Number	Date of Filing	
10.6	<a href="#">Sublease Agreement, dated July 7, 2015, by and between Nabriva Therapeutics AG and Card Connect, LLC</a>	F-1	333-205073	8/24/15	10.11
10.7 <sup>#</sup>	<a href="#">Amended and Restated Employment Agreement dated June 17, 2016 by and between Nabriva Therapeutics US, Inc. and Colin Broom</a>	6-K	001-37558	08/09/16	10.1
10.8 <sup>#</sup>	<a href="#">Employment Agreement dated May 2, 2016 by and between Nabriva Therapeutics US, Inc. and Gary Sender</a>	6-K	001-37558	08/09/16	10.2
10.9 <sup>#</sup>	<a href="#">Employment Agreement, dated June 14, 2017, by and between Nabriva Therapeutics US, Inc. and Robert Crotty.</a>	10-Q	001-37558	08/07/2017	10.4
10.10 <sup>#</sup>	<a href="#">Employment Agreement, dated July 6, 2017, by and among the Registrant, Nabriva Therapeutics US, Inc. and Francesco M. Lavino.</a>	10-Q	001-37558	08/07/2017	10.5
10.11 <sup>#</sup>	<a href="#">Separation and Release of Claims Agreement, dated as of August 31, 2017, by and between Nabriva Therapeutics US, Inc. and Elyse Seltzer.</a>	8-K	001-37558	08/31/2017	10.1
10.12 <sup>#</sup>	<a href="#">Form of Restricted Share Unit Agreement under the 2017 Share Incentive Plan</a>	8-K	001-37558	02/02/2018	10.1
10.13 <sup>#</sup>	<a href="#">Form of Share Option Agreement under the 2017 Share Incentive Plan</a>	8-K	001-37558	02/02/2018	10.2
10.14 <sup>*</sup>	<a href="#">Manufacturing Services Agreement, dated May 8, 2017, by and between Patheon UK Limited and Nabriva Therapeutics AG</a>	10-K	03/16/2018	03/16/2018	10.16



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Exhibit Number	Description of Exhibit	Incorporated by Reference			Filed Herewith
		Form	File Number	Date of Filing	
10.15*	<a href="#">Master Agreement for the Manufacture, Packaging and Supply of Products, dated August 7, 2017, by and between ALMAC Pharma Services Limited and Nabriva Therapeutics Ireland DAC</a>	10-K	03/16/2018	03/16/2018	10.17
10.16*	<a href="#">Key Intermediate Supply Agreement, dated of August 28, 2017 by and among Nabriva Therapeutics Ireland DAC, and SEL Biochem Xinjiang Co., Ltd, and Fountain International Development Holding Limited</a>	10-K	03/16/2018	03/16/2018	10.18
10.17	<a href="#">Controlled Equity Offering Sales Agreement dated March 16, 2018, by and between the registrant and cantor Fitzgerald &amp; Co.</a>	8-K	001-37558	03/16/2018	1.1
10.18*	<a href="#">License Agreement, dated March 26, 2018, by and among Nabriva Therapeutics Ireland DAC, Sinovant Sciences, Ltd., Nabriva Therapeutics GmbH and Roivant Sciences, Ltd.</a>	10-Q	001-37558	05/08/2018	10.2
10.19	<a href="#">Transition, Separation and Release of Claims Agreement, by and between Nabriva Therapeutics US, Inc. and Colin Broom, dated as of July 23, 2018</a>	8-K	001-37558	07/25/2018	10.1
10.20#	<a href="#">Employment Agreement, by and between Nabriva Therapeutics US, Inc. and Theodore Schroeder, dated as of July 23, 2018</a>	8-K	001-37558	07/25/2018	10.2
10.21	<a href="#">Consulting Agreement, by and between Nabriva Therapeutics US, Inc. and Colin Broom, dated as of July 24, 2018 (included as Attachment A to Exhibit 10.1)</a>	8-K	001-37558	07/25/2018	10.1
10.22	<a href="#">Form of Inducement Option Award Agreement.</a>	S-8	333-226330	07/25/2018	99.2

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Exhibit Number	Description of Exhibit	Incorporated by Reference			Filed Herewith
		Form	File Number	Date of Filing	
10.23	<a href="#">Form of Inducement Performance-Based Share Award Agreement.</a>	S-8	333- 226330	07/25/2018	99.3
10.24	<a href="#">Stock Purchase Agreement by and among SG Pharmaceuticals, Inc., the Sellers named on Annex A, and Julia Feliciano, as Sellers' Representative, dated as of May 5, 2015</a>	10-Q	001- 37558	11/06/2018	10.4
10.25*	<a href="#">License Agreement by and between ICPD Holdings, LLC and Evelyn J. Ellis-Grosse and Zavante Therapeutics, Inc., dated as of March 1, 2014</a>	10-Q	001- 37558	11/06/2018	10.5
10.26	<a href="#">Office Lease by and between AGP Sorrento R&amp;D, LP and Zavante Therapeutics, Inc., dated as of June 16, 2016</a>	10-Q	001- 37558	11/06/2018	10.6
10.27*	<a href="#">Manufacturing and Supply Agreement by and between Zavante Therapeutics, Inc. and Ercros, S.A., dated as of July 28, 2016</a>	10-Q	001- 37558	11/06/2018	10.7
10.28*	<a href="#">Amended and Restated Three-Way Agreement by and between Laboratorios ERN, S.A, Ercros, S.A., and Zavante Therapeutics, Inc., dated as of July 28, 2016</a>	10-Q	001- 37558	11/06/2018	10.8
10.29*	<a href="#">Amended and Restated Pharmaceutical Manufacturing and Exclusive Supply Agreement by and between Laboratorios ERN, S.A. and Zavante Therapeutics, Inc. dated as of July 28, 2016, as amended</a>	10-Q	001- 37558	11/06/2018	10.9
10.30*	<a href="#">Manufacturing and Supply Agreement by and between Zavante Therapeutics, Inc. and Fisiopharma, S.r.l., dated as of April 25, 2017</a>	10-Q	001- 37558	11/06/2018	10.10

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Exhibit Number	Description of Exhibit	Incorporated by Reference			Filed Herewith
		Form	File Number	Date of Filing	
10.31*	<a href="#">Commercial Packaging Agreement by and between Zavante Therapeutics, Inc. and Anderson Brecon Inc., d/b/a PCI of Illinois, dated as of December 26, 2017</a>	10-Q	001-37558	11/06/2018	10.11
10.32*	<a href="#">Packaging and Supply Agreement by and between Sharp Corporation and Nabriva Therapeutics US, Inc., dated as of August 30, 2018</a>	10-Q	001-37558	11/06/2018	10.12
10.33#	<a href="#">Second Amended and Restated Employment Agreement by and between Nabriva Therapeutics US, Inc. and Steven Gelone, dated as of July 24, 2018</a>	10-Q	001-37558	11/06/2018	10.13
10.34#	<a href="#">2018 Employee Share Purchase Plan (incorporated by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on June 19, 2018).</a>	DEF 14A	001-37558	06/19/2018	99.1
10.35**	<a href="#">Loan and Security Agreement, dated as of December 20, 2018, by and among Nabriva Therapeutics plc, Nabriva Therapeutics Ireland DAC, certain other subsidiaries of Nabriva Therapeutics plc from time to time party thereto, any bank and other financial institution or entity from time to time party thereto and Hercules Capital, Inc. as administrative agent and collateral agent.</a>				X
10.36#	<a href="#">Employment Agreement, by and between Nabriva Therapeutics US, Inc. and Jennifer Schranz, dated as of March 21, 2018</a>				X

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Exhibit Number	Description of Exhibit	Incorporated by Reference			Filed Herewith
		Form	File Number	Date of Filing	
10.37**	<a href="#">Agreement for the Commercial Supply of Products by and between Arran Chemical Company Limited and Nabriva Therapeutics Ireland DAC, dated as of November 12, 2018</a>				X
10.38**	<a href="#">Active Pharmaceutical Ingredient Supply Agreement by and between Nabriva Therapeutics Ireland DAC and Hovione Limited, dated as of November 23, 2018.</a>				X
21.1	<a href="#">Subsidiaries of Nabriva Therapeutics plc</a>				X
23.1	<a href="#">Consent of KPMG LLP</a>				X
31.1	<a href="#">Certification of principal executive officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				X
31.2	<a href="#">Certification of principal financial officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				X
32.1	<a href="#">Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				X
32.2	<a href="#">Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				X
101.INS	XBRL Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X

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Exhibit Number	Description of Exhibit	Incorporated by Reference			Filed Herewith
		Form	File Number	Date of Filing	
101.CAL	XBRL Taxonomy Calculation Linkbase Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	XBRL Taxonomy Label Linkbase Document				X
101.PRE	XBRL Taxonomy Presentation Linkbase Document				X
#	Management contract or compensatory plan or arrangement filed in response to Item 15(a)(3) of the Instructions to the Annual Report on Form 10-K.				
*	Confidential treatment was granted for certain portions that are omitted from this exhibit. The omitted information has been filed separately with the U.S. Securities and Exchange Commission (the "SEC") pursuant to the registrant's application for confidential treatment. In addition, schedules have been omitted from this exhibit pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule will be furnished supplementally to the SEC upon request; provided, however, that the registrant may request confidential treatment for any document so furnished.				
**	Confidential treatment has been requested as to certain portions, which portions have been omitted and separately filed with the Securities and Exchange Commission.				



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<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ STEPHEN WEBSTER</u> Stephen Webster	Director	March 12, 2019
<u>/s/ MARK CORRIGAN</u> Mark Corrigan	Director	March 12, 2019

INDEX TO FINANCIAL STATEMENTS

**Nabriva Therapeutics plc**

**Audited Consolidated Financial Statements**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Stockholders and Board of Directors  
Nabriva Therapeutics plc.:

*Opinion on the Consolidated Financial Statements*

We have audited the accompanying consolidated balance sheets of Nabriva Therapeutics plc and subsidiaries (the Company) as of December 31, 2017 and 2018, the related consolidated statements of operations and comprehensive income (loss), changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2018, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2018, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

*Basis for Opinion*

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2017.

Philadelphia, Pennsylvania  
March 12, 2019

**NABRIVA THERAPEUTICS plc**

**Consolidated Balance Sheets**

<u>(in thousands, except share data)</u>	As of December 31, 2017	As of December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 86,769	\$ 102,003
Short-term investments	110	225
Other receivables	5,402	3,871
Contract asset	—	1,500
Prepaid expenses	1,558	1,154
Total current assets	93,839	108,753
Property, plant and equipment, net	1,327	1,139
Intangible assets, net	172	98
Long-term receivables	425	428
<b>Total assets</b>	<b>\$ 95,763</b>	<b>\$ 110,418</b>
<b>Liabilities and Stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 5,136	\$ 3,304
Accrued expense and other current liabilities	8,124	14,502
Total current liabilities	13,260	17,806
Non-current liabilities		
Long-term debt	232	23,718
Other non-current liabilities	203	264
Total non-current liabilities	435	23,982
<b>Total liabilities</b>	<b>13,695</b>	<b>41,788</b>
Commitments and contingencies (Note 14)		
Stockholders' Equity:		
Ordinary shares, nominal value \$0.01, 1,000,000,000 ordinary shares authorized at December 31, 2018; 36,707,685 and 67,019,094 issued and outstanding at December 31, 2017 and 2018, respectively	367	670
Preferred shares, par value \$0.01, 100,000,000 shares authorized at December 31, 2018; None issued and outstanding	—	—
Additional paid in capital	360,872	461,911
Accumulated other comprehensive income	27	27
Accumulated deficit	(279,198)	(393,978)
<b>Total stockholders' equity</b>	<b>82,068</b>	<b>68,630</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 95,763</b>	<b>\$ 110,418</b>

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

NABRIVA THERAPEUTICS plc

Consolidated Statements of Operations and Comprehensive Income (Loss)

(in thousands, except share and per share data)	Year ended December 31,		
	2016	2017	2018
<b>Revenues:</b>			
Collaboration revenue	\$ —	\$ —	\$ 6,500
Research premium and grant revenue	6,482	5,319	3,156
<b>Total revenues</b>	<b>6,482</b>	<b>5,319</b>	<b>9,656</b>
<b>Operating expenses:</b>			
Research and development	(47,994)	(49,615)	(82,288)
General and administrative	(13,535)	(29,472)	(41,743)
Total operating expenses	(61,529)	(79,087)	(124,031)
<b>Loss from operations</b>	<b>(55,047)</b>	<b>(73,768)</b>	<b>(114,375)</b>
<b>Other income (expense):</b>			
Other income (expense), net	(783)	492	(272)
Interest income	343	318	49
Interest expense	(75)	(43)	(133)
<b>Loss before income taxes</b>	<b>(55,562)</b>	<b>(73,001)</b>	<b>(114,731)</b>
Income tax (expense) benefit	672	(1,355)	(49)
<b>Net loss</b>	<b>(54,890)</b>	<b>(74,356)</b>	<b>(114,780)</b>
<b>Other comprehensive income (loss), net of tax</b>			
Unrealized losses on available-for-sale securities	(18)	(26)	—
Reclassification to net income	68	43	—
Other comprehensive income, net of tax	50	17	—
<b>Comprehensive loss</b>	<b>\$ (54,840)</b>	<b>\$ (74,339)</b>	<b>\$ (114,780)</b>
<b>Loss per share</b>			
Basic and diluted	<b>\$ (2.56)</b>	<b>\$ (2.49)</b>	<b>\$ (2.26)</b>
<b>Weighted average number of shares:</b>			
Basic and diluted	<b>21,478,320</b>	<b>29,830,669</b>	<b>50,795,768</b>

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

**NABRIVA THERAPEUTICS plc**

**Consolidated Statements of Changes in Stockholders' Equity**

(in thousands)	Common Stock/ Ordinary Shares		Treasury Shares		Additional paid in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total Stockholders' Equity
	Number of shares	Amount	Number of shares	Amount				
<b>January 1, 2016</b>	<b>2,120</b>	<b>\$ 2,308</b>	<b>3</b>	<b>\$ (22)</b>	<b>\$ 256,412</b>	<b>\$ (40)</b>	<b>\$ (149,952)</b>	<b>\$ 108,706</b>
Issuance of common stock	588	618	—	—	24,204	—	—	24,822
Exercise of stock options	12	13	(3)	22	235	—	—	270
Equity transaction costs	—	—	—	—	(4,247)	—	—	(4,247)
Stock-based compensation expense	—	—	—	—	2,545	—	—	2,545
Other comprehensive income, net of tax	—	—	—	—	—	50	—	50
Net loss	—	—	—	—	—	—	(54,890)	(54,890)
<b>December 31, 2016</b>	<b>2,720</b>	<b>2,939</b>	<b>—</b>	<b>—</b>	<b>279,149</b>	<b>10</b>	<b>(204,842)</b>	<b>77,256</b>
Issuance of common stock	9,412	94	—	—	79,906	—	—	80,000
Exercise of stock options	54	3	—	—	51	—	—	54
Equity transaction costs	—	—	—	—	(6,635)	—	—	(6,635)
Redomiciliation share exchange	24,522	(2,669)	—	—	2,669	—	—	—
Stock-based compensation expense	—	—	—	—	5,732	—	—	5,732
Other comprehensive income, net of tax	—	—	—	—	—	17	—	17
Net loss	—	—	—	—	—	—	(74,356)	(74,356)
<b>December 31, 2017</b>	<b>36,708</b>	<b>367</b>	<b>—</b>	<b>—</b>	<b>360,872</b>	<b>27</b>	<b>(279,198)</b>	<b>82,068</b>
Issuance of common stock	22,974	230	—	—	73,989	—	—	74,219
Equity transaction costs	—	—	—	—	(4,933)	—	—	(4,933)
Stock-based compensation expense	—	—	—	—	5,154	—	—	5,154
Shares issued in connection with the acquisition of Zavante Therapeutics, Inc.	7,337	73	—	—	26,829	—	—	26,902
Net loss	—	—	—	—	—	—	(114,780)	(114,780)
<b>December 31, 2018</b>	<b>67,019</b>	<b>\$ 670</b>	<b>—</b>	<b>\$ —</b>	<b>\$ 461,911</b>	<b>\$ 27</b>	<b>\$ (393,978)</b>	<b>\$ 68,630</b>

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

**NABRIVA THERAPEUTICS plc**  
**Consolidated Statements of Cash Flows**

(in thousands)	Year ended December 31		
	2016	2017	2018
<b>Cash flows from operating activities</b>			
Net loss	\$ (54,890)	\$ (74,356)	\$ (114,780)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash other income, net	996	(1,371)	362
Non-cash interest income	(52)	—	45
Non-cash interest expense	35	—	(104)
Depreciation and amortization expense	233	432	510
Stock-based compensation	2,545	5,732	5,154
In-process research and development	—	—	32,048
Deferred income taxes	(794)	1,410	—
Other, net	1	131	14
Changes in operating assets and liabilities:			
Changes in long-term receivables	10	(5)	(3)
Changes in other receivables	(1,932)	(223)	1,139
Changes in accounts payable	(383)	2,585	(2,969)
Changes in accrued expenses and other liabilities	6,034	(3,778)	5,742
Changes in other non-current liabilities	24	96	61
Changes in income tax liabilities	(152)	(1)	58
Net cash used in operating activities	(48,325)	(69,348)	(72,723)
<b>Cash flows from investing activities</b>			
Purchases of plant and equipment and intangible assets	(603)	(1,173)	(229)
Purchases of available-for-sale securities	(57,035)	—	—
Purchases of term deposits	(10)	(30)	(115)
Proceeds from sale of property, plant and equipment	—	2	—
Proceeds from maturities of term deposits	45,000	—	—
Proceeds from sales of available-for-sale securities	36,000	50,950	—
Transaction costs for Zavante acquisition, net of cash acquired	—	—	(4,260)
Net cash provided (used in) by investing activities	23,352	49,749	(4,604)
<b>Cash flows from financing activities</b>			
Proceeds from December 2016 financing	24,822	—	—
Proceeds from September 2017 public offering	—	80,000	—
Proceeds from July 2018 public offering	—	—	50,000
Proceeds from at-the-market facility	—	—	24,219
Proceeds from long-term debt	—	228	25,535
Proceeds from exercise of stock options	269	83	—
Debt transaction costs	—	—	(1,990)
Equity transaction costs	(2,790)	(8,092)	(4,841)
Net cash provided by financing activities	22,301	72,219	92,923
Effects of foreign currency translation on cash and cash equivalents	(996)	1,371	(362)
Net increase (decrease) in cash and cash equivalents	(3,668)	53,991	15,234
Cash and cash equivalents at beginning of year	36,446	32,778	86,769
Cash and cash equivalents at end of year	\$ 32,778	\$ 86,769	\$ 102,003
Supplemental disclosures of cash flow information:			
Interest paid	\$ (41)	\$ (1)	\$ (7)
Taxes paid	\$ (867)	\$ (5)	\$ (4)
Equity transaction costs included in accounts payable and accrued expenses	\$ 1,451	\$ 28	\$ 120

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

## NABRIVA THERAPEUTICS plc

### Notes to the Consolidated Financial Statements

(in thousands, except per share data)

#### 1. Organization and Business Activities

Nabriva Therapeutics plc ("Nabriva Ireland"), together with its wholly owned and consolidated subsidiaries, Nabriva Therapeutics GmbH ("Nabriva Austria"), Nabriva Therapeutics US, Inc., and Nabriva Therapeutics Ireland DAC, (collectively, "Nabriva", or the "Company") is a biopharmaceutical company engaged in the development of novel anti-infective agents to treat serious infections. On July 23, 2018, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") for the acquisition of Zavante Therapeutics Inc., ("Zavante") a biopharmaceutical company focused on developing CONTEPO (fosfomycin for injection). The Company has two product candidates that have been submitted to the U.S. Food and Drug Administration (the "FDA") for approval: lefamulin, potentially the first pleuromutilin antibiotic available for systemic administration in humans, and CONTEPO, a potentially first-in-class epoxide antibiotic for intravenous ("IV") administration in the United States. The Company is developing both IV and oral formulations of lefamulin for the treatment of community-acquired bacterial pneumonia ("CABP"). The Company is developing CONTEPO IV for complicated urinary tract infections ("cUTI") and may potentially develop lefamulin and CONTEPO for additional indications. The Company's headquarters are located at 25-28 North Wall Quay, Dublin, Ireland.

On June 23, 2017, Nabriva Therapeutics plc, a public limited company organized under the laws of Ireland, or Nabriva Ireland, became the successor issuer to Nabriva Therapeutics AG, a stock corporation (*Aktiengesellschaft*) organized under the laws of Austria ("Nabriva Austria"), for certain purposes under both the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, or the Exchange Act. Such succession occurred following the conclusion of a tender offer related to the exchange of American Depositary Shares and common shares of Nabriva Austria for ordinary shares of Nabriva Ireland, which resulted in Nabriva Ireland, a new Irish holding company, becoming the ultimate holding company of Nabriva Austria (the predecessor registrant and former ultimate holding company) and its subsidiaries, which we refer to as the Redomiciliation Transaction. On October 19, 2017, Nabriva Austria was converted into a limited liability company under Austrian law and renamed Nabriva Therapeutics GmbH.

Throughout these notes to the consolidated financial statements, unless the context requires otherwise, all references to "Nabriva," "the Company," or similar terms on or prior to June 23, 2017 (the effective date of the Redomiciliation Transaction), refer to the predecessor of the Company, Nabriva Austria, together with its subsidiaries.

#### *Liquidity*

Since its inception, the Company has incurred net losses and generated negative cash flows from its operations. To date, it has financed its operations through the sale of equity securities, convertible and term debt financings and research and development support from governmental grants and loans. As of December 31, 2018, the Company had cash, cash equivalents and short-term investments of \$102.2 million.

The Company follows the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 205-40, *Presentation of Financial Statements—Going Concern* ("ASC 205-40"), which requires management to assess the Company's ability to continue as a going concern for one year after the date the consolidated financial statements are issued.

**NABRIVA THERAPEUTICS plc**

**Notes to the Consolidated Financial Statements (Continued)**

**(in thousands, except per share data)**

**1. Organization and Business Activities (Continued)**

As of the date of this filing, management assessed the Company's ability to continue as a going concern and determined that it expects that its cash, cash equivalents and short-term investments as of December 31, 2018, proceeds from the sale of ordinary shares under the Company's ATM Agreement (as defined below) of \$5.9 million in the first quarter of 2019, as well as a \$1.5 million milestone payment received in February 2019 under its license agreement with Sinovant Sciences, Ltd., and research premiums from the Austrian government for its qualified research and development expenditures, will be sufficient to enable the Company to fund its operating expenses, debt service obligations and capital expenditure requirements into the second quarter of 2020. The Company has based this estimate on assumptions that may prove to be wrong, and the Company could use its capital resources sooner than it currently expects. This estimate assumes, among other things, that the Company does not obtain any additional funding through grants and clinical trial support, collaboration agreements, equity or debt financings, including additional advances under the Loan Agreement with Hercules. The Company may be eligible to borrow up an additional \$50.0 million under its Loan Agreement with Hercules if it achieves specified regulatory and product revenue milestones, including \$10.0 million that it will be eligible to borrow upon the approval by the FDA of an NDA for lefamulin and \$5.0 million that it will be eligible to borrow upon the approval by the FDA of an NDA for CONTEPO.

The Company's expenses will increase if it suffers any regulatory delays or is required to conduct additional clinical trials to satisfy regulatory requirements. If the Company obtains marketing approval for lefamulin, CONTEPO or any other product candidate that it develops, it expects to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. The Company will continue to invest in critical commercialization and supply chain activities prior to potentially receiving marketing approval and making lefamulin and CONTEPO available to patients.

The Company expects to seek additional funding in future periods for purposes of investment in its commercial and medical affairs organization as well as investing in its supply chain, including building active pharmaceutical ingredient safety stock for the commercial supply of lefamulin and CONTEPO, in an effort to enhance the potential commercial launch of lefamulin and CONTEPO.

In December 2018, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Hercules Capital, Inc., pursuant to which a term loan of up to an aggregate principal amount of \$75.0 million is available to the Company. The Loan Agreement provides for an initial term loan advance of \$25.0 million which was funded in connection with the closing of the Loan Agreement. The remaining \$50.0 million under the Loan Agreement is available to the Company from time to time subject to conditions further described in Note 8 below.

In March 2018, the Company entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement (the "ATM Agreement"), with Cantor Fitzgerald & Co. ("Cantor"), pursuant to which, from time to time, the Company may offer and sell its ordinary shares having aggregate gross proceeds of up to \$50.0 million through Cantor. As of March 5, 2019, the Company has issued and sold an aggregate of 7,742,379 ordinary shares under the ATM Agreement, for gross proceeds of \$30.3 million, and net proceeds of \$28.9 million, after deducting commissions and offering costs.

On July 31, 2018, the Company completed an underwritten public offering of 18,181,818 ordinary shares at a public offering price of \$2.75 per share, resulting in gross proceeds of \$50.0 million and net

**NABRIVA THERAPEUTICS plc**

**Notes to the Consolidated Financial Statements (Continued)**

**(in thousands, except per share data)**

**1. Organization and Business Activities (Continued)**

proceeds to the Company of \$46.3 million, after deducting underwriting discounts and commissions and offering expenses.

**2. Summary of Significant Accounting Policies**

**Basis of Preparation**

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("US GAAP") and US Securities and Exchange Commission ("SEC") regulations for annual reporting. The consolidated financial statements include the accounts of Nabriva Therapeutics plc and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

**Functional Currency Transactions and Balances**

In preparing the consolidated financial statements, transactions in currencies other than the U.S. dollar are recognized at the exchange rates prevailing at the dates of the transactions. Foreign currency exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the consolidated statements of comprehensive income (loss).

**Use of Estimates**

The preparation of consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the amount of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**Cash and Cash Equivalents**

The Company considers highly liquid investments with original maturities of three months or less to be cash equivalents.

**Short-term Investments**

The Company has designated its investments in securities as available-for-sale securities and measures these securities at their respective fair values. Investments that mature in one year or less are classified as short-term available-for-sale securities. Investments that are not considered available for use in current operations are classified as long-term available-for-sale securities. Changes in the fair value of available-for-sale investments are recognized in other comprehensive income (loss).

**Property, Plant and Equipment**

Property, plant and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. The estimated useful lives of property, plant and equipment are as follows: 3-5 years for IT equipment, 5-10 years for



**NABRIVA THERAPEUTICS plc**

**Notes to the Consolidated Financial Statements (Continued)**

**(in thousands, except per share data)**

**2. Summary of Significant Accounting Policies (Continued)**

laboratory equipment and 3-10 years for other plant and office equipment. The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at each reporting date. When assets are sold or otherwise disposed of, the difference between the net proceeds, if any, and the net carrying amount of the asset is recognized as a gain or a loss in other operating income or expenses.

**Intangible Assets and Other Long-lived Assets**

Intangible assets, such as acquired computer software licenses, are capitalized on the basis of the costs incurred to acquire the software and bring it into use. These costs are amortized on a straight-line basis over their estimated useful lives (3-10 years).

Long-lived assets are assessed for potential impairment when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recovered. An impairment loss would be recognized when undiscounted cash flows expected to be generated by an asset, is less than its carrying amount. The impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value and recognized in these financial statements.

**Research Premium and Grant Revenue**

Grant revenue comprises (a) the research premium from the Austrian government, (b) grants received from the Vienna Business Promotion Fund (*Wiener Wirtschaftsförderungsfonds, or WWFF*), (c) grants received from the Austrian Research Promotion Agency (*Österreichische Forschungsförderungsgesellschaft, or FFG*), and (d) the benefit of government loans at below-market interest rates. Please refer to Note 10 for further details on all forms of grant revenue.

The research premium the Company receives from the Austrian government is calculated at a specified percent of specified research and development cost base. The Company recognizes the research premium as long as it has incurred research and development expenses. The WWFF grant is paid out through the landlord in the form of a monthly reduction in lease payments and is recognized over the period from grant date in March 2010 until end of the lease termination waiver term in December 2017. All grants are non-refundable as long as the conditions of the grant are met. Nabriva is and has been in full compliance with the conditions of the grants and all related regulations.

The benefit of a government loan at a below-market rate of interest is treated as a government grant. The benefit due to the difference between the market rate of interest and the rate of interest charged by the governmental organization is measured as the difference between the initial carrying value of the loan determined and the proceeds received. This benefit is deferred, and recognized through profit and loss over the term of the corresponding liabilities.

**Research and Development Expenses**

All research and development costs are expensed as incurred. Research and development costs included direct personnel and material costs, related overheads, depreciation of equipment used for research or development purposes; costs for clinical research; costs for the utilization of third parties' patents for research and development purposes and other taxes related to research facilities.

**NABRIVA THERAPEUTICS plc**

**Notes to the Consolidated Financial Statements (Continued)**

**(in thousands, except per share data)**

**2. Summary of Significant Accounting Policies (Continued)**

**Share-Based Payments**

The Company measures the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award in accordance with ASC 718, *Compensation—Stock Compensation*. The fair value of stock options is estimated using the Black-Scholes option pricing model. All grants under share-based payment programs are accounted for at fair value and that cost is recognized over the period during which an employee is required to provide service in exchange for the award—the requisite service period (vesting period). The Company accounts for forfeitures as incurred. Compensation expense for options granted to non-employees is determined as the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of awards granted to non-employees is re-measured each period until the related service is complete.

**Income Taxes**

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, the Company determines deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that it believes that these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If the Company determines that it would be able to realize its deferred tax assets in the future in excess of their net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

In recognizing the benefit of tax positions, the Company has taken or expects to take, the Company determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

The Company's policy is to record interest and penalties related to tax matters in income tax expense.

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; 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

**NABRIVA THERAPEUTICS plc**

**Notes to the Consolidated Financial Statements (Continued)**

**(in thousands, except per share data)**

**2. Summary of Significant Accounting Policies (Continued)**

related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017.

The Tax Act reduces the U.S. corporate income tax rate from 35% 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 35% to 21% under the Tax Act, the Company revalued the ending net deferred tax assets and liabilities of our U.S. subsidiary at December 31, 2017.

**Subsequent Events**

Material subsequent events are evaluated and disclosed through the report issuance date.

**Recent Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date.

*Adopted as of the current period:*

- In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers*, an updated standard on revenue recognition. ASU 2014-09 provides enhancements to the quality and consistency of how revenue is reported by companies while also improving comparability in the financial statements of companies reporting using International Financial Reporting Standards or US GAAP. The main purpose of the new standard is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which a company expects to be entitled in exchange for those goods or services. The new standard also results in enhanced revenue disclosures, guidance for transactions that were not previously addressed comprehensively and improve guidance for multiple-element arrangements. The effective date of ASU 2014-09 for the Company is the first quarter of fiscal year 2018. The Company recognized \$1.5 million of revenue related to a contract asset (note 16) upon the adoption of this new standard during 2018 that would not have been recognized under the prior standard.
- In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation: Scope of Modification Accounting*. ASU 2017-09 clarifies which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718, *Compensation—Stock Compensation*. ASU 2017-09 is effective for annual periods beginning after December 15, 2017. An entity should apply the amendments prospectively to a modification that occurs on or after the adoption date. The Company adopted ASU 2017-09 in the first quarter of fiscal year 2018. The impact of adopting this standard did not have a material effect on the Company's financial position, results of operation or cash flow and related disclosures.

*To be adopted in future periods:*

- In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which sets out the principles for the recognition, measurement,

**NABRIVA THERAPEUTICS plc**

**Notes to the Consolidated Financial Statements (Continued)**

**(in thousands, except per share data)**

**2. Summary of Significant Accounting Policies (Continued)**

presentation and disclosure of leases for both lessees and lessors. Originally, entities were required to adopt ASU 2016-02 using a modified retrospective approach at the beginning of the earliest comparative period presented in the financial statements and the recognition of a cumulative-effect adjustment to the opening balance of retained earnings. The FASB subsequently issued ASU 2018-10 and ASU 2018-11 in July 2018, which provide clarifications and improvements and also provides for an optional transition method which allows companies to apply the new lease standard at the adoption date instead of at the earliest comparative period presented and continue to apply the provisions of the previous lease standard in its annual disclosures for the comparative periods. The new lease standard requires lessees to present a right-of-use asset and a corresponding lease liability on the balance sheet.

On January 1, 2019, the Company adopted the new lease standard using the optional transition method under which comparative financial information will not be restated. In addition, the new lease standard provides a number of optional practical expedients in transition. The Company elected the package of practical expedients. As such, the Company will not reassess whether expired or existing contracts are or contain a lease; will not need to reassess the lease classifications or reassess the initial direct costs associated with expired or existing leases.

The new lease standard also provides practical expedients for an entity's ongoing accounting. The Company elected the short-term lease recognition exemption under which the Company will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases. The Company elected the practical expedient to not separate lease and non-lease components for certain classes of assets (office buildings).

On January 1, 2019, the Company expects to recognize ROU assets and lease liabilities of approximately \$2.1 million. The Company does not expect the adoption of the new lease standard to materially impact its consolidated statements of operations or of cash flows.

- In June 2018, the FASB issued ASU 2018-07, *Compensation—Stock Compensation (Topic 718): "Improvements to Nonemployee Share-Based Payment Accounting,"* which largely aligns the accounting for share-based payment awards issued to nonemployees with the accounting for share-based payment awards issued to employees. Under previous GAAP, the accounting for nonemployee share-based payments differed from that applied to employee awards, particularly with regard to the measurement date and the impact of performance conditions. Under the new guidance, (i) equity-classified share-based payment awards issued to nonemployees will be measured at the grant date, instead of the previous requirement to remeasure the awards through the performance completion date, (ii) for performance conditions, compensation cost associated with the award will be recognized when the achievement of the performance condition is probable, rather than upon achievement of the performance condition, and (iii) the current requirement to reassess the classification (equity or liability) for nonemployee awards upon vesting will be eliminated, except for awards in the form of convertible instruments. This new guidance will be effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company does not expect the adoption of the new guidance to have a material effect on its consolidated financial statements.

**NABRIVA THERAPEUTICS plc**

**Notes to the Consolidated Financial Statements (Continued)**

(in thousands, except per share data)

**2. Summary of Significant Accounting Policies (Continued)**

- In August 2018, the FASB issued AS 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which eliminates, adds and modifies certain disclosure requirements for fair value measurements. Entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, but public companies will be required to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The guidance on fair value disclosures eliminates the following requirements for all entities: the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; the entity's policy for the timing of transfers between levels of the fair value hierarchy; and, the entity's valuation processes for Level 3 fair value measurements. The ASU adds the following disclosure requirements, but it exempts nonpublic entities from these requirements: the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements of instruments held at the end of the reporting period; and, for recurring and nonrecurring Level 3 fair value measurements, the range and weighted average used to develop significant unobservable inputs and how the weighted average was calculated, with certain exceptions. The guidance is effective for all entities for fiscal years beginning after December 15, 2019 and for interim periods within those fiscal years, but entities are permitted to early adopt either the entire standard or only the provisions that eliminate or modify the requirements. The Company does not expect the adoption of the new guidance to have a material effect on its consolidated financial statements.

**3. Short-term investments**

The Company's short-term investments were as follows:

(in thousands)	As of December 31, 2018			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
<b>Short-term investments:</b>				
Available-for-sale securities	\$ 50	\$ —	\$ —	\$ 50
Term deposits	175	—	—	175
<b>Total</b>	<b>\$ 225</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 225</b>

(in thousands)	As of December 31, 2017			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
<b>Short-term investments:</b>				
Available-for-sale securities	\$ 76	\$ —	\$ (26)	\$ 50
Term deposits	60	—	—	60
<b>Total</b>	<b>\$ 136</b>	<b>\$ —</b>	<b>\$ (26)</b>	<b>\$ 110</b>

As of December 31, 2018 and 2017 the Company's short-term investments were classified as available-for-sale and comprised a (i) money market fund that invests all of its assets, excluding cash and deposits, in short term USD-denominated debt securities, and (ii) a U.S. treasury note.

**NABRIVA THERAPEUTICS plc****Notes to the Consolidated Financial Statements (Continued)****(in thousands, except per share data)****4. Fair Value Measurement**

US GAAP establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows:

- Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly (as prices) or indirectly (as exchange rates).
- Level 3: Valuation techniques that include inputs for the asset or liability that are not based on observable market data (those are unobservable inputs) and significant to the overall fair value measurement.

The following table presents the financial instruments measured at fair value and classified by level according to the fair value measurement hierarchy:

<u>(in thousands)</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
<b>December 31, 2018</b>				
<b>Assets:</b>				
Short-term investments:				
Available-for-sale securities	\$ —	\$ 50	\$ —	\$ 50
Term deposits	175	—	—	175
<b>Total Assets</b>	<u>\$ 175</u>	<u>\$ 50</u>	<u>\$ —</u>	<u>\$ 225</u>

<u>(in thousands)</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
<b>December 31, 2017</b>				
<b>Assets:</b>				
Short-term investments:				
Available-for-sale securities	\$ —	\$ 50	\$ —	\$ 50
Term deposits	60	—	—	60
<b>Total Assets</b>	<u>\$ 60</u>	<u>\$ 50</u>	<u>\$ —</u>	<u>\$ 110</u>

As of December 31, 2018 and 2017, the Company held short-term investments classified as both Level 1 and Level 2, and the Company did not hold any Level 3 financial instruments measured at fair value. There were no transfers between Level 1 and 2 in the years ended December 31, 2018 and 2017. There were no changes in valuation techniques during the years ended December 31, 2018 and 2017.

As of December 31, 2018 and 2017, the Company did not hold any financial instruments as liabilities that were held at fair value.

Other receivables and accounts payable are carried at their historical cost which approximates fair value due to their short-term nature.

**NABRIVA THERAPEUTICS plc****Notes to the Consolidated Financial Statements (Continued)****(in thousands, except per share data)****5. Other receivables**

<u>(in thousands)</u>	<u>As of December 31</u>	
	<u>2017</u>	<u>2018</u>
Research premium	\$ 5,124	\$ 2,657
VAT and other taxes	28	1,024
Receivables from grant revenue	231	104
Other receivables	19	86
<b>Total current receivables</b>	<b>\$ 5,402</b>	<b>\$ 3,871</b>

**6. Property, Plant and Equipment**

<u>(in thousands)</u>	<u>As of December 31</u>	
	<u>2017</u>	<u>2018</u>
IT equipment	\$ 1,060	\$ 1,079
Laboratory equipment	3,299	3,392
Other equipment	15	124
	<b>4,374</b>	<b>4,595</b>
Less: Accumulated depreciation	<b>(3,047)</b>	<b>(3,456)</b>
<b>Property, plant and equipment, net</b>	<b>\$ 1,327</b>	<b>\$ 1,139</b>

**7. Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities include the following:

<u>(in thousands)</u>	<u>As of December 31</u>	
	<u>2017</u>	<u>2018</u>
Research and development related costs	\$ 2,308	\$ 5,032
Payroll and related costs	4,426	7,427
Accounting, tax and audit services	231	398
Other	1,159	1,645
<b>Total other current liabilities</b>	<b>\$ 8,124</b>	<b>\$ 14,502</b>

**8. Debt**

In December 2018, the Company entered into the Loan Agreement by and among the Company, Nabriva Therapeutics Ireland DAC, and certain other subsidiaries of the Company and Hercules Capital, Inc. (the "Lender"), pursuant to which a term loan of up to an aggregate principal amount of \$75.0 million is available to the Company. The Loan Agreement provides for an initial term loan advance of \$25.0 million, which was funded in December 2018, and, at the Company's option and subject to the occurrence of the funding conditions described below and other customary funding conditions, five additional term loan advances comprised of the following; 1) \$10.0 million ("Tranche 2 Advance"), 2) \$5.0 million ("Tranche 3 Advance"), 3) \$10.0 million ("Tranche 4 Advance"),

**NABRIVA THERAPEUTICS plc**

**Notes to the Consolidated Financial Statements (Continued)**

**(in thousands, except per share data)**

**8. Debt (Continued)**

4) \$15.0 million ("Tranche 5 Advance") and 5) \$5.0 million ("Tranche 6 Advance"). The Tranche 2 Advance will be available to the Borrowers through September 30, 2019 upon the approval by the U.S. Food and Drug Administration ("FDA") of a new drug application ("NDA") for lefamulin. The Tranche 3 Advance will be available to the Borrowers through September 30, 2019 upon the approval by the FDA of an NDA for CONTEPO. The Tranche 4 Advance will be available to the Borrowers from January 1, 2020 through December 31, 2020 upon the approval by the FDA of NDAs for lefamulin and CONTEPO and upon the achievement of specified product revenue milestones. The Tranche 5 Advance will be available to the Borrowers from July 1, 2020 through June 30, 2021 upon the approval by the FDA of NDAs for lefamulin and CONTEPO and upon the achievement of specified product revenue milestones. The Tranche 6 Advance will be available to the Borrowers from January 1, 2021 through September 30, 2021 upon the approval by the FDA of NDAs for lefamulin and CONTEPO and upon the achievement of specified product revenue milestones. The Borrowers may request a seventh term loan advance of \$5.0 million prior to December 31, 2021 subject to the Lender's sole discretion.

The term loan bears interest at an annual rate equal to the greater of 9.80% or 9.80% plus the prime rate of interest minus 5.50%. The Loan Agreement provides for interest-only payments through July 1, 2020, which may be incrementally extended from time to time upon the occurrence of certain conditions through January 1, 2022, and repayment of the outstanding principal balance of the term loan thereafter in monthly installments through June 1, 2023 (the "Maturity Date"). In addition, the is required to pay a fee of 6.95% of the aggregate amount of advances under the Loan Agreement at the Maturity Date (the "End of Term Fee"). At the Company's option, the Company may elect to prepay any portion of the outstanding term loan that is greater than or equal to \$5.0 million by paying such portion of the principal balance and all accrued and unpaid interest thereon plus a prepayment charge equal to the following percentage of the principal amount being prepaid: (i) 3.0% if the term loan is prepaid during the first 12 months following the initial closing, (ii) 2.0% if the term loan is prepaid after 12 months following the initial closing but before 24 months following the initial closing and (iii) 1.0% if the term loan is prepaid any time thereafter but prior to the Maturity Date. The Company is also required to satisfy certain financial covenants, including an obligation to maintain specified minimum amounts of cash and cash equivalents in accounts pledged to Hercules.

The Company's obligations under the Loan Agreement are guaranteed by all current and future subsidiaries of the Company, and each of the Company and its subsidiaries has granted the Lender a security interest in all of their respective personal property, intellectual property and other assets owned or later acquired. The Loan Agreement also contains certain events of default, representations, warranties and covenants of the Company and its subsidiaries. For example, the Loan Agreement contains representations and covenants that, subject to exceptions, restrict the Company's and its subsidiaries' ability to do the following, among things: declare dividends or redeem or repurchase equity interests; incur additional indebtedness and liens; make loans and investments; engage in mergers, acquisitions and asset sales; certain transactions with affiliates; undergo a change in control; add or change business locations or settle in cash potential milestone payment obligations that may become payable by the Company in the future to former security holders of Zavante. Under the terms of the Loan Agreement, the Company and its subsidiaries are also required to satisfy certain financial covenants, including an obligation to maintain specified minimum amounts of cash and cash equivalents in accounts pledged to the Lender.



**NABRIVA THERAPEUTICS plc****Notes to the Consolidated Financial Statements (Continued)****(in thousands, except per share data)****8. Debt (Continued)**

The Loan Agreement also grants Lender or its nominee an option to purchase up to an aggregate of \$2.0 million of the Company's equity securities, or instruments exercisable for or convertible into equity securities, sold to investors in any private financing upon the same terms and conditions afforded to such other investors for as long as there are amounts outstanding under the Loan Agreement.

The Company incurred \$1,290,000 of costs in connection with the Loan Agreement which along with the initial fee of \$700,000 paid to the Lender were recorded as debt issuance cost and will be amortized as interest expense using the effective interest method over the term of the loan. The End of Term Fee will also be accrued as additional interest expense using the effective interest method over the term of the loan.

Long-term debt as December 31, 2017 and 2018 consisted of the following:

<u>(in thousands)</u>	<u>As of December 31</u>	
	<u>2017</u>	<u>2018</u>
Term loan payable	\$ —	\$ 25,000
Unamortized debt issuance costs	—	(1,990)
Carrying value of term loan	—	23,010
Other long-term debt	232	708
<b>Total long-term debt</b>	<b>\$ 232</b>	<b>\$ 23,718</b>

Maturities of long-term debt as of December 31, 2018 were as follows:

<u>(in thousands)</u>	
2019	\$ —
2020	3,656
2021	8,592
2022	8,704
2023	4,756

**9. Stockholders' Equity**

On July 31, 2018, the Company completed an underwritten public offering of 18,181,818 ordinary shares at a public offering price of \$2.75 per share, resulting in gross proceeds of \$50.0 million and net proceeds to the Company of \$46.3 million, after deducting underwriting discounts and commissions and offering expenses.

In March 2018, the Company entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement (the "ATM Agreement"), with Cantor Fitzgerald & Co. ("Cantor"), pursuant to which, from time to time, the Company may offer and sell its ordinary shares having aggregate gross proceeds of up to \$50.0 million through Cantor. As of December 31, 2018, the Company has issued and sold an aggregate of 4,778,031 ordinary shares under the ATM Agreement, for gross proceeds of \$23.0 million, and net proceeds of \$23.6 million, after deducting commissions and offering costs.

**NABRIVA THERAPEUTICS plc****Notes to the Consolidated Financial Statements (Continued)****(in thousands, except per share data)****9. Stockholders' Equity (Continued)**

On September 22, 2017 the Company completed an underwritten public offering of 9,411,765 ordinary shares at a public offering price of \$8.50 per share, resulting in gross proceeds of \$80.0 million and net proceeds to the Company of \$73.3 million, after deducting underwriting discounts and commissions and offering expenses.

On December 19, 2016, the Company completed a rights offering and a related underwritten offering for the sale of an aggregate of 588,127 common shares resulting in aggregate gross proceeds of \$24.8 million and net proceeds of \$20.6 million, after deducting underwriting fees and offering expenses.

**10. Revenue**

<u>(in thousands)</u>	<u>Year ended December 31,</u>		
	<u>2016</u>	<u>2017</u>	<u>2018</u>
Collaboration revenue	\$ —	\$ —	\$ 6,500
Research premium	6,232	4,842	2,594
Government grants	—	369	562
Grants from WWFF	250	108	—
<b>Total</b>	<b>\$ 6,482</b>	<b>\$ 5,319</b>	<b>\$ 9,656</b>

**11. Share-Based Payments*****Stock Option Plan 2015***

On April 2, 2015, the Company's shareholders, management board and supervisory board adopted the Stock Option Plan 2015 (the "SOP 2015") and the shareholders approved an amended and restated version of the SOP 2015 on June 30, 2015. An amendment to the amended and restated SOP 2015 was approved by the shareholders on July 22, 2015. SOP 2015 became effective on July 3, 2015 upon the registration with the commercial register in Austria of the conditional capital increase approved by the shareholders on June 30, 2015. The SOP 2015 initially provided for the grant of options for up to 95,000 Nabriva Austria common shares to the Company's employees, including members of the management board, and to members of the supervisory board. Following the closing of the initial public offering of the Company, the overall number of options increased to 177,499 Nabriva Austria common shares. Following approval by the Company's shareholders at its 2016 annual general meeting, the number of shares available for issuance under the SOP 2015 was increased to 346,235 Nabriva Austria common shares.

Each vested option grants the beneficiary the right to acquire one share in the Company. The vesting period for the options is four years following the grant date. On the last day of the last calendar month of the first year of the vesting period, 25% of the options attributable to each beneficiary are automatically vested. During the second, third and fourth years of the vesting period, the remaining 75% of the options vest on a monthly pro rata basis (i.e. 2.083% per month). Options granted under the SOP 2015 have a term of no more than ten years from the beneficiary's date of participation.

NABRIVA THERAPEUTICS plc

Notes to the Consolidated Financial Statements (Continued)

(in thousands, except per share data)

11. Share-Based Payments (Continued)

The following table summarizes information regarding our stock option awards under the SOP 2015:

Stock Option Plan 2015	2016		2017		2018		Aggregate intrinsic value
	Weighted average exercise price in \$ per share	Options	Weighted average exercise price in \$ per share	Options	Weighted average exercise price in \$ per share	Options	
<b>Outstanding as of January 1</b>	7.61	1,092,300	7.83	1,794,360	8.35	3,044,899	
Granted	8.02	922,130	9.02	1,458,300	—	—	
Exercised	7.21	(23,360)	—	—	—	—	
Forfeited	7.64	(196,710)	8.60	(207,761)	8.41	(201,986)	
<b>Outstanding as of December 31</b>	<b>7.83</b>	<b>1,794,360</b>	<b>8.35</b>	<b>3,044,899</b>	<b>8.34</b>	<b>2,842,913</b>	—
<b>Vested and exercisable as of December 31</b>	<b>7.52</b>	<b>452,210</b>	<b>7.68</b>	<b>989,656</b>	<b>8.10</b>	<b>1,844,590</b>	—

The total intrinsic value of options exercised during the year ended December 31, 2016 was \$181.

The Company has 2,842,913 option grants outstanding at December 31, 2018 with exercise prices ranging from \$4.06 per share to \$11.00 per share and a weighted average remaining contractual life of 7.4 years.

Stock-based compensation expense under the SOP 2015 was \$2.5 million, \$5.6 million and \$3.2 million for the years ended December 31, 2016, 2017 and 2018, respectively. The weighted average fair value of the options granted during the years ended December 31, 2016 and 2017 was \$4.76 per share, \$5.05 per share, respectively.

The grant date fair value of each option grant was estimated throughout the year using the Black-Scholes option-pricing model using the following assumptions:

Input parameters	2016	2017
Expected volatility	59.8% - 67.2%	55.6% - 62.0%
Expected term of options	6.0 years	6.1 years
Risk-free interest rate	1.15% - 2.09%	1.89% - 2.10%
Expected dividend yield	—	—

The expected price volatility is based on historical trading volatility for the publicly traded peer companies under consideration of the remaining life of the options. The risk free interest for the years 2016 and 2017, is based on the average of 5 and 7-year market yield on U.S. treasury securities in effect at the time of grant.

As of December 31, 2018, there was \$5.4 million of unrecognized compensation expense, related to unvested options granted under the SOP 2015 Plan, which will be recognized over the weighted average remaining vesting period of 2.1 years.

**NABRIVA THERAPEUTICS plc**

**Notes to the Consolidated Financial Statements (Continued)**

(in thousands, except per share data)

**11. Share-Based Payments (Continued)**

**2017 Share Incentive Plan**

On July 26, 2017, the Company's board of directors adopted the 2017 Share Incentive Plan (the "2017 Plan") and the shareholders approved the 2017 Plan at the Company's Extraordinary General Meeting of Shareholders on September 15, 2017. Following shareholder approval of the 2017 Plan, the Company ceased making awards under the SOP 2015, and future awards will be made under the 2017 Plan. However, all outstanding awards under SOP 2015 will remain in effect and continue to be governed by the terms of the SOP 2015. The 2017 Plan permits the award of share options (both incentive and nonstatutory options), share appreciation rights ("SARs"), restricted shares, restricted share units ("RSUs"), and other share-based awards to the Company's employees, officers, directors, consultants and advisers. The 2017 Plan is administered by the Company's board of directors.

Under the 2017 Plan, the number of ordinary shares that will be reserved for issuance will be the sum of (1) 3,000,000 ordinary shares; plus (2) a number of ordinary shares (up to 3,438,990 ordinary shares) which is equal to the sum of the number of the Company's ordinary shares then available for issuance under the SOP 2015 and the number of ordinary shares subject to outstanding awards under the SOP 2015 that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual increase, to be added on the first day of each fiscal year beginning in the fiscal year ending December 31, 2018 and continuing until, and including, the fiscal year ending December 31, 2027, equal to the least of (i) 2,000,000 ordinary shares, (ii) 4% of the number of outstanding ordinary shares on such date and (iii) an amount determined by the board of directors.

At December 31, 2018, 5,064,378 ordinary shares were available for issuance under the 2017 Plan.

Options and SARs granted will be exercisable at such times and subject to such terms and conditions as the board may specify in the applicable option agreement; provided, however, that no option or SAR will be granted with a term in excess of ten years. The board will also determine the terms and conditions of restricted shares and RSUs, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

The following table summarizes information regarding our stock option awards under the 2017 Plan at December 31, 2018:

	2017		2018		
	Weighted average exercise price in \$ per share	Options	Weighted average exercise price in \$ per share	Options	Aggregate intrinsic value
<b>Stock Option Plan 2017</b>					
<b>Outstanding as of January 1</b>	—	—	6.92	294,100	—
Granted	6.92	294,100	5.27	2,199,225	—
Exercised	—	—	—	—	—
Forfeited	—	—	6.75	(94,900)	—
<b>Outstanding as of December 31</b>	<b>6.92</b>	<b>294,100</b>	<b>5.41</b>	<b>2,398,425</b>	<b>—</b>
<b>Vested and exercisable as of December 31</b>	<b>—</b>	<b>—</b>	<b>6.88</b>	<b>119,287</b>	<b>—</b>

**NABRIVA THERAPEUTICS plc****Notes to the Consolidated Financial Statements (Continued)****(in thousands, except per share data)****11. Share-Based Payments (Continued)**

There were no options exercised during the years ended December 31, 2017 and 2018.

The Company has 2,398,425 option grants outstanding at December 31, 2018 with exercise prices ranging from \$1.46 per share to \$8.35 per share and a weighted average remaining contractual life of 9.3 years.

Stock-based compensation expense under the 2017 Plan was \$0.1 million and \$1.8 million for the years ended December 31, 2017 and 2018, respectively. The weighted average fair value of the options granted during years ended December 31, 2017 and 2018 was \$3.98 and \$3.06 per share, respectively, based on a Black Scholes option pricing model using the following assumptions:

<u>Input parameters</u>	<u>2017</u>	<u>2018</u>
Expected volatility	59.5% - 63.0%	59.8% - 61.4%
Expected term of options	6.0	6.1
Risk-free interest rate	1.93% - 2.27%	2.55% - 3.03%
Expected dividend yield	—	—

The expected price volatility is based on historical trading volatility for the publicly traded peer companies under consideration of the remaining life of the options. The risk free interest rate is based on the average of 5 and 7 year market yield on U.S. treasury securities in effect at the time of grant.

As of December, 2018, there was \$5.7 million of total unrecognized compensation expense, related to unvested options granted under the 2017 Plan, which will be recognized over the weighted-average remaining vesting period of 3.1 years.

***Restricted Stock Units ("RSUs")***

During the year ended December 31, 2018, the Company granted 407,150 RSUs with a weighted average grant date fair value of \$5.82 per share. As of December 31, 2018, there were 387,800 RSUs outstanding. Vesting of the RSUs is subject to FDA approval of the new drug application ("NDA") for lefamulin. Fifty percent (50%) of each RSU award will vest upon FDA approval of an NDA for lefamulin, and the remaining fifty percent (50%) will vest on the one-year anniversary of such approval. If the FDA does not approve an NDA for lefamulin within two years of the grant date, the RSU award will terminate in full. No compensation expense was recognized for these RSUs as vesting is not probable at December 31, 2018.

Also, during the year ended December 31, 2018, the Company granted 834,300 RSUs to certain employees with a grant date fair value of \$2.16 per share. These RSUs will vest in three six month increments beginning in May of 2019 and ending in May 2020. As of December 31, 2018, there were 834,300 of such RSUs outstanding. As of December 31, 2018, \$0.2 million of compensation expense was recognized for these RSUs.

**Inducement Award**

In July 2018, the Company granted a non-statutory option to purchase 850,000 of its ordinary shares and 150,000 performance-based RSUs to the Company's newly appointed Chief Executive Officer (the "CEO"). These equity awards were granted outside of the 2017 Plan, were approved by

**NABRIVA THERAPEUTICS plc****Notes to the Consolidated Financial Statements (Continued)****(in thousands, except per share data)****11. Share-Based Payments (Continued)**

the Company's compensation committee and board of directors and were made as an inducement material to the CEO entering into employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4). The exercise price per share for the share option is \$3.53 per share, and the option award has a ten-year term and will vest over a four-year period, with 25% of the shares underlying the award vesting on the first anniversary of the grant date and the remaining 75% of the shares underlying the option award to vest monthly over the subsequent 36-month period. The performance-based RSUs are subject to vesting as follows: 50% will vest upon certification by the board of directors of the receipt of approval by the FDA of an NDA for each of lefamulin and CONTEPO for any indication, and 50% will vest on the first anniversary of such certification by the board of directors, provided, in each case, the CEO is performing services to the Company on the applicable vesting dates. If the FDA does not approve an NDA for both lefamulin and CONTEPO by January 31, 2020, the performance-based RSUs will terminate in full.

Stock-based compensation expense was \$0.2 million for the year ended December 31, 2018. The performance-based RSUs had a grant date fair value of \$3.53 per share and the options had a grant date fair value of \$2.05 per share based on a Black Scholes option pricing model using the following assumptions.

<b>Input parameters</b>	
Expected volatility	59.8%
Expected term of options (in years)	6.1
Range of risk-free interest rate	2.9%
Dividend yield	—

The weighted average remaining contractual life of the options as of December 31, 2018 is 9.6 years.

Our share-based compensation expense has been allocated to research and development and general and administrative expenses in the Consolidated Statement of Operations and Comprehensive Loss as follows:

<b>(in thousands)</b>	<b>Year ended December 31,</b>		
	<b>2016</b>	<b>2017</b>	<b>2018</b>
Research and development	\$ 894	\$ 2,128	\$ 1,406
General and administrative	1,651	3,604	3,748
<b>Total</b>	<b>\$ 2,545</b>	<b>\$ 5,732</b>	<b>\$ 5,154</b>

**Employee Stock Purchase Plan**

The Company's board of directors adopted, and in August 2018 Company's stockholders approved, the 2018 employee stock purchase plan (the "2018 ESPP"). The maximum aggregate number of shares of ordinary shares that may be purchased under the 2018 ESPP is 500,000 shares, (the "ESPP Share Pool"), subject to adjustment as provided for in the 2018 ESPP. The ESPP Share Pool represented 0.75% of the total number of shares of ordinary shares outstanding as of December 31, 2018. The 2018 ESPP allows eligible employees to purchase shares at a 15% discount to the then current market price

**NABRIVA THERAPEUTICS plc****Notes to the Consolidated Financial Statements (Continued)****(in thousands, except per share data)****11. Share-Based Payments (Continued)**

of the Company's ordinary shares during certain offering periods, which will be six -month periods commencing November 1 and ending April 30 and commencing May1 and ending October 31 of each year. The first offering under the 2018 ESPP commenced on November 1, 2018.

**12. Post-employment benefit obligations**

As required under Austrian labor law, the Company makes contributions to a state plan classified as defined contribution plan (Mitarbeitervorsorgekasse) for its employees in Austria. Monthly contributions to the plan are 1.53% of salary with respect to each employee and are recognized as expense in the period incurred. In the years ended December 31, 2016, 2017 and 2018, contribution costs amounted to \$59,000, \$58,000 and \$68,000, respectively.

For employees of Nabriva Therapeutics US, Inc., the Company makes contributions to a defined contribution plan as defined in subsection 401(k) of the Internal Revenue Code. The Company matches 100% of the first 3% of the employee's voluntary contribution to the plan and 50% of the next 2% contributed by the employee. Contributions are recognized as expense in the period incurred. In the years ended December 31, 2016, 2017 and 2018 contribution expenses were \$152,000, \$213,000 and \$448,000, respectively.

**13. Income tax (expense) benefit**

Loss before income taxes attributable to domestic and international operations, consists of the following:

<u>(in thousands)</u>	<u>Year ended December 31</u>		
	<u>2016</u>	<u>2017</u>	<u>2018</u>
Domestic	\$ (54,509)	\$ (66,109)	\$ (113,699)
Foreign	(1,053)	(6,892)	(1,032)
<b>Loss before income taxes</b>	<b>\$ (55,562)</b>	<b>\$ (73,001)</b>	<b>\$ (114,731)</b>

Income tax (expense) benefit consists of the following:

<u>(in thousands)</u>	<u>Year ended December 31</u>		
	<u>2016</u>	<u>2017</u>	<u>2018</u>
Current tax			
Domestic	\$ (4)	\$ —	\$ —
Foreign	(118)	55	(49)
Deferred tax			
Domestic	—	—	—
Foreign	794	(1,410)	—
<b>Total income tax (expense) benefit</b>	<b>\$ 672</b>	<b>\$ (1,355)</b>	<b>\$ (49)</b>

**NABRIVA THERAPEUTICS plc**

**Notes to the Consolidated Financial Statements (Continued)**

(in thousands, except per share data)

**13. Income tax (expense) benefit (Continued)**

The reconciliation to our effective tax rate from the Austrian statutory income tax rate of 25% for the year ended December 31, 2016 and from the Irish statutory income tax rate of 12.5% for the years ended December 31, 2017 and 2018 is as follows:

(% of pre-tax income)	Year ended December 31		
	2016	2017	2018
Statutory income tax rate	25.0%	12.5%	12.5%
Non-deductible expenses	(0.2)	(0.8)	(0.1)
Income not subject to tax	2.8	0.9	0.3
Impairment	—	1.4	—
Tax credits	0.4	0.2	0.1
Foreign rate differential	(2.5)	21.0	(3.1)
In-process research and development	—	—	(3.5)
Other	0.2	(1.4)	0.2
Valuation allowance	(24.5)	(35.6)	(6.5)
<b>Effective income tax rate</b>	<u>1.2%</u>	<u>(1.8)%</u>	<u>(0.1)%</u>

The following table summarizes the components of deferred income tax balances:

(in thousands)	As of December 31,	
	2017	2018
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 70,871	\$ 91,995
Tax loss on liquidation of subsidiary	7,846	6,245
Equity compensation	1,450	2,473
Non-deductible reserves	57	203
<b>Total deferred tax assets</b>	80,224	100,916
Valuation allowance	(80,087)	(100,832)
<b>Net deferred tax assets</b>	137	84
<b>Deferred tax liabilities:</b>		
Financial liabilities	80	55
Property, plant and equipment	57	29
<b>Total deferred tax liability</b>	137	84
<b>Deferred tax, net</b>	<u>\$ —</u>	<u>\$ —</u>



NABRIVA THERAPEUTICS plc

Notes to the Consolidated Financial Statements (Continued)

(in thousands, except per share data)

13. Income tax (expense) benefit (Continued)

The table below summarizes changes in the deferred tax valuation allowance:

(in thousands)	Year ended December 31,		
	2016	2017	2018
Balance at beginning of year	\$ (40,487)	\$ (54,114)	\$ (80,087)
Tax benefit	(13,627)	(25,973)	(7,301)
Acquired tax attributes	—	—	(13,444)
<b>Balance at end of year</b>	<b>\$ (54,114)</b>	<b>\$ (80,087)</b>	<b>\$ (100,832)</b>

The following table summarizes carryforwards of net operating losses as of December 31, 2018.

(in thousands)	Amount	Expiration
Ireland	\$ 107,671	Indefinite
Austria	\$ 259,229	Indefinite
United States	\$ 44,728	2033

Due to uncertainty regarding the ability to realize the benefit of deferred tax assets primarily relating to net operating loss carryforwards, valuation allowances have been established to reduce deferred tax assets to an amount that is more likely than not to be realized.

On the basis of this evaluation, as of December 31, 2016, 2017 and 2018, the Company has recorded a valuation allowance of \$54.1 million, \$80.1 million and \$100.8 million, respectively, to recognize only the portion of the deferred tax asset that is more likely than not to be realized. The amount of the deferred tax asset considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period are reduced or increased or if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to subjective evidence such as our projections for growth.

The Tax Cuts and Jobs Act (the "TCJA") was enacted on December 22, 2017 and became effective January 1, 2018. The Tax Act had significant changes to U.S. tax law, lowering U.S. corporate income tax rates, implementing a territorial tax system, and modified the taxation of other income and expense items.

The TCJA reduces the U.S. corporate income tax rate from 35% 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 35% to 21% under the TCJA, the Company revalued the ending net deferred tax assets and liabilities of its U.S. subsidiary as of December 31, 2017. The tax impact of the revaluation of these deferred tax assets, net was \$0.8 million, which was wholly offset by a corresponding reduction in the valuation allowance for these net deferred tax assets resulting in a no net impact to income tax expense.

At December 31, 2017 and 2018, the Company had no uncertain tax positions and does not expect any material increase or decrease in income tax expense related to examinations or changes in uncertain tax positions.

**NABRIVA THERAPEUTICS plc****Notes to the Consolidated Financial Statements (Continued)****(in thousands, except per share data)****13. Income tax (expense) benefit (Continued)**

The Company files income tax returns in Ireland. In addition, the Company's foreign subsidiaries file separate income tax returns in Austria and the United States and state jurisdictions in which they are located. Tax years 2013 and forward remain open for examination for Austrian tax purposes and years 2014 and forward remain open for examination for United States tax purposes.

The Company's policy is to record interest and penalties related to tax matters in income tax expense.

**14. Earnings (Loss) per Share****Basic and diluted loss per share**

Basic and diluted loss per share is calculated by dividing the net loss attributable to shareholders by the weighted average number of shares outstanding during the year. Diluted net loss per share is the same as basic net loss per share during the periods presented as the effects of the Company's common stock equivalents are antidilutive and thus not included in the calculation.

<b>(in thousands, except per share data)</b>	<b>Year ended December 31,</b>		
	<b>2016</b>	<b>2017</b>	<b>2018</b>
Net loss for the period	\$ (54,890)	\$ (74,356)	\$ (114,780)
Weighted average number of shares outstanding	21,478,320	29,830,669	50,795,768
<b>Basic and diluted loss per share</b>	<b>\$ (2.56)</b>	<b>\$ (2.49)</b>	<b>\$ (2.26)</b>

The following ordinary share equivalents were excluded from the calculations of diluted loss per share as their effect would be anti-dilutive:

	<b>Year ended December 31,</b>		
	<b>2016</b>	<b>2017</b>	<b>2018</b>
Stock options	1,904,320	3,338,999	6,091,338
Restricted stock units	—	—	1,372,100

**15. Acquisition of Zavante**

On July 24, 2018, the Company acquired Zavante. The acquisition was completed on July 24, 2018 (the "Closing"). In connection with the Closing, the Company issued 7,336,906 Company ordinary shares to former Zavante stockholders, which together with the 815,186 ordinary shares that are issuable upon release of the Holdback Shares (as defined below) constitute approximately 19.9% of the Company ordinary shares outstanding as of immediately prior to the Closing (the "Upfront Shares").

Pursuant to the Merger Agreement, former Zavante stockholders and other equity holders, in the aggregate and subject to the terms and conditions of the Merger Agreement, will also be entitled to receive from the Company up to \$97.5 million in contingent consideration, of which \$25.0 million would become payable upon the first approval of a NDA from the FDA for CONTEPO for any indication (the "Approval Milestone Payment") and an aggregate of up to \$72.5 million would become payable upon the achievement of specified sales milestones (the "Net Sales Milestone Payments").

**NABRIVA THERAPEUTICS plc**

**Notes to the Consolidated Financial Statements (Continued)**

**(in thousands, except per share data)**

**15. Acquisition of Zavante (Continued)**

At the Company's Extraordinary General Meeting of Shareholders held in October 2018, the shareholders approved the issuance of the Company's ordinary shares in settlement of potential milestone payment obligations that may become payable in the future to former Zavante stockholders, including the Approval Milestone Payment which will be settled in Company ordinary shares. The Company also now has the right to settle the Net Sales Milestone Payments in Company ordinary shares, except as otherwise provided in the Merger Agreement.

Subject to the terms of the Merger Agreement, 10% of the Upfront Shares (the "Holdback Shares") will serve as a source for the satisfaction of indemnification and other obligations of the former Zavante stockholders and, subject to reduction in respect of these obligations, will be issued to the former Zavante stockholders following the first anniversary of the Closing.

Former Zavante stockholders who do not comply with specified procedural requirements set forth in the Merger Agreement, and former holders of Zavante options and warrants, will receive cash in lieu of any Company ordinary shares that otherwise would be issuable to them pursuant to the Merger Agreement. As of December 31, 2018 the Company did not distribute any cash in lieu of ordinary shares to former Zavante stockholders. Also, the Company anticipates that cash distributions, if any, will not be material.

The Company accounted for the acquisition of Zavante as an asset acquisition as the arrangement did not meet the definition of a business pursuant to the guidance prescribed in ASC Topic 805, *Business Combinations* because the transaction resulted in the acquisition of the exclusive rights to IV fosfomycin in the U.S. which is a single identifiable asset and represented substantially all the fair value of the assets acquired.

The Company expensed the acquired intellectual property as of the acquisition date as in-process research and development with no alternative future uses. The Company recorded an in-process research and development expense of \$32.0 million which represents \$26.9 million for the fair value of the Upfront Shares, \$4.9 million of transaction costs and \$0.2 million of net liabilities assumed.

In addition, the Company assumed certain liabilities and obligations, including contractual liabilities and obligations, that were assumed by the Company upon closing of the acquisition. See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations Acquisition of Zavante" for further information regarding the agreements that were assumed by the Company.

**16. Sinovant License Agreement**

In March 2018, the Company entered into a license agreement (the "License Agreement"), with Sinovant Sciences, Ltd. ("Sinovant"), an affiliate of Roivant Sciences, Ltd., to develop and commercialize lefamulin in the greater China region. As part of the License Agreement, Nabriva Therapeutics Ireland DAC and Nabriva Therapeutics GmbH, our wholly owned subsidiaries, granted Sinovant an exclusive license to develop and commercialize, and a non-exclusive license to manufacture, certain products containing lefamulin (the "Licensed Products"), in the People's Republic of China, Hong Kong, Macau, and Taiwan (together the "Territory").

**NABRIVA THERAPEUTICS plc**

**Notes to the Consolidated Financial Statements (Continued)**

**(in thousands, except per share data)**

**16. Sinovant License Agreement (Continued)**

Under the License Agreement, Sinovant and the Company's subsidiaries have established a joint development committee (the "JDC"), to review and oversee development and commercialization plans in the Territory. The Company received a non-refundable \$5.0 million upfront payment pursuant to the terms of the License Agreement and will be eligible for up to an additional \$91.5 million in milestone payments upon the achievement of certain regulatory and commercial milestone events related to lefamulin for CABP, plus an additional \$4.0 million in milestone payments if any Licensed Product receives a second or any subsequent regulatory approval in the People's Republic of China. The first milestone is a \$1.5 million payment for the submission of a clinical trial application ("CTA"), by Sinovant to the Chinese Food and Drug Administration which was received in February 2019. The remaining milestone payments are tied to additional regulatory approvals and annual sales targets. In addition, the Company will be eligible to receive low double-digit royalties on sales, if any, of Licensed Products in the Territory.

Sinovant will be solely responsible for all costs related to developing, obtaining regulatory approval of and commercializing Licensed Products in the Territory and is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize Licensed Product in the Territory. The Company is obligated to use commercially reasonable efforts to supply, pursuant to supply agreements to be negotiated by the parties, to Sinovant sufficient supply of lefamulin for Sinovant to manufacture finished drug products for development and commercialization of the Licensed Products in the Territory.

Unless earlier terminated, the License Agreement will expire upon the expiration of the last royalty term for the last Licensed Product in the Territory, which the Company expects will occur in 2033. Following the expiration of the last royalty term, the license granted to Sinovant will become non-exclusive, fully-paid, royalty-free and irrevocable. The License Agreement may be terminated in its entirety by Sinovant upon 180 days' prior written notice at any time. Either party may, subject to specified cure periods, terminate the License Agreement in the event of the other party's uncured material breach. Either party may also terminate the License Agreement under specified circumstances relating to the other party's insolvency. The Company has the right to terminate the License Agreement immediately if Sinovant does not reach certain development milestones by certain specified dates (subject to specified cure periods). The License Agreement contemplates that the Company will enter into ancillary agreements with Sinovant, including clinical and commercial supply agreements and a pharmacovigilance agreement.

The Company has identified two performance obligations at inception: (1) the delivery of the licenses to Sinovant; and, (2) the participation in the JDC. The \$5.0 million non-refundable upfront payment was allocated to the delivery of the licenses as the JDC deliverable was deemed to be de minimis. In addition, since the first \$1.5 million milestone payment related to the submission of the CTA is within the control of the parties, the Company recorded such milestone as variable consideration allocated to the licenses at the inception of the arrangement as the Company believes it is probable to be met. The \$1.5 million payment was received in February 2019 upon submission of the CTA. The future regulatory and commercial milestone payments will be recorded during the period the milestones become probable of achievement.

**NABRIVA THERAPEUTICS plc****Notes to the Consolidated Financial Statements (Continued)****(in thousands, except per share data)****17. Commitments and Contingencies**

In March 2007, a lease agreement for an unlimited period starting in December 2007 was entered into for the use of business and research premises in Vienna. The contract has a six-month notice period and can be terminated every quarter end.

In July 2015, a lease agreement was entered into for the use of approximately 15,000 square feet of office space in King of Prussia, PA, with the lease term continuing until December 2023 with no renewal options.

In February 2018, a lease agreement starting in March 2018 was entered into for the use of office space in Dublin and has a month-to-month term.

We also enter into lease agreements for equipment such as copiers and printers.

Lease expense was \$1.3 million, \$1.3 million, and \$1.4 million for the years ended December 31, 2016, 2017 and 2018, respectively.

Future minimum contractual obligations and commitments at December 31, 2018 are as follows:

(in thousands)	Year ending December 31,						
	Total	2019	2020	2021	2022	2023	Thereafter
Operating lease obligations	\$ 3,507	\$ 1,456	\$ 507	\$ 515	\$ 522	\$ 507	\$ —
Other contractual commitments	10,166	10,166	—	—	—	—	—
<b>Total</b>	<b>\$ 13,673</b>	<b>\$ 11,622</b>	<b>\$ 507</b>	<b>\$ 515</b>	<b>\$ 522</b>	<b>\$ 507</b>	<b>\$ —</b>

In addition to the agreements described above, the Company has other contractual commitments related primarily to contracts entered into with contract research organizations and contract manufacturing organizations in connection with the conduct of clinical trials and other research and development activities. The estimated payments to the service providers included in the table above are based solely on the estimated work to be performed by them to complete the trials and other activities along with the anticipated achievement of milestones included within the agreements. Also, some of these contracts are subject to early termination clauses exercisable at the discretion of the Company. The Company is not obligated to make minimum required payments under these service agreements.

The Company has no contingent liabilities in respect of legal claims arising in the ordinary course of business.

**NABRIVA THERAPEUTICS plc**

**Notes to the Consolidated Financial Statements (Continued)**

**(in thousands, except per share data)**

**18. Selected Quarterly Financial Information (Unaudited)**

The table summarizes the unaudited consolidated financial results of operations for the quarters ended:

<u>(amounts in thousands, except per share data)</u>	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>
<b>2018 Quarter Ended</b>				
Revenues	\$ 7,551	\$ 847	\$ 461	\$ 797
Operating expenses	(20,415)	(18,554)	(53,386)	(31,676)
Loss from operations	(12,864)	(17,707)	(52,925)	(30,879)
Other income (expense)	28	(129)	(51)	(204)
Income tax (expense) benefit	(506)	48	151	259
Net loss	(13,342)	(17,788)	(52,825)	(30,824)
Basic and diluted loss per share	<b>\$ (0.36)</b>	<b>\$ (0.44)</b>	<b>\$ (0.90)</b>	<b>\$ (0.46)</b>
<b>2017 Quarter Ended</b>				
Revenues	\$ 1,678	\$ 1,051	\$ 1,468	\$ 1,122
Operating expenses	(16,878)	(16,613)	(22,193)	(23,403)
Loss from operations	(15,200)	(15,562)	(20,725)	(22,281)
Other income (expense)	326	(7)	328	120
Income tax (expense) benefit	(349)	967	(1,872)	(101)
Net loss	(15,223)	(14,602)	(22,269)	(22,262)
Basic and diluted loss per share(1)	<b>\$ (0.56)</b>	<b>\$ (0.54)</b>	<b>\$ (0.79)</b>	<b>\$ (0.61)</b>

- (1) Net loss per share amounts may not agree to the per share amounts for the full year due to the use of weighted average shares for each period. Additionally, loss per share for the quarter ended March 31, 2017 is recast to reflect the Redomiciliation Transaction, accordingly the loss per share presented is based on the equivalent number of Nabriva Ireland ordinary shares outstanding in all periods.

**19. Subsequent Events**

The Company evaluated all events or transactions that occurred subsequent to December 31, 2018 through the date the consolidated financial statements were issued, and have not identified any such events.



Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

#### LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT is made and dated as of December 20, 2018 and is entered into by and among Nabriva Therapeutics Public Limited Company, a public limited company incorporated in Ireland under registration number 599588 and having its registered office at 25-28 North Wall Quay, Dublin 1, Ireland (“Parent”), Nabriva Therapeutics Ireland Designated Activity Company, a designated activity company incorporated in Ireland under registration number 612454 and having its registered office at Suite 510, Regus Dublin Airport, Skybridge House, Dublin Airport, Swords, County Dublin, Ireland (“Nabriva Ireland”); together with Parent, individually and collectively, jointly and severally, the “Borrower”), Nabriva Therapeutics GmbH, a limited liability company (*Gesellschaft mit beschränkter Haftung*) incorporated under the laws of the Republic of Austria, having its seat in Vienna and its registered address at Leberstraße 20, 1110 Vienna, and registered with the companies’ register (*Firmenbuch*) of the commercial court of Vienna (*Handelsgericht Wien*) under registration number 269261 y (“Nabriva Austria”), Nabriva Therapeutics US, Inc., a Delaware corporation (“Nabriva US”), Zavante Therapeutics, Inc., a Delaware corporation (“Zavante”), and each of their Subsidiaries from time to time party hereto (together with Nabriva Austria and Nabriva US, collectively referred to as the “Guarantors” and each, a “Guarantor”), Hercules Capital, Inc., a Maryland corporation, as lender and any other banks and other financial institutions or entities from time to time parties to this Agreement (collectively, referred to as “Lender”) and Hercules Capital, Inc., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and the Lender (together with its successors and assigns, in such capacity, the “Agent”).

#### RECITALS

- A. Borrower has requested Lender to make available to Borrower one or more loans in an aggregate principal amount of up to the Term Commitment (the “Term Loan”); and
- B. Lender is willing to make the Term Loan on the terms and conditions set forth in this Agreement.

#### AGREEMENT

NOW, THEREFORE, each Loan Party, Agent and Lender agree as follows:

#### **SECTION 1. DEFINITIONS AND RULES OF CONSTRUCTION**

- 1.1 Unless otherwise defined herein, the following capitalized terms shall have the following meanings:

“Account Control Agreement(s)” means (i) any agreement to be entered into on or about the date of this Agreement or thereafter by and among the Agent, any Loan Party

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organized in the United States or a state, district or territory thereof and a third party bank or other institution (including a Securities Intermediary) in which such Loan Party maintains a Deposit Account or an account holding Investment Property and which, together with this Agreement, grants Agent a perfected first priority security interest in the subject account or accounts, (ii) a notice of assignment given in respect of any Deposit Account or Securities Account of any Loan Party incorporated in Ireland, including as provided for in the Irish Security Documents, or (iii) an Austrian law governed bank account pledge agreement entered into by and among the Agent and Nabriva Austria, granting a security interest over any and all accounts held by Nabriva Austria with a bank located in Austria, except Excluded Accounts.

“Advance(s)” means a Term Loan Advance.

“Advance Date” means the funding date of any Advance.

“Advance Request” means a request for an Advance submitted by the applicable Borrower to Agent in substantially the form of Exhibit A.

“Affiliate” means (a) any Person that directly or indirectly controls, is controlled by, or is under common control with the Person in question, (b) any Person directly or indirectly owning, controlling or holding with power to vote twenty percent (20%) or more of the outstanding voting securities of another Person, or (c) any Person twenty percent (20%) or more of whose outstanding voting securities are directly or indirectly owned, controlled or held by another Person with power to vote such securities. As used in the definition of “Affiliate,” the term “control” means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through ownership of voting securities, by contract or otherwise.

“Agent” has the meaning given to it in the preamble to this Agreement.

“Agreement” means this Loan and Security Agreement, as amended, amended and restated, supplemented or otherwise modified from time to time.

“Allocable Amount” has the meaning given to it in Section 12.7(b).

“Amortization Date” means July 1, 2020; *provided however*, if Interest Only Extension Conditions I is satisfied, then January 1, 2021; provided further, if Interest Only Extension Conditions II is satisfied (regardless of the achievement of Interest Only Extension Conditions I), then July 1, 2021; provided further, if Interest Only Extension Conditions III is satisfied, then October 1, 2021; provided further, if Interest Only Extension Conditions IV is satisfied, then January 1, 2022.

“Anti-Corruption Laws” shall mean all laws, rules, and regulations of any jurisdiction applicable to Parent or any of its Subsidiaries from time to time concerning or relating to bribery or corruption, including without limitation the United States Foreign Corrupt Practices Act of 1977, as amended, the UK Bribery Act 2010 and other similar legislation in any other applicable jurisdictions.

“Anti-Terrorism Laws” means any laws, rules, regulations or orders relating to terrorism or money laundering, including without limitation Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

“Assignee” has the meaning given to it in Section 11.13.

“Austrian Capital Maintenance Rules” has the meaning given to it in Section 12.11.

“Austrian Guarantor” means a Guarantor that is incorporated (or in case of a partnership established) in the Republic of Austria or otherwise subject to mandatory Austrian corporate law (e.g. a company incorporated and registered in a non-EU member state having its actual seat of administration in the Republic of Austria).

“Austrian Security Documents” means the following documents to be entered into on or about the date of this Agreement, each in form and substance reasonably satisfactory to Agent and each as amended, amended and restated, supplemented or otherwise modified from time to time: (i) the Pledge Agreement in relation to 100% of the shares in Nabriva Austria, (ii) the Account Control Agreement in the form of an Austrian law governed bank account pledge agreement in relation to all bank accounts of Nabriva Austria maintained in Austria, except Excluded Accounts, (iii) the IP Security Agreement in relation to Nabriva Austria, excluding FFG Restricted Assets and (iv) the Pledge Agreement in relation to Receivables of Nabriva Austria.

“Bail-In Action” means the exercise of any Write-Down and Conversion Powers by the applicable EEA Resolution Authority in respect of any liability of an EEA Financial Institution.

“Bail-In Legislation” means, with respect to any EEA Member Country implementing Article 55 of Directive 2014/59/EU of the European Parliament and of the Council of the European Union, the implementing law for such EEA Member Country from time to time that is described in the EU Bail-In Legislation Schedule.

“Blocked Person” means any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports “terrorism” as defined in Executive Order No. 13224, or (e) a Person that is named a “specially designated national” or “blocked person” on the most current list published by OFAC or other similar list.

“Borrower Products” means all compounds or products currently being developed, manufactured or sold by Borrower or any of its Subsidiaries or which Borrower or any of its Subsidiaries, manufacture, license, or distribute in the future, including any products or service offerings under development, collectively, together with all products, software, service offerings,

technical data or technology that have been sold, developed, licensed or distributed by Borrower or any of its Subsidiaries since its incorporation.

“Business Day” means any day other than Saturday, Sunday and any other day on which banking institutions in the State of California or Dublin, Ireland are closed for business.

“Cash” means all cash, cash equivalents and liquid funds.

“Change in Control” means any (i) reorganization, recapitalization, consolidation or merger (or similar transaction or series of related transactions) of Borrower in which the holders of Borrower’s outstanding shares immediately before consummation of such transaction or series of related transactions do not, immediately after consummation of such transaction or series of related transactions, retain shares representing more than fifty percent (50%) of the voting power of the surviving entity of such transaction or series of related transactions (or the parent of such surviving entity if such surviving entity is wholly owned by such parent), in each case without regard to whether a Loan Party is the surviving entity; (ii) sale or issuance by any Loan Party of equity securities to investors, none of whom are current investors in such Loan Party (or their Affiliates), which securities represent, as of immediately following the closing (or, if there be more than one, any closing) thereof, fifty percent (50%) or more of the then-outstanding total combined voting power of such Loan Party, or (iii) the Parent ceases to own, directly or indirectly, 100% of the ownership interests in each Subsidiary.

“Claims” has the meaning given to it in Section 11.10.

“Closing Date” means the date of this Agreement.

“Code” means the U.S. Internal Revenue Code of 1986, as amended.

“Collateral” means the property described in Section 3.

“Companies Act” means the Companies Act 2014 of Ireland (as amended).

“Confidential Information” has the meaning given to it in Section 11.12.

“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.

“Contingent Obligation” means, as applied to any Person, any direct or indirect liability, contingent or otherwise, of that Person with respect to (i) any Indebtedness of another Person, including any such obligation guaranteed, endorsed, co-made or discounted or sold with recourse by that Person, or in respect of which that Person is otherwise directly or indirectly liable; (ii) any obligations with respect to undrawn letters of credit, corporate credit cards or merchant services issued for the account of that Person; and (iii) all obligations arising under any interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; provided, however, that the term “Contingent Obligation” shall not include endorsements for collection or deposit in the

ordinary course of business. The amount of any Contingent Obligation shall be deemed to be an amount equal to the stated or determined amount of the primary obligation in respect of which such Contingent Obligation is made or, if not stated or determinable, the maximum reasonably anticipated liability in respect thereof as determined by such Person in good faith; provided, however, that such amount shall not in any event exceed the maximum amount of the obligations under the guarantee or other support arrangement.

“Control” or “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 and policies of such Person, whether through the ability to exercise voting power, by contract or otherwise. “Controlling” and “Controlled” have meanings correlative thereto.

“Copyright License” means any written agreement to which a Loan Party is a party, now or hereafter, granting any right to use any Copyright or Copyright registration.

“Copyrights” means all copyrights, whether registered or unregistered, held pursuant to the laws of the United States of America, any State thereof, or of any other country, supranational or intergovernmental organization (including without limitation the World Intellectual Property Organization or the European Union).

“Corresponding Debt” has the meaning given to it in Section 11.17(e).

“Deposit Accounts” means any “deposit accounts,” as such term is defined in the UCC, and includes any checking account, savings account, or certificate of deposit.

“Disclosure Letter” means that certain letter, dated as of the date hereof, delivered by the Loan Parties to Agent.

“Due Diligence Fee” means \$50,000, which fee is due to and has been paid to Lender on or prior to the Closing Date, which fee shall be used to pay the Lender’s non-legal transaction costs and due diligence expenses, and shall be deemed fully earned on such date regardless of the early termination of this Agreement.

“EEA Financial Institution” means (a) any credit institution or investment firm established in any EEA Member Country that is subject to the supervision of an EEA Resolution Authority, (b) any entity established in an EEA Member Country that is a parent of an institution described in clause (a) of this definition, or (c) any financial institution established in an EEA Member Country that is a subsidiary of an institution described in clauses (a) or (b) of this definition and is subject to consolidated supervision with its parent.

“EEA Member Country” means any of the member states of the European Union, Iceland, Liechtenstein, and Norway and any other country which may become a member of the European Economic Area or subject to Bail-In Legislation from time to time.

“EEA Resolution Authority” means any public administrative authority or any person entrusted with public administrative authority of any EEA Member Country (including any delegee) having responsibility for the resolution of any EEA Financial Institution.

“Eligible Accounts” means Accounts receivable arising in the ordinary course of Borrower’s business. Unless otherwise agreed by Agent, Eligible Accounts shall not include the following:

- (a) Accounts that the account debtor has failed to pay in full within 90 days of invoice date;
- (b) Accounts owing by an account debtor that does not have its principal place of business in the United States of America;
- (c) Accounts arising out of deferred revenue;
- (d) Accounts owing by an Affiliate of Borrower;
- (e) Accounts (i) upon which Borrower’s right to receive payment is not absolute or is contingent upon the fulfillment of any condition whatsoever or (ii) as to which Borrower is not able to bring suit or otherwise enforce its remedies against the account debtor through judicial process; and
- (f) Accounts the collection of which Agent determines in its good faith credit judgment to be doubtful.

“Equity Interests” means, with respect to any Person, the capital stock, partnership or limited liability company interest, securities offered in Permitted Convertible Debt Financing or other equity securities or equity ownership interests of such Person.

“ERISA” means the Employee Retirement Income Security Act of 1974, as amended, and the regulations promulgated thereunder.

“EU Bail-In Legislation Schedule” means the EU Bail-In Legislation Schedule published by the Loan Market Association (or any successor person), as in effect from time to time.

“Event of Default” has the meaning given to it in Section 9.

“Examiner” has the meaning given to that term in Section 509 of the Companies Act.

“Excluded Accounts” means (i) any Deposit Account that is used solely as either a benefits account or a payroll account for the employees of any Loan Party or any of its Subsidiaries (provided that with respect to payroll accounts, the funds in any payroll account shall not exceed the amount to be paid in the ordinary course of business in the then-next payroll cycle); provided that each such accounts are disclosed in writing to Agent on the Closing Date or the next Compliance Certificate required to be delivered pursuant to Section 7.1(d) hereof for any such accounts opened on or after the Closing Date, (ii) Deposit Account number [\*\*] with [\*\*] in an aggregate amount not to exceed \$[\*\*] at any time and (iii) accounts pledged to the extent permitted pursuant to clause (xiv) of the definition of Permitted Liens.

“Excluded Collateral” has the meaning given to it in Section 3.

“Excluded Taxes” means any of the following Taxes imposed on or with respect to a Lender or Agent or required to be withheld or deducted from a payment to a Lender or Agent, (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 Lender or Agent 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) in the case of a Lender, U.S. federal and Austrian withholding Taxes imposed on amounts payable to or for the account of such Lender with respect to an applicable interest in a Loan or Term Commitment pursuant to a law in effect on the date on which (i) such Lender acquires such interest in the Loan or (ii) such Lender changes its lending office, except in each case to the extent that, pursuant to Section 2.9, amounts with respect to such Taxes were payable either to such Lender’s assignor immediately before such Lender became a party hereto or to such Lender immediately before it changed its lending office, (c) Taxes attributable to such Lender or Agent’s failure to comply with Section 2.9(g), (d) any withholding Taxes imposed under FATCA and (e) any Tax imposed by Ireland where such Tax would not be imposed if on the date on which the payment falls due (i) Lender is not, or has ceased to be, a Qualifying Lender other than as a result of a change after the date it became a Lender under this Agreement in (or in the interpretation, administration, or application of) any law, or any Irish double tax agreement or (ii) the Assignee had complied with its obligations under Section 2.9(g)(i).

“Facility Office” means the office or offices through which the Lender will perform its obligations under this Agreement.

“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 materially more onerous to comply with, any current or future regulations or official interpretations thereof, any agreement entered into pursuant to Section 1471(b)(1) of the Code, and any fiscal or regulatory legislation, rules or practices adopted pursuant to any intergovernmental agreement, treaty or convention among Governmental Authorities and implementing such Sections of the Code.

“FDA” means the U.S. Food and Drug Administration or any successor thereto or any other comparable Governmental Authority whether in the United States or elsewhere.

“FFG” means the Austrian Research Promotion Agency (*Österreichischen Forschungsförderungsgesellschaft mbH*).

“FFG Agreements” means the following grant agreements (*Förderungsverträge*) entered into between FFG as grantor and Nabriva Austria as recipient: (a) the agreement dated 22 December 2016 subsidizing the evolution of pleuromutilin antibiotics pursuant to which FFG agreed to make available to Nabriva Austria up to (i) €[\*\*] as grant (*Zuschuss*) and (ii) €[\*\*] as loan and (b) the agreement dated February 12, 2018, as amended April 9, 2018 subsidizing the evolution of pleuromutilin antibiotics pursuant to which FFG agreed to make available to Nabriva Austria up to (i) €[\*\*] as grant (*Zuschuss*) and (ii) €[\*\*] as loan.

“FFG Restricted Assets” means (i) Intellectual Property (other than with respect to CONTEPO, lefamulin or any other Borrower Products reflected in any Forecast) for the portfolio of Next Generation Pleuromutilins financed under the FFG Agreements and (ii) any of Nabriva Austria’s rights or claims arising out of or in connection with the FFG Agreements (in each case, other than with respect to CONTEPO, lefamulin or any other Borrower Products reflected in any Forecast).

“Forecast” means the projections for Parent and its consolidated Subsidiaries as delivered and accepted by Agent on November 26, 2018; provided that Parent (i) may from time to time update the Forecast with the written consent of Agent in its reasonable discretion, and (ii) must update the Forecast upon the manufacture, license, or distribution of any Borrower Products other than CONTEPO or lefamulin and such updated Forecast shall be subject to Agent’s approval in its reasonable discretion.

“GAAP” means generally accepted accounting principles in the United States of America, as in effect from time to time provided that the parties agree that GAAP as in effect on the date of this Agreement shall be applicable for the interpretation of (a) “capital lease obligations” in the definition of “Indebtedness” and (b) “revenue” for purposes of the definition of “Net Product Revenue”, unless the Agent otherwise agrees in writing in its sole discretion.

“Governmental Authority” means the government of any nation or any political subdivision thereof, whether state, local, territory, province or otherwise, and any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to government (including any supranational bodies such as the European Union or the European Central Bank).

“Guarantor” has the meaning given to it in the preamble to this Agreement.

“Guarantor Payment” has the meaning given to it in Section 12.7(a).

“Indebtedness” means (a) all indebtedness for borrowed money or the deferred purchase price of property or services (excluding trade credit entered into in the ordinary course of business due within one hundred eighty (180) days), including reimbursement and other obligations with respect to surety bonds and letters of credit, (b) all obligations evidenced by notes, bonds, debentures or similar instruments, (c) all capital lease obligations and synthetic lease obligations, (d) all direct or contingent obligations of such Person arising under letters of credit (including standby and commercial), bankers’ acceptances, bank guaranties, surety bonds and similar instruments and (e) all Contingent Obligations.

“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 of any Loan Party under any Loan Document and (b) to the extent not otherwise described in clause (a), Other Taxes.

“Initial Facility Charge” means \$700,000.

“Insolvent” means (a) in case of an Austrian Guarantor, without limitation any situation where that Austrian Guarantor is illiquid (*zahlungsunfähig*) within the meaning of

section 66 of the Austrian Insolvency Code (*Insolvenzordnung*) or, over-indebted (*überschuldet*) within the meaning of section 67 of the Austrian Insolvency Code (*Insolvenzordnung*); and (b) in case of Nabriva Ireland or Parent, it is deemed to be unable to pay its debts within the meaning of s. 570 of the Companies Act.

“Insolvency Proceeding” is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions or compromises or other arrangements generally with its creditors, or proceedings seeking reorganization, arrangement, or other similar relief. In case of an Austrian Guarantor Insolvency Proceeding includes, without limitation, in particular (i) the opening of insolvency proceedings (*Insolvenzverfahren*) including restructuring proceedings with or without self-administration (*Sanierungsverfahren mit oder ohne Eigenverwaltung*) and bankruptcy proceedings (*Konkursverfahren*) or (ii) the denial of the opening of insolvency proceedings due to lack of assets (*Abweisung mangels kostendeckendes Vermögen*).

“Insolvency Regulation” means Regulation (EU) No 2015/848 of the European Parliament and of the Council of 20 May 2015 on insolvency proceedings.

“Intellectual Property” means all of each Loan Party’s Copyrights; Trademarks; Patents; Licenses; trade secrets and inventions; mask works; service marks, designs, business names, data base rights, design rights, domain names, moral rights, inventions, confidential information, know-how and other intellectual property rights and interests whether registered or unregistered; each Loan Party’s applications therefor or reissues, extensions, or renewals thereof; and each Loan Party’s goodwill associated with any of the foregoing, together with each Loan Party’s rights to sue for past, present and future infringement of Intellectual Property and the goodwill associated therewith.

“Interest Only Extension Conditions I” means satisfaction of each of the following: (a) no Event of Default has occurred and is continuing and (b) as of or prior to September 30, 2019, Borrower has achieved Performance Milestone 6.

“Interest Only Extension Conditions II” means satisfaction of each of the following: (a) no Event of Default has occurred and is continuing and (b) as of or prior to September 30, 2019, the Tranche 2 Advance has been funded in full.

“Interest Only Extension Conditions III” means satisfaction of each of the following: (a) no Event of Default has occurred and is continuing and (b) as of or prior to December 31, 2020, the Tranche 4 Advance has been funded in full.

“Interest Only Extension Conditions IV” means satisfaction of each of the following: (a) no Event of Default has occurred and is continuing, (b) the Interest Only Extension Conditions II has been met, and (c) as of or prior to June 30, 2021, the Tranche 5 Advance has been funded in full.

“Inventory” means “inventory” as defined in Article 9 of the UCC.



“Investment” means any beneficial ownership (including stock, partnership or limited liability company interests) of or in any Person, or any loan, advance or capital contribution to any Person or the acquisition of any material asset or property of another Person.

“IP Security Agreement” means, collectively, each certain Intellectual Property Security Agreement to be executed and delivered by any Loan Party to Agent as of the Closing Date, and any other intellectual property security agreement in favor of Agent, in each case as amended, amended and restated, supplemented or otherwise modified from time to time.

“Irish Security Documents” means the following documents to be entered into on or about the date of this Agreement, each in form and substance reasonably satisfactory to Agent and each as amended, amended and restated, supplemented or otherwise modified from time to time: Irish Law Debenture dated on or about the date of this Agreement and made between (1) Parent and Nabriva Ireland (as chargors) and (2) the Lender (as chargee) (the “Irish Debenture”).

“Joinder Agreements” means for each Subsidiary, a completed and executed (i) Joinder Agreement in substantially the form attached hereto as Exhibit G with respect to Subsidiaries formed or organized under the laws of the United States of America or any state, commonwealth or territory thereof, or (ii) joinder documentation in form and substance reasonably satisfactory to Agent joining such Subsidiary as a party under the Irish Security Documents, Austrian Security Documents or similar security documents under the relevant jurisdictions, as applicable, with respect to Subsidiaries formed, incorporated or organized outside of the United States, Ireland or Austria.

“Lender” has the meaning given to it in the preamble to this Agreement.

“License” means any Copyright License, Patent License, Trademark License or other license of rights or interests.

“Lien” means any mortgage, deed of trust, pledge, hypothecation, assignment for security, security interest, encumbrance, levy, lien or charge of any kind, whether voluntarily incurred or arising by operation of law or otherwise, against any property, any conditional sale or other title retention agreement, and any lease in the nature of a security interest.

“Liquidity” means the sum of (a) Unrestricted Cash *plus* (b) an amount equal to 80% of Eligible Accounts.

“Loan” means the Advances made under this Agreement.

“Loan Documents” means this Agreement, the Notes (if any), the Disclosure Letter, the Account Control Agreements, each IP Security Agreement, the Joinder Agreements, all UCC Financing Statements, the Pledge Agreement, the Irish Security Documents, the Austrian Security Documents, each Process Letter and any other documents executed in connection with the Secured Obligations or the transactions contemplated hereby, as the same may from time to time be amended, modified, supplemented or restated.

“Loan Party” means each Borrower and each Guarantor.

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“Material Adverse Effect” means an occurrence that has a material adverse effect upon: (i) the business, operations, properties, assets or financial condition of any Loan Party and its Subsidiaries taken as a whole; or (ii) the ability of any Loan Party to perform when due the Secured Obligations in accordance with the terms of the Loan Documents, or the ability of Agent or Lender to enforce any of its rights or remedies with respect to the Secured Obligations; or (iii) the Collateral or Agent’s Liens on the Collateral or the priority of such Liens.

“Maximum Rate” shall have the meaning assigned to such term in Section 2.3.

“Maximum Term Loan Amount” means Seventy Million and No/100 Dollars (\$70,000,000); *provided that if* Tranche 7 is fully available pursuant to the terms herein, then Seventy-Five Million and No/100 Dollars (\$75,000,000).

“NDA” means a new drug application in the United States for authorization to market a product, as defined in the applicable laws and regulations and submitted to the FDA.

“Net Financing Proceeds” means unrestricted (including not subject to any clawback, redemption, escrow or similar contractual restriction) net cash proceeds from bona fide equity financings and/or upfront proceeds from business development, corporate collaborations or similar arrangements, in each case on terms and conditions and with counterparties satisfactory to Agent and received in an account subject to an Account Control Agreement. For the avoidance of doubt, the requirements of Section 7.21 of this Agreement (financial covenants) shall not operate as a restriction for the purposes the definition of “Net Financing Proceeds.”

“Net Product Revenue” means for any period of measurement, the aggregate net revenue of Parent or any of its Subsidiaries from worldwide commercial sales of CONTEPO, lefamulin or other Borrower Products (including royalty revenue from the sale of such products in geographies in which such products have been outlicensed) reflected in the Forecast, in each case, on a consolidated basis as determined in accordance with GAAP for such period. “Net Product Revenue” does not include upfront business development proceeds and business development milestones.

“Non-Disclosure Agreement” means that certain Non-Disclosure Agreement by and between Hercules Capital, Inc. and Nabriva Therapeutics Public Limited Company dated as of August 24, 2018.

“Note(s)” means a Term Note.

“OFAC” is the U.S. Department of Treasury Office of Foreign Assets Control.

“OFAC Lists” are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

“Other Connection Taxes” means, with respect to any Lender, Taxes imposed as a result of a present or former connection between such Lender and the jurisdiction imposing such

Tax (other than connections arising from such Lender 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 (i) 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, including Austrian stamp duty (Rechtsgeschäftsgebühr), except any such Taxes that are Other Connection Taxes imposed with respect to an assignment and (ii) any Taxes (other than (A) Indemnified Taxes, (B) Taxes described in clauses (b) through (e) of the definition of Excluded Taxes and (C) Connection Income Taxes) imposed by a change in law on a Lender’s or Agent’s loans, loan principal, letters of credit, commitments, or other obligations, or its deposits, reserves, other liabilities or capital attributable thereto that result to increase the cost to such Lender or Agent of making, converting to, continuing or maintaining any Loan or of maintaining its obligation to make any such Loan, or to reduce the amount of any sum received or receivable by such Lender or Agent.

“Parallel Debt” has the meaning given to it in Section 11.17(e).

“Patent License” means any written agreement to which a Loan Party is a party, now or hereafter, granting any right with respect to any invention on which a Patent is in existence or a Patent application is pending.

“Patents” means all letters patent or utility model of, or rights corresponding thereto, in the United States of America or in any other country, all registrations and recordings thereof, and all applications for letters patent or utility model of, or rights corresponding thereto, in the United States of America or any other country or any supranational or intergovernmental organization (including without limitation the World Intellectual Property Organization or the European Patent Organization).

“Performance Covenant Trigger Date” means the date that is the later of the dates described in clauses (a) and (b) (both of which must occur in order for the Performance Covenant Trigger Date to occur): (a) the earliest Advance Date of a Tranche 2 Advance, a Tranche 3 Advance, a Tranche 4 Advance, Tranche 5 Advance, or a Tranche 6 Advance and (b) the date that is six (6) months following the earliest of the (i) achievement of Performance Milestone 1 and (ii) achievement of Performance Milestone 2.

“Performance Milestone 1” means satisfaction of each of the following events: (a) no Event of Default shall have occurred and be continuing and (b) Borrower or any other Loan Party shall have received the approval from the FDA of the NDA for lefamulin for the treatment of community-acquired bacterial pneumonia, with a label generally consistent with the target label included in Borrower’s NDA filing.

“Performance Milestone 2” means satisfaction of each of the following events: (a) no Event of Default shall have occurred and be continuing and (b) Borrower or any other Loan Party shall have received the approval from the FDA of the NDA for CONTEPO for the

treatment of complicated urinary tract infections, with a label generally consistent with the target label included in Borrower's NDA filing.

"Performance Milestone 3" means satisfaction of each of the following events: (a) no Event of Default shall have occurred and be continuing, (b) achievement of Performance Milestone 1, (c) achievement of Performance Milestone 2, and (d) Borrower shall have recognized no less than \$[\*\*] in trailing six month Net Product Revenue from commercial sales of CONTEPO and lefamulin as of the last day of any month on or prior to December 2020.

"Performance Milestone 4" means satisfaction of each of the following events: (a) no Event of Default shall have occurred and be continuing, (b) achievement of Performance Milestone 1, (c) achievement of Performance Milestone 2 and (d) Borrower shall have recognized no less than \$[\*\*] in trailing six month Net Product Revenue from commercial sales of CONTEPO and lefamulin as of the last day of any month as of or prior to June 2021.

"Performance Milestone 5" means satisfaction of each of the following events: (a) no Event of Default shall have occurred and be continuing, (b) achievement of Performance Milestone 1, (c) achievement of Performance Milestone 2 and (d) Borrower shall have recognized no less than \$[\*\*] in trailing six month Net Product Revenue from commercial sales of CONTEPO and lefamulin as of the last day of any month as of or prior to September 2021.

"Performance Milestone 6" means receipt by Borrower after November 1, 2018 and on or before [\*\*], of at least [\*\*] Dollars (\$[\*\*]) of Net Financing Proceeds.

"Permitted Acquisition" shall mean any acquisition (including by way of merger) by any Loan Party of all or substantially all of the assets of another Person or of a division or line of business of another Person, in each case located entirely within the United States of America, or capital stock of another Person which is conducted in accordance with the following requirements:

- (a) such acquisition is of a business or Person engaged in a line of business related to that of the Loan Parties or their Subsidiaries;
- (b) if such acquisition is structured as a stock acquisition, then the Person so acquired shall either (i) become a wholly-owned Subsidiary of a Loan Party or its Subsidiary and such Loan Party shall comply, or cause such Subsidiary to comply, with 7.13 hereof or (ii) such Person shall be merged with and into a Loan Party (with such Loan Party being the surviving entity);
- (c) if such acquisition is structured as the acquisition of assets, such assets shall be acquired by a Loan Party and shall be free and clear of Liens other than Permitted Liens;
- (d) the Loan Party shall have delivered to Lender not less than fifteen (15) nor more than forty five (45) days prior to the date of such acquisition, notice of such acquisition together with pro forma projected financial information, copies of all material documents relating to such acquisition, and historical financial statements for such acquired entity, division or line of business, and demonstrating compliance with the covenants set forth in Section 7.21(a) hereof and (to the extent the Performance Covenant Trigger Date has occurred) 7.21(b) hereof on

a pro forma basis as if the acquisition occurred on the first day of the most recent measurement period;

(e) both immediately before and after such acquisition no Event of Default shall have occurred and be continuing; and

(f) the sum of the purchase price of such proposed new acquisition, computed on the basis of total acquisition consideration paid or incurred, or to be paid or incurred, by any Loan Party with respect thereto, including the amount of Permitted Indebtedness assumed or to which such assets, businesses or business or ownership interest or shares, or any Person so acquired, is subject, shall not be greater than \$1,000,000 for all such acquisitions during the term of this Agreement.

“Permitted Convertible Debt Financing” means issuance by Parent of unsecured convertible or exchangeable notes in an aggregate principal amount of not more than One Hundred Fifty Million Dollars (\$150,000,000); provided that such notes shall (a) be unsecured and not be guaranteed by any Subsidiary that does not guarantee this Agreement, (b) does not (i) provide for any scheduled payment or mandatory prepayment of principal earlier than one hundred eighty-one (181) days after the Term Loan Maturity Date or (ii) have a scheduled maturity date or any mandatory prepayments or redemptions of principal (other than customary change of control or fundamental change repurchase obligations and cash payments in lieu of fractional shares upon the conversion or exchange thereof) at the option of the holder thereof, in each case earlier than one hundred eighty-one (181) days after the Term Loan Maturity Date, (c) contain usual and customary subordination terms for underwritten offerings of senior subordinated convertible notes, (d) specifically designate this Agreement and all Secured Obligations as “designated senior indebtedness” or similar term so that the subordination terms referred to in clause (c) of this definition specifically refer to such notes as being subordinated to the Secured Obligations pursuant to such subordination terms and (e) be convertible or exchangeable for ordinary shares of Parent at the option of Parent.

“Permitted Indebtedness” means: (i) Indebtedness of any Loan Party in favor of Lender or Agent arising under this Agreement or any other Loan Document; (ii) Indebtedness existing on the Closing Date which is disclosed in Schedule 1A of the Disclosure Letter; (iii) Indebtedness of up to \$[\*] outstanding at any time secured by a Lien described in clause (vii) of the defined term “Permitted Liens”, provided such Indebtedness does not exceed the lesser of cost or fair market value of the Equipment financed with such Indebtedness; (iv) Indebtedness to trade creditors incurred in the ordinary course of business, including Indebtedness incurred in the ordinary course of business with corporate credit cards; (v) Indebtedness that also constitutes a Permitted Investment; (vi) Subordinated Indebtedness; (vii) reimbursement obligations in connection with letters of credit, banker acceptances or bank guarantees that are unsecured or are secured by Cash and issued on behalf of any Loan Party or its Subsidiary thereof in an amount not to exceed \$[\*] at any time outstanding, (viii) other unsecured (or secured solely by specific assets of any Loan Party) Indebtedness in an amount not to exceed \$[\*] at any time outstanding, (ix) intercompany Indebtedness as long as one of the following is satisfied: (A) the Indebtedness is among the Loan Parties, (B) (I) the Indebtedness is of any Subsidiary to a Loan Party in the maximum principal amount outstanding not to exceed \$[\*], or (II) the Indebtedness is of any Loan Party to any Subsidiary, and such Indebtedness constitutes Subordinated Indebtedness

subject to a subordination agreement in form and substance satisfactory to Agent and otherwise qualifies as a Permitted Investment, or (C) each of the Subsidiary obligor and the Subsidiary obligee under such Indebtedness is a Subsidiary that has executed a Joinder Agreement; (x) guarantees of any items of Permitted Indebtedness; (xi) Permitted Convertible Debt Financing, (xii) extensions, refinancings and renewals of any items of Permitted Indebtedness, provided that the principal amount is not increased or the terms modified to impose materially more burdensome terms upon any Loan Party or its Subsidiary, as the case may be; (xiii) Indebtedness under the Zuperbug Merger Agreement; and (xiv) Indebtedness incurred under the FFG Agreements as in effect as of the Closing Date not to exceed €[\*\*]; and (xv) Indebtedness consisting of compensation owed to employees in the ordinary course of business not to exceed \$[\*\*] in any fiscal year.

“Permitted Investment” means: (i) Investments existing on the Closing Date which are disclosed in Schedule 1B of the Disclosure Letter; (ii) (a) marketable direct obligations issued or unconditionally guaranteed by the United States of America or any agency or any State thereof maturing within one year from the date of acquisition thereof, (b) commercial paper maturing no more than one year from the date of creation thereof and at the time of the Investment by any Loan Party or the applicable Subsidiary having a rating of at least A-2 or P-2 from either Standard & Poor’s Corporation or Moody’s Investors Service, (c) certificates of deposit issued by any bank with assets of at least \$500,000,000 maturing no more than one year from the date of investment therein, (d) money market accounts, and (e) corporate debt obligations maturing no more than 12 months from the date of acquisition thereof and at the time of investment having a rating of at least A3 or A- from either Standard & Poor’s or Moody’s Investor Service; (iii) repurchases of stock from former employees, directors, or consultants of any Loan Party under agreements approved by such Loan Party’s board of directors (or applicable governing body) in an aggregate amount not to exceed \$[\*\*] in any fiscal year, provided that no Event of Default has occurred, is continuing or would exist after giving effect to the repurchases; (iv) Investments accepted in connection with Permitted Transfers, and Investments permitted pursuant to Section 7.7 hereof; (v) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of the Loan Parties’ business; (vi) 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, provided that this subparagraph (vi) shall not apply to Investments of any Loan Party in any Subsidiary; (vii) Investments consisting of loans not involving the net transfer on a substantially contemporaneous basis of cash proceeds to employees, officers or directors relating to the purchase of capital stock of any Loan Party pursuant to employee stock purchase plans or other similar agreements approved by such Loan Party’s board of directors (or applicable governing body); (viii) Investments consisting of travel advances, reimbursement of moving expenses, commuter and travel expenses, and tax gross up payments to employees or consultants relating to income received by such employees or consultants in connection with the same, in an aggregate amount not to exceed \$[\*\*] per fiscal year; (ix) Investments in existing or newly-formed Subsidiaries organized in the United States, provided that such Subsidiaries enter into a Joinder Agreement and execute such other documents as shall be reasonably requested by Lender; (x) Investments in Affiliates formed, incorporated or organized outside of the United States approved in advance by the Required Lenders; (xi) licenses, joint ventures or strategic alliances and similar arrangements in the ordinary course of the Loan Parties’ business consisting of licenses permitted hereunder or

the providing of technical support, provided that any cash Investments by any Loan Party in another Person (other than another Loan Party or a Subsidiary that has entered into a Joinder Agreement pursuant to the terms hereof) do not exceed \$[\*\*] in the aggregate in any fiscal year; (xii) Permitted Indebtedness that constitutes Investments; (xiii) Investments in Permitted Acquisitions; (xiv) additional Investments that do not exceed \$[\*\*] in the aggregate per fiscal year; (xv) Investments consistent with the Parent's investment policy as delivered to Agent in connection with the closing; (xvi) Investments by Loan Parties in Loan Parties (other than Nabriva Austria), (xvii) Investments by Loan Parties in Nabriva Austria, so long as (a) the Loan Parties are in compliance with Section 7.21(a) immediately before and after giving effect to such Investment and (b) no Event of Default has occurred and is continuing and (xviii) the [\*\*].

"Permitted Liens" means any and all of the following: (i) Liens in favor of Agent or Lender; (ii) Liens existing on the Closing Date which are disclosed in Schedule 1C of the Disclosure Letter; (iii) Liens for taxes, fees, assessments or other governmental charges or levies, either not delinquent or being contested in good faith by appropriate proceedings; provided, that the Loan Parties maintain adequate reserves therefor in accordance with GAAP; (iv) Liens securing claims or demands of materialmen, artisans, mechanics, carriers, warehousemen, landlords and other like Persons arising in the ordinary course of the Loan Parties' business and imposed without action of such parties; provided, that the payment of such claims is not yet overdue; (v) Liens arising from judgments, decrees or attachments in circumstances which do not constitute an Event of Default hereunder; (vi) the following deposits, to the extent made in the ordinary course of business: deposits under worker's compensation, unemployment insurance, social security and other similar laws, or to secure the performance of bids, tenders or contracts (other than for the repayment of borrowed money) or to secure indemnity, performance or other similar bonds for the performance of bids, tenders or contracts (other than for the repayment of borrowed money) or to secure statutory obligations (other than Liens arising under ERISA or environmental Liens) or surety or appeal bonds, or to secure indemnity, performance or other similar bonds; (vii) Liens on Equipment, software, other Intellectual Property in connection with such Equipment or other capital assets constituting purchase money Liens and Liens in connection with capital leases securing Indebtedness permitted in clause (iii) of "Permitted Indebtedness"; (viii) Liens incurred in connection with Subordinated Indebtedness; (ix) leasehold interests in leases or subleases and licenses granted in the ordinary course of business and not interfering in any material respect with the business of the licensor; (x) Liens in favor of customs and revenue authorities arising as a matter of law to secure payment of custom duties that are promptly paid on or before the date they become due or being contested in good faith by appropriate proceedings; provided, that the Loan Parties maintain adequate reserves therefor in accordance with GAAP; (xi) Liens on insurance proceeds securing the payment of financed insurance premiums that are promptly paid on or before the date they become due (provided that such Liens extend only to such insurance proceeds and not to any other property or assets); (xii) statutory, common law and contractual rights of set-off and other similar rights as to deposits of cash and securities in favor of banks, other depository institutions and brokerage firms; (xiii) easements, zoning restrictions, rights-of-way and similar encumbrances on real property imposed by law or arising in the ordinary course of business so long as they do not materially impair the value or marketability of the related property; (xiv) (A) Liens on Cash securing obligations permitted under clause (vii) of the definition of Permitted Indebtedness, (B) Liens on Cash securing credit card obligations permitted under clause (iv) of the definition of Permitted

Indebtedness and (C) security deposits in connection with real property leases, the combination of (A), (B) and (C) in an aggregate amount not to exceed \$[\*] at any time; and (xv) precautionary filings in connection with operating leases in the Equipment that is the subject of such leases; (xvi) contractual liens in connection with Permitted Transfers; and (xvii) Liens incurred in connection with the extension, renewal or refinancing of the Indebtedness secured by Liens of the type described in clauses (i) through (xvii) above; provided, that any extension, renewal or replacement Lien shall be limited to the property encumbered by the existing Lien and the principal amount of the Indebtedness being extended, renewed or refinanced (as may have been reduced by any payment thereon) does not increase.

“Permitted Transfers” means (i) sales of Inventory in the ordinary course of business, (ii) transfers among Loan Parties, (iii) transfers in connection with the Sinovant License Agreement entered into in March 2018 between Sinovant Sciences Ltd., Nabriva Ireland and Nabriva Therapeutics GmbH, (iv) non-exclusive licenses and similar arrangements for the use of Intellectual Property or Borrower Products in the ordinary course of business or in connection with business development transactions and exclusive licenses for the use of the Intellectual Property or the use or transfer of Borrower Products of any Loan Party or any of its Subsidiaries entered into in the ordinary course of business or in connection with business development transactions, provided, that, with respect to each such license described in this clause (iv), the license (A) constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment by any Loan Party of any Intellectual Property and do not restrict the ability of any Loan Party or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on any Intellectual Property, and (B) is limited in territory with respect to a specific geographic country or region outside of the United States (e.g. Japan, Europe, China), (v) dispositions of worn-out, obsolete or surplus Equipment at fair market value in the ordinary course of business, (vi) Permitted Investments to the extent constituting transfers of property, (vii) Permitted Liens to the extent constituting transfers of property, (viii) the [\*\*], and (ix) other transfers of assets having a fair market value of not more than \$[\*\*] in the aggregate in any fiscal year.

“Person” means any individual, sole proprietorship, partnership, joint venture, trust, unincorporated organization, association, corporation, limited liability company, institution, other entity or government.

“Pledge Agreement” means the Pledge Agreement to be entered into on or about the date of this Agreement between any Loan Party and Agent, as the same may from time to time be amended, restated, modified or otherwise supplemented.

“Prepayment Charge” shall have the meaning assigned to such term in Section 2.5.

“Prime Rate” means the rate of interest last quoted by The Wall Street Journal as the “Prime Rate” in the United States or, if The Wall Street Journal ceases to quote such rate, the highest *per annum* interest rate published by the Federal Reserve Board in Federal Reserve Statistical Release H.15 (519) (Selected Interest Rates) as the “bank prime loan” rate or, if such rate is no longer quoted therein, any similar rate quoted therein (as determined by the Agent acting in good faith and in a commercially reasonable manner) or any similar release by the



Federal Reserve Board (as determined by the Agent acting in good faith and in a commercially reasonable manner).

“Process Letter” means each of that certain letter agreement whereby Parent and each Subsidiary that is formed, incorporated or organized outside of the United States appoint CT Corporation System, or other agent reasonably acceptable to Agent, as its agent for the purpose of accepting service of any process under this Agreement.

“Publicity Materials” has the meaning given to it in Section 11.18.

“Qualifying Lender” means a Lender which is beneficially entitled to interest payable to that Lender in respect of an advance under this Agreement and is:

- (a) a bank within the meaning of section 246 of the TCA which is carrying on a bona fide banking business in Ireland for the purposes of section 246(3)(a) of the TCA and whose Facility Office is located in Ireland; or
- (b) a body corporate:
  - (i) which, by virtue of the law of a Relevant Territory is resident in the Relevant Territory for the purposes of tax and that jurisdiction imposes a tax that generally applies to interest receivable in that jurisdiction by companies from sources outside that jurisdiction; or
  - (ii) which is a U.S. company which is incorporated in the United States and is taxed in the United States on its worldwide income; or
  - (iii) which is a U.S. limited liability company where:
    - (A) the ultimate recipients of the interest would themselves be Qualifying Lenders under (i), (ii) or (iv) of this Section (b); and
    - (B) business is conducted through the such U.S. limited liability company for market reasons and not for tax avoidance purposes; or
  - (iv) in receipt of interest in respect of an advance under this Agreement which:
    - (A) is exempted from the charge to Irish income tax pursuant to the terms of a double taxation treaty entered into between Ireland and another jurisdiction that is in force on the date the relevant interest is paid; or
    - (B) would be exempted from the charge to Irish income tax pursuant to the terms of a double taxation treaty entered into between Ireland and another jurisdiction signed on or before the date on which the relevant interest is paid but not in force on that date, assuming that treaty had the force of law on that date,

provided that, in each case (i) to (iv) above, such body corporate does not provide its commitment through a branch or agency in Ireland; or

- (c) a body corporate which advances money in the ordinary course of a trade which includes the lending of money where the interest payable on monies so advanced is taken into account in computing the trading income of such body corporate and such body corporate has complied with the notification requirements under section 246(5)(a) of the TCA and whose Facility Office is located in Ireland; or
- (d) a qualifying company within the meaning of section 110 of the TCA and whose Facility Office is located in Ireland; or
- (e) an investment undertaking within the meaning of section 739B of the TCA and whose Facility Office is located in Ireland; or
- (f) an exempt approved scheme within the meaning of section 774 of the TCA and whose Facility Office is located in Ireland; or
- (g) a Treaty Lender.

“Receivables” means all of the Loan Parties’ Accounts, Instruments, Documents, Chattel Paper, Supporting Obligations, letters of credit, proceeds of any letter of credit, and Letter of Credit Rights.

“Relevant Territory” means:

- (a) a member state of the European Communities (other than Ireland); or
- (b) to the extent not a member state of the European Communities, a jurisdiction with which Ireland has entered into a double taxation treaty that either has the force of law by virtue of section 826(1) of the TCA or which will have the force of law on completion of the procedures set out in section 826(1) of the TCA.

“Required Lenders” means at any time, the holders of more than 50% of the sum of the aggregate unpaid principal amount of the Term Loans then outstanding.

“Sanctioned Country” shall mean, at any time, a country or territory which is the subject or target of any Sanctions.

“Sanctioned Person” shall mean, at any time, (a) any Person listed in any Sanctions-related list of designated Persons maintained by the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State, or by the United Nations Security Council, the European Union or any EU member state, (b) any Person operating, organized or resident in a Sanctioned Country or (c) any Person controlled by any such Person.

“Sanctions” shall mean economic or financial sanctions or trade embargoes imposed, administered or enforced from time to time by (a) the U.S. government, including those

administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State, or (b) the United Nations Security Council, the European Union or Her Majesty's Treasury of the United Kingdom.

"SEC" means the Securities and Exchange Commission.

"Secured Obligations" means the Loan Parties' obligations and liabilities under or in connection with this Agreement and any Loan Document, including any obligation to pay any amount now owing or later arising.

"Subordinated Indebtedness" means Indebtedness subordinated to the Secured Obligations in amounts and on terms and conditions reasonably satisfactory to Agent and subject to a "deep" subordination agreement in form and substance satisfactory to Agent.

"Subsequent Financing" means any Parent financing which becomes effective after the Closing Date and before all amounts outstanding under this Agreement and the other Loan Documents are repaid, in a single transaction or series of related transactions not registered under the Securities Act of 1933, as amended, of shares of its preferred stock, common stock or other equity security, or of any instrument exercisable for or convertible into or otherwise representing the right to acquire shares of Borrower preferred stock, common stock or other equity security, to one or more investors for cash for financing purposes (including, without limitation, any so-called PIPE transaction).

"Subsidiary" means an entity, whether corporate, partnership, limited liability company, joint venture or otherwise, in which any Loan Party owns or controls more than 50% of the outstanding voting securities, including each entity listed on Schedule 1 of the Disclosure Letter.

"Tax" means all present or future taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees, stamp-duty (*Rechtsgeschäftsgebühren*) or other charges imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

"TCA" means the Taxes Consolidation Act 1997 of Ireland.

"Term Commitment" means as to Lender, the obligation of Lender, if any, to make a Term Loan Advance to the Borrower in a principal amount not to exceed the amount set forth under the heading "Term Commitment" opposite Lender's name on Schedule 1.1.

"Term Loan Advance" means each Tranche 1 Advance, Tranche 2 Advance, Tranche 3 Advance, Tranche 4 Advance, Tranche 5 Advance, Tranche 6 Advance, Tranche 7 Advance and any other Term Loan funds advanced under this Agreement.

"Term Loan Interest Rate" means for any day a per annum rate of interest equal to the greater of either (i) 9.80% *plus* the Prime Rate *minus* 5.50% or (ii) 9.80%, in each case per annum.

"Term Loan Maturity Date" means June 1, 2023.

"Term Note" means a promissory note in substantially the form of Exhibit B.

"Trademark License" means any written agreement to which any Loan Party is a party, now or hereafter, granting any right to use any Trademark or Trademark registration.

"Trademarks" means all trademarks (registered, common law or otherwise) and any applications in connection therewith, including registrations, recordings and applications in the United States Patent and Trademark Office or in any similar office or agency of the United States of America, any State thereof or any other country, supranational or intergovernmental organization or any political subdivision thereof (including without limitation the World Intellectual Property Organization or the European Union Intellectual Property Office).

"Treaty Lender" means a Lender, other than a Lender falling within Section (b) of the definition of Qualifying Lender set out above, which, on the date any relevant payment is made:

- (a) is entitled under a double taxation treaty entered into by Ireland which has the force of law on that date (subject to the completion of any procedural formalities) to that payment without any deduction of Tax; and
- (b) where such procedural formalities include obtaining an authorization from the Revenue Commissioners of Ireland to enable any payment to be made without Irish Tax being withheld, such an authorization has been obtained and provided to the Borrower prior to any interest payment date.

"Tranche 1 Advance" shall have the meaning assigned to such term in Section 2.2(a).

"Tranche 2 Advance" shall have the meaning assigned to such term in Section 2.2(a).

"Tranche 3 Advance" shall have the meaning assigned to such term in Section 2.2(a).

"Tranche 4 Advance" shall have the meaning assigned to such term in Section 2.2(a).

"Tranche 5 Advance" shall have the meaning assigned to such term in Section 2.2(a).

"Tranche 6 Advance" shall have the meaning assigned to such term in Section 2.2(a).

"Tranche 7 Advance" shall have the meaning assigned to such term in Section 2.2(a).

“Tranche 7 Facility Charge” means one percent (1%) of the Tranche 7 Advance.

“UCC” means the Uniform Commercial Code as the same is, from time to time, in effect in the State of New York; provided, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection or priority of, or remedies with respect to, Agent’s Lien on any Collateral is governed by the Uniform Commercial Code as the same is, from time to time, in effect in a jurisdiction other than the State of New York, then the term “UCC” shall mean the Uniform Commercial Code as in effect, from time to time, in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority or remedies and for purposes of definitions related to such provisions.

“Unrestricted Cash” means Cash held by the Loan Parties in account(s) subject to an Account Control Agreement in favor of Agent.

“U.S. Person” means any Person that is a “United States person” as defined in Section 7701(a)(30) of the Code.

“[\*\*]” means [\*\*].

“Withholding Agent” means any Loan Party and the Agent.

“Write-Down and Conversion Powers” means, with respect to any EEA Resolution Authority, the write-down and conversion powers of such EEA Resolution Authority from time to time under the Bail-In Legislation for the applicable EEA Member Country, which write-down and conversion powers are described in the EU Bail-In Legislation Schedule.

“Zuperbug Merger Agreement” means that certain Agreement and Plan of Merger, dated as of July 23, 2018 without giving any effects to any amendments, restatements or modifications after the Closing Date unless consented to in writing by Agent in its sole discretion, among Parent, Zuperbug Merger Sub I Inc., Zuperbug Merger Sub II, Inc., Zavante Therapeutics Inc., and Cam Gallagher.

Unless otherwise specified, all references in this Agreement or any Annex or Schedule hereto to a “Section,” “subsection,” “Exhibit,” “Annex,” or “Schedule” shall refer to the corresponding Section, subsection, Exhibit, Annex, or Schedule in or to this Agreement or the Disclosure Letter, as applicable. Unless otherwise specifically provided herein, any accounting term used in this Agreement or the other Loan Documents shall have the meaning customarily given such term in accordance with GAAP, and all financial computations hereunder shall be computed in accordance with GAAP, consistently applied. Unless otherwise defined herein or in the other Loan Documents, terms that are used herein or in the other Loan Documents and defined in the UCC shall have the meanings given to them in the UCC. For all purposes under the Loan Documents, in connection with any division or plan of division under Delaware law (or any comparable event under a different jurisdiction’s laws): (a) if any asset, right, obligation or liability of any Person becomes the asset, right, obligation or liability of a different Person, then it shall be deemed to have been transferred from the original Person to the subsequent Person and (b) if any new Person comes into existence, such new Person shall be deemed to have been organized on the first date of its existence by the holders of its Equity Interests at such time. Where any reference is made to any amount expressed in US Dollar it shall also cover its equivalent in another currency or currencies.

In this Agreement, where it relates to an asset or right that is located in Austria or an Austrian Guarantor, a reference to (i) a liquidator includes a Liquidator within the meaning of the Austrian Act on Limited Liability Companies (*GmbH-Gesetz, GmbHG*) or the Austrian Act on Joint Stock Companies (*Aktiengesetz - AktG*), (ii) a receiver, administrator, administrative receiver or compulsory manager includes, without limitation, any *Insolvenzverwalter* within the meaning of the Austrian Insolvency Code (*Insolvenzordnung*), (iii) a winding-up, dissolution or the like includes, without limitation, a Liquidation within the meaning of the GmbHG (iv) gross negligence means *grobe Fahrlässigkeit*, and (v) a lien, security or security interest includes any *Hypothek, Pfandrecht, Sicherungszession, Sicherungsübereignung, Eigentumsvorbehalt, Finanzsicherheit* or any other *in rem* right (*sonstiges dingliches Recht*). This Agreement is made in the English language. However, where a German translation of a word or phrase appears in the text of this Agreement, the relevant translation of such word or phrase shall prevail.

## **SECTION 2. THE LOAN**

2.1 [Reserved].

2.2 Term Loan.

(a) Advances. Subject to the terms and conditions of this Agreement, Lender will severally (and not jointly) make in an amount not to exceed its respective Term Commitment, and Borrower agrees to draw, a Term Loan Advance of \$25,000,000 on the Closing Date (the “Tranche 1 Advance”). Subject to the terms and conditions of this Agreement, beginning on the date Borrower achieves Performance Milestone 1 and continuing through September 30, 2019, Borrower may request and Lender shall make an additional Term Loan Advance in a principal amount of \$10,000,000 (the “Tranche 2 Advance”). Subject to the terms and conditions of this Agreement, beginning on the date Borrower achieves Performance Milestone 2 and continuing through September 30, 2019, Borrower may request and Lender shall make an additional Term Loan Advance in an aggregate principal amount of \$5,000,000 (the “Tranche 3 Advance”). Subject to the terms and conditions of this Agreement, beginning on the later of January 1, 2020 and the date Borrower achieves Performance Milestone 3 and continuing through December 31, 2020, Borrower may request and Lender shall make an additional Term Loan Advance in a principal amount of \$10,000,000 (the “Tranche 4 Advance”). Subject to the terms and conditions of this Agreement, beginning on the later of July 1, 2020 and the date Borrower achieves Performance Milestone 4 and continuing through June 30, 2021, Borrower may request and Lender shall make an additional Term Loan Advance in a principal amount of \$15,000,000 (the “Tranche 5 Advance”). Subject to the terms and conditions of this Agreement, beginning on the later of January 1, 2021 and the date Borrower achieves Performance Milestone 5 and continuing through September 30, 2021, Borrower may request and Lender shall make an additional Term Loan Advance in a principal amount of \$5,000,000 (the “Tranche 6 Advance”). Subject to the terms and conditions of this Agreement and conditioned on approval by Lender’s investment committee in its sole discretion, beginning on the date determined by Lender’s investment committee and continuing through December 31, 2021, Borrower may request an additional Term Loan Advance in an aggregate principal amount of \$5,000,000 (the “Tranche 7 Advance”). The aggregate outstanding Term Loan Advances may be up to

the Maximum Term Loan Amount. For the avoidance of doubt, each Advance will be available on the terms stated herein, without regard to the drawdown of any of the Tranche 2 Advance, Tranche 3 Advance, Tranche 4 Advance, Tranche 5 Advance and Tranche 6 Advance.

(b) Advance Request. To obtain a Term Loan Advance, Parent shall complete, sign and deliver an Advance Request (at least three (3) Business Days before the Advance Date other than the Closing Date, which shall be at least one (1) Business Day) to Agent. Lender shall fund the Term Loan Advance in the manner requested by the Advance Request provided that each of the conditions precedent to such Term Loan Advance is satisfied or waived by Agent in writing as of the requested Advance Date.

(c) Interest. The principal balance of each Term Loan Advance shall bear interest thereon from such Advance Date at the Term Loan Interest Rate based on a year consisting of 360 days, with interest computed daily based on the actual number of days elapsed. The Term Loan Interest Rate will float and change on the day the Prime Rate changes from time to time.

(d) Payment. Borrower will pay interest in arrears on each Term Loan Advance on the first Business Day of each month, beginning the month after the Advance Date. Borrower shall repay the aggregate Term Loan principal balance that is outstanding on the day immediately preceding the Amortization Date, in equal monthly installments of principal and interest (mortgage style) beginning on the Amortization Date and continuing on the first Business Day of each month thereafter until the Secured Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) are repaid. The entire Term Loan principal balance and all accrued but unpaid interest hereunder, shall be due and payable on Term Loan Maturity Date. Subject to Section 2.9(b), Borrower shall make all payments under this Agreement without setoff, recoupment or deduction and regardless of any counterclaim or defense. Borrower shall wire in immediately available funds in US dollars to Agent or Lender, as applicable as specified in writing by Agent, and in each case (i) on each payment date, all periodic obligations payable to Lender under each Term Loan Advance and (ii) documented out-of-pocket legal fees and costs incurred by Agent or Lender in connection with Section 11.11 of this Agreement; provided that Borrower shall pay to Lender such amount in full in immediately available funds within ten (10) Business Days of Agent or Lender furnishing Borrower an invoice of such out-of-pocket legal fees and costs incurred by Agent or Lender.

2.3 Maximum Interest. Notwithstanding any provision in this Agreement or any other Loan Document, it is the parties' intent not to contract for, charge or receive interest at a rate that is greater than the maximum rate permissible by law that a court of competent jurisdiction shall deem applicable hereto (which under the laws of the State of New York shall be deemed to be the laws relating to permissible rates of interest on commercial loans) (the "Maximum Rate"). If a court of competent jurisdiction shall finally determine that Borrower has actually paid to Lender an amount of interest in excess of the amount that would have been payable if all of the Secured Obligations had at all times borne interest at the Maximum Rate, then such excess interest actually paid by Borrower shall be applied as

follows: first, to the payment of the Secured Obligations consisting of the outstanding principal amount of the Term Loan Advances; second, after all principal is repaid, to the payment of Lender's accrued interest, costs, expenses, professional fees and any other Secured Obligations; and third, after all Secured Obligations are repaid, the excess (if any) shall be refunded to Borrower.

2.4 Default Interest. In the event any payment is not paid on the scheduled payment date (other than due to ACH failure), an amount equal to four percent (4%) of the past due amount shall be payable on demand. In addition, upon the occurrence and during the continuation of an Event of Default hereunder, all Secured Obligations, including principal, interest, compounded interest, and professional fees, shall bear interest at a rate per annum equal to the rate set forth in Section 2.2(c) plus four percent (4%) per annum. In the event any interest is not paid when due hereunder, delinquent interest shall be added to principal and shall bear interest on interest, compounded at the rate set forth in Section 2.2(c) or Section 2.4, as applicable.

2.5 Prepayment. At its option upon at least five (5) Business Days prior written notice to Agent, Borrower may prepay all or any portion greater than or equal to Five Million Dollars (\$5,000,000) of the outstanding Advances by paying the entire principal balance (or portion thereof), all accrued and unpaid interest with respect to the principal balance being prepaid, together with a prepayment charge equal to the following percentage of the Advance amount being prepaid: if such Advance amounts are prepaid in any of the first twelve (12) months following the Closing Date, 3.0%; after twelve (12) months but prior to twenty four (24) months, 2.0%; and thereafter, 1.0% (each, a "Prepayment Charge"). Borrower agrees that the Prepayment Charge is a reasonable calculation of Lender's lost profits in view of the difficulties and impracticality of determining actual damages resulting from an early repayment of the Advances. Borrower shall prepay the outstanding amount of all principal and accrued interest through the prepayment date and the Prepayment Charge upon the occurrence of a Change in Control. Notwithstanding the foregoing, Agent and Lender agree to waive the Prepayment Charge if Agent, Lender or any of their respective Affiliates (in its sole discretion) agree in writing to refinance the Advances on or prior to the Term Loan Maturity Date.

2.6 End of Term Charge. On the earliest to occur of (i) the Term Loan Maturity Date, (ii) the date that Borrower prepays all or any portion of the outstanding Secured Obligations (other than any inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement), or (iii) the date that the Secured Obligations become due and payable, Borrower shall pay Lender a charge equal to 6.95% of the aggregate principal amount of all Advances; provided that the pro rata portion of such charge shall be due and payable with respect to the amount of any partial prepayments made pursuant to the terms of Section 2.5. Notwithstanding the required payment date of such charge, it shall be deemed earned by Lender as of the Closing Date.

2.7 Notes. If so requested by Lender by written notice to Borrower, then Borrower shall execute and deliver to Lender (and/or, if applicable and if so specified in such notice, to any Person who is an assignee of Lender pursuant to Section 11.13)



(promptly after the Borrower's receipt of such notice) a Note or Notes to evidence Lender's Loans.

2.8 Pro Rata Treatment. Each payment (including prepayment) on account of any fee and any reduction of the Term Loans shall be made pro rata according to the Term Commitments of the relevant Lender.

2.9 Taxes.

(a) Defined Terms. For purposes of this Section 2.9, the term "applicable law" includes FATCA.

(b) Payments Free of Taxes. Any and all payments by or on account of any obligation of any Loan Party under any Loan Document shall be made without deduction or withholding for any Taxes, except as required by applicable law. If any applicable law (as determined in the good faith discretion of an applicable Withholding Agent) 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 Loan Party 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) the Lender or Agent, as applicable, receives an amount equal to the sum it would have received had no such deduction or withholding been made.

(c) Payment of Other Taxes by the Loan Parties. The Loan Parties shall timely pay to the relevant Governmental Authority in accordance with applicable law, or at the option of Agent timely reimburse it for the payment of, any Other Taxes.

(d) Indemnification by the Loan Parties. The Loan Parties shall indemnify the Lender or Agent, as applicable, within 10 days after written 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) payable or paid by such Lender or Agent, as applicable, or required to be withheld or deducted from a payment to such Lender or Agent, as applicable, 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 Borrower by a Lender (with a copy to Agent), or by Agent on its own behalf or on behalf of a Lender, shall be conclusive absent manifest error.

(e) Indemnification by the Lender. Lender shall severally indemnify Agent, within 10 days after demand therefor, for (i) any Indemnified Taxes attributable to such Lender (but only to the extent that any Loan Party has not already indemnified Agent for such Indemnified Taxes and without limiting the obligation of the Loan Parties to do so) and (ii) any Excluded Taxes attributable to such Lender, in each case, that are payable or

paid by Agent in connection with any Loan Document, and any reasonable expenses arising therefrom or with respect thereto, whether or not such 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 any Lender by Agent shall be conclusive absent manifest error. Lender hereby authorizes Agent to set off and apply any and all amounts at any time owing to such Lender under any Loan Document or otherwise payable by Agent to the Lender from any other source against any amount due to Agent under this paragraph (e).

(f) Evidence of Payments. As soon as practicable after any payment of Taxes by any Loan Party to a Governmental Authority pursuant to this Section 2.9, such Loan Party shall deliver to Agent the original or a certified copy of a receipt issued by such Governmental Authority evidencing such payment, a copy of the return reporting such payment or other evidence of such payment reasonably satisfactory to Agent.

(g) Status of Lender.

(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 deliver to Borrower and Agent, at the time or times reasonably requested by Borrower or Agent, such properly completed and executed documentation reasonably requested by Borrower or Agent as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, any Lender, if reasonably requested by Borrower or Agent, shall deliver such other documentation prescribed by applicable law or reasonably requested by Borrower or Agent as will enable Borrower or 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 2.9(g)(ii), (iii) and (v) below) 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, any Lender that is a U.S. Person shall deliver to Borrower and 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 Borrower or Agent), executed copies of IRS Form W-9 certifying that such Lender is exempt from U.S. federal backup withholding tax.

(iii) 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 deliver to Borrower and Agent at the time or times

prescribed by law and at such time or times reasonably requested by Borrower or Agent such documentation prescribed by applicable law (including as prescribed by Section 1471(b)(3)(C)(i) of the Code) and such additional documentation reasonably requested by Borrower or Agent as may be necessary for Borrower and 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 clause (iii), "FATCA" shall include any amendments made to FATCA after the date of this Agreement.

(iv) Lender agrees that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or promptly notify Borrower and Agent in writing of its legal inability to do so.

(v) Without limiting the generality of Section 2.9(g)(i), following a request from a Borrower, each Lender shall as soon as reasonably practicable provide such information to the Borrower as may be required for the Borrower to comply with its obligations under sections 891A, 891E, 891F and 891G of the TCA (and any regulations made pursuant to those sections).

(h) 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 2.9 (including by the payment of additional amounts pursuant to this Section 2.9), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnity payments made, or additional amounts paid, under this Section 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 (h) (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 paragraph (h), in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this paragraph (h) 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 Tax subject to indemnification and giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such Tax had never been paid. This paragraph 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) Survival. Each party's obligations under this Section 2.9 shall survive the resignation or replacement of Agent or any assignment of rights by, or the replacement

of, a Lender, the termination of the Term Commitment and the repayment, satisfaction or discharge of all obligations under any Loan Document.

(j) Each Lender by executing this Agreement on the date hereof represents and warrants that it is a Qualifying Lender (other than solely by virtue of being a Treaty Lender) as at the date of this Agreement.

(k) Each Lender shall promptly notify the Borrower in writing if it becomes aware that there has been a change in its status as a Qualifying Lender since the date such Lender became a party to this Agreement.

### **SECTION 3. SECURITY INTEREST**

3.1 As security for the prompt and complete payment when due (whether on the payment dates or otherwise) of all the Secured Obligations, each Loan Party grants to Agent, in addition to and not as replacement of any security interest granted under any other Loan Document, a security interest in all of such Loan Party's right, title, and interest in and to the following personal property and other assets including without limitation the following (except as set forth herein) wherever located whether now owned or hereafter acquired (collectively, the "Collateral"): (a) Receivables; (b) Equipment; (c) Fixtures; (d) General Intangibles (including Intellectual Property); (e) Inventory; (f) Investment Property; (g) Deposit Accounts; (h) Documents (i) Cash; (j) Goods; (k) all commercial tort claims and (l) all other tangible and intangible personal property of such Loan Party whether now or hereafter owned or existing, or acquired by, such Loan Party and wherever located, and any of such Loan Party's property in the possession or under the control of Agent; and, to the extent not otherwise included, all Proceeds of each of the foregoing and all accessions to, substitutions and replacements for, and rents, profits and products of each of the foregoing.

3.2 Notwithstanding the broad grant of the security interest set forth in Section 3.1, above, the Collateral shall not include (collectively, the "Excluded Collateral"): (i) any "intent to use" trademarks at all times prior to the first use thereof, whether by the actual use thereof in commerce, the recording of a statement of use with the United States Patent and Trademark Office or otherwise, provided, that upon submission and acceptance by the United States Patent and Trademark Office of an amendment to allege use of an intent-to-use trademark application pursuant to 15 U.S.C. Section 1060(a) (or any successor provision) such intent-to-use application shall constitute Collateral, (ii) any interest of any Loan Party as a lessee under an Equipment lease or other capital assets constituting purchase money Liens to the extent permitted pursuant to clause (vii) of the definition of Permitted Liens if such Loan Party is prohibited by the terms of such lease from granting a security interest in such lease or under which such an assignment or Lien would cause a default to occur under such lease; provided, however, that upon termination or cessation of such prohibition, such interest shall immediately become Collateral without any action by any Loan Party, Agent or Lenders, (iii) Excluded Accounts or (iv) any FFG Restricted Assets.

#### **SECTION 4. CONDITIONS PRECEDENT TO LOAN**

The obligations of Lender to make the Loan hereunder are subject to the satisfaction by the Loan Parties of the following conditions:

4.1 Initial Advance. On or prior to the Closing Date, the Loan Parties shall have delivered to Agent the following:

- (a) executed copies of the Loan Documents, Account Control Agreements, a legal opinion of the Loan Parties' Irish counsel with respect to authority and capacity, a legal opinion of the Loan Parties' Austrian counsel, a legal opinion of the Loan Parties' United States counsel, all other documents and instruments reasonably required by Agent to effectuate the transactions contemplated hereby or to create and perfect the Liens of Agent with respect to all Collateral, in all cases in form and substance reasonably acceptable to Agent;
- (b) certified copy of resolutions of each Loan Party's respective board of directors (or applicable governing body) and in case of an Austrian Guarantor a copy of a resolution of the shareholder(s) (*Gesellschafter*) evidencing approval of the Loan and other transactions evidenced by the Loan Documents;
- (c) certified copies of the constitutional documents and the bylaws (if any), as amended through the Closing Date, of each Loan Party;
- (d) a corporate certificate signed by a director of the Parent and Nabriva Ireland and Nabriva Austria, addressed to the Lender and the Lender's Austrian and Irish Counsel, attesting to certain facts including that the borrowing or guaranteeing or securing, as appropriate, will not cause any borrowing, guarantee, security or similar limit binding on either the Parent or Nabriva Ireland or Nabriva Austria to be exceeded;
- (e) a certificate of good standing for each Loan Party (other than an Austrian Guarantor, Parent or Nabriva Ireland) from its jurisdiction of incorporation or formation, as applicable, and similar certificates from all other jurisdictions in which it does business and where the failure to be qualified would have a Material Adverse Effect and, in the case of Parent or Nabriva Ireland, a letter of status issued by the Companies Registration Office and in the case of Nabriva Austria, a register excerpt (*Firmenbuchauszug*) from the Austrian companies register;
- (f) a search at the Companies Registration Office and High Court Central Office in Dublin, Ireland and all other appropriate registries or public offices revealing no adverse entries against the Parent or Nabriva Ireland or, in the event that acts appear, accompanied by explanations satisfactory to Lender;
- (g) payment of the Due Diligence Fee and the Initial Facility Charge and reimbursement of Agent's and Lender's current expenses reimbursable pursuant to this Agreement, which amounts may be deducted (if not already paid by Borrower) from the initial Advance;
- (h) all certificates of insurance and copies of each insurance policy required hereunder; and

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- (i) such other documents as Agent may reasonably request.

4.2 All Advances. On each Advance Date:

- (a) Agent shall have received (i) an Advance Request for the relevant Advance as required by Section 2.2(b), as applicable, duly executed by Nabriva Ireland's or Parent's Chief Executive Officer or Chief Financial Officer, as applicable, and (ii) any other documents Agent may reasonably request to demonstrate satisfaction of any applicable performance milestone.
- (b) With respect to the Tranche 7 Advance, Agent shall have received payment of the Tranche 7 Facility Charge for such Advance.
- (c) The representations and warranties set forth in this Agreement shall be true and correct in all material respects on and as of the Advance Date with the same effect as though made on and as of such date, except to the extent such representations and warranties expressly relate to an earlier date.
- (d) [Reserved].
- (e) Immediately after and before such Advance no Event of Default or event that with the passage of time could result in an Event of Default shall have occurred and be continuing.
- (f) Each Advance Request shall be deemed to constitute a representation and warranty by Nabriva Ireland or Parent, as applicable, on the relevant Advance Date as to the matters specified in paragraphs (c) and (e) of this Section 4.2 and as to the matters set forth in the Advance Request.

4.3 No Default. As of the Closing Date and each Advance Date, as applicable, (i) no fact or condition exists that could (or could, with the passage of time, the giving of notice, or both) constitute an Event of Default and (ii) no event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing.

#### **SECTION 5. REPRESENTATIONS AND WARRANTIES**

Each Loan Party represents and warrants that:

5.1 Corporate Status. Each Loan Party (other than Nabriva Ireland or Parent) is duly organized, legally existing and in good standing under the laws of (a) Austria (with respect to Nabriva Austria), or (b) the State of Delaware (with respect to Nabriva US and Zavante) and with respect to Nabriva Ireland and Parent, is duly incorporated and validly existing under the laws of Ireland. Where relevant, each Loan Party is duly qualified as a foreign corporation in all jurisdictions in which the nature of its business or location of its properties require such qualifications and where the failure to be qualified would reasonably be expected to have a Material Adverse Effect. Each Loan Party's present name, former names (if any), place of



information are correctly set forth in Exhibit C of the Disclosure Letter, as may be updated by the Loan Parties in a written notice (including any Compliance Certificate) provided to Agent after the Closing Date.

5.2 Collateral. Each Loan Party owns the Collateral owned by it and owns or has the right to use its Intellectual Property, free of all Liens, except for Permitted Liens. Each Loan Party has the power and authority to grant to Agent a Lien in the applicable Collateral owned by it as security for the Secured Obligations.

5.3 Consents. The Loan Parties' execution, delivery and performance of this Agreement and all other Loan Documents, (i) have been duly authorized by all necessary corporate action of the applicable Loan Parties, (ii) will not result in the creation or imposition of any Lien upon the Collateral, other than Permitted Liens and the Liens created by this Agreement and the other Loan Documents, (iii) do not violate any provisions of the applicable Loan Party's Certificate or Articles of Incorporation (as applicable), bylaws, or any material law, regulation, order, injunction, judgment, decree or writ to which any Loan Party is subject and (iv) except as described on Schedule 5.3 of the Disclosure Letter, do not violate any contract or agreement binding on a Loan Party or require the consent or approval of any other Person which has not already been obtained. The individual or individuals executing the Loan Documents on behalf of each Loan Party are duly authorized to do so.

5.4 Material Adverse Effect. No event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing.

5.5 Actions Before Governmental Authorities. Except as described on Schedule 5.5 of the Disclosure Letter, there are no actions, suits or proceedings at law or in equity or by or before any Governmental Authority now pending or, to the knowledge of any Loan Party, threatened against or affecting any Loan Party or its property, that is reasonably expected to result in a Material Adverse Effect.

5.6 Laws. No Loan Party nor any of its Subsidiaries is in violation of any law, rule or regulation, or in default with respect to any judgment, writ, injunction or decree of any Governmental Authority, where such violation or default is reasonably expected to result in a Material Adverse Effect. No Loan Party is in default under any provision of any agreement or instrument evidencing Indebtedness, or any other agreement to which it is a party or by which it is bound, which default would constitute an Event of Default or reasonably be expected to have a Material Adverse Effect.

No Loan Party nor any of its Subsidiaries is an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. No Loan Party nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Each Loan Party and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. No Loan Party nor any of its Subsidiaries is a "holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term is defined and

used in the Public Utility Holding Company Act of 2005. No Loan Parties' nor any of its Subsidiaries' properties or assets has been used by such Loan Party or such Subsidiary or, to such Loan Party's knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in compliance with applicable laws. Each Loan Party and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted except where the failure to do so would not reasonably be expected to have a Material Adverse Effect.

No Loan Party nor any of its Subsidiaries is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. No Loan Party nor any of its Subsidiaries, or to the knowledge of any Loan Party, any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law. None of the funds to be provided under this Agreement will be used, directly or indirectly, (a) for any activities in violation of any applicable anti-money laundering, economic sanctions and anti-bribery laws and regulations laws and regulations or (b) for any payment to any governmental official or employee, political party, official of a political party, candidate for political office, or anyone else acting in an official capacity, in order to obtain, retain or direct business or obtain any improper advantage, in violation of the United States Foreign Corrupt Practices Act of 1977, as amended.

5.7 Information Correct and Current. No information, report, Advance Request, financial statement, exhibit or schedule furnished, by or on behalf of any Loan Party to Agent in connection with any Loan Document or included therein or delivered pursuant thereto contained, or, when taken together with all such other reports, statements or other documents or writings, contains any material misstatement of fact or omits to state any material fact necessary to make the statements therein, in the light of the circumstances under which they are made, not materially misleading at the time such statement was made or deemed made (it being recognized by Agent and the Lender that the projections and forecasts provided by the Loan Parties, in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts, may differ from the projected or forecasted results). Additionally, any and all financial or business projections provided by the Loan Parties to Agent, are at the time delivered (i) provided in good faith and based on the most current data and information available to the Loan Parties, and (ii) the most current of such projections provided to any Loan Party's board of directors (or applicable governing body) (it being understood that such projections are subject to significant uncertainties and contingencies, many of which are beyond the control of such Loan Party, that no assurance is given that any particular projections will be realized, that actual results may differ).



5.8 Tax Matters. Except as described on Schedule 5.8 of the Disclosure Letter and except those being contested in good faith with adequate reserves under GAAP, (a) each Loan Party has filed all income and other material tax returns that it is required to file, (b) each Loan Party has duly paid or fully reserved for all taxes or installments thereof (including any interest or penalties) as and when due, which have or may become due pursuant to such returns, and (c) each Loan Party has paid or reserved for in accordance with GAAP any tax assessment received by such Loan Party for the three (3) years preceding the Closing Date, if any (including any taxes being contested in good faith and by appropriate proceedings).

5.9 Intellectual Property Claims. Except for Permitted Liens, the Loan Parties are the sole owner of, or otherwise have the right to use, the Intellectual Property owned by the Loan Parties and material to the Loan Parties' business. Except as described on Schedule 5.9 of the Disclosure Letter, (i) to the Loan Parties' knowledge, each of the material Copyrights, Trademarks and issued Patents is valid and enforceable, (ii) no material part of the Intellectual Property owned by the Loan Parties have been judged by a decision of a court of competent jurisdiction, invalid or unenforceable, in whole or in part, and (iii) no claim has been made to any Loan Party in writing that any material Intellectual Property of the Loan Parties violates the rights of any third party except to the extent such claim would not reasonably be expected to have a Material Adverse Effect. Exhibit D of the Disclosure Letter contains a true, correct and complete list of each of the Loan Party's Patents, registered Trademarks, registered Copyrights, if any, together with application or registration numbers, as applicable, owned by such Loan Party or any Subsidiary, and material agreements under which such Loan Party licenses Intellectual Property from third parties (other than shrink-wrap software licenses), in each case as of the Closing Date. The Loan Parties are not in breach of, nor have the Loan Parties failed to perform any obligations under, any of the foregoing contracts, licenses or agreements and, to the Loan Parties' knowledge, no third party to any such contract, license or agreement is in breach thereof or has failed to perform any obligations thereunder, in each case, except where such breach or failure to perform would not reasonably be expected to have a Material Adverse Effect.

5.10 Intellectual Property. Except as described on Schedule 5.10 of the Disclosure Letter, the Loan Parties have all material rights with respect to Intellectual Property necessary or material in the operation or conduct of the Loan Parties' business. Without limiting the generality of the foregoing, and in the case of Licenses, except (w) for restrictions that are unenforceable under Division 9 of the UCC, (x) as provided in clauses (iii) and (iv) of the definition of Permitted Transfers, (y) FFG Restricted Assets and (z) as provided in Schedule 5.10 of the Disclosure Letter, the Loan Parties have the right, to the extent required to operate the Loan Parties' business, to freely transfer, license or assign the Loan Parties' owned Intellectual Property without condition, restriction or payment of any kind (other than license payments in the ordinary course of business) to any third party, and to the extent applicable, the Loan Parties own or have the right to use, pursuant to valid licenses, all material software development tools, library functions, compilers and all other third-party software and other items that are used in the design, development, promotion, sale, license, manufacture, import, export, use or distribution of Borrower Products. For the avoidance of doubt, shrink-wrap licenses, click on license agreements, equipment

leases where any Loan Party is the licensee or lessee, open source code and other licenses available to the public without customization shall not be considered a material License. Subject to Section 7.23(d), all utilized Intellectual Property of Nabriva Austria is registered in the current legal name of Nabriva Austria as the owner of such Intellectual Property in the registry in the United States, Ireland and Austria.

5.11 Borrower Products. Except as described on Schedule 5.11 of the Disclosure Letter, no material Intellectual Property owned by any Loan Party or Borrower Product has been or is subject to any actual or, to the knowledge of any Loan Party, threatened (in writing) litigation, inter-party proceeding (including any proceeding in the United States Patent and Trademark Office or any corresponding foreign office or agency) or outstanding decree, order, judgment, settlement agreement or stipulation that restricts in any material respect the Loan Parties' use, transfer or licensing thereof or that may affect the validity, use or enforceability thereof. To the Loan Parties' knowledge there is no decree, order, judgment, agreement, stipulation, arbitral award or other provision entered into in connection with any litigation or proceeding that obligates any Loan Party to grant licenses or ownership interest in any future material Intellectual Property related to the operation or conduct of the business of the Loan Parties or Borrower Products. The Loan Parties have not received any written notice or claim, or, to the knowledge of the Loan Parties, oral notice or claim, challenging the Loan Parties' ownership in or right to use any material Intellectual Property (or written notice of any claim challenging or questioning the ownership in any licensed Intellectual Property of the owner thereof) or suggesting that any third party (other than the licensor to or co-owner with any Loan Party) has any claim of legal or beneficial ownership with respect thereto. To the Loan Parties' knowledge, neither the Loan Parties' use of its material Intellectual Property nor the production and sale of Borrower Products infringes in any material respect the Intellectual Property or other rights of others.

5.12 Financial Accounts. Exhibit E of the Disclosure Letter, as may be updated by the Loan Parties in a written notice or Compliance Certificate provided to Agent after the Closing Date, is a true, correct and complete list of (a) all banks and other financial institutions at which any Loan Party or any Subsidiary maintains Deposit Accounts and (b) all institutions at which the Loan Parties and their Subsidiaries maintain accounts holding Investment Property, and such exhibit correctly identifies in all non-ministerial respects, the name, address and telephone number of each bank or other institution, the name in which the account is held, a description of the purpose of the account, and the complete account number therefor.

5.13 Employee Loans. Except as permitted in clause (viii) of Permitted Investments, no Loan Party has outstanding loans to any employee, officer or director of any Loan Party nor has any Loan Party guaranteed the payment of any loan made to an employee, officer or director of any Loan Party by a third party.

5.14 Capitalization and Subsidiaries. Parent's capitalization as of the Closing Date is set forth on Schedule 5.14 of the Disclosure Letter. The Loan Parties do not own any stock, partnership interest or other securities of any Person, except for Permitted Investments. Attached as Schedule 5.14 of the Disclosure Letter, as may be updated by

Parent in a written notice provided after the Closing Date, is a true, correct and complete list of each direct and indirect Subsidiary of Parent.

5.15 No conflict with other obligations of Austrian Guarantor: Each Austrian Guarantor (a) has performed its own independent investigation into the financial and commercial standing, creditworthiness, and legal status of the other Guarantors and has not relied on any information from the Agent or the Lender(s) in this respect and (b) any and all transactions entered into by that Austrian Guarantor in connection with the Loan Documents have been thoroughly considered by the managing directors (Geschäftsführer or Vorstände) of that Austrian Guarantor as regards the potential corporate benefits of such transactions for such Austrian Guarantor and on such basis have been determined to be in the best interest of such Austrian Guarantor.

5.16 FFG Agreements.

- (a) No FFG Agreement is secured by any property (including Intellectual Property) of any Loan Party.
- (b) FFG does not have any right, title, or security interest in any property (including Intellectual Property) of any Loan Party.
- (c) The execution, delivery and performance of this Agreement and any other Loan Document (including the Austrian Security Documents) (i) does not violate or conflict with any terms contained in any FFG Agreement and (ii) does not entitle FFG to accelerate any loans or other amounts due under any FFG Agreement.
- (d) No Intellectual Property relating to CONTEPO, lefamulin or any other Borrower Products reflected in any Forecast is included in the portfolio of Next Generation Pleuromutilins financed under any FFG Agreement.
- (e) None of Nabriva Austria's or FFG's rights or claims arising out of or in connection with the FFG Agreements relate to CONTEPO, lefamulin or any other Borrower Products reflected in any Forecast.
- (f) The aggregate amount of all of Nabriva Austria's rights and claims arising out of or in connection with the FFG Agreements does not exceed €[\*\*].

#### **SECTION 6. INSURANCE; INDEMNIFICATION**

6.1 Coverage. The Loan Parties shall cause to be carried and maintained commercial general liability insurance, on an occurrence form, against risks customarily insured against in the Loan Parties' line of business. Such risks shall include the risks of bodily injury, including death, property damage, personal injury, advertising injury, and contractual liability per the terms of the indemnification agreement found in Section 6.3. The Loan Parties must maintain a minimum of \$[\*\*] of commercial general liability insurance (primary and excess liability) for each occurrence. The Loan Parties have and agree to maintain a minimum of \$[\*\*] of directors' and officers' insurance for each

occurrence and \$[\*\*] in the aggregate. So long as there are any Secured Obligations outstanding, the Loan Parties shall also cause to be carried and maintained insurance upon the Collateral, insuring against all risks of physical loss or damage howsoever caused, in an amount not less than the full replacement cost of the Collateral, provided that such insurance may be subject to standard exceptions and deductibles.

6.2 Certificates. The Loan Parties shall deliver to Agent certificates of insurance that evidence the Loan Parties' compliance with its insurance obligations in Section 6.1 and the obligations contained in this Section 6.2. The Loan Parties' insurance certificates shall state Agent (shown as "Hercules Capital, Inc.", as "Agent") is an additional insured for commercial general liability, and a lender's loss payee for all risk property damage insurance and a loss payee and subrogation is waived against Agent for property insurance and additional insured for liability insurance for any future insurance that any Loan Party may acquire from such insurer. Attached to the certificates of insurance will be additional insured endorsements for liability and lender's loss payable and waiver of subrogation against Agent endorsements for all risk property damage insurance. All certificates of insurance will provide for a minimum of thirty (30) days advance written notice to Agent of cancellation (other than cancellation for non-payment of premiums, for which ten (10) days' advance written notice shall be sufficient) or any other change adverse to Agent's interests. Any failure of Agent to scrutinize such insurance certificates for compliance is not a waiver of any of Agent's rights, all of which are reserved. The Loan Parties shall provide Agent with copies of each insurance policy, and upon entering or amending any insurance policy required hereunder, the Loan Parties shall provide Agent with copies of such policies and shall promptly deliver to Agent updated insurance certificates with respect to such policies.

6.3 Indemnity. Each Loan Party agrees to indemnify and hold Agent, Lender and their officers, directors, employees, agents, in-house attorneys, representatives and shareholders (each, an "Indemnified Person") harmless from and against any and all claims, costs, expenses, damages and liabilities (including such claims, costs, expenses, damages and liabilities based on liability in tort, including strict liability in tort), including reasonable attorneys' fees and disbursements and other costs of investigation or defense (including those incurred upon any appeal) (collectively, "Liabilities"), that may be instituted or asserted against or incurred by such Indemnified Person as the result of credit having been extended, suspended or terminated under this Agreement and the other Loan Documents or the administration of such credit, or in connection with or arising out of the transactions contemplated hereunder and thereunder, or any actions or failures to act in connection therewith, or arising out of the disposition or utilization of the Collateral, excluding in all cases Liabilities to the extent resulting directly from any Indemnified Person's gross negligence or willful misconduct. This Section 6.3 shall survive the repayment of indebtedness under, and otherwise shall survive the expiration or other termination of, the Agreement. In no event shall any Indemnified Person be liable on any theory of liability for any special, indirect, consequential or punitive damages (including any loss of profits, business or anticipated savings). This Section shall not apply with respect to Taxes other than any Taxes that represent losses, claims, damages or liabilities arising from any non-Tax claim.

## SECTION 7. COVENANTS

Each Loan Party agrees as follows:

### 7.1 Financial Reports. The Loan Parties shall furnish to Agent the financial statements and reports listed hereinafter:

(a) as soon as practicable (and in any event within 30 days) after the end of each month, (i) before the Loan Parties start generating revenue, monthly cash balances, (ii) once the Loan Parties start generating revenue, monthly cash balances and monthly revenue, and (iii) in the event the Parent prepares monthly financial statements (provided that upon the occurrence and continuation of an Event of Default, Parent shall prepare monthly financial statements), unaudited interim and year-to-date financial statements as of the end of such month (prepared on a consolidated basis), including balance sheet and related statements of income, retained earnings and cash flows accompanied by details (which may be provided in the accompanying Compliance Certificate) of any material contingencies (including the commencement of any material litigation by or against any Loan Party) or any other occurrence that could reasonably be expected to have a Material Adverse Effect, all certified by Parent's Chief Executive Officer or Chief Financial Officer to the effect that they have been prepared in accordance with GAAP, except (x) for the absence of footnotes, (y) that they are subject to normal year-end adjustments, and (z) they do not contain certain non-cash items that are customarily included in quarterly and annual financial statements;

(b) as soon as practicable after the end of each calendar quarter (and in any event within 45 days after the end of each calendar quarter ending March 31, June 30 and September 30 and 60 days after the end of each calendar quarter ending December 31), unaudited interim and year-to-date financial statements as of the end of such calendar quarter (prepared on a consolidated basis), including balance sheet, and related statements of income, retained earnings and cash flows accompanied by details (which may be provided in the accompanying Compliance Certificate) of any material contingencies (including the commencement of any material litigation by or against any Loan Party) or any other occurrence that could reasonably be expected to have a Material Adverse Effect, certified by Parent's Chief Executive Officer or Chief Financial Officer to the effect that they have been prepared in accordance with GAAP, except (i) for the absence of footnotes, (ii) that they are subject to normal year-end adjustments and (iii) that they do not contain certain equity-related non-cash items that are customarily included in annual financial statements (e.g., warrant liabilities and stock-based compensation);

(c) as soon as practicable (and in any event within ninety (90) days) after the end of each fiscal year, unqualified audited financial statements as of the end of such year (prepared on a consolidated basis), including balance sheet and related statements of income, retained earnings and cash flows, and setting forth in comparative form the corresponding figures for the preceding fiscal year, certified by a firm of independent certified public accountants selected by Parent and reasonably acceptable to Agent, accompanied by any management report from such accountants, provided that

Borrower's unqualified opinion on financial statements may contain a limitation as to going concern;

(d) as soon as practicable (and in any event within 30 days) after the end of each fiscal month, a Compliance Certificate in the form of Exhibit F;

(e) as soon as practicable (and in any event within 30 days) after the end of each month, a report showing agings of accounts receivable and accounts payable;

(f) promptly after the sending or filing thereof, as the case may be, copies of any proxy statements, financial statements or reports that the Loan Parties have made available generally to holders of its preferred stock and copies of any regular, periodic and special reports or registration statements that Parent files with the SEC or any Governmental Authority that may be substituted therefor, or any national securities exchange;

(g) financial and business projections promptly following their approval by Parent's board of directors, and in any event no later than 75 days after the end of each fiscal year, as well as budgets, operating plans and other financial information reasonably requested by Agent;

(h) promptly following each meeting of the Board, copies of all presentation materials and minutes that each Loan Party provides to its directors in connection with meetings of the board of directors within 30 days after each such meeting, provided that in all cases such Loan Party may exclude any information or materials related to executive compensation, confidential information, any attorney-client privileged information and any information that would raise a conflict of interest with Agent or Lenders; and

(i) prompt notice if any Loan Party or any of its Subsidiaries have knowledge that any Loan Party, or any Subsidiary, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, or (c) is indicted on charges involving money laundering.

No Loan Party shall make any change in its (a) accounting policies or reporting practices, except as required or permitted by GAAP or (b) fiscal years or fiscal quarters. The fiscal year of each Loan Party shall end on December 31.

The executed Compliance Certificate and all financial statements required to be delivered pursuant to clauses (a), (b) and (c) shall be sent via e-mail to [financialstatements@htgc.com](mailto:financialstatements@htgc.com) with a copy to [legal@htgc.com](mailto:legal@htgc.com), [\*\*]; provided, that if e-mail is not available or sending such Financial Statements via e-mail is not possible, they shall be faxed to Agent at: (650) 473-9194, attention Chief Credit Officer.

Notwithstanding the foregoing, documents required to be delivered under Sections 7.1(a), (b), (c) or, (f) (to the extent any such documents are included in materials otherwise filed with the SEC or posted on the Borrower's website) shall be deemed to have been delivered on the date on which such information is so filed or posted.

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7.2 Management Rights. The Loan Parties shall permit any representative that Agent or Lender authorizes, including its attorneys and accountants, to inspect the Collateral and examine and make copies and abstracts of the books of account and records of any Loan Party at reasonable times and upon reasonable notice during normal business hours (but in any event no more than once in any 12 month period unless an Event of Default has occurred and is continuing). In addition, any such representative shall have the right to meet with management and officers of any Loan Party to discuss such books of account and records. In addition, Agent or Lender shall be entitled at reasonable times and intervals to consult with and advise the management and officers of any Loan Party concerning significant business issues affecting such Loan Party. Such consultations shall not unreasonably interfere with the Loan Parties' business operations. The parties intend that the rights granted Agent and Lender shall constitute "management rights" within the meaning of 29 C.F.R. Section 2510.3-101(d)(3)(ii), but that any advice, recommendations or participation by Agent or Lender with respect to any business issues shall not be deemed to give Agent or Lender, nor be deemed an exercise by Agent or Lender of, control over the Loan Parties management or policies. For the avoidance of doubt, all information, materials and inspections under this provision, and all representatives of the Agent or the Lenders, shall be subject to the confidentiality obligations set forth in Section 11.12.

7.3 Further Assurances. Each Loan Party shall from time to time execute, deliver and file, alone or with Agent, any financing statements, security agreements, collateral assignments, notices, control agreements, or other documents reasonably requested by Agent to perfect or give to Agent a first priority Lien on the Collateral (subject to Permitted Liens). Each Loan Party shall from time to time procure any instruments or documents as may be reasonably requested by Agent, and take all further action that may be necessary, or that Agent may reasonably request, to perfect and protect the Liens granted hereby and thereby. In addition, and for such purposes only, each Loan Party (other than any Austrian Guarantor) hereby authorizes Agent to execute and deliver on behalf of such Loan Party and to file such financing statements (including an indication that the financing statement covers "all assets or all personal property" of such Loan Party in accordance with Section 9-504 of the UCC), collateral assignments, notices, control agreements, security agreements and other documents without the signature of such Loan Party either in Agent's name or in the name of Agent as agent and attorney-in-fact for such Loan Party. Each Loan Party shall in its reasonable business judgment protect and defend such Loan Party's title to the Collateral and Agent's Lien thereon against all Persons claiming any interest adverse to any Loan Party or Agent other than Permitted Liens.

7.4 Indebtedness. No Loan Party shall create, incur, assume, guarantee or be or remain liable with respect to any Indebtedness, or permit any Subsidiary so to do, other than Permitted Indebtedness, or prepay any Indebtedness or take any actions which impose on such Loan Party an obligation to prepay any Indebtedness, except for (a) the exchange or conversion of Indebtedness into equity securities and the payment of cash in lieu of fractional shares in connection with such exchange or conversion, (b) purchase money Indebtedness, (c) prepayment by any Subsidiary of (i) inter-company Indebtedness owed by such Subsidiary to any Loan Party, or (ii) if such Subsidiary is not a Loan Party, intercompany Indebtedness owed by such Subsidiary to either a Loan Party or another Subsidiary that is not a Loan Party, (d) obligations providing for the payment in full of the

Secured Obligations (other than any inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement), or (e) as otherwise permitted hereunder or approved in writing by Agent.

7.5 Collateral. Each Loan Party shall at all times keep the Collateral and all its other property and assets free and clear from any Liens whatsoever (except for Permitted Liens), and shall give Agent prompt written notice when such Loan Party knows of any legal process adversely affecting such, or any Liens thereon, provided however, that the Collateral and such other property and assets may be subject to Permitted Liens. No Loan Party shall agree with any Person other than Agent or Lender not to encumber its property other than (i) in connection with Permitted Liens solely to the extent such restriction applies to assets permitted to be excluded from the Collateral pursuant to Section 3.2, (ii) customary restrictions on the assignment of leases, licenses and other agreements, and (iii) in connection with Permitted Transfers (provided that this clause (iii) shall not be construed to permit a Loan Party to agree with any Person (other than Agent or Lender) to grant a security interest on a Loan Party's property in connection with a Permitted Transfer). No Loan Party shall enter into or suffer to exist or become effective any agreement that prohibits or limits the ability of any Loan Party to create, incur, assume or suffer to exist any Lien upon any of its Intellectual Property, whether now owned or hereafter acquired, to secure its obligations under the Loan Documents to which it is a party, in each case, other than (a) this Agreement and the other Loan Documents, (b) any agreements governing any purchase money Liens or capital lease obligations otherwise permitted hereby (in which case, any prohibition or limitation shall only be effective against the assets financed thereby), (c) in connection with Permitted Liens, Permitted Indebtedness and Permitted Transfers, and (d) customary restrictions on the assignment of leases, licenses and other agreements. Each Loan Party shall cause its Subsidiaries to protect and defend such Subsidiary's title to its assets from and against all Persons claiming any interest adverse to such Subsidiary, and each Loan Party shall cause its Subsidiaries at all times to keep such Subsidiary's property and assets free and clear from any Liens whatsoever (except for Permitted Liens), and shall give Agent prompt written notice of any legal process adversely affecting such Subsidiary's assets.

7.6 Investments. No Loan Party shall directly or indirectly acquire or own, or make any Investment in or to any Person, or permit any of its Subsidiaries so to do, other than Permitted Investments.

7.7 Distributions. No Loan Party shall, nor shall any Subsidiary of a Loan Party, (a) repurchase or redeem any class of stock or other Equity Interest of such Loan Party or such Subsidiary other than pursuant to employee, director or consultant repurchase plans or other similar agreements, in an aggregate amount not to exceed \$[\*\*] per fiscal year, (b) declare or pay any cash dividend or make a cash distribution on any class of stock or other Equity Interest of such Loan Party or such Subsidiary, except that a Subsidiary or any Loan Party may pay dividends or make distributions to any Loan Party.

7.8 Transfers. Except for Permitted Transfers, no Loan Party shall and shall not allow any Subsidiary of a Loan Party to, voluntarily or involuntarily transfer, sell, lease,

license, lend or in any other manner convey any equitable, beneficial or legal interest in any material portion of its assets.

7.9 Mergers or Acquisitions. No Loan Party shall (A) merge, amalgamate or consolidate, or permit any of its Subsidiaries to merge, amalgamate or consolidate, with or into any other business organization (other than mergers, amalgamations or consolidations of (a) a Subsidiary which is not a Loan Party into another Subsidiary or into a Loan Party, or (b) a Loan Party into another Loan Party) or (B) acquire, or permit any of its Subsidiaries to acquire, including without limitation through any in-licensing or other similar arrangement where such Loan Party or its Subsidiaries obtains sole or exclusive rights to manage or control, all or substantially all of the capital stock or any material (both in terms of the value to such other Person or to the Loan Party or its Subsidiaries) property (including without limitation, any Intellectual Property) of another Person, other than Permitted Investments. A Loan Party may dissolve any Subsidiary so long as such assets are promptly distributed or transferred to the Subsidiary's shareholder.

7.10 Taxes. Each Loan Party and its Subsidiaries shall file all income and other material tax returns that it is required to file and pay when due all income and other material Taxes now or hereafter imposed or assessed against any Loan Party or the Collateral or upon any Loan Party's ownership, possession, use, operation or disposition thereof or upon any Loan Party's rents, receipts or earnings arising therefrom. Each Loan Party shall file on or before the due date therefor all personal property tax returns (or extensions) in respect of the Collateral. Notwithstanding the foregoing, each Loan Party may contest, in good faith and by appropriate proceedings, taxes for which such Loan Party maintains adequate reserves therefor in accordance with GAAP.

7.11 Corporate Changes. No Loan Party nor any Subsidiary shall change its corporate name, legal form or jurisdiction of formation without twenty (20) days' prior written notice to Agent. No Change in Control shall occur. No Loan Party nor any Subsidiary shall relocate its chief executive office or its principal place of business unless: (i) it has provided prior written notice to Agent; and (ii) such relocations shall be within the continental United States, Ireland or Austria. No Loan Party nor any Subsidiary shall relocate any item of Collateral (other than (i) relocations of Borrower Products (including compounds and materials used to manufacture biopharmaceuticals or which are used for nonclinical or clinical studies, testing or trials) to Loan Parties, contract manufacturing organizations, distribution service firms, contract research organizations, clinical sites, clinical investigators and other institutions necessary for the conduct of clinical studies, in each case, in the ordinary course of business, (ii) Permitted Transfers (iii) Inventory in the ordinary course of business, (iv) relocations of Equipment having an aggregate value of up to \$[\*\*] in any fiscal year, and (v) relocations of Collateral from a location described on Exhibit C of the Disclosure Letter to another location described in Exhibit C of the Disclosure Letter, and (vi) relocations of works-in-progress, raw materials or otherwise in the supply chain for commercial manufacturing) unless (a) it has provided prompt written notice to Agent, (b) such relocation is within the continental United States of America, Ireland, Austria, the United Kingdom, Italy or Spain and, (c) if such relocation is to a third party bailee and the Collateral has a book value in excess of \$[\*\*], it has use commercially



reasonable efforts to deliver a bailee agreement in form and substance reasonably acceptable to Agent.

7.12 Deposit Accounts.

(a) Other than Excluded Accounts, no Loan Party nor any Subsidiary shall maintain any Deposit Accounts, or accounts holding Investment Property, except with respect to which Agent has (i) an Account Control Agreement or (ii) such other agreement or arrangement as a result of which the Agent shall have a perfected security interest therein or as may be otherwise acceptable to Agent for Deposit Accounts and accounts holding Investment Property outside of the United States of America (a "Foreign Account Pledge Agreement").

(b) The Loan Parties shall be required to hold an amount of Unrestricted Cash in Deposit Accounts in the United States and Ireland with respect to which Agent has an Account Control Agreement or a Foreign Account Pledge Agreement equal to the lesser of (i) 120% of the outstanding Secured Obligations, and (ii) 75% of all Unrestricted Cash (excluding amounts held in Excluded Accounts) of Parent and its Subsidiaries.

7.13 Parent shall notify Agent of each Subsidiary formed subsequent to the Closing Date and, within the later of 15 days of formation and delivery of the next Compliance Certificate, shall cause any such Subsidiary to execute and deliver to Agent a Joinder Agreement.

7.14 FFG Agreements. No Loan Party shall amend any FFG Agreement as in effect on the Closing Date in any manner adverse to Agent or the Lenders.

7.15 Notification of Event of Default. Parent shall notify Agent immediately of the occurrence of any Event of Default.

7.16 [Reserved].

7.17 Use of Proceeds. Each Loan Party agrees that the proceeds of the Loans shall be used solely to pay related fees and expenses in connection with this Agreement and for working capital and general corporate purposes. The proceeds of the Loans will not be used in violation of Anti-Corruption Laws or applicable Sanctions.

7.18 Transactions with Affiliates. No Loan Party shall nor shall any Loan Party permit any of its Subsidiaries to, directly or indirectly, enter into or permit to exist any transaction of any kind with any Affiliate of such Loan Party or its Subsidiaries (other than transactions among Loan Parties) on terms that are less favorable to such Loan Party or its Subsidiaries, as the case may be, than those that might be obtained in an arm's length transaction from a Person who is not an Affiliate of such Loan Party or its Subsidiaries.

7.19 Intellectual Property. Each Loan Party shall (i) defend and maintain the validity and enforceability of its material Intellectual Property; (ii) promptly advise Agent in writing of material infringements of its Intellectual Property of which such Loan Party is aware; and (iii) not allow any Intellectual Property material to such Loan Party's business

to be abandoned, forfeited or dedicated to the public without Agent's written consent. If a Loan Party (i) obtains any Patent, registered Trademark, registered Copyright, registered mask work, or any pending application for any of the foregoing, whether as owner, licensee or otherwise, or (ii) applies for any Patent or the registration of any Trademark, then such Loan Party shall together with the next Compliance Certificate due at least 15 days thereafter, provide written notice thereof to Agent and, at the reasonable request of the Agent, shall within a reasonable time period, execute such intellectual property security agreements and other documents and take such other actions as Agent may reasonably request to perfect and maintain a first priority perfected security interest in favor of Agent in such property. If a Loan Party decides to register any Copyrights or mask works in the United States Copyright Office, such Loan Party shall: (x) provide Agent with at least fifteen (15) days prior written notice of such Loan Party's intent to register such Copyrights or mask works together with a copy of the application it intends to file with the United States Copyright Office (excluding exhibits thereto and any confidential information); (y) promptly execute an intellectual property security agreement and such other documents and take such other actions as Agent may reasonably request to perfect and maintain a first priority perfected security interest in favor of Agent in the Copyrights or mask works intended to be registered with the United States Copyright Office; and (z) record such intellectual property security agreement with the United States Copyright Office contemporaneously with filing the Copyright or mask work application(s) with the United States Copyright Office. Each Loan Party shall promptly provide to Agent copies of all applications (excluding confidential information) that it files for Patents or for the registration of Trademarks, Copyrights or mask works, together with evidence of the recording of the intellectual property security agreement required for Agent to perfect and maintain a first priority perfected security interest in such property. Subject to Section 7.23(d), each Loan Party shall ensure that, with respect to any utilized Intellectual Property, Nabriva Austria has executed, delivered and filed the appropriate corrective filings with the appropriate registry in the United States, Ireland and Austria, to update its name to its current legal name as the registered owner of such Intellectual Property in such offices.

#### 7.20 OFAC/Sanctions/Anti-Corruption.

(a) Each Loan Party shall maintain, and shall cause its Subsidiaries to maintain, compliance in all material respect with all applicable laws, rules or regulations (including any law, rule or regulation with respect to the making or brokering of loans or financial accommodations), and shall, or cause its Subsidiaries to, obtain and maintain all required governmental authorizations, approvals, licenses, franchises, permits or registrations reasonably necessary in connection with the conduct of the Loan Parties' business.

(b) No Loan Party nor any of its Subsidiaries shall, nor shall any Loan Party or any of its Subsidiaries permit any Affiliate under Parent's direct or indirect control to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. No Loan Party nor any of its Subsidiaries shall, nor shall any Loan Party or any of its Subsidiaries permit any Affiliate under Parent's direct or indirect control to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without

limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

(c) Each Loan Party shall maintain in effect policies and procedures designed to ensure compliance by such Loan Party, its Subsidiaries and their respective directors, officers, employees and agents with Anti-Corruption Laws and applicable Sanctions, and each Loan Party's, its Subsidiaries and their respective officers and employees and to the knowledge of such Loan Party's, its directors and agents, are in compliance with Anti-Corruption Laws and applicable Sanctions in all material respects.

(d) No Loan Party, any of its Subsidiaries or any of their respective directors, officers or employees, or to the knowledge of such Loan Party, any agent for such Loan Party or its Subsidiaries that will act in any capacity in connection with or benefit from the credit facility established hereby, is a Sanctioned Person. No Loan, use of proceeds or other transaction contemplated by this Agreement will violate Anti-Corruption Laws or applicable Sanctions.

#### 7.21 Financial Covenants.

(a) **Minimum Cash.** At all times, the Loan Parties shall be required to maintain Unrestricted Cash *plus* the amount of the Loan Parties' accounts payable under GAAP not paid after the 90th day following the invoice date for such accounts payable in Deposit Accounts held in the United States and Ireland in an amount greater than or equal to [\*\*] Dollars (\$[\*\*]).

(b) **Performance Covenant.** At all times following the Performance Covenant Trigger Date, Parent shall either (i) as determined as of the last day of each month achieve trailing six month Net Product Revenue of an amount greater than or equal to [\*\*]% of forecasted trailing six month Net Product Revenue as set forth in the Forecast, or (ii) maintain Liquidity (on a consolidated basis) in an amount greater than or equal to the principal balance of then-outstanding Advances plus the amount of the Loan Parties' accounts payable under GAAP not paid after the 90th day following the invoice date for such accounts payable; provided that for purposes of this covenant "Liquidity" must include a minimum of \$[\*\*] in Unrestricted Cash (i.e. not Eligible Accounts).

Borrower shall provide Agent evidence of compliance with the financial covenants under this Section 7.21 in each Compliance Certificate and upon request in form and substance reasonably acceptable to Agent and supporting documentation reasonably requested by Agent.

7.22 **Zuperbug Merger Agreement.** So long as there are any Secured Obligations outstanding (other than inchoate indemnity obligations and any other obligations which, by

their terms, are to survive the termination of this Agreement), no Loan Party shall permit or cause to be paid in Cash all or any part of any Milestone Payment (as defined in Section 3.10 of the Zuperbug Merger Agreement) (other than certain obligations that are required under the Zuperbug Merger Agreement to be paid in cash, such as obligations to option holders and unaccredited investors) without Agent's prior written consent.

7.23 Post-Closing Obligations. Notwithstanding any provision herein or in any other Loan Document to the contrary, to the extent not actually delivered on or prior to the Closing Date, Borrower shall:

- (a) within 30 days of the Closing Date, deliver to Agent all insurance endorsements required hereunder which shall be in form and substance reasonably satisfactory to Agent in its reasonable discretion;
- (b) file a Form C1 pursuant to s. 409 of the Companies Act in the Companies Registration Office in Ireland for both Nabriva Ireland and Parent;
- (c) notify the Revenue Commissioners pursuant to s. 1001 of the Taxes Consolidation Act, 1997 of the potential creation of a fixed charge over book debts pursuant to the Irish Security Documents;
- (d) on or before March 31, 2019, evidence that Nabriva Austria has executed, delivered and filed the appropriate corrective filings with the appropriate registry in the United States, Ireland and Austria, to update its name to its current legal name as the registered owner of Intellectual Property in such offices with respect to all utilized Intellectual Property; and
- (e) within 60 days of the Closing Date, deliver to Agent (or such later date as Agent may agree to in its sole discretion), fully-executed copies of landlord waivers or bailee waivers, as applicable, in form and substance reasonably satisfactory to Agent, for Borrower's locations at:
  - (i) 1000 Continental Drive, Suite 600, King of Prussia, PA 19406;
  - (ii) [\*\*]; and
  - (iii) [\*\*].

7.24 Shareholder(s) of Austrian Guarantor. Any Loan Party being a shareholder of an Austrian Guarantor (and procure that any of its Subsidiaries being a shareholder of an Austrian Guarantor) shall (A) not resolve to increase (i) the stated share capital (*Stammkapital or Grundkapital*) of an Austrian Guarantor by way of capital increase from free reserves (including a profit carry-forward) (*Kapitalerhöhung aus Gesellschaftsmitteln*) or (ii) any restricted reserves (*gebundene Rücklagen*) (unless required by Austrian law) of an Austrian Guarantor (B) shall exercise their shareholder rights in such way that the respective Austrian Guarantor covers any possible balance sheet loss (*Bilanzverlust*) by dissolving restricted reserves (*gebundene Rücklagen*) rather than free reserves (*ungebundene Rücklagen*) to the extent possible pursuant to Austrian law, and (C) exercise

their membership rights, including the voting rights, in such a way that any and all amounts which can be converted into amounts freely available for distribution under the GmbHG or AktG (as the case may be) and the UCC (i.e., the Austrian Commercial Code) (such as, for instance, unrestricted reserves (*freie Rücklagen*)) at the time or times payment under or pursuant to Section 12 (*Guaranty*) is requested from that Austrian Guarantor are promptly so converted by passing the necessary corporate resolutions and taking all other steps required by law for distribution at the relevant point in time in accordance with Austrian law. Each Austrian Guarantor shall abide by the requirement set out in Clause 7.24(B) when preparing its financial statements.

#### **SECTION 8. RIGHT TO INVEST**

8.1 Lender or its assignee or nominee shall have the right, in its discretion, to participate in any Subsequent Financing in an aggregate amount, for all such Subsequent Financings in which Lender and/or its assignee(s) or nominee(s) participate, of up to \$2,000,000 on the same terms, conditions and pricing afforded to others participating in any such Subsequent Financing. For any purchase by Lender, or an entity affiliated with Lender, the purchasing entity shall be an “accredited investor” as defined in Regulation D promulgated under the Securities Act, and such purchasing entity shall execute the definitive share purchase agreement, LLC Agreement, investor rights agreement and other agreements executed by such other purchasers in connection with such Subsequent Financing. The Parent shall give Lender not less than one (1) Business Day written notice prior to the closing of any Subsequent Financing, which notice shall state the principal terms (including without limitation, the principal investors) of such Subsequent Financing. This Section 8, and all rights and obligations hereunder, shall terminate upon the repayment in full of all the Secured Obligations (other than any inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement).

#### **SECTION 9. EVENTS OF DEFAULT**

The occurrence of any one or more of the following events shall be an Event of Default:

9.1 Payments. Any Loan Party fails to (i) pay any principal, interest, fees or other scheduled amount due under this Agreement or any of the other Loan Documents on the due date; provided, however, that an Event of Default shall not occur on account of a failure to pay due solely to an administrative or operational error of Agent or Lender or any Loan Party’s bank if such Loan Party had the funds to make the payment when due and makes the payment within three (3) Business Days following such Loan Party’s knowledge of such failure to pay, or (ii) fails to pay any non-scheduled amounts within five (5) days after demand by Lender; or

9.2 Covenants. Any Loan Party breaches or defaults in the performance of any covenant or Secured Obligation under this Agreement, or any of the other Loan Documents, and (a) with respect to a default under any covenant under this Agreement (other than under Sections 6, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 7.14, 7.15, 7.17, 7.18, 7.19, 7.20, 7.21, 7.22 and 7.23) or any other Loan Document, such breach or default continues for

more than ten (10) Business Days after the earlier of the date on which (i) Agent or Lender has given notice of such default to such Loan Party and (ii) such Loan Party has actual knowledge of such default or (b) with respect to a default under any of Sections 6, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 7.14, 7.15, 7.17, 7.18, 7.19, 7.20, 7.21, 7.22 and 7.23 the occurrence of such default; or

9.3 Material Adverse Effect. A circumstance has occurred that has had a Material Adverse Effect; provided that solely for purposes of this Section 9.3, the failure to achieve Performance Milestone 1, Performance Milestone 2, Performance Milestone 3, Performance Milestone 4, Performance Milestone 5 or Performance Milestone 6, in each case in and of itself, shall not constitute a Material Adverse Effect; or

9.4 Representations. Any representation or warranty made by any Loan Party in any Loan Document shall have been false or misleading in any material respect when made or when deemed made; or

9.5 Insolvency. Any Loan Party (A) (i) shall make an assignment for the benefit of creditors; or (ii) shall be unable to pay its debts as they become due, or be unable to pay the Secured Obligations under the Loan Documents, or shall become insolvent (and in the case of (i) an Austrian Guarantor or (ii) Nabriva Ireland or Parent, Insolvent); or (iii) shall file a voluntary petition in bankruptcy; or (iv) shall file any petition, answer, or document seeking for itself any reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief under any present or future statute, law or regulation pertinent to such circumstances; or (v) shall seek or consent to or acquiesce in the appointment of any trustee, Examiner, receiver, or liquidator of such Loan Party or of all or any substantial part (i.e., 33-1/3% or more) of the assets or property of such Loan Party; or (vi) shall cease operations of its business as its business has normally been conducted for 3 consecutive Business Days, or terminate substantially all of its employees; or (vii) any Loan Party or its directors or majority shareholders shall take any action initiating any of the foregoing actions described in clauses (i) through (vi); or (B) either (i) forty-five (45) days shall have expired after the commencement of an involuntary action against such Loan Party seeking reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief under any present or future statute, law or regulation, without such action being dismissed or all orders or proceedings thereunder affecting the operations or the business of such Loan Party being stayed; or (ii) a stay of any such order or proceedings shall thereafter be set aside and the action setting it aside shall not be timely appealed; or (iii) any Loan Party shall file any answer admitting or not contesting the material allegations of a petition filed against such Loan Party in any such proceedings; or (iv) the court in which such proceedings are pending shall enter a decree or order granting the relief sought in any such proceedings; or (v) forty five (45) days shall have expired after the appointment, without the consent or acquiescence of such Loan Party, of any trustee, Examiner, receiver or liquidator of such Loan Party or of all or any substantial part of the properties of such Loan Party without such appointment being vacated; or

9.6 Attachments; Judgments. Any portion of any Loan Party's assets is attached or seized, or a levy is filed against any such assets, or a judgment or judgments is/are

entered for the payment of money (not covered by independent third party insurance as to which liability has not been rejected by such insurance carrier), individually or in the aggregate, of at least \$[\*\*] and remains unstayed, unbonded and unsatisfied for more than ten (10) days, or any Loan Party is enjoined or in any way prevented by court order from conducting any material part of its business; or

9.7 Other Obligations. The occurrence of any default under any agreement or obligation of any Loan Party involving any Indebtedness in excess of \$[\*\*]; or

9.8 FFG Agreements.

- (a) Any FFG Agreement is secured by any property (including Intellectual Property) of any Loan Party.
- (b) FFG has any right, title, or security interest in any property (including Intellectual Property) of any Loan Party.
- (c) The execution, delivery and performance of this Agreement or any other Loan Document (including the Austrian Security Documents) (i) violates or conflicts with any terms contained in any FFG Agreement or (ii) entitles FFG to accelerate any loans or other amounts due under any FFG Agreement.
- (d) Intellectual Property relating to CONTEPO, lefamulin or any other Borrower Products reflected in any Forecast is included in the portfolio of Next Generation Pleuromutilins financed under any FFG Agreement.
- (e) Nabriva Austria's or FFG's rights or claims arising out of or in connection with the FFG Agreements relate to CONTEPO, lefamulin or any other Borrower Products reflected in any Forecast.
- (f) The aggregate amount of all of Nabriva Austria's rights and claims arising out of or in connection with the FFG Agreements exceeded €[\*\*].

#### **SECTION 10. REMEDIES**

10.1 General. Upon and during the continuance of any one or more Events of Default, (i) Agent may, and at the direction of the Required Lenders shall, accelerate and demand payment of all or any part of the Secured Obligations together with a Prepayment Charge and declare them to be immediately due and payable (provided, that upon the occurrence of an Event of Default of the type described in Section 9.5, all of the Secured Obligations shall automatically be accelerated and made due and payable, in each case without any further notice or act), (ii) Agent may, at its option, sign and file in any Loan Party's name any and all collateral assignments, notices, control agreements, security agreements and other documents it deems necessary or appropriate to perfect or protect the repayment of the Secured Obligations, and in furtherance thereof, each Loan Party hereby grants Agent an irrevocable power of attorney coupled with an interest, and (iii) Agent may notify any of the Loan Parties' account debtors to make payment directly to Agent, compromise the amount of any such account on the Loan Parties' behalf and endorse

Agent's name without recourse on any such payment for deposit directly to Agent's account. Agent may, and at the direction of the Required Lenders shall, exercise all rights and remedies with respect to the Collateral under the Loan Documents or otherwise available to it under the UCC and other applicable law, including the right to release, hold, sell, lease, liquidate, collect, realize upon, or otherwise dispose of all or any part of the Collateral and the right to occupy, utilize, process and commingle the Collateral. All Agent's rights and remedies shall be cumulative and not exclusive.

10.2 Collection; Foreclosure. Upon the occurrence and during the continuance of any Event of Default (and regarding any Collateral pledged under the Austrian Security Agreements provided that the Secured Obligations have become due and payable ("*Pfandreife*" under Austrian law) and any conditions set out in the respective Austrian Security Agreement are being complied with), Agent may, and at the direction of the Required Lenders shall, at any time or from time to time, apply, collect, liquidate, sell in one or more sales, lease or otherwise dispose of, any or all of the Collateral, in its then condition or following any commercially reasonable preparation or processing, in such order as Agent may elect. Any such sale may be made either at public or private sale at its place of business or elsewhere. Each Loan Party agrees that any such public or private sale may occur upon ten (10) calendar days' prior written notice to such Loan Party. Agent may require any Loan Party to assemble the Collateral and make it available to Agent at a place designated by Agent that is reasonably convenient to Agent and such Loan Party. The proceeds of any sale, disposition or other realization upon all or any part of the Collateral shall be applied by Agent in the following order of priorities:

First, to Agent and Lender in an amount sufficient to pay in full Agent's and Lender's reasonable costs and professionals' and advisors' fees and expenses as described in Section 11.11;

Second, to Lender in an amount equal to the then unpaid amount of the Secured Obligations (including principal, interest, and the interest in accordance with Section 2.4), in such order and priority as Agent may choose in its sole discretion; and

Finally, after the full and final payment in Cash of all of the Secured Obligations (other than inchoate indemnity obligations and obligations that are stated to survive the payment of the Secured Obligations), to any creditor holding a junior Lien on the Collateral, or to the Loan Parties or its representatives or as a court of competent jurisdiction may direct.

Agent shall be deemed to have acted reasonably in the custody, preservation and disposition of any of the Collateral if it complies with the obligations of a secured party under the UCC and other applicable law and, with respect to Collateral pledged under the Austrian Security Agreements any conditions specifically set out in the Austrian Security Agreements.

10.3 No Waiver. Agent shall be under no obligation to marshal any of the Collateral for the benefit of the Loan Parties or any other Person, and each Loan Party expressly waives all rights, if any, to require Agent to marshal any Collateral.

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10.4 Cumulative Remedies. The rights, powers and remedies of Agent hereunder shall be in addition to all rights, powers and remedies given by statute or rule of law and are cumulative. The exercise of any one or more of the rights, powers and remedies provided herein shall not be construed as a waiver of or election of remedies with respect to any other rights, powers and remedies of Agent.

#### **SECTION 11. MISCELLANEOUS**

11.1 Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement shall be prohibited by or invalid under such law, such provision shall be ineffective only to the extent and duration of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.

11.2 Notice. Except as otherwise provided herein, any notice, demand, request, consent, approval, declaration, service of process or other communication (including the delivery of Financial Statements) that is required, contemplated, or permitted under the Loan Documents or with respect to the subject matter hereof shall be in writing, and shall be deemed to have been validly served, given, delivered, and received upon the earlier of: (i) the day of transmission by electronic mail or hand delivery or delivery by an overnight express service or overnight mail delivery service; or (ii) the third calendar day after deposit in the United States of America mails, with proper first class postage prepaid, in each case addressed to the party to be notified as follows:

(a) If to Agent:

HERCULES CAPITAL, INC.  
Legal Department  
Attention: Chief Legal Officer, [\*\*]  
400 Hamilton Avenue, Suite 310  
Palo Alto, CA 94301  
Email: legal@htgc.com; [\*\*]  
Telephone: [\*\*]

(b) If to Lender:

HERCULES CAPITAL, INC.  
Legal Department  
Attention: Chief Legal Officer, [\*\*]  
400 Hamilton Avenue, Suite 310  
Palo Alto, CA 94301  
Email: legal@htgc.com; [\*\*]  
Telephone: [\*\*]

(c) If to Loan Parties:





Nabriva Therapeutics Public Limited Company  
Attention: General Counsel  
1000 Continental Drive, Suite 600  
King of Prussia, PA 19406  
Email: [\*\*]  
Telephone: [\*\*]  
With a copy (which shall not constitute notice) to each of:

WilmerHale  
60 State Street  
Boston, MA 02109  
Attn: Jamie N. Class  
jamie.class@wilmerhale.com  
Tel: (617) 526-6000

WilmerHale  
7 World Trade Center  
250 Greenwich Street  
New York, NY 10007  
Attn: Brian A. Johnson  
Brian.Johnson@wilmerhale.com  
Tel: (212) 937-7206

or to such other address as each party may designate for itself by like notice.

11.3 Entire Agreement; Amendments.

(a) This Agreement, the Notes (if any) and the other Loan Documents constitute the entire agreement and understanding of the parties hereto in respect of the subject matter hereof and thereof, and supersede and replace in their entirety any prior proposals, term sheets, non-disclosure or confidentiality agreements, letters, negotiations or other documents or agreements, whether written or oral, with respect to the subject matter hereof or thereof (including Agent's proposal letter dated October 25, 2018, and prior versions thereof).

(b) Neither this Agreement, any other Loan Document, nor any terms hereof or thereof may be amended, supplemented or modified except in accordance with the provisions of this Section 11.3(b). The Required Lenders and the Loan Parties party to the relevant Loan Document may, or, with the written consent of the Required Lenders, the Agent and the Loan Parties party to the relevant Loan Document may, from time to time, (i) enter into written amendments, supplements or modifications hereto and to the other Loan Documents for the purpose of adding any provisions to this Agreement or the other Loan Documents or changing in any manner the rights of the Lenders or of the Loan Parties hereunder or thereunder or (ii) waive, on such terms and conditions as the Required Lenders or the Agent, as the case may be, may specify in such instrument, any of the requirements of this Agreement or the other Loan Documents or any default or Event of Default and its consequences; provided, however, that no such waiver and no such amendment, supplement or modification shall (A) forgive the principal amount or

extend the final scheduled date of maturity of any Loan, extend the scheduled date of any amortization payment in respect of any Term Loan, reduce the stated rate of any interest or fee payable hereunder or extend the scheduled date of any payment thereof, without the written consent of each Lender directly affected thereby (provided that the milestones to establish the maturity date and amortization payments may be modified with the consent of the Required Lenders and the Loan Parties); (B) eliminate or reduce the voting rights of any Lender under this Section 11.3(b) without the written consent of such Lender; (C) reduce any percentage specified in the definition of Required Lenders, or, except as otherwise permitted under this Agreement, consent to the assignment or transfer by the Loan Parties of any of its rights and obligations under this Agreement and the other Loan Documents, release all or substantially all of the Collateral or release a Loan Party from its obligations under the Loan Documents, in each case without the written consent of Lender; or (D) amend, modify or waive any provision of Section 11.17 without the written consent of the Agent. Any such waiver and any such amendment, supplement or modification shall apply equally to each Lender and shall be binding upon the Loan Parties, the Lender, the Agent and all future holders of the Loans.

11.4 No Strict Construction. The parties hereto have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties hereto and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provisions of this Agreement.

11.5 No Waiver. The powers conferred upon Agent and Lender by this Agreement are solely to protect its rights hereunder and under the other Loan Documents and its interest in the Collateral and shall not impose any duty upon Agent or Lender to exercise any such powers. No omission or delay by Agent or Lender at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants or provisions hereof by the Loan Parties at any time designated, shall be a waiver of any such right or remedy to which Agent or Lender is entitled, nor shall it in any way affect the right of Agent or Lender to enforce such provisions thereafter.

11.6 Survival. All agreements, representations and warranties contained in this Agreement and the other Loan Documents or in any document delivered pursuant hereto or thereto shall be for the benefit of Agent and Lender and shall survive the execution and delivery of this Agreement. Sections 6.3 and 11.14 shall survive the termination of this Agreement.

11.7 Successors and Assigns. The provisions of this Agreement and the other Loan Documents shall inure to the benefit of and be binding on the Loan Parties and their permitted assigns (if any). Subject to the terms of this Agreement, No Loan Party shall assign its obligations under this Agreement or any of the other Loan Documents without Agent's express prior written consent, and any such attempted assignment shall be void and of no effect. Agent and Lender may assign, transfer, or endorse its rights hereunder and under the other Loan Documents without prior notice to the Loan Parties, and all of such rights shall inure to the benefit of Agent's and Lender's successors and assigns; provided, however, that Lender shall maintain a register for the recordation of the names and

addresses of the Lenders and the principal amounts owing to each Lender; provided further that as long as no Event of Default has occurred and is continuing, neither Agent nor any Lender may assign, transfer or endorse its rights hereunder or under the Loan Documents to any party that is a direct competitor of Borrower (as reasonably determined by Agent), it being acknowledged that in all cases, any transfer to an Affiliate of any Lender or Agent shall be allowed.

11.8 **Governing Law.** This Agreement and the other Loan Documents (other than the Irish Security Documents and Austrian Security Documents) have been negotiated and delivered to Agent and Lender in the State of New York. This Agreement and the other Loan Documents (other than the Irish Security Documents and the Austrian Security Documents) shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction.

**11.9 CONSENT TO JURISDICTION AND VENUE. ALL JUDICIAL PROCEEDINGS ARISING IN OR UNDER OR RELATED TO THIS AGREEMENT OR ANY OF THE OTHER LOAN DOCUMENTS MAY BE BROUGHT IN ANY STATE COURT LOCATED IN THE STATE OF NEW YORK SITTING IN NEW YORK COUNTY, AND IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK, AND ANY APPELLATE COURTS FROM ANY THEREOF, AND EACH OF THE PARTIES HERETO IRREVOCABLY AND UNCONDITIONALLY SUBMITS TO THE JURISDICTION OF SUCH COURTS AND AGREES THAT ALL CLAIMS IN RESPECT OF ANY SUCH ACTION, LITIGATION OR PROCEEDING MAY BE HEARD AND DETERMINED IN SUCH NEW YORK COURT OR, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, IN SUCH FEDERAL COURT. EACH OF THE PARTIES HERETO AGREES THAT A NON-APPEALABLE FINAL JUDGMENT IN ANY SUCH ACTION, LITIGATION OR PROCEEDING SHALL BE CONCLUSIVE AND MAY BE ENFORCED IN OTHER JURISDICTIONS BY SUIT ON THE JUDGMENT OR IN ANY OTHER MANNER PROVIDED BY LAW. NOTHING IN THIS AGREEMENT OR IN ANY OTHER LOAN DOCUMENT SHALL AFFECT ANY RIGHT THAT AGENT OR ANY LENDER MAY OTHERWISE HAVE TO BRING ANY ACTION OR PROCEEDING RELATING TO THIS AGREEMENT OR ANY OTHER LOAN DOCUMENT AGAINST BORROWER OR ANY OTHER LOAN PARTY OR ITS OR THEIR PROPERTIES IN THE COURTS OF ANY JURISDICTION. BORROWER AND EACH OTHER LOAN PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY OBJECTION THAT IT MAY NOW OR HEREAFTER HAVE TO THE LAYING OF VENUE OF ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER LOAN DOCUMENT IN ANY COURT REFERRED TO IN THIS SECTION 11.9. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THE DEFENSE OF AN INCONVENIENT FORUM TO THE MAINTENANCE OF SUCH ACTION OR PROCEEDING IN ANY SUCH COURT. SERVICE OF PROCESS ON ANY**

**PARTY HERETO IN ANY ACTION ARISING OUT OF OR RELATING TO THIS AGREEMENT SHALL BE EFFECTIVE IF GIVEN IN ACCORDANCE WITH THE REQUIREMENTS FOR NOTICE SET FORTH IN SECTION 11.02, AND SHALL BE DEEMED EFFECTIVE AND RECEIVED AS SET FORTH IN SECTION 11.02. NOTHING HEREIN SHALL AFFECT THE RIGHT TO SERVE PROCESS IN ANY OTHER MANNER PERMITTED BY LAW.**

11.10 Mutual Waiver of Jury Trial.

(a) Because disputes arising in connection with complex financial transactions are most quickly and economically resolved by an experienced and expert Person and the parties wish applicable state and federal laws to apply (rather than arbitration rules), the parties desire that their disputes be resolved by a judge applying such applicable laws. EACH OF THE LOAN PARTIES, AGENT AND LENDER SPECIFICALLY WAIVES ANY RIGHT IT MAY HAVE TO TRIAL BY JURY OF ANY CAUSE OF ACTION, CLAIM, CROSS-CLAIM, COUNTERCLAIM, THIRD PARTY CLAIM OR ANY OTHER CLAIM (COLLECTIVELY, "**CLAIMS**") ASSERTED BY THE LOAN PARTIES AGAINST AGENT, LENDER OR THEIR RESPECTIVE ASSIGNEE OR BY AGENT, LENDER OR THEIR RESPECTIVE ASSIGNEE AGAINST ANY LOAN PARTY. This waiver extends to all such Claims, including Claims that involve Persons other than Agent, the Loan Parties and Lender; Claims that arise out of or are in any way connected to the relationship among the Loan Parties, Agent and Lender; and any Claims for damages, breach of contract, tort, specific performance, or any equitable or legal relief of any kind, arising out of this Agreement or any other Loan Document.

11.11 Professional Fees. Each Loan Party promises to pay Agent's and Lender's reasonable and invoiced fees and expenses necessary to finalize the loan documentation, including but not limited to reasonable and invoiced attorneys' fees, UCC searches, filing costs, and other miscellaneous expenses. In addition, each Loan Party promises to pay any and all reasonable attorneys' and other reasonable professionals' fees and expenses incurred by Agent and Lender after the Closing Date in connection with or related to: (a) the Loan; (b) the administration, collection, or enforcement of the Loan; (c) the amendment or modification of the Loan Documents; (d) any waiver, consent, release, or termination under the Loan Documents; (e) the protection, preservation, audit, field exam, sale, lease, liquidation, or disposition of Collateral or the exercise of remedies with respect to the Collateral; (f) any legal, litigation, administrative, arbitration, or out of court proceeding in connection with or related to the Loan Parties or the Collateral, and any appeal or review thereof; and (g) any bankruptcy, restructuring, reorganization, assignment for the benefit of creditors, workout, foreclosure, or other action related to the Loan Parties, the Collateral, the Loan Documents, including representing Agent or Lender in any adversary proceeding or contested matter commenced or continued by or on behalf of any Loan Party's estate, and any appeal or review thereof.

11.12 Confidentiality. Agent and Lender acknowledge that certain items of Collateral and information provided to Agent and Lender by the Loan Parties in connection with this Agreement, the Loan Documents, and the diligence and term sheet negotiation relating to same, are confidential and proprietary information of the Loan Parties, if and to

the extent such information either (x) is marked as confidential, proprietary or secret by the Loan Parties at the time of disclosure, or (y) should reasonably be understood to be confidential, proprietary or secret (the "Confidential Information"). Accordingly, Agent and Lender agree that any Confidential Information it may obtain in the course of acquiring, administering, or perfecting Agent's security interest in the Collateral shall not be disclosed to any other Person or entity in any manner whatsoever, in whole or in part, without the prior written consent of the Loan Parties, except that Agent and Lender may disclose any such information: (a) to its own directors, officers, employees, accountants, counsel and other professional advisors and to its controlled affiliates if Agent or Lender in their reasonable discretion determines that any such party should have access to such information in connection with such party's responsibilities in connection with the Loan or this Agreement and, provided that such recipient of such Confidential Information either (i) agrees to be bound by the confidentiality provisions of this paragraph or (ii) is otherwise subject to confidentiality restrictions that reasonably protect against the disclosure of Confidential Information; (b) if such information is generally available to the public without any disclosure by Agent or Lender that would otherwise breach this Section; (c) if required or appropriate in any report, statement or testimony submitted to any Governmental Authority having or claiming to have jurisdiction over Agent or Lender; (d) if required or advisable in response to any summons or subpoena or in connection with any litigation, to the extent permitted or deemed advisable by Agent's or Lender's counsel; (e) to comply with any legal requirement or law applicable to Agent or Lender; (f) to the extent reasonably necessary in connection with the exercise of any right or remedy under any Loan Document, including Agent's sale, lease, or other disposition of Collateral during the continuation of an Event of Default; (g) to any participant or assignee of Agent or Lender or any prospective participant or assignee; provided, that such participant or assignee or prospective participant or assignee agrees in writing to be bound by this Section prior to disclosure; or (h) otherwise with the prior written consent of the Loan Parties; provided, that any disclosure made in violation of this Agreement shall not affect the obligations of the Loan Parties or any of its Affiliates or any guarantor under this Agreement or the other Loan Documents. Agent's and Lender's obligations under this Section 11.12 shall supersede all of their respective obligations under the Non-Disclosure Agreement.

11.13 Assignment of Rights. Each Loan Party acknowledges and understands that Agent or Lender may, subject to Section 11.7, sell and assign all or part of its interest hereunder and under the Loan Documents to any Person or entity (an "Assignee"). After such assignment the term "Agent" or "Lender" as used in the Loan Documents shall mean and include such Assignee, and such Assignee shall be vested with all rights, powers and remedies of Agent and Lender hereunder with respect to the interest so assigned; but with respect to any such interest not so transferred, Agent and Lender shall retain all rights, powers and remedies hereby given. No such assignment by Agent or Lender shall relieve any Loan Party of any of its obligations hereunder. Lender agrees that in the event of any transfer by it of the Note(s) (if any), it will endorse thereon a notation as to the portion of the principal of the Note(s), which shall have been paid at the time of such transfer and as to the date to which interest shall have been last paid thereon.

11.14 Revival of Secured Obligations. This Agreement and the Loan Documents shall remain in full force and effect and continue to be effective if any petition is filed by or against any Loan Party for liquidation or reorganization, if any Loan Party becomes insolvent or Insolvent or makes an assignment for the benefit of creditors, if a receiver or trustee is appointed for all or any significant part of any Loan Party's assets, or if any payment or transfer of Collateral is recovered from Agent or Lender. The Loan Documents and the Secured Obligations and Collateral security shall continue to be effective, or shall be revived or reinstated, as the case may be, if at any time payment and performance of the Secured Obligations or any transfer of Collateral to Agent, or any part thereof is rescinded, avoided or avoidable, reduced in amount, or must otherwise be restored or returned by, or is recovered from, Agent, Lender or by any obligee of the Secured Obligations, whether as a "voidable preference," "fraudulent conveyance," or otherwise, all as though such payment, performance, or transfer of Collateral had not been made. In the event that any payment, or any part thereof, is rescinded, reduced, avoided, avoidable, restored, returned, or recovered, the Loan Documents and the Secured Obligations shall be deemed, without any further action or documentation, to have been revived and reinstated except to the extent of the full, final, and indefeasible payment to Agent or Lender in Cash.

11.15 Counterparts. This Agreement and any amendments, waivers, consents or supplements hereto may be executed in any number of counterparts, and by different parties hereto in separate counterparts, each of which when so delivered shall be deemed an original, but all of which counterparts shall constitute but one and the same instrument.

11.16 No Third Party Beneficiaries. No provisions of the Loan Documents are intended, nor will be interpreted, to provide or create any third-party beneficiary rights or any other rights of any kind in any Person other than Agent, Lender and the Loan Parties unless specifically provided otherwise herein, and, except as otherwise so provided, all provisions of the Loan Documents will be personal and solely among Agent, the Lender and the Loan Parties.

11.17 Agency.

(a) Lender hereby irrevocably appoints Hercules Capital, Inc. to act on its behalf as the Agent hereunder and under the other Loan Documents and authorizes the Agent to take such actions on its behalf and to exercise such powers as are delegated to the Agent by the terms hereof or thereof, together with such actions and powers as are reasonably incidental thereto.

(b) Lender agrees to indemnify the Agent in its capacity as such (to the extent not reimbursed by the Loan Parties and without limiting the obligation of the Loan Parties to do so), according to its respective Term Commitment percentages (based upon the total outstanding Term Commitments) in effect on the date on which indemnification is sought under this Section 11.17, from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements of any kind whatsoever that may at any time be imposed on, incurred by or asserted against the Agent in any way relating to or arising out of, this Agreement, any of the other Loan Documents or any documents contemplated by or referred to herein or therein or the

transactions contemplated hereby or thereby or any action taken or omitted by the Agent under or in connection with any of the foregoing; The agreements in this Section shall survive the payment of the Loans and all other amounts payable hereunder.

(c) Agent in Its Individual Capacity. The Person serving as the Agent hereunder shall have the same rights and powers in its capacity as a Lender as any other Lender and may exercise the same as though it were not the Agent and the term "Lender" shall, unless otherwise expressly indicated or unless the context otherwise requires, include each such Person serving as Agent hereunder in its individual capacity.

(d) Each Guarantor and the Borrower irrevocably and unconditionally undertakes to pay to the Agent, as creditor in its own right and not as representative of any other Lender, amounts equal to, and in the currency of, any amounts owing from time to time by that Guarantor or Borrower to any Lender under any Loan Document, as and when those amounts are due.

(e) Each Guarantor, the Borrower and the Agent acknowledge that the obligations of each Guarantor and the Borrower to the Agent pursuant to Section 11.17(d) are several and are separate and independent from, and shall not in any way limit or affect, the corresponding obligations of that Guarantor and the Borrower to any Lender under any Loan Document (its "Corresponding Debt") nor shall the amounts for which each Guarantor or the Borrower is liable under obligations of each Guarantor and the Borrower to the Agent pursuant to Section 11.17(d) above (for the purposes of this Section 11.17, its "Parallel Debt") be limited or affected in any way by its Corresponding Debt, provided that notwithstanding any other provision of this Agreement or the Loan Documents:

(i) the Parallel Debt of each Guarantor and the Borrower shall be automatically decreased and discharged to the extent that its Corresponding Debt has been irrevocably paid or (in the case of guarantee obligations) discharged;

(ii) the Corresponding Debt of each Guarantor and the Borrower shall be automatically decreased and discharged to the extent that its Parallel Debt has been irrevocably paid or (in the case of guarantee obligations) discharged; and

(iii) the aggregate amount outstanding owed by the Guarantor and the Borrower under the Loan Documents at any time shall not exceed the amount of the Corresponding Debt at that time.

(f) For the purpose of this Section 11.17 the Agent acts in its own name and not as a trustee, and its claims in respect of the Parallel Debt shall not be held on trust. The Agent shall have its own independent right to demand payment of the amounts payable by each Guarantor and the Borrower. The security granted under the Account Control Agreements, the IP Security Agreements, the Pledge Agreements (including the Irish Security Documents and the Austrian Security Documents) to the Agent to secure the Parallel Debt is granted to the Agent in its capacity as creditor of the Parallel Debt and shall not be held on trust.



(g) All moneys received or recovered by the Agent pursuant to this Section 11.17 (*Agency*), and all amounts received or recovered by the Agent from or by the enforcement of any of the Account Control Agreements, the IP Security Agreements, the Pledge Agreements (including the Irish Security Documents and the Austrian Security Documents) granted to secure the Parallel Debt, shall be applied as set out under Section 10.2.

(h) Exculpatory Provisions. The Agent shall have no duties or obligations except those expressly set forth herein and in the other Loan Documents. Without limiting the generality of the foregoing, the Agent shall not:

- (i) be subject to any fiduciary or other implied duties, regardless of whether any default or any Event of Default has occurred and is continuing;
- (ii) have any duty to take any discretionary action or exercise any discretionary powers, except discretionary rights and powers expressly contemplated hereby or by the other Loan Documents that the Agent is required to exercise as directed in writing by the Lender, provided that the Agent shall not be required to take any action that, in its opinion or the opinion of its counsel, may expose the Agent to liability or that is contrary to any Loan Document or applicable law; and
- (iii) except as expressly set forth herein and in the other Loan Documents, have any duty to disclose, and the Agent shall not be liable for the failure to disclose, any information relating to the Loan Parties or any of their Affiliates that is communicated to or obtained by any Person serving as the Agent or any of its Affiliates in any capacity.

(i) The Agent shall not be liable to the Lender for any action taken or not taken by it (i) with the consent or at the request of the Lender or as the Agent shall believe in good faith shall be necessary, under the circumstances or (ii) in the absence of its own gross negligence or willful misconduct.

(j) The Agent shall not be responsible for or have any duty to ascertain or inquire into (i) any statement, warranty or representation made in or in connection with this Agreement or any other Loan Document, (ii) the contents of any certificate, report or other document delivered hereunder or thereunder or in connection herewith or therewith, (iii) the performance or observance of any of the covenants, agreements or other terms or conditions set forth herein or therein or the occurrence of any default or Event of Default, (iv) the validity, enforceability, effectiveness or genuineness of this Agreement, any other Loan Document or any other agreement, instrument or document or (v) the satisfaction of any condition set forth in Section 4 or elsewhere herein, other than to confirm receipt of items expressly required to be delivered to the Agent.

(k) Reliance by Agent. Agent may rely, and shall be fully protected in acting, or refraining to act, upon, any resolution, statement, certificate, instrument, opinion,

report, notice, request, consent, order, bond or other paper or document that it has no reason to believe to be other than genuine and to have been signed or presented by the proper party or parties or, in the case of cables, teletypes and telexes, to have been sent by the proper party or parties. In the absence of its gross negligence or willful misconduct, Agent may conclusively rely, as to the truth of the statements and the correctness of the opinions expressed therein, upon any certificates or opinions furnished to Agent and conforming to the requirements of this Agreement or any of the other Loan Documents. Agent may consult with counsel, and any opinion or legal advice of such counsel shall be full and complete authorization and protection in respect of any action taken, not taken or suffered by Agent hereunder or under any Loan Documents in accordance therewith. Agent shall have the right at any time to seek instructions concerning the administration of the Collateral from any court of competent jurisdiction. Agent shall not be under any obligation to exercise any of the rights or powers granted to Agent by this Agreement and the other Loan Documents at the request or direction of Lender unless Agent shall have been provided by Lender with adequate security and indemnity against the costs, expenses and liabilities that may be incurred by it in compliance with such request or direction.

11.18 **Publicity.** None of the parties hereto nor any of its respective member businesses and Affiliates shall, without the other parties' prior written consent (which shall not be unreasonably withheld or delayed), publicize or use (a) the other party's name (including a brief description of the relationship among the parties hereto), logo or hyperlink to such other parties' web site, separately or together, in written and oral presentations, advertising, promotional and marketing materials, client lists, public relations materials or on its web site (together, the "Publicity Materials"); (b) the names of officers of such other parties in the Publicity Materials; and (c) such other parties' name, trademarks, servicemarks in any news or press release concerning such party; provided however, notwithstanding anything to the contrary herein, no such consent shall be required (i) to the extent necessary to comply with the requests of any regulators, legal requirements or laws applicable to such party, pursuant to any listing agreement with any national securities exchange (so long as such party provides prior notice to the other party hereto to the extent reasonably practicable) and (ii) to comply with Section 11.12.

11.19 **Confidentiality — Consent pursuant to Austrian Banking Act.** For the avoidance of doubt, each Austrian Guarantor herewith explicitly consents pursuant to § 38 para 2 no 5 of the Austrian Banking Act (*Bankwesengesetz — BWG*) to a disclosure of Confidential Information pursuant to, and in accordance with the limitations of, Subsection 11.12 (*Confidentiality*) and explicitly waives any banking secrecy obligations any Lender or third party bank maintaining a Deposit Account for such Austrian Guarantor may have under § 38 of the Austrian Banking Act in this respect.

#### 11.20 **Multiple Borrowers.**

(a) **Borrower's Agent.** Each Borrower hereby irrevocably appoints Nabriva Therapeutics Public Limited Company as its agent, attorney-in-fact and legal representative for all purposes, including requesting disbursement of the Term Loan and receiving account statements and other notices and communications to Borrowers (or any

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of them) from the Agent or any Lender. The Agent may rely, and shall be fully protected in relying, on any request for the Term Loan, disbursement instruction, report, information or any other notice or communication made or given by Nabriva Therapeutics Public Limited Company, whether in its own name or on behalf of one or more of the other Borrowers, and the Agent shall not have any obligation to make any inquiry or request any confirmation from or on behalf of any other Borrower as to the binding effect on it of any such request, instruction, report, information, other notice or communication, nor shall the joint and several character of the Borrowers' obligations hereunder be affected thereby.

(b) **Waivers.** Each Borrower hereby waives: (i) any right to require the Agent to institute suit against, or to exhaust its rights and remedies against, any other Borrower or any other person, or to proceed against any property of any kind which secures all or any part of the Secured Obligations, or to exercise any right of offset or other right with respect to any reserves, credits or deposit accounts held by or maintained with the Agent or any Indebtedness of the Agent or any Lender to any other Borrower, or to exercise any other right or power, or pursue any other remedy the Agent or any Lender may have; (ii) any defense arising by reason of any disability or other defense of any other Borrower or any guarantor or any endorser, co-maker or other person, or by reason of the cessation from any cause whatsoever of any liability of any other Borrower or any guarantor or any endorser, co-maker or other person, with respect to all or any part of the Secured Obligations, or by reason of any act or omission of the Agent or others which directly or indirectly results in the discharge or release of any other Borrower or any guarantor or any other person or any Secured Obligations or any security therefor, whether by operation of law or otherwise; (iii) any defense arising by reason of any failure of the Agent to obtain, perfect, maintain or keep in force any Lien on, any property of any Borrower or any other person; (iv) any defense based upon or arising out of any bankruptcy, insolvency, reorganization, arrangement, readjustment of debt, liquidation or dissolution proceeding commenced by or against any other Borrower or any guarantor or any endorser, co-maker or other person, including without limitation any discharge of, or bar against collecting, any of the Secured Obligations (including without limitation any interest thereon), in or as a result of any such proceeding. Until all of the Secured Obligations have been paid, performed, and discharged in full, nothing shall discharge or satisfy the liability of any Borrower hereunder except the full performance and payment of all of the Secured Obligations. If any claim is ever made upon the Agent for repayment or recovery of any amount or amounts received by the Agent in payment of or on account of any of the Secured Obligations, because of any claim that any such payment constituted a preferential transfer or fraudulent conveyance, or for any other reason whatsoever, and the Agent repays all or part of said amount by reason of any judgment, decree or order of any court or administrative body having jurisdiction over the Agent or any of its property, or by reason of any settlement or compromise of any such claim effected by the Agent with any such claimant (including without limitation the any other Borrower), then and in any such event, each Borrower agrees that any such judgment, decree, order, settlement and compromise shall be binding upon such Borrower, notwithstanding any revocation or release of this Agreement or the cancellation of any note or other instrument evidencing any of the Secured Obligations, or any release of any of the Secured Obligations, and each Borrower shall be and remain

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liable to the Agent and the Lenders under this Agreement for the amount so repaid or recovered, to the same extent as if such amount had never originally been received by the Agent or any Lender, and the provisions of this sentence shall survive, and continue in effect, notwithstanding any revocation or release of this Agreement. Until the payment of the Secured Obligations and thereafter upon any recovery, disgorgement or set aside of any Secured Obligations, each Borrower hereby expressly and unconditionally waives all rights of subrogation, reimbursement and indemnity of every kind against any other Borrower, and all rights of recourse to any assets or property of any other Borrower, and all rights to any collateral or security held for the payment and performance of any Secured Obligations, including (but not limited to) any of the foregoing rights which Borrower may have under any present or future document or agreement with any other Borrower or other person, and including (but not limited to) any of the foregoing rights which any Borrower may have under any equitable doctrine of subrogation, implied contract, or unjust enrichment, or any other equitable or legal doctrine.

(c) Consents. Each Borrower hereby consents and agrees that, without notice to or by the other Borrower and without affecting or impairing in any way the obligations or liability of such Borrower hereunder, the Agent may, from time to time before or after revocation of this Agreement, do any one or more of the following in its sole discretion: (i) accept partial payments of, compromise or settle, renew, extend the time for the payment, discharge, or performance of, refuse to enforce, and release all or any parties to, any or all of the Secured Obligations; (ii) grant any other indulgence to any Borrower or any other Person in respect of any or all of the Secured Obligations or any other matter; (iii) accept, release, waive, surrender, enforce, exchange, modify, impair, or extend the time for the performance, discharge, or payment of, any and all property of any kind securing any or all of the Secured Obligations or any guaranty of any or all of the Secured Obligations, or on which the Agent at any time may have a Lien, or refuse to enforce its rights or make any compromise or settlement or agreement therefor in respect of any or all of such property; (iv) substitute or add, or take any action or omit to take any action which results in the release of, any one or more other Borrowers or any endorsers or guarantors of all or any part of the Secured Obligations, including, without limitation one or more parties to this Agreement, regardless of any destruction or impairment of any right of contribution or other right of Borrower; (v) during the continuance of an Event of Default, apply any sums received from any other Borrower, any guarantor, endorser, or co-signer, or from the disposition of any Collateral or security, to any Indebtedness whatsoever owing from such person or secured by such Collateral or security, in such manner and order as the Agent determines in its sole discretion, and regardless of whether such Indebtedness is part of the Secured Obligations, is secured, or is due and payable. Each Borrower consents and agrees that the Agent shall be under no obligation to marshal any assets in favor of Borrower, or against or in payment of any or all of the Secured Obligations. Each Borrower further consents and agrees that the Agent shall have no duties or responsibilities whatsoever with respect to the care of any property securing any or all of the Secured Obligations other than as required under this Agreement. Without limiting the generality of the foregoing, the Agent shall have no obligation to monitor, verify, audit, examine, or obtain or maintain any insurance with respect to, any property securing any or all of the Secured Obligations.

(d) Independent Liability. Each Borrower hereby agrees that one or more successive or concurrent actions may be brought hereon against such Borrower, in the same action in which any other Borrower may be sued or in separate actions, as often as deemed advisable by Agent. Each Borrower is fully aware of the financial condition of each other Borrower and is executing and delivering this Agreement based solely upon its own independent investigation of all matters pertinent hereto, and such Borrower is not relying in any manner upon any representation or statement of the Agent or any Lender with respect thereto. Each Borrower represents and warrants that it is in a position to obtain, and each Borrower hereby assumes full responsibility for obtaining, any additional information concerning any other Borrower's financial condition and any other matter pertinent hereto as such Borrower may desire, and such Borrower is not relying upon or expecting the Agent to furnish to it any information now or hereafter in the Agent's possession concerning the same or any other matter.

(e) Subordination. All Indebtedness of a Borrower now or hereafter arising held by another Borrower is subordinated to the Secured Obligations and after the occurrence and during the continuation of an Event of Default, the Borrower holding the Indebtedness shall take all actions reasonably requested by Agent to effect, to enforce and to give notice of such subordination.

#### **SECTION 12. GUARANTY.**

12.1 Guaranty. Each Guarantor hereby agrees that such Guarantor is jointly and severally liable for, and hereby absolutely and unconditionally guarantees to the Agent and the Lender and their respective successors and assigns, the full and prompt payment (whether at stated maturity, by acceleration or otherwise) and performance of, all Secured Obligations owed or hereafter owing to the Agent and the Lender by each other Loan Party. Each Guarantor agrees that its guaranty obligation hereunder is a continuing guaranty of payment and performance and not of collection, and that its obligations under this Section 12 shall be absolute and unconditional, irrespective of, and unaffected by:

- (a) the genuineness, validity, regularity, enforceability or any future amendment of, or change in, this Agreement, any other Loan Document or any other agreement, document or instrument to which any Loan Party is or may become a party;
- (b) the absence of any action to enforce this Agreement (including this Section 12) or any other Loan Document or the waiver or consent by the Agent and the Lender with respect to any of the provisions thereof;
- (c) the existence, value or condition of, or failure to perfect its Lien against, any security for the Secured Obligations or any action, or the absence of any action, by the Agent and the Lender in respect thereof (including the release of any such security);
- (d) the insolvency of any Loan Party; or
- (e) any other action or circumstances which might otherwise constitute a legal or equitable discharge or defense of a surety or guarantor;

it being agreed by each Guarantor that its obligations under this Section 12 shall not be discharged until the full and final payment in Cash of all of the Secured Obligations (other than inchoate indemnity obligations). Each Guarantor shall be regarded, and shall be in the same position, as principal debtor with respect to the Secured Obligations guaranteed hereunder.

12.2 Waivers by the Loan Parties. Each Loan Party expressly waives all rights it may have now or in the future under any statute, or at common law, or pursuant to any other laws or in equity, or otherwise, to compel the Agent or the Lender to marshal assets or to proceed in respect of the Secured Obligations guaranteed hereunder against any other Loan Party, any other party or against any security for the payment and performance of the Secured Obligations before proceeding against, or as a condition to proceeding against, such Loan Party. It is agreed among each Loan Party, the Agent and the Lender that the foregoing waivers are of the essence of the transaction contemplated by this Agreement and the other Loan Documents and that, but for the provisions of this Section 12 and such waivers, the Agent and the Lender would decline to enter into this Agreement.

12.3 Benefit of Guaranty. Each Loan Party agrees that the provisions of this Section 12 are for the benefit of the Agent and the Lender and their respective successors, transferees, endorsees and assigns, and nothing herein contained shall impair, as between Borrower, on the one hand, and the Agent and the Lender, on the other hand, the obligations of such other Loan Party under the Loan Documents.

12.4 Subordination of Subrogation, Etc. Notwithstanding anything to the contrary in this Agreement or in any other Loan Document, and except as set forth in Section 12.7, each Loan Party hereby expressly and irrevocably subordinates to the prior payment in full, in cash, of the Secured Obligations (other than contingent indemnity obligations for which no claim is outstanding) any and all rights pursuant to any laws or in equity to subrogation, reimbursement, exoneration, contribution, indemnification or set off and any and all defenses available to a surety, guarantor or accommodation co-obligor until the full and final payment in Cash of all of the Secured Obligations (other than inchoate indemnity obligations). Each Loan Party acknowledges and agrees that this subordination is intended to benefit the Agent and the Lender and shall not limit or otherwise affect such Loan Party's liability hereunder or the enforceability of this Section 12, and that the Agent, the Lender and their respective successors and assigns are intended third party beneficiaries of the waivers and agreements set forth in this Section 12.4.

12.5 Election of Remedies. If the Agent or Lender may, under applicable law, proceed to realize its benefits under any of the Loan Documents giving the Agent or Lender a Lien upon any Collateral, whether owned by any Loan Party or by any other Person, either by judicial foreclosure or by non-judicial sale or enforcement, the Agent or Lender may, at its sole option, determine which of its remedies or rights it may pursue without affecting any of its rights and remedies under this Section 12. If, in the exercise of any of its rights and remedies, the Agent or Lender shall forfeit any of its rights or remedies, including its right to enter a deficiency judgment against any Loan Party or any other Person, whether because of any applicable laws pertaining to "election of remedies" or the like, each Loan Party hereby consents to such action by the Agent or Lender and waives any claim based upon such action, even if such action by the Agent or Lender shall result in a full or partial loss of any rights of subrogation which each Loan Party might otherwise have had but for such action by the Agent or Lender. Any election of

remedies which results in the denial or impairment of the right of the Agent or Lender to seek a deficiency judgment against any Loan Party shall not impair any other Loan Party's obligation to pay the full amount of the Secured Obligations. In the event the Agent or Lender shall bid at any foreclosure or trustee's sale or at any private sale permitted by law or the Loan Documents, the Agent (either directly or through one or more acquisition vehicles) or Lender may offset the Secured Obligations against the purchase price of such bid in lieu of accepting cash or other non-cash consideration in connection with such sale or other disposition. The amount of the successful bid at any such sale, whether the Agent, Lender or any other party is the successful bidder, shall be conclusively deemed to be the fair and reasonably equivalent value of the Collateral and the difference between such bid amount and the remaining balance of the Secured Obligations shall be conclusively deemed to be the amount of the Secured Obligations guaranteed under this Section 12, notwithstanding that any present or future law or court decision or ruling may have the effect of reducing the amount of any deficiency claim to which the Agent or Lender might otherwise be entitled but for such bidding at any such sale.

12.6 Limitation. Notwithstanding any provision herein contained to the contrary, the liability of each Loan Party (other than the Borrower) under this Section 12 (which liability is in any event in addition to amounts for which such Loan Party is primarily liable under Section 2) shall be limited to an amount not to exceed as of any date of determination the greater of:

- (a) the net amount of all Loans (plus all other Secured Obligations owing in connection therewith) advanced to any other Loan Party under this Agreement and then re-loaned or otherwise transferred to, or for the benefit of, such Loan Party;
- (b) the amount which could be claimed by the Agent and the Lender from such Loan Party under this Section 12 without rendering such claim voidable or avoidable under Section 548 of Chapter 11 of the United States Bankruptcy Code, as amended, or under any applicable state Uniform Fraudulent Transfer Act, Uniform Fraudulent Conveyance Act or similar statute or common law after taking into account, among other things, such Loan Party's right of contribution and indemnification from each other Loan Party under Section 12.7; and
- (c) this Guaranty does not apply to any liability to the extent it would result in this Guaranty constituting unlawful financial assistance within the meaning of Section 82 of the Companies Act 2014 of Ireland or any equivalent and applicable provisions under the laws of the jurisdiction of the relevant Guarantor.

The provisions of this Section 12.6 shall be implemented automatically without the need for any amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document.

12.7 Contribution with Respect to Guaranty Obligations.

- (a) To the extent that any Loan Party shall make a payment under this Section 12 of all or any of the Secured Obligations (other than Loans made to that Loan Party for which it is primarily liable) (a "Guarantor Payment") which, taking into account all other Guarantor Payments then previously or concurrently made by any other Loan Party, exceeds the amount which such Loan Party would otherwise have paid if each Loan Party had paid the aggregate

Secured Obligations satisfied by such Guarantor Payment in the same proportion that such Loan Party's "Allocable Amount" (as defined below) (as determined immediately prior to such Guarantor Payment) bore to the aggregate Allocable Amounts of each of the Loan Parties as determined immediately prior to the making of such Guarantor Payment, then, following the occurrence of the full and final payment in Cash of all of the Secured Obligations (other than inchoate indemnity obligations), such Loan Party shall be entitled to receive contribution and indemnification payments from, and be reimbursed by, each other Loan Party for the amount of such excess, pro rata based upon their respective Allocable Amounts in effect immediately prior to such Guarantor Payment.

(b) As of any date of determination, the "Allocable Amount" of any Loan Parties shall be equal to the maximum amount of the claim which could then be recovered from such Loan Parties under this Section 12 without rendering such claim voidable or avoidable under Section 548 of Chapter 11 of the United States Bankruptcy Code, as amended or under any applicable state Uniform Fraudulent Transfer Act, Uniform Fraudulent Conveyance Act or similar statute or common law.

(c) This Section 12.7 is intended only to define the relative rights of Loan Parties and nothing set forth in this Section 12.7 is intended to or shall impair the obligations of Loan Parties, jointly and severally, to pay any amounts as and when the same shall become due and payable in accordance with the terms of this Agreement, including Section 12.1. Nothing contained in this Section 12.7 shall limit the liability of any Loan Party to pay the Loans made directly or indirectly to that Loan Party and accrued interest, fees, expenses and all other Secured Obligations with respect thereto for which such Loan Party shall be primarily liable.

(d) The parties hereto acknowledge that the rights of contribution and indemnification hereunder shall constitute assets of the Loan Party to which such contribution and indemnification is owing.

(e) The rights of the indemnifying Loan Parties against other Loan Parties under this Section 12.7 shall be exercisable upon and after the full and final payment in Cash of all of the Secured Obligations (other than inchoate indemnity obligations).

12.8 **Liability Cumulative.** The liability of Loan Parties under this Section 12 is in addition to and shall be cumulative with all liabilities of each Loan Party to the Agent and the Lender under this Agreement and the other Loan Documents to which such Loan Party is a party or in respect of any Secured Obligations or obligation of any other Loan Party, without any limitation as to amount, unless the instrument or agreement evidencing or creating such other liability specifically provides to the contrary.

12.9 **Acknowledgement and Consent to Bail-In of EEA Financial Institutions.** Notwithstanding anything to the contrary in any Loan Document or in any other agreement, arrangement or understanding among any such parties, each party hereto acknowledges that any liability of any EEA Financial Institution arising under any Loan Document, to the extent such liability is unsecured, may be subject to the write-down and conversion powers of an EEA Resolution Authority and agrees and consents to, and acknowledges and agrees to be bound by:

- (a) the application of any Write-Down and Conversion Powers by an EEA Resolution Authority to any such liabilities arising hereunder that may be payable to it by any party hereto that is an EEA Financial Institution; and
- (b) the effects of any Bail-in Action on any such liability, including, if applicable:
- (i) a reduction in full or in part or cancellation of any such liability;
  - (ii) a conversion of all, or a portion of, such liability into shares or other instruments of ownership in such EEA Financial Institution, its parent undertaking, or a bridge institution that may be issued to it or otherwise conferred on it, and that such shares or other instruments of ownership will be accepted by it in lieu of any rights with respect to any such liability under this Agreement or any other Loan Document; or
  - (iii) the variation of the terms of such liability in connection with the exercise of the write-down and conversion powers of any EEA Resolution Authority.

12.10 Guaranty Construction. Notwithstanding anything to the contrary herein or in any other of the Loan Documents, the guarantee pursuant to Section 12.1 to Section 12.3 is meant to be and shall be interpreted as an “abstract guarantee” (*abstrakter Garantievertrag*) pursuant to § 880a second case of the Austrian Civil Code (*Allgemeines Bürgerliches Gesetzbuch — ABGB*) and the obligations of the Guarantors hereunder shall, subject only to the guarantee limitations set out in Sections 12.6 and 12.7, be obligations of the Guarantors as principal debtors and not as sureties (*Bürgen*) or sureties upon first demand (*Bürgen auf erstes Anfordern*) and not joint obligations as co-debtor (*Mitschuldner*) and the Guarantors undertake to pay the amounts so demanded under or pursuant to this guarantee unconditionally, irrevocably, upon first demand and without raising any defenses or objections, set-off or counterclaim and without verification of the legal ground (*unbedingt, unwiderruflich, auf erste Aufforderung und unter Verzicht auf alle Einwendungen oder Einreden, ohne Aufrechnung oder die Geltendmachung von Gegenforderungen und ohne Prüfung des Rechtsgrunds*).

12.11 General Limitations — Austrian Guarantor. The obligations (*Verpflichtungen*) and liabilities (*Haftungen*) of an Austrian Guarantor under or in connection with the Loan Documents including, but not limited to those set out in Clause 2.9(d) (Indemnification by the Loan Parties), Section 3 (Security Interest), Clause 6.3 (Indemnity), and Section 12 (Guaranty), shall at all times be limited so that at no time the assumption of an obligation and/or liability under any Loan Document would violate or contradict Austrian capital maintenance rules (*Kapitalerhaltungsvorschriften*) pursuant to mandatory Austrian company law, in particular, without limitation, § 52 et seq. of the Austrian Act on Joint Stock Companies (*Aktiengesetz — AktG*) (and for the avoidance of doubt including § 66a AktG), § 82 of the Austrian Act on Limited Liabilities Companies (*Gesetz über Gesellschaft mit beschränkter Haftung*) or any analogous application thereof (the “Austrian Capital Maintenance Rules”).

If and to the extent the obligations (*Verpflichtungen*) and liabilities (*Haftungen*) of an Austrian Guarantor under any Loan Document would violate or contradict Austrian Capital



Maintenance Rules and therefore be held invalid or unenforceable, then such obligations (*Verpflichtungen*) and liabilities (*Haftungen*) shall be limited in a way (i) to comply with Austrian Capital Maintenance Rules and (ii) to not expose the managing directors or members of the supervisory board of an Austrian Guarantor, if applicable, to any personal liability or criminal responsibility. To the extent any such obligation or liability of an Austrian Guarantor (i) infringes or contradicts Austrian Capital Maintenance Rules or (ii) would expose the managing directors or members of the supervisory board of an Austrian Guarantor, if applicable, to any personal liability or criminal responsibility (it being understood that the managing directors or members of the supervisory board of such Austrian Guarantor need to be able to demonstrate that the assumption or enforcement of the respective obligations or liability may result in such exposure), such obligation or liability shall be deemed to be replaced by an obligation of a similar nature which is in compliance with Austrian Capital Maintenance Rules and payment obligations shall be limited to the maximum amount permitted to be paid in accordance with Austrian Capital Maintenance Rules. According to the Parties' understanding of the Austrian Capital Maintenance Rules as interpreted as of the Closing Date, the amount payable shall, except to the extent the incurrence of an obligation or liability would be prohibited by § 66a AktG, shall not be less than:

- (a) the Austrian Guarantor's balance sheet profit (including retained earnings) (*Bilanzgewinn*) as defined in § 224 (3) lit A no. IV of the Austrian Commercial Code as calculated by reference to the most recent (audited, if applicable, and approved (*festgestellt*)) financial statements of that Austrian Guarantor to the extent available for distribution in accordance with the respective articles of association and applicable law at the relevant point in time in accordance with Austrian law, plus
- (b) any other amounts which are freely available or can be converted into amounts freely available for distribution to the shareholder(s) under the GmbHG or the AktG (as the case may be) and the Austrian Commercial Code (such as, for instance, unrestricted reserves (*freie Rücklagen*)) at the time or times payment under or pursuant to this Agreement is requested from an Austrian Guarantor to the extent these have been made available for distribution by passing the necessary corporate resolutions and taking other steps required by law for distribution at the relevant point in time in accordance with Austrian law, plus
- (c) to the extent applicable, the equivalent of a Loan (plus any accrued interest, commission and fees thereon) borrowed by the Borrower under this Agreement and made available to an Austrian Guarantor and/or its Subsidiaries to the extent repayable by that Austrian Guarantor or its Subsidiaries to that Borrower (provided however that the proceeds resulting from an enforcement of any obligations under this Agreement or any other Loan Document of the respective Austrian Guarantor shall discharge the respective Austrian Guarantor from, or enable the respective Austrian Guarantor to effect a unilateral set-off of, a corresponding amount of the obligations that the respective Austrian Guarantor has assumed as a result of the receipt of any such amounts), plus
- (d) the amount of any indebtedness capable of being discharged by way of such Austrian Guarantor unilaterally setting off its recourse claim against another Guarantor or the Parent following payment under the guarantee and indemnity pursuant

to this Agreement against any indebtedness owed by that Austrian Guarantor to that other Guarantor or the Parent to the extent such set-off is enforceable and is permitted under this Agreement or any other Loan Document at the time of payment under such guarantee or indemnity.

Whereas the parties acknowledge that the limitations set out in this Section 12.11 may reduce any payment permissible at a given time by an Austrian Guarantor under the Loan Documents to zero, no reduction of an amount enforceable hereunder pursuant to these limitations will prejudice the rights of any Lender or the Agent to continue enforcing its rights under the guarantee or indemnity under the Loan Documents (subject always to the limitations set out in this Clause 12.11) until full satisfaction of the Secured Obligations.

[Signature pages follow.]

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**IN WITNESS WHEREOF**, each Loan Party, Agent and Lender have duly executed and delivered this Loan and Security Agreement as of the day and year first above written.

**Notice: Under the Credit Reporting Act 2013 lenders are required to provide personal and credit information for credit applications and credit agreements of €500 and above to the Central Credit Register. This information will be held on the Central Credit Register and may be used by other lenders when making decisions on your credit applications and credit agreements.**

The Central Credit Register is maintained and operated by the Central Bank of Ireland. For information on your rights and duties under the Credit Reporting Act 2013 please refer to the factsheet prepared by the Central Bank of Ireland. This factsheet is available on [www.centralcreditregister.ie](http://www.centralcreditregister.ie).

**BORROWER:**

Nabriva Therapeutics Public Limited Company

**GIVEN** under the **COMMON SEAL** of

**NABRIVA THERAPEUTICS PUBLIC LIMITED COMPANY**

and **DELIVERED** as a **DEED**:

/s/ Gary Sender  
Gary Sender  
Authorised Signatory

[Signature Page to Loan and Security Agreement (Hercules/Nabriva)]

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Nabriva Therapeutics Ireland Designated Activity Company

**SIGNED AND DELIVERED** as a Deed

for and on behalf of

**NABRIVA THERAPEUTICS IRELAND DESIGNATED ACTIVITY COMPANY**

by its lawfully appointed attorney

**GARY SENDER**

/s/ Gary Sender  
Signature of Attorney

in the presence of:

/s/ Illegible  
Signature of Witness

Attorney  
Occupation of Witness

[redacted]  
Address of Witness

[Signature Page to Loan and Security Agreement (Hercules/Nabriva)]

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**GUARANTORS:**

**NABRIVA THERAPEUTICS GMBH**

By: /s/ Gary Sender  
Name: Gary Sender  
Title: Authorised Signatory

**NABRIVA THERAPEUTICS US, INC.**

By: /s/ Gary Sender  
Name: Gary Sender  
Title: Treasurer

By: /s/ Gary Sender  
Name: Gary Sender  
Title: Treasurer

[Signature Page to Loan and Security Agreement (Hercules/Nabriva)]

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**AGENT:**

**HERCULES CAPITAL, INC.**

By: /s/ Melanie Grace  
Name: Melanie Grace  
Title: General Counsel

**LENDER:**

**HERCULES CAPITAL, INC.**

By: /s/ Melanie Grace  
Name: Melanie Grace  
Title: General Counsel

[Signature Page to Loan and Security Agreement (Hercules/Nabriva)]

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Table of Exhibits and Schedules

Exhibit A:	Advance Request; Attachment to Advance Request
Exhibit B:	Term Note
Exhibit F:	Compliance Certificate
Exhibit G:	Joinder Agreement
Schedule 1.1	Commitments

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EXHIBIT A

ADVANCE REQUEST

To: Agent:

Date: , 20[ ]

Hercules Capital, Inc. (the "Agent")  
400 Hamilton Avenue, Suite 310  
Palo Alto, CA 94301  
email: legal@herculestech.com  
Attn:

[Nabriva Therapeutics Public Limited Company, a public limited company incorporated in Ireland under registration number 599588 and having its registered office at 25-28 North Wall Quay, Dublin 1, Ireland ("Parent")][Nabriva Therapeutics Ireland Designated Activity Company, a designated activity company incorporated in Ireland under registration number 612454 and having its registered office at Suite 510, Regus Dublin Airport, Skybridge House, Dublin Airport, Swords, County Dublin, Ireland ("Nabriva Ireland")] hereby requests from Hercules Capital, Inc. ("Lender") an Advance in the amount of Dollars (\$) on , (the "Advance Date") pursuant to the Loan and Security Agreement by and among Borrower, the parties thereto from time to time as Guarantors, Agent and Lender (the "Agreement"). Capitalized words and other terms used but not otherwise defined herein are used with the same meanings as defined in the Agreement.

Please:

(a) Issue a check payable to [Parent] [Nabriva Ireland]

or

(b) Wire Funds to [Parent's] [Nabriva Ireland's] account [ ]

Bank:  
Address:

ABA Number:  
Account Number:  
Account Name:  
Contact Person:  
Phone Number  
To Verify Wire Info:  
Email address:

[Parent][Nabriva Ireland] represents that the conditions precedent to the Advance set forth in the Agreement are satisfied and shall be satisfied upon the making of such Advance, including but not limited to: (i) that no event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing; (ii) that the representations and

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warranties by [Parent][Nabriva Ireland] set forth in the Agreement are and shall be true and correct in all material respects on and as of the Advance Date with the same effect as though made on and as of such date, except to the extent such representations and warranties expressly relate to an earlier date; (iii) that [Parent][Nabriva Ireland] is in compliance with all the terms and provisions set forth in each Loan Document on its part to be observed or performed; and (iv) that as of the Advance Date, no Event of Default under the Loan Documents shall have occurred and be continuing. [Parent][Nabriva Ireland] understands and acknowledges that Agent has the right to review the financial information supporting this representation and, based upon such review in its sole discretion, Lender may decline to fund the requested Advance.

[Parent][Nabriva Ireland] hereby represents that [Parent's][Nabriva Ireland's] corporate status and locations have not changed since the date of the Agreement (except as otherwise disclosed to Agent) or, if the Attachment to this Advance Request is completed, are as set forth in the Attachment to this Advance Request.

[Parent][Nabriva Ireland] agrees to notify Agent promptly before the funding of the Loan if any of the matters which have been represented above shall not be true and correct on the Advance Date and if Agent has received no such notice before the Advance Date then the statements set forth above shall be deemed to have been made and shall be deemed to be true and correct as of the Advance Date.

Executed as of [            ], 20[    ].

[NABRIVA THERAPEUTICS PUBLIC LIMITED COMPANY:]

[NABRIVA THERAPEUTICS IRELAND DESIGNATED ACTIVITY COMPANY: ]

[            ]

SIGNATURE: \_\_\_\_\_

TITLE: \_\_\_\_\_

PRINT NAME: \_\_\_\_\_

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**ATTACHMENT TO ADVANCE REQUEST**

Dated:

Parent hereby represents and warrants to Agent that Parent's current name and organizational status is as follows:

Name: [ ]

Type of organization: Corporation

State of organization: [ ]

Organization file number:

Parent hereby represents and warrants to Agent that the street addresses, cities, states and postal codes of its current locations are as follows:

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**EXHIBIT B**

**SECURED TERM NOTE**

**THIS NOTE IS BEING ISSUED WITH ORIGINAL ISSUE DISCOUNT ("OID"). PURSUANT TO TREASURY REGULATION SECTION 1.1275-3, FOR INFORMATION REGARDING THE ISSUE PRICE, AMOUNT OF OID, ISSUE DATE, AND YIELD TO MATURITY, PLEASE CONTACT NABRIVA THERAPEUTICS PUBLIC LIMITED COMPANY, ATTENTION: [INSERT NAME, ADDRESS, EMAIL] TELEPHONE: [ ]**

\$[ ],000,000

Advance Date: , 20[ ]

Maturity Date: , 20[ ]

FOR VALUE RECEIVED, Nabriva Therapeutics Public Limited Company, a public limited company incorporated in Ireland under registration number 599588 and having its registered office at 25-28 North Wall Quay, Dublin 1, Ireland ("Parent") and Nabriva Therapeutics Ireland Designated Activity Company, a designated activity company incorporated in Ireland under registration number 612454 and having its registered office at Suite 510, Regus Dublin Airport, Skybridge House, Dublin Airport, Swords, County Dublin, Ireland ("Nabriva Ireland"; together with Parent, individually and collectively, jointly and severally, the "Borrower") hereby promises to pay to Hercules Capital, Inc., a Maryland corporation or the registered holder of this Note (the "Lender") at 400 Hamilton Avenue, Suite 310, Palo Alto, CA 94301 or such other place of payment as the registered holder of this Secured Term Promissory Note (this "Promissory Note") may specify from time to time in writing, in lawful money of the United States of America, the principal amount of [ ] Million Dollars (\$[ ],000,000) or such other principal amount as Lender has advanced to Borrower, together with interest at a rate as set forth in Section 2.2(c) of the Loan Agreement based upon a year consisting of 360 days, with interest computed daily based on the actual number of days in each month.

This Promissory Note is the Note referred to in, and is executed and delivered in connection with, that certain Loan and Security Agreement dated December 20, 2018, by and among Parent, Nabriva Ireland, Nabriva Therapeutics GmbH, a limited liability company (*Gesellschaft mit beschränkter Haftung*) incorporated under the laws of the Republic of Austria, having its seat in Vienna and its registered address at Leberstraße 20, 1110 Vienna, and registered with the companies' register (*Firmenbuch*) of the commercial court of Vienna (*Handelsgericht Wien*) under registration number 269261 y ("Nabriva Austria"), Nabriva Therapeutics US, Inc., a Delaware corporation ("Nabriva US"), Zavante Therapeutics, Inc., a Delaware corporation ("Zavante"), and each of their Subsidiaries from time to time party thereto (together with Nabriva Austria, and Nabriva US, collectively referred to as the "Guarantors" and each, a "Guarantor"), Hercules Capital, Inc., a Maryland corporation (the "Agent") and the several banks and other financial institutions or entities from time to time party thereto as lender (as the same may from time to time be amended, modified or supplemented in accordance with its terms, the "Loan Agreement"), and is entitled to the benefit and security of the Loan Agreement and the other Loan Documents (as defined in the Loan Agreement), to which reference is made for a statement of all of the terms and conditions thereof. All payments shall be made in

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accordance with the Loan Agreement. All terms defined in the Loan Agreement shall have the same definitions when used herein, unless otherwise defined herein. An Event of Default under the Loan Agreement shall constitute a default under this Promissory Note.

Borrower waives presentment and demand for payment, notice of dishonor, protest and notice of protest under the UCC or any applicable law. Borrower agrees to make all payments under this Promissory Note without setoff, recoupment or deduction and regardless of any counterclaim or defense. This Promissory Note shall be governed by and construed and enforced in accordance with, the laws of the State of New York, excluding any conflicts of law rules or principles that would cause the application of the laws of any other jurisdiction.

BORROWER FOR ITSELF AND  
ON BEHALF OF ITS SUBSIDIARIES:

[ ]

By:  
Title:

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**EXHIBIT F**  
**COMPLIANCE CERTIFICATE**

[           , 20 ]

Hercules Capital, Inc. (as “Agent”)  
400 Hamilton Avenue, Suite 310  
Palo Alto, CA 94301

Reference is made to that certain Loan and Security Agreement dated December 20, 2018 and the Loan Documents (as defined therein) entered into in connection with such Loan and Security Agreement all as may be amended from time to time (hereinafter referred to collectively as the “Loan Agreement”) by and among the lenders from time to time party thereto (collectively, the “Lender”), Hercules Capital, Inc., as agent for the Lender (the “Agent”), Nabriva Therapeutics Public Limited Company, a public limited company incorporated in Ireland under registration number 599588 and having its registered office at 25-28 North Wall Quay, Dublin 1, Ireland (“Parent”), Nabriva Therapeutics Ireland Designated Activity Company, a designated activity company incorporated in Ireland under registration number 612454 and having its registered office at Suite 510, Regus Dublin Airport, Skybridge House, Dublin Airport, Swords, County Dublin, Ireland (“Nabriva Ireland”); together with Parent, individually and collectively, jointly and severally, the “Borrower”), Nabriva Therapeutics GmbH, a limited liability company (*Gesellschaft mit beschränkter Haftung*) incorporated under the laws of the Republic of Austria, having its seat in Vienna and its registered address at Leberstraße 20, 1110 Vienna, and registered with the companies’ register (*Firmenbuch*) of the commercial court of Vienna (*Handelsgericht Wien*) under registration number 269261 y (“Nabriva Austria”), Nabriva Therapeutics US, Inc., a Delaware corporation (“Nabriva US”), and Zavante Therapeutics, Inc., a Delaware corporation (“Zavante”), and each of their Subsidiaries from time to time party thereto (together with Nabriva Austria, and Nabriva US, collectively referred to as the “Guarantors” and each, a “Guarantor”). All capitalized terms not defined herein shall have the same meaning as defined in the Loan Agreement.

The undersigned is an Officer of the Parent, knowledgeable of all Loan Party financial matters, and is authorized to provide certification of information regarding the Loan Parties; hereby certifies, in such capacity, that in accordance with the terms and conditions of the Loan Agreement, the Loan Parties are in compliance for the period ending            of all covenants, conditions and terms therein and hereby reaffirms that all representations and warranties contained therein are true and correct in all material respects, other than as disclosed in this Compliance Certificate, on and as of the date of this Compliance Certificate with the same effect as though made on and as of such date, except to the extent such representations and warranties expressly relate to an earlier date, after giving effect in all cases to any standard(s) of materiality contained in the Loan Agreement as to such representations and warranties. Attached are the required documents supporting the above certification. The undersigned further certifies that these are prepared in accordance with GAAP (except for the absence of footnotes with

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respect to unaudited financial statement and subject to normal year-end adjustments) and are consistent from one period to the next except as explained below.

<u>REPORTING REQUIREMENT</u>	<u>REQUIRED</u>	<u>CHECK IF ATTACHED</u>
Interim Financial Statements	[**]	<input type="checkbox"/>
Interim Financial Statements	[**]	<input type="checkbox"/>
Audited Financial Statements	[**]	<input type="checkbox"/>
Accounts Receivable and Accounts Payable (7.1(e))	[**]	<input type="checkbox"/>
Projections (7.1(g))	[**]	<input type="checkbox"/>

**7.12(b) — Cash Management**

(a) The amount of Unrestricted Cash in Ireland and the United States as of the date hereof: \$

(b) outstanding Secured Obligations: \$ multiplied by [\*\*] = \$

(c) all Cash (excluding amounts held in Excluded Accounts) of Parent and its consolidated Subsidiaries: \$ multiplied by [\*\*] = \$

(d) Is the amounts reported in clause (a) greater than or equal to either (b) or (c)?  Yes;  No

If No: not in compliance

**7.21(a) — Minimum Cash**

(a) The amount of Unrestricted Cash in the United States and Ireland as of the date hereof \$

(b) The amount of the Loan Parties' accounts payable under GAAP not paid after the 90th day following the invoice date for such accounts payable \$

(c) Clause (a) plus clause (b) is \$

(d) Is the amount reported in clause (c) equal to or greater than \$[\*\*]?  Yes;  No

If No: not in compliance.

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**7.21(b) — Performance Covenant**

(a) Has the Performance Covenant Trigger Date passed?  Yes;  No

If Yes:

(i) Trailing six month Net Product Revenue: \$

(ii) [\*\*]% of forecasted trailing six month Net Product Revenue in the Forecast: \$

(iii) Is clause (i) greater than or equal to clause (ii)?  Yes;  No

If Yes: in compliance.

If No:

(iv) The amount of Unrestricted Cash as of the date of this Compliance Certificate: \$

(v) [\*\*]% of Eligible Accounts as of the date of this Compliance Certificate, if clause (iv) is equal to or greater than \$[\*\*] (zero if clause (iv) is less than \$[\*\*]): \$

(vi) Clause (iv) *plus* clause (v) is: \$

(vii) The amount of Advances plus the amount of accounts payable under GAAP not paid after the 90<sup>th</sup> day following the invoice date for such accounts payable as of the date of this Compliance Certificate is: \$

(viii) Is cause (vi) greater than or equal to clause (vii)?  Yes;  No

If No: not in compliance.

If Yes: in compliance.

**Section 7.19 — Intellectual Property**

(a) Has any Loan Party filed or obtained any new Patent, registered Trademark, or registered Copyright since the last reported period?  Yes;  No

If yes: Borrower shall supplement such intellectual property security agreements and or other documents as needed to maintain a first priority perfected security interest in favor of Agent within 90 days of the date hereof.

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(b) Is any utilized Intellectual Property not registered in the current legal name of Nabriva Austria as the owner of such Intellectual Property in the registry in the United States, Ireland and Austria?  Yes (not in compliance);  No (in compliance)

(c) Has Nabriva Austria filed corrective filings in the United States, Ireland or Austria to updated its name from Nabriva Therapeutics AG to Nabriva Therapeutics GmbH since the last reported period?  Yes;  No

If yes: Borrower shall supplement such intellectual property security agreements and or other documents as needed to maintain a first priority perfected security interest in favor of Agent within 90 days of the date hereof.

If yes: the IP Security Agreement, Debenture, and/or IP Security Agreement in relation to Nabriva Austria, as applicable, shall be supplemented within 90 days of the date hereof.

The undersigned hereby also confirms the below disclosed accounts represent all depository accounts and securities accounts presently open in the name of each Loan Party or and their Subsidiaries, as applicable.

	Depository AC #	Financial Institution	Account Type (Depository / Securities)	Last Month Ending Account Balance	Purpose of Account	New Account Since Last Reporting Period?
<b>BORROWER</b>						
<b>Name/Address:</b>	1					
	2					
	3					
	4					
	5					
	6					
	7					
<b>BORROWER SUBSIDIARY</b>						
<b>Name/Address</b>	1					
	2					
	3					
	4					
	5					
	6					
	7					

Very Truly Yours,

[ \_\_\_\_\_ ],  
on behalf of itself and its Subsidiaries

By: \_\_\_\_\_

Name: \_\_\_\_\_

Its: \_\_\_\_\_

Date Submitted: \_\_\_\_\_

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## EXHIBIT G

**WARNING: THE TAKING OF THIS DOCUMENT OR ANY CERTIFIED COPY THEREOF OR ANY OTHER DOCUMENT WHICH CONSTITUTES SUBSTITUTE DOCUMENTATION OF THIS DOCUMENT, INCLUDING WRITTEN CONFIRMATIONS OR REFERENCES THERETO, INTO THE REPUBLIC OF AUSTRIA, AS WELL AS THE PRODUCTION IN, OR THE SENDING TO OR FROM, THE REPUBLIC OF AUSTRIA OF ANY OF THE FOREGOING DOCUMENTS, AS WELL AS THE SENDING TO OR FROM THE REPUBLIC OF AUSTRIA OF FAX MESSAGES OR E-MAILS CARRYING AN ELECTRONIC SIGNATURE (WHETHER DIGITALLY, MANUSCRIPT OR OTHERWISE TECHNICALLY REPRODUCED) WHICH REFER TO THIS DOCUMENT OR TO WHICH A COPY OF THIS DOCUMENT IS ATTACHED, MAY CAUSE THE IMPOSITION OF AUSTRIAN STAMP DUTY. ACCORDINGLY, KEEP THE ORIGINAL OF THIS DOCUMENT AS WELL AS ANY CERTIFIED COPY THEREOF AND WRITTEN AND SIGNED REFERENCES THERETO OUTSIDE OF THE REPUBLIC OF AUSTRIA AND AVOID SENDING FAX MESSAGES OR E-MAILS CARRYING AN ELECTRONIC SIGNATURE (WHETHER DIGITALLY, MANUSCRIPT OR OTHERWISE TECHNICALLY REPRODUCED) WHICH REFER TO THIS DOCUMENT OR TO WHICH A COPY OF THIS DOCUMENT IS ATTACHED TO OR FROM THE REPUBLIC OF AUSTRIA.**

### FORM OF JOINDER AGREEMENT

This Joinder Agreement (the "Joinder Agreement") is made and dated as of [ ], 20[ ], and is entered into by and between , a corporation ("Subsidiary"), and HERCULES CAPITAL, INC., a Maryland corporation (as "Agent").

### RECITALS

A. Subsidiary's Affiliates, Nabriva Therapeutics Public Limited Company, a public limited company incorporated in Ireland under registration number 599588 and having its registered office at 25-28 North Wall Quay, Dublin 1, Ireland ("Parent"), Nabriva Therapeutics Ireland Designated Activity Company, a designated activity company incorporated in Ireland under registration number 612454 and having its registered office at Suite 510, Regus Dublin Airport, Skybridge House, Dublin Airport, Swords, County Dublin, Ireland ("Nabriva Ireland"; together with Parent, individually and collectively, jointly and severally, the "Borrower"), Nabriva Therapeutics GmbH, a limited liability company (*Gesellschaft mit beschränkter Haftung*) incorporated under the laws of the Republic of Austria, having its seat in Vienna and its registered address at Leberstraße 20, 1110 Vienna, and registered with the companies' register (*Firmenbuch*) of the commercial court of Vienna (*Handelsgericht Wien*) under registration number 269261 y ("Nabriva Austria"), Nabriva Therapeutics US, Inc., a Delaware corporation ("Nabriva US"), Zavante Therapeutics, Inc., a Delaware corporation ("Zavante"), and each of their Subsidiaries (together with Nabriva Austria, and Nabriva US, collectively referred to as the "Guarantors" and each, a "Guarantor") [has entered/desires to enter] into that certain Loan and Security Agreement dated December 20, 2018, with Borrower, the Guarantors, the several banks and other financial institutions or entities from time to time party thereto as lender (collectively, the "Lender") and the Agent, as such agreement may be amended (the "Loan Agreement"), together with the other agreements executed and delivered in connection therewith;

B. Subsidiary acknowledges and agrees that it will benefit both directly and indirectly from the Loan Parties' execution of the Loan Agreement and the other agreements executed and delivered in connection therewith;

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## AGREEMENT

NOW THEREFORE, Subsidiary and Agent agree as follows:

1. The recitals set forth above are incorporated into and made part of this Joinder Agreement. Capitalized terms not defined herein shall have the meaning provided in the Loan Agreement.
2. By signing this Joinder Agreement, Subsidiary shall be bound by the terms and conditions of the Loan Agreement the same as if it were the Borrower (as defined in the Loan Agreement) under the Loan Agreement, mutatis mutandis, provided however, that (a) with respect to (i) Section 5.1 of the Loan Agreement, Subsidiary represents that it is an entity duly organized, legally existing and (save for a Subsidiary incorporated in Ireland) in good standing under the laws of [ ], (b) neither Agent nor Lender shall have any duties, responsibilities or obligations to Subsidiary arising under or related to the Loan Agreement or the other Loan Documents, (c) that if Subsidiary is covered by any Loan Party's insurance, Subsidiary shall not be required to maintain separate insurance or comply with the provisions of Sections 6.1 and 6.2 of the Loan Agreement, and (d) that as long as the Loan Parties satisfy the requirements of Section 7.1 of the Loan Agreement, Subsidiary shall not have to provide Agent separate Financial Statements. To the extent that Agent or Lender has any duties, responsibilities or obligations arising under or related to the Loan Agreement or the other Loan Documents, those duties, responsibilities or obligations shall flow only to the Loan Parties and not to Subsidiary or any other Person or entity. By way of example (and not an exclusive list): (i) Agent's providing notice to any Loan Party in accordance with the Loan Agreement or as otherwise agreed among the Loan Parties, Agent and Lender shall be deemed provided such notice to Subsidiary; (ii) a Lender's providing an Advance to Borrower shall be deemed an Advance to Subsidiary; and (iii) Subsidiary shall have no right to request an Advance or make any other demand on Lender.
3. Subsidiary agrees not to certificate its equity securities without Agent's prior written consent, which consent may be conditioned on the delivery of such equity securities to Agent in order to perfect Agent's security interest in such equity securities.
4. Subsidiary acknowledges that it benefits, both directly and indirectly, from the Loan Agreement, and hereby waives, for itself and on behalf on any and all successors in interest (including without limitation any assignee for the benefit of creditors, Examiner, receiver, bankruptcy trustee or itself as debtor-in-possession under any bankruptcy proceeding) to the fullest extent provided by law, any and all claims, rights or defenses to the enforcement of this Joinder Agreement on the basis that (a) it failed to receive adequate consideration for the execution and delivery of this Joinder Agreement or (b) its obligations under this Joinder Agreement are avoidable as a fraudulent conveyance.
5. As security for the prompt, complete and indefeasible payment when due (whether on the payment dates or otherwise) of all the Secured Obligations, Subsidiary grants to Agent a security interest in all of Subsidiary's right, title, and interest in and to the Collateral and the Intellectual Property Collateral (as defined in the IP Security Agreement).

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

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[SIGNATURE PAGE TO JOINDER AGREEMENT]

SUBSIDIARY:

By:  
Name:  
Title:

Address:

Telephone:  
email:

AGENT:

HERCULES CAPITAL, INC.

By:  
Name:  
Title:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Address:  
400 Hamilton Ave., Suite 310  
Palo Alto, CA 94301  
email: legal@herculestech.com  
Telephone: [\*\*]

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SCHEDULE 1.1

COMMITMENTS

LENDER	TRANCHE	TERM COMMITMENT
Hercules Capital, Inc.	Tranche 1	\$25,000,000
Hercules Capital, Inc.	Tranche 2	\$10,000,000
Hercules Capital, Inc.	Tranche 3	\$5,000,000
Hercules Capital, Inc.	Tranche 4	\$10,000,000
Hercules Capital, Inc.	Tranche 5	\$15,000,000
Hercules Capital, Inc.	Tranche 6	\$5,000,000
Hercules Capital, Inc.	Tranche 7*	\$5,000,000*
TOTAL COMMITMENTS		\$70,000,000
		(\$75,000,000 if Tranche 7 fully available)*

\*Funding of Tranche 7 is subject to approval by Lender's investment committee in its sole discretion.

## EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement"), is made as of March 21, 2018 among Nabriva Therapeutics US, Inc. (the "Company"), Nabriva Therapeutics plc and Jennifer Schranz (the "Executive") (together, the "Parties").

## RECITALS

WHEREAS, the Company desires to employ the Executive as its Chief Medical Officer and as Chief Medical Officer of its group of companies; and

WHEREAS, the Executive has agreed to accept such employment on the terms and conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements of the Parties herein contained, the Parties hereto agree as follows:

1. *Agreement.* This Agreement shall be effective as of the date first set forth above (the "Effective Date"). Following the Effective Date, the Executive shall continue to be an employee of the Company until such employment relationship is terminated in accordance with Section 7 hereof (the "Term of Employment").
  2. *Position.* During the Term of Employment, the Executive shall serve as the Chief Medical Officer of the Company and Nabriva Therapeutics plc, working out of the Company's office in King of Prussia, Pennsylvania, and travelling as reasonably required by the Executive's job duties.
  3. *Scope of Employment.* During the Term of Employment, the Executive shall be responsible for the performance of those duties consistent with the Executive's position as Chief Medical Officer. The Executive shall report to the Chief Executive Officer of the Company and shall be accountable to the Board of Directors of Nabriva Therapeutics plc (the "Board") and shall perform and discharge faithfully, diligently, and to the best of the Executive's ability, the Executive's duties and responsibilities hereunder. The Executive shall devote substantially all of the Executive's business time, loyalty, attention and efforts to the business and affairs of the Company, Nabriva Therapeutics plc, and their affiliates. Membership on boards of directors of any additional companies will be permitted only with the express approval of the Board. Notwithstanding the previous sentence, the Executive may engage in charitable activities and serve on a charitable board with the approval of the Chief Executive Officer. The Executive agrees to abide by the rules, regulations, instructions, personnel practices and policies of the Company and Nabriva Therapeutics plc and any changes therein that may be adopted from time to time by the Company and/or Nabriva Therapeutics plc.
  4. *Compensation.* As full compensation for all services rendered by the Executive to the Company, Nabriva Therapeutics plc, and any affiliate thereof, during the Term of Employment, the Company will provide to the Executive the following:
    - (a) *Base Salary.* The Executive shall receive a base salary at the annualized rate of \$400,000 (the "Base Salary"), paid in equal bi-weekly installments in accordance with the
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Company's regularly established payroll procedure. Such Base Salary shall be reviewed by the Company's compensation committee and the Board in the first quarter of each fiscal year; any adjustment to the Executive's Base Salary shall be retroactively effective as of the first day of such fiscal year.

(b) *Cash Payment.* A single cash payment of \$100,000 will be made no later than thirty (30) days following execution of this Agreement subject to applicable tax withholdings; provided, however that \$50,000 will need to be repaid by Executive to the Company if Executive voluntarily terminates her employment with the Company or if the Company terminates Executive's employment for cause within one year of the date of this Agreement; provided, further that no such repayment will be required upon a change of control that occurs three (3) months before or twelve (12) months after Executive's employment terminates.

(c) *Annual Discretionary Bonus.* Following the end of each fiscal year and subject to the approval of the Board, the Executive may be eligible to receive a discretionary annual retention and performance bonus of 35% of the Executive's then current Base Salary (the "Target Bonus"), based on the Executive's performance and the performance of the Company and Nabriva Therapeutics plc during the applicable fiscal year, as determined by the Board in its sole discretion. All annual bonuses, if any, will be payable no later than March 15 of the year following the year in which they are earned. The Executive must be employed on the date of payment in order to be eligible for any annual bonus, except as specifically set forth below. Any bonus determined by the Board to be payable to the Executive with respect to 2017 shall be determined as if the Executive were employed by the Company for the entire 2017 fiscal year (i.e., such bonus, if any, shall not be pro-rated).

(d) *Equity Award.* Subject to the approval of the Board, the Company shall grant to the Executive a sign-on stock option grant with respect to 150,000 ordinary shares of Nabriva Therapeutics plc, with an exercise price equal to the closing price of the stock on the grant date, and vesting over a period of 4 years, subject to the terms of the Company's stock option plan and the applicable award agreement. The Executive will be eligible to receive additional equity awards, if any, at such times and on such terms and conditions as the Board shall, in its sole discretion, determine.

(e) *Vacation.* The Executive shall be eligible for up to 20 days of paid vacation per calendar year. The number of vacation days for which the Executive is eligible shall accrue at the rate of 1.67 days per month that the Executive is employed during such calendar year. At the end of a calendar year, the Executive may carry over to the next year any accrued but unused vacation days, but any such carried over days will be forfeited if not used by six (6) months following the end of the calendar year.

(f) *Benefits.* The Executive may participate in any and all benefit programs that the Company establishes and makes available to its senior executive employees from time to time, provided that the Executive is eligible under (and subject to all provisions of) the plan documents governing those programs. Benefits are subject to change at any time in the Company's sole discretion.

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(g) *Withholdings.* All compensation payable to the Executive shall be subject to applicable taxes and withholdings.

5. *Expenses.* The Executive shall be entitled to reimbursement by the Company for all reasonable business and travel expenses incurred by the Executive on the Company's behalf during the course of the Executive's employment, upon the presentation by the Executive of documentation itemizing such expenditures and attaching all supporting vouchers and receipts. Reimbursement will be made no later than 30 calendar days after the expense is substantiated (which must occur within 30 calendar days after the expense is incurred). The expenses eligible for reimbursement under this provision may not affect the amount of such expenses eligible for reimbursement in any other taxable year, and the right to reimbursement is not subject to liquidation or exchange for another benefit.

6. *Restrictive Covenants Agreement.* As a condition to your employment, you will be required to execute the enclosed Proprietary Rights, Non-Disclosure, Developments, Non-Competition and Non-Solicitation Agreement.

7. *Employment Termination.* This Agreement and the employment of the Executive shall terminate upon the occurrence of any of the following:

(a) Upon the death or "Disability" of the Executive. As used in this Agreement, the term "Disability" shall mean a physical or mental illness or disability that prevents the Executive from performing the duties of the Executive's position for a period of more than any three consecutive months or for periods aggregating more than twenty-six weeks. The Company shall determine in good faith and in its sole discretion whether the Executive is unable to perform the services provided for herein.

(b) At the election of the Company, with or without "Cause" (as defined below), immediately upon written notice by the Company to the Executive. As used in this Agreement, "Cause" shall mean a finding by the Board that the Executive:

(i) failed to perform (other than by reason of physical or mental illness or disability for a period of less than three consecutive months or in aggregate less than twenty-six weeks) the Executive's assigned duties diligently or effectively or was negligent in the performance of these duties;

(ii) materially breached this Agreement;

(iii) materially breached the Executive's Proprietary Rights, Non-Disclosure and Developments Agreement, or any similar agreement between the Executive and the Company;

(iv) engaged in willful misconduct, fraud, or embezzlement;

(v) engaged in any conduct that is materially harmful to the business, interests or reputation of the Company, except if the Executive had a reasonable and good faith belief that such conduct was in the best interest of the Company; or

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(vi) was convicted of, or pleaded guilty or nolo contendere to a crime involving moral turpitude or any felony.

To the extent any of the above grounds, other than the grounds set forth in Section 7(b)(iv) and 7(b)(vi), is capable of being cured, the Company shall provide Executive with written notice of the ground, and thirty (30) days within which to cure such ground.

(c) At the election of the Executive, with or without “Good Reason” (as defined below), immediately upon written notice by the Executive to the Company (subject, if it is with Good Reason, to the timing provisions set forth in the definition of Good Reason). As used in this Agreement, “Good Reason” shall mean:

- (i) the Company’s failure to pay or provide in a timely manner any material amounts owed to Executive in accordance with this Agreement;
  - (ii) a material diminution in the nature or scope of Executive’s duties, responsibilities, or authority;
  - (iii) the Company’s requiring Executive to relocate Executive’s primary office more than fifty (50) miles from King of Prussia, Pennsylvania;
- or
- (iv) any material breach of this Agreement by the Company not otherwise covered by this paragraph;

provided, however, that in each case, the Company shall have a period of not less than thirty (30) days to cure any act constituting Good Reason following Executive’s delivery to the Company of written notice within sixty (60) days of the action or omission constituting Good Reason.

#### 8. Effect of Termination.

(a) *All Terminations Other Than by the Company Without Cause or by the Executive With Good Reason.* If the Executive’s employment is terminated under any circumstances other than a Qualifying Termination (as defined below) (including a voluntary termination by the Executive without Good Reason pursuant to Section 7(c), a termination by the Company for Cause pursuant to Section 7(b) or due to the Executive’s death or Disability pursuant to Section 7(a)), the Company’s obligations under this Agreement shall immediately cease and the Executive shall only be entitled to receive (i) the Base Salary that has accrued and to which the Executive is entitled as of the effective date of such termination and to the extent consistent with general Company policy, accrued but unused paid time off through and including the effective date of such termination, to be paid in accordance with the Company’s established payroll procedure and applicable law but no later than the next regularly scheduled pay period, (ii) unreimbursed business expenses for which expenses the Executive has timely submitted appropriate documentation in accordance with Section 5 hereof, and (iii) any amounts or benefits to which the Executive is then entitled under the terms of the benefit plans then-sponsored by the Company in accordance with their terms (and not accelerated to the extent acceleration does not satisfy Section 409A of the Internal Revenue Code of 1986, as amended, (the “Code”) (the payments described in this sentence, the “Accrued Obligations”). The Executive shall not be entitled to any other compensation or consideration that the Executive may have received had the

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Executive’s Term of Employment not ceased, except that if Executive’s employment terminated because of his death or Disability, he or his estate, as the case may be, shall, subject to Section 8(d) hereof, be paid on the later of the Payment Date and the date on which annual bonuses are paid to all other employees, any earned but unpaid annual bonus from any previously completed calendar year notwithstanding the requirement that the individual be employed on the payment date of such annual bonus (such payment, the “Earned but Unpaid Bonus”).

(b) *Termination by the Company Without Cause or by the Executive With Good Reason Prior to or More Than Twelve Months Following a Change in Control.* If the Executive’s employment is terminated by the Company without Cause pursuant to Section 7(b) or by the Executive with Good Reason pursuant to Section 7(c) (in either case, a “Qualifying Termination”) prior to or more than twelve (12) months following a Change in Control (as defined below), the Executive shall be entitled to the Accrued Obligations. In addition, and subject to the conditions of Section 8(d), the Company shall: (i) continue to pay to the Executive, in accordance with the Company’s regularly established payroll procedure, the Executive’s Base Salary for a period of twelve (12) months; (ii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the “COBRA” law, continue to pay (but in no event longer than twelve (12) months following the Executive’s termination date) the share of the premium for health coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage, unless the Company’s provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case this benefit will not apply; (iii) pay the Executive any earned but unpaid annual bonus from a previously completed calendar year on the later of the Payment Date and the date on which annual bonuses are paid to all other employees, notwithstanding the requirement that the individual be employed on the payment date of such annual bonus; and (iv) pay the Executive a prorated annual bonus for the year in which the Qualifying Termination occurs, calculated by multiplying 100% of the Target Bonus by a fraction, the numerator of which is equal to the number of days in the calendar year during which Executive was employed and the denominator of which equals 365 (the “Pro-Rated Bonus Payment”), which Pro-Rated Bonus Payment shall be paid in a single lump-sum on the Payment Date (collectively, the “Severance Benefits”).

(c) *Termination by the Company Without Cause or by the Executive With Good Reason Within Twelve Months Following a Change in Control.* If a Qualifying Termination occurs within twelve (12) months following a Change in Control, then the Executive shall be entitled to the Accrued Obligations. In addition, and subject to the conditions of Section 8(d): (i) the Executive will be eligible to receive the Severance Benefits as set forth in Section 8(b) other than the Pro-Rated Bonus Payment, subject to the same terms, conditions and limitations described therein, and (ii) in lieu of the Pro-Rated Bonus Payment, the Executive will be eligible to receive a lump sum payment equal to 100% of the Executive’s Target Bonus for the year in which the Qualifying Termination occurs without regard to whether the performance goals applicable to such Target Bonus had been established or satisfied at the date of termination of employment, payable in a lump sum on the Payment Date (collectively, the “Change in Control Severance Benefits”). For the avoidance of doubt, a Qualifying Termination occurring within twelve (12) months following a Change in Control shall also constitute a Good Leaver Event (as such term is defined in the Nabriva Therapeutics plc Amended and Restated Stock Option Plan 2015 (the “Plan”)) and as such, in accordance with the terms of the Plan, the vesting of 100% of the

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Executive's assumed and then-unvested equity awards shall be accelerated, such that all then unvested equity awards vest and become fully exercisable or non-forfeitable as of the termination date, with the same treatment applying to any assumed and then-unvested equity awards granted by the Company to the Executive under any successor equity incentive plan.

(d) *Release.* As a condition of the Executive's receipt of the Earned but Unpaid Bonus, the Severance Benefits or the Change in Control Severance Benefits, as applicable, the Executive or his estate, as applicable, must execute and deliver to the Company a severance and release of claims agreement in substantially the form attached hereto (the "Severance Agreement"), which Severance Agreement must become irrevocable within 60 days following the date of the Executive's termination of employment (or such shorter period as may be directed by the Company). The Earned but Unpaid Bonus, the Severance Benefits or the Change in Control Severance Benefits, as applicable, will be paid or commence to be paid in the first regular payroll beginning after the Severance Agreement becomes effective, provided that if the foregoing 60 day period would end in a calendar year subsequent to the year in which the Executive's employment ends, the Earned but Unpaid Bonus, the Severance Benefits or Change in Control Severance Benefits, as applicable, will not be paid or begin to be paid before the first payroll of the subsequent calendar year (the date the Earned but Unpaid Bonus, the Severance Benefits or Change in Control Severance Benefits, as applicable, commence pursuant to this sentence, the "Payment Date"). The Executive must continue to comply with the Proprietary Rights, Non-Disclosure and Developments Agreement in order to be eligible to continue receiving the Severance Benefits or Change in Control Severance Benefits, as applicable.

(e) *Change in Control Definition.* For purposes of this Agreement, Change in Control shall mean: (i) an exclusive license of or the sale, the lease or other disposal of all or substantially all of the assets of the Company; (ii) a sale or other disposal (for the avoidance of doubt, the term disposal shall not include a pledge) in any transaction or series of transactions to which the Company is a party of 50% or more of the voting power of the Company, other than any transaction or series of transactions principally for bona fide equity financing purposes in which cash is received by the Company or indebtedness of the Company is cancelled or converted, or a combination thereof; (iii) a merger or consolidation of the Company with or into any third party, other than any merger or consolidation in which the shares of the Company immediately preceding such merger or consolidation continue to represent a majority of the voting power of the surviving entity immediately after the closing of such merger or consolidation; and (iv) a liquidation, winding up or any other form of dissolution of the Company.

9. *Modified Section 280G Cutback.* Notwithstanding any other provision of this Agreement, except as set forth in Section 9(b), in the event that the Company undergoes a "Change in Ownership or Control" (as defined below), the following provisions shall apply:

(a) The Company shall not be obligated to provide to the Executive any portion of any "Contingent Compensation Payments" (as defined below) that the Executive would otherwise be entitled to receive to the extent necessary to eliminate any "excess parachute payments" (as defined in Section 280G(b)(1) of the Code) for the Executive. For purposes of this Section 9, the Contingent Compensation Payments so eliminated shall be referred to as the "Eliminated Payments" and the aggregate amount (determined in accordance with Treasury Regulation

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Section 1.280G-1, Q/A-30 or any successor provision) of the Contingent Compensation Payments so eliminated shall be referred to as the “Eliminated Amount.”

(b) Notwithstanding the provisions of Section 9(a), no such reduction in Contingent Compensation Payments shall be made if (1) the Eliminated Amount (computed without regard to this sentence) exceeds (2) 100% of the aggregate present value (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-31 and Q/A-32 or any successor provisions) of the amount of any additional taxes that would be incurred by the Executive if the Eliminated Payments (determined without regard to this sentence) were paid to the Executive (including state and federal income taxes on the Eliminated Payments, the excise tax imposed by Section 4999 of the Code payable with respect to all of the Contingent Compensation Payments in excess of the Executive’s “base amount” (as defined in Section 280G(b)(3) of the Code), and any withholding taxes). The override of such reduction in Contingent Compensation Payments pursuant to this Section 9(b) shall be referred to as a “Section 9(b) Override.” For purpose of this paragraph, if any federal or state income taxes would be attributable to the receipt of any Eliminated Payment, the amount of such taxes shall be computed by multiplying the amount of the Eliminated Payment by the maximum combined federal and state income tax rate provided by law.

(c) For purposes of this Section 9 the following terms shall have the following respective meanings:

(i) “Change in Ownership or Control” shall mean a change in the ownership or effective control of the Company or in the ownership of a substantial portion of the assets of the Company determined in accordance with Section 280G(b)(2) of the Code.

(ii) “Contingent Compensation Payment” shall mean any payment (or benefit) in the nature of compensation that is made or made available (under this Agreement or otherwise) to or for the benefit of a “disqualified individual” (as defined in Section 280G(c) of the Code) and that is contingent (within the meaning of Section 280G(b)(2)(A)(i) of the Code) on a Change in Ownership or Control of the Company.

(d) Any payments or other benefits otherwise due to the Executive following a Change in Ownership or Control that could reasonably be characterized (as determined by the Company) as Contingent Compensation Payments (the “Potential Payments”) shall not be made until the dates provided for in this Section 9(d). Within thirty (30) days after each date on which the Executive first become entitled to receive (whether or not then due) a Contingent Compensation Payment relating to such Change in Ownership or Control, the Company shall determine and notify the Executive (with reasonable detail regarding the basis for its determinations) (1) which Potential Payments constitute Contingent Compensation Payments, (2) the Eliminated Amount and (3) whether the Section 9(b) Override is applicable. Within thirty (30) days after delivery of such notice to the Executive, the Executive shall deliver a response to the Company (the “Executive Response”) stating either (A) that the Executive agrees with the Company’s determination pursuant to the preceding sentence or (B) that the Executive disagrees with such determination, in which case the Executive shall set forth (x) which Potential Payments should be characterized as Contingent Compensation Payments, (y) the Eliminated Amount, and (z) whether the Section 9(b) Override is applicable. In the event that the Executive fails to deliver an Executive

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Response on or before the required date, the Company's initial determination shall be final. If the Executive states in the Executive Response that the Executive agrees with the Company's determination, the Company shall make the Potential Payments to the Executive within three (3) business days following delivery to the Company of the Executive Response (except for any Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). If the Executive states in the Executive Response that the Executive disagrees with the Company's determination, then, for a period of sixty (60) days following delivery of the Executive Response, the Executive and the Company shall use good faith efforts to resolve such dispute. If such dispute is not resolved within such 60-day period, such dispute shall be settled exclusively by arbitration in King of Prussia, Pennsylvania, in accordance with the rules of the American Arbitration Association then in effect. Judgment may be entered on the arbitrator's award in any court having jurisdiction. The Company shall, within three (3) business days following delivery to the Company of the Executive Response, make to the Executive those Potential Payments as to which there is no dispute between the Company and the Executive regarding whether they should be made (except for any such Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). The balance of the Potential Payments shall be made within three (3) business days following the resolution of such dispute.

(e) The Contingent Compensation Payments to be treated as Eliminated Payments shall be determined by the Company by determining the "Contingent Compensation Payment Ratio" (as defined below) for each Contingent Compensation Payment and then reducing the Contingent Compensation Payments in order beginning with the Contingent Compensation Payment with the highest Contingent Compensation Payment Ratio. For Contingent Compensation Payments with the same Contingent Compensation Payment Ratio, such Contingent Compensation Payment shall be reduced based on the time of payment of such Contingent Compensation Payments with amounts having later payment dates being reduced first. For Contingent Compensation Payments with the same Contingent Compensation Payment Ratio and the same time of payment, such Contingent Compensation Payments shall be reduced on a pro rata basis (but not below zero) prior to reducing Contingent Compensation Payment with a lower Contingent Compensation Payment Ratio. The term "Contingent Compensation Payment Ratio" shall mean a fraction the numerator of which is the value of the applicable Contingent Compensation Payment that must be taken into account by the Executive for purposes of Section 4999(a) of the Code, and the denominator of which is the actual amount to be received by the Executive in respect of the applicable Contingent Compensation Payment. For example, in the case of an equity grant that is treated as contingent on the Change in Ownership or Control because the time at which the payment is made or the payment vests is accelerated, the denominator shall be determined by reference to the fair market value of the equity at the acceleration date, and not in accordance with the methodology for determining the value of accelerated payments set forth in Treasury Regulation Section 1.280G-1 Q/A-24(b) or (c).

(f) The provisions of this Section 9 are intended to apply to any and all payments or benefits available to the Executive under this Agreement or any other agreement or plan under which the Executive receives Contingent Compensation Payments.

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10. *Absence of Restrictions.* The Executive represents and warrants that the Executive is not bound by any employment contracts, restrictive covenants or other restrictions that prevent the Executive from entering into employment with, or carrying out the Executive's responsibilities for, the Company, or which are in any way inconsistent with any of the terms of this Agreement.

11. *Notice.* Any notice delivered under this Agreement shall be deemed duly delivered three (3) business days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) business day after it is sent for next-business day delivery via a reputable nationwide overnight courier service, or immediately upon hand delivery, in each case to the address of the recipient set forth below.

To Executive:

At the address set forth in the Executive's personnel file

To Company:

Nabriva Therapeutics US, Inc  
1000 Continental Drive  
King of Prussia, PA 19406 USA  
Attention: Colin Broom

Either Party may change the address to which notices are to be delivered by giving notice of such change to the other Party in the manner set forth in this Section 11.

12. *Applicable Law; Jury Trial Waiver.* This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania (without reference to the conflict of laws provisions thereof). Any action, suit or other legal proceeding arising under or relating to any provision of this Agreement shall be commenced only in a court of the Commonwealth of Pennsylvania (or, if appropriate, a federal court located within the Commonwealth of Pennsylvania), and the Company and the Executive each consents to the jurisdiction of such a court. The Company and the Executive each hereby irrevocably waives any right to a trial by jury in any action, suit or other legal proceeding arising under or relating to any provision of this Agreement.

13. *Successors and Assigns.* This Agreement shall be binding upon and inure to the benefit of both Parties and their respective successors and assigns, including any corporation with which or into which the Company may be merged or which may succeed to its assets or business; provided, however, that the obligations of the Executive are personal and shall not be assigned by the Executive.

14. *Effect of Section 409A of the Code.*

(a) *Six Month Delay.* If and to the extent any portion of any payment, compensation or other benefit provided to the Executive in connection with the Executive's employment termination is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code and the Executive is a specified employee as defined in Section 409A(a)(2)(B)(i) of the Code, as determined by the Company in accordance with its procedures,

by which determination Executive hereby agrees that the Executive is bound, such portion of the payment, compensation or other benefit shall not be paid before the earlier of (i) the expiration of the six month period measured from the date of the Executive's "separation from service" (as determined under Section 409A of the Code) and (ii) the tenth day following the date of the Executive's death following such separation from service (the "New Payment Date"). The aggregate of any payments that otherwise would have been paid to the Executive during the period between the date of separation from service and the New Payment Date shall be paid to the Executive in a lump sum in the first payroll period beginning after such New Payment Date, and any remaining payments will be paid on their original schedule.

(b) *General 409A Principles.* For purposes of this Agreement, a termination of employment will mean a "separation from service" as defined in Section 409A of the Code, each amount to be paid or benefit to be provided will be construed as a separate identified payment for purposes of Section 409A of the Code, and any payments that are due within the "short term deferral period" as defined in Section 409A of the Code or are paid in a manner covered by Treas. Reg. Section 1.409A-1(b)(9)(iii) will not be treated as deferred compensation unless applicable law requires otherwise. Neither the Company nor the Executive will have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A of the Code. This Agreement is intended to comply with the provisions of Section 409A of the Code and this Agreement shall, to the extent practicable, be construed in accordance therewith. Terms defined in this Agreement will have the meanings given such terms under Section 409A of the Code if and to the extent required to comply with Section 409A of the Code. In any event, the Company makes no representations or warranty and will have no liability to the Executive or any other person if any provisions of or payments under this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but not to satisfy the conditions of that section.

15. *Acknowledgment.* The Executive states and represents that the Executive has had an opportunity to fully discuss and review the terms of this Agreement with an attorney. The Executive further states and represents that the Executive has carefully read this Agreement, understands the contents herein, freely and voluntarily assents to all of the terms and conditions hereof, and signs the Executive's name of the Executive's own free *act*.

16. *No Oral Modification, Waiver, Cancellation or Discharge.* This Agreement may be amended or modified only by a written instrument executed by both the Company and the Executive. No delay or omission by the Company in exercising any right under this Agreement shall operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.

17. *Captions and Pronouns.* The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular forms of nouns and pronouns shall include the plural, and vice versa.

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18. *Interpretation.* The Parties agree that this Agreement will be construed without regard to any presumption or rule requiring construction or interpretation against the drafting Party. References in this Agreement to “include” or “including” should be read as though they said “without limitation” or equivalent forms.

19. *Severability.* Each provision of this Agreement must be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement. Moreover, if a court of competent jurisdiction determines any of the provisions contained in this Agreement to be unenforceable because the provision is excessively broad in scope, whether as to duration, activity, geographic application, subject or otherwise, it will be construed, by limiting or reducing it to the extent legally permitted, so as to be enforceable to the extent compatible with then applicable law to achieve the intent of the Parties.

20. *Entire Agreement.* This Agreement constitutes the entire agreement between the Parties and supersedes all prior agreements and understandings, whether written or oral, relating to the subject matter of this Agreement, including, without limitation, the Offer Letter dated February 22, 2018.

[Signatures on Page Following]

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IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the day and year set forth above.

NABRIVA THERAPEUTICS US, INC. NABRIVA THERAPEUTICS PLC

By: /s/ Colin Broom  
Name: Colin Broom  
Title: CEO

EXECUTIVE:

/s/ Jennifer Schranz, MD  
Name: Jennifer Schranz, MD  
Title: Chief Medical Officer, Nabriva Therapeutics.

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Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

Execution Version 12-Nov 2018



### **AGREEMENT FOR THE COMMERCIAL & SUPPLY OF PRODUCTS**

**THIS AGREEMENT** (the “**Agreement**”) is made on the 12<sup>th</sup> day of November, 2018 between **ARRAN CHEMICAL COMPANY LIMITED**, of Units 1-3 Monksland Industrial Estate, Athlone, Republic of Ireland (hereinafter referred to as “**ARRAN**”); and **NABRIVA THERAPEUTICS IRELAND DAC**, of Suite 510, Regus Dublin Airport, Skybridge House Dublin Airport, Swords, County Dublin, Ireland (“**CLIENT**”)

**WHEREAS:-** Client sells and supplies certain substances for pharmaceutical use to third parties and CLIENT wishes to engage ARRAN to provide Services (defined below) including but not limited to development, manufacture, storage, analysis and release and supply of the Product to CLIENT.

#### **IT IS NOW AGREED AS FOLLOWS:-**

#### **1. DEFINITIONS**

1.1 In this Agreement unless the context otherwise requires:-

“**Affiliate**” means any company or business entity which controls, is controlled by, or is under common control with either ARRAN or CLIENT. For the purpose of this definition “**control**” means direct or indirect beneficial ownership of at least fifty per cent (50%) of the issued share capital with voting rights in such company or business entity;

“**ARRAN’s Facility**” shall mean ARRAN’s facility situated at Monksland Industrial Estate, Athlone, or such other place at which ARRAN or its sub-contractors (if applicable and as agreed between ARRAN and CLIENT), may from time to time provide the Services;

“**Applicable Laws**” shall mean all applicable rules, regulations and laws of European Union;

“**Claims**” means any and all claims, demands, suits, losses, liability, damage, fines, expenses and costs (including without limitation attorney’s fees and expenses and settlement costs) arising from any cause of action brought by any party (including without limitation either Party and/or a Third Party or Third Parties), whether in contract, tort (including, without limitation, negligence) warranty, strict liability, product liability, statutory duty or otherwise;

“**Confidential Information**” means all information whether commercial, financial, technical, operational or otherwise in any format, disclosed by one Party to the other Party in connection with this Agreement which by its nature is clearly confidential (whether or not that information is marked or designated as confidential or proprietary) whether disclosed orally in documentary form, by documentation or otherwise (including information obtained visually during site visits to either party) and including the terms of this Agreement;

“**Effective Date**” means the date of this Agreement or the commencement date of the Services whichever is earlier;

“**EU**” means the European Union;

“**EXW**” shall mean “*Ex works*”, as that term is defined in INCOTERMS 2010;

“**Intellectual Property Rights**” means any and all trade marks, rights in designs, get-up, trade, business or domain names, copyrights, future copyrights, patents, rights in databases (whether registered or not and any applications to register or rights to apply for registration of any of the foregoing), rights in inventions, know how, trade secrets and other confidential information and all other intellectual property rights of a similar or corresponding nature which may now or in the future subsist in any part of the world;

“**Party**” means a party to this Agreement;

“**Product**” means (R)-3-Cyclohexene-1-carboxylic Acid, CAS Number 5709-98-8;

“**Product Batch(es)**” means certain quantities of the Product to be agreed between the Parties from time to time;

“**Product Price**” means the price for the Product as set forth in Schedule 3 attached hereto.

“**Purchase Order**” means a formal document in written form issued by CLIENT to ARRAN containing a firm instruction as to the manufacture, testing, storage, release of the Product giving the following: purchase order number; Product identity; quantity required; Product Price; delivery date required; delivery address required; and invoice address;

“**Raw Materials**” means the materials, used in the manufacture of the Product, the specifications for which are set out in the Specification, to be procured by ARRAN on behalf of CLIENT and the cost of which shall be included in the Product Price;

“**Services**” means the services that ARRAN agrees to perform pursuant to Section 2.1 hereof in connection with the Product;

“**Specification**” means the written specifications for the development, manufacture, testing, and release of the Product as agreed between the Parties and as set out in Schedule 2 to this Agreement;

“**Territory**” means the US and/or EU (as defined herein) or such other territory as may be agreed by the Parties in writing from time to time, such agreement not to be unreasonably withheld;

“**Third Party**” shall mean a party other than ARRAN or Client and their respective Affiliates, officers, directors, employees and agents; and

“**US**” means the United States of America.

1.2 A reference to the singular includes the plural and vice-versa.

## 2. **PROVISION OF THE SERVICES**

2.1 In consideration of the payment to be made by the Client pursuant to the terms of this Agreement, ARRAN agrees to provide the Services, including but not limited to manufacture, storage, analysis, commercial release and supply of the Product to CLIENT.

2.2 In accordance with the terms and conditions of this Agreement, CLIENT shall:

- (a) provide ARRAN with full and comprehensive information concerning the intended use of the Product by CLIENT to enable ARRAN to understand and discharge its obligations under this Agreement; and
- (b) give full details to ARRAN of any complaint received by CLIENT in regard to the Product and discuss the appropriate response to the complaint with ARRAN where appropriate.

**3. FORECASTING AND ORDERING**

- 3.1 Client will place written orders and forecasts of its requirements for the Products in accordance with Schedule 1.
- 3.2 Client shall purchase its requirement of the Products in accordance with the binding elements of the Forecast as detailed in Schedule 1.

**4. DELIVERY**

- 4.1 Delivery of the Product shall be EXW ARRAN's Facility in accordance with Incoterms 2010. If requested by CLIENT, ARRAN shall assist CLIENT in arranging shipment of the Product to CLIENT or CLIENT's designated location in accordance with CLIENT's instructions and at CLIENT's risk and expense. All shipments will be subject to the standard terms and conditions of the selected courier and ARRAN shall have no liability to CLIENT for any loss, damage or delay in a shipment attributable to the selected courier or any Third Party.
- 4.2 Delivery of the Product shall be made together with the relevant batch documentation as required for release and in accordance with the Purchase Order, unless otherwise agreed between the Parties from time to time.
- 4.3 Risk of loss and title in the Product shall pass to CLIENT in accordance with the Incoterm set out in Section 4.1.
- 4.4 CLIENT will prepare, obtain, and maintain all necessary import and export registrations relating to the Product.

**5. CHARGES AND PAYMENT TERMS**

- 5.1 In consideration of ARRAN's provision of the Services under this Agreement, ARRAN shall submit invoices to CLIENT upon delivery of each Product Batch (or part thereof). CLIENT shall pay to ARRAN the charges set-forth in the applicable invoice for each Product Batch (or part thereof) delivered.
- 5.2 Payment will be made in full within [\*\*] from the date of the invoice being issued to CLIENT. All sums payable under this Agreement are exclusive of any applicable levy or taxes.
- 5.3 Where any undisputed payment due under this Section 5 has not been made by [\*\*] after the due date, ARRAN reserves the right to suspend the Services until all outstanding amounts have been paid.
- 5.4 The Product Price will updated annually in line with inflation in the Republic of Ireland and with changes in volumes, process efficiencies, yields, and batch sizes.



- 5.5 Notwithstanding Section 5.4 above, ARRAN shall have the right at any time to adjust the price of a batch of the Product by giving [\*\*] written notice thereof, provided that such adjustment represents the true substantiated change in costs of the Services resulting from changes in Raw Materials or changes in the costs of any and all activities sub-contracted.
- 5.6 In the event that CLIENT cancels a portion of the binding forecast or postpones the Services, ARRAN shall be entitled to charge CLIENT for any costs arising as a result of such cancellation or postponement, including all fees for Services rendered to the effective date of cancellation or postponement, non-cancellable costs, the cost of Raw Materials, and expenses and lost capacity reserved to perform the Services for the binding forecast, which cannot, with reasonable endeavours, be substituted with (an) alternative project(s). ARRAN shall provide CLIENT with an itemized invoice for its cancellation or postponement expenses and charges as soon as reasonably practicable following termination and winding-up of such work.

## 6. AUDITS, INSPECTIONS AND REGULATORY PROCEDURES

- 6.1 Subject to the undertakings as to confidentiality in this Agreement and on reasonable prior written notice, ARRAN shall permit employees or authorised representatives of CLIENT on any business day to enter and inspect those areas of ARRAN's Facility which directly relate to the manufacture and supply of the Product to:
- (a) conduct [\*\*] audit of ARRAN's Facility;
  - (b) as a result of a quality complaint relating to the Product, to conduct a for-cause audit provided however that ARRAN has been provided with not less than [\*\*] of such inspection,

PROVIDED THAT CLIENT shall ensure that such employees and representatives are qualified and competent to conduct such audits and that those employees and representatives comply with confidentiality provisions equivalent to those under this Agreement and with all regulations and reasonable instructions issued by ARRAN relating to the conduct of persons at ARRAN's Facility.

- 6.2 Either Party shall promptly notify the other Party of any regulatory inspections of ARRAN's Facility which it becomes aware in so far as such inspection relates to the Product. ARRAN shall have primary responsibility for preparing any responses which may be required by the regulatory authority and CLIENT shall upon request of ARRAN use its best endeavours to support and assist ARRAN in preparing such responses.

## 7. CONFIDENTIALITY

- 7.1 The Parties undertake to maintain any Confidential Information disclosed hereunder in confidence and not to disclose it to any Third Party without the prior written consent of the disclosing party, provided that the receiving party may disclose such Confidential Information to its Affiliates, employees, officers, directors and representatives who need to know such Confidential Information for the purpose of performing the Services. The obligations set out in this Section 7.1 shall not apply to any Confidential Information which:
- (a) was in the receiving party's possession prior to the date of disclosure by the disclosing Party, as evidenced by contemporaneous written records; or
  - (b) was subsequently disclosed to the receiving party, without any obligation of confidence, by a Third Party provided that the source was acting lawfully; or

- (c) is or subsequently becomes generally available to the public other than as a result of its disclosure by the receiving party in breach of this Agreement; or
- (d) is developed by or for the receiving party independently of the information disclosed by the disclosing party, as evidenced by contemporaneous written records.

7.2 A Party may disclose Confidential Information to the extent required by law, by any governmental or other regulatory authority, or by a court or other authority of competent jurisdiction provided that, to the extent it is legally permitted to do so, it gives the other Party as much notice as possible to permit such Party to seek a protective order or other similar order with respect to such Confidential Information.

## 8. WARRANTIES

- 8.1 ARRAN warrants only that (i) the Product supplied to CLIENT hereunder will have been manufactured and tested in accordance with the Specification, and will at the time of delivery conform with the Specification, and (ii) the ARRAN Background Intellectual Property (as defined below) does not infringe the Intellectual Property Rights of any Third Party. The foregoing shall be the sole and exclusive warranty of ARRAN and the remedies provided in Sections 8.4 and 8.5 provide the sole and exclusive remedies of CLIENT with respect to the Services and to this warranty provided by ARRAN.
- 8.2 All other warranties, express or implied including without limitations any implied warranty of merchantability or fitness for a particular purpose, are hereby disclaimed by ARRAN and excluded from these terms.
- 8.3 CLIENT warrants that:
- (a) it has authority to supply (and to authorise ARRAN to use in the manner contemplated by this Agreement) all specifications, instructions or information furnished by it to ARRAN and that any work undertaken on the basis of them or the sale of goods produced on the basis of such work shall not infringe the rights of any Third Party.
  - (b) it will comply with all applicable import and export laws and regulations.
- 8.4 CLIENT shall have the right to reject Product by notifying ARRAN in writing of any claim that any Product is damaged or defective or that any Product does not comply with the Specification: (i) in the case of a defect that is apparent upon normal visual inspection, within [\*\*] of receipt of such Product by CLIENT; or, (ii) in the case of latent defects or non-conformities that are not reasonably discoverable by visual inspection or through review of the manufacturing documentation provided by ARRAN, by notifying ARRAN of the defect or non-conformity after such period (within [\*\*] after CLIENT becomes aware of such defect or non-conformity). In the event of any notification and rejection pursuant to the preceding sentence, ARRAN shall (subject to the supply and availability of all Raw Materials to the extent that the Raw Materials cannot be reworked or re-used and provided that CLIENT demonstrates that the Product has been shipped, stored and/or handled by the CLIENT or any Third Party in accordance with the Specification and unless the cause of the notified problem has occurred post-delivery and through no fault of ARRAN's, or the notified problem is caused by faults in the Specification or other instructions or information provided by the CLIENT), replace the Defective Product within [\*\*] (or such other period which may be agreed between the Parties), at no extra cost to the CLIENT, and shall make arrangements with the CLIENT for the return or destruction of such Defective Product. ARRAN shall be liable only for the cost of any additional Raw Materials (to the extent that the Raw Materials cannot be reworked or re-used) required for ARRAN to replace the Defective Product. ARRAN's liability for the cost of replacement of Defective Product

shall be limited to the total value of the applicable Purchase Order. If replacement is not possible or if the replacement cost of the Defective Product exceeds the value of the applicable Purchase Order, ARRAN shall refund to CLIENT the portion of fees attributable to the Defective Product. Where the fault for non-conformity lies with the CLIENT in accordance with the provisions of this Section, the CLIENT shall pay to ARRAN the invoice price for the Services and the CLIENT will bear all costs associated with the rework and/or replacement of Defective Product by ARRAN (including for the avoidance of doubt, the cost of any Raw Materials).

- 8.5 Should the Product be rejected pursuant to Section 8.4 above, and should ARRAN (or CLIENT, if applicable) within [\*\*], of notice of such rejection, fail to agree that such rejection was reasonable, the Parties shall mutually agree upon a Third Party to test samples of such Product and to review records and test data and other relevant information developed by both Parties relating thereto to ascertain whether the particular batch of Product adheres to the requirements set forth in the Purchase Order. The findings of such Third Party shall be binding on both Parties. If the Product is found not to be Defective Product, the CLIENT shall pay the costs of such tests and shall be deemed to have accepted the applicable Product and the CLIENT shall pay to ARRAN the invoice price for the Product. If the Product is found to be Defective Product, ARRAN shall pay the costs of such tests and shall provide replacement Product in accordance with the provisions of Section 8.4.

## 9. INTELLECTUAL PROPERTY

- 9.1 Nothing in this Agreement shall affect, or grant any right to any Intellectual Property Rights owned by the Parties prior to the Effective Date or to the improvements, modifications or developments thereto arising during the term of this Agreement.
- 9.2 Subject to Section 9.3 of this Agreement, all Intellectual Property Rights which may arise in any documents, drawings, items, designs, processes, software or any other thing developed or produced by ARRAN or any of its employees or agents (whether in conjunction with CLIENT's employees or agents or not) in performance of the Services on behalf of CLIENT shall vest in CLIENT, unless otherwise agreed in writing between the Parties.
- 9.3 Notwithstanding anything to the contrary contained herein, CLIENT acknowledges that ARRAN and its professional staff currently possess certain inventions, processes, know-how, trade secrets, methods, approaches, analyses, improvements, other intellectual properties and other assets including, but not limited to, clinical trial management analyses, analytical methods, procedures and techniques, computer technical expertise and proprietary software, and technical and conceptual expertise in the area of manufacture, packaging and supplying products, all of which have been developed independently by ARRAN without the benefit of any information provided by CLIENT (collectively, "ARRAN Background Intellectual Property"). CLIENT agrees that any improvements, modifications or developments to the ARRAN Background Intellectual Property shall be and remain the sole and exclusive property of ARRAN.
- 9.5 No warranty is given by ARRAN that the Products do not infringe the Intellectual Property Rights of any Third Party and ARRAN shall not be liable for any liability, loss, costs, expenses or proceedings whatsoever and howsoever arising because of any such infringement.

## 10. INDEMNIFICATION

- 10.1 CLIENT agrees to indemnify ARRAN, its Affiliates, and their respective employees, agents, officers and directors from any and all Losses arising due to Third Party claims resulting from any of the following:

- (a) the infringement of a Third Party's intellectual property rights, to the extent arising from the use of information or instructions provided by CLIENT; and
- (b) the violation by CLIENT of any Applicable Law.

10.2 ARRAN agrees to indemnify CLIENT, its Affiliates, and their respective employees, agents, officers and directors from any and all Losses arising due to Third Party claims resulting from:

- (a) ARRAN's material breach of any term of this Agreement;
- (b) personal injury to any person arising as a result of ARRAN's negligence or intentional misconduct in performing the Services; and
- (c) the violation of any Applicable Law.

10.3 Notwithstanding the foregoing, each Party's obligation of indemnification in this Section 10 shall be reduced to the extent that the Third Party claim is held to have been caused by acts of negligence, wilful misconduct or breach of this Agreement by the Party seeking indemnification.

10.4 In this section the term "Losses" shall mean (i) all final damages and costs awarded against any of the indemnitees, (ii) reasonable legal fees in the case of litigation or arbitration, and (iii) out-of-pocket expenses reasonably incurred by the indemnitees in connection with the investigation or defence of the claims.

## 11. LIMITATION OF LIABILITY

11.1 Nothing in this Section 11 shall be deemed to exclude or limit the liability of either Party for any form of liability that may not be excluded or limited by law.

11.2 Neither Party, its Affiliates or their respective officers, directors, employees, agents and representatives shall be liable to the other, its Affiliates or their respective officers, directors, employees, agents and representatives whether in contract, tort (including negligence) or for breach of statutory duty or misrepresentation, or otherwise, for any:

- (a) loss of profits;
- (b) loss of contracts or opportunity;
- (c) increased production costs or cost of substitute services; or
- (d) indirect, special, incidental or consequential damages

suffered by any person under or in connection with this Agreement.

11.3 Except with respect to Claims for (a) wilful intent or gross negligence, (b) breach of confidentiality obligations under Section 7 (Confidentiality), (c) breach of intellectual property obligations under Section 9 (Intellectual Property) and (d) indemnification obligations under Section 10 (Indemnification), in which case ARRAN's liability shall be limited as set forth in Section 11.4 (below), the total aggregate liability of ARRAN and its Affiliates and their respective officers, directors, employees, agents and representatives for Claims arising under or in connection with this Agreement shall be limited to direct damages not to exceed [\*\*].

11.4 The total aggregate liability of ARRAN and its Affiliates and their respective officers, directors, employees, agents and representatives for Claims for (a) wilful intent or gross negligence, (b)

breach of confidentiality obligations under Section 7 (Confidentiality), (c) breach of intellectual property obligations under Section 9 (Intellectual Property) and (d) indemnification obligations under Section 10 (Indemnification) shall be limited to direct damages not to exceed [\*\*].

## 12. **INSURANCE**

- 12.1 Each Party shall maintain in full force and effect during the term of this Agreement, insurance in such amounts and covering such risks as is considered reasonable and prudent in the industry.
- 12.2 Each Party shall provide reasonable evidence of the current insurance held pursuant to Section 12.1, if requested by the other Party from time to time.

## 13. **TERM AND TERMINATION**

- 13.1 Subject to earlier termination as provided for in Sections 13.2 and 13.3 below this Agreement shall commence on the Effective Date and shall remain in force for a period of five (5) years from that date and shall continue thereafter unless or until terminated by either Party giving not less than twelve (12) months' written notice to terminate to the other Party expiring on or at any time after the expiry of the initial five (5) year term.

- 13.2 In the event that either Party:

- (a) suffers the appointment of a receiver or administrator over any part of its property or the presentation of a winding-up or passes a resolution for its winding-up except for amalgamation or reconstruction;
- (b) enters into any composition or arrangement with its creditors or becomes insolvent;
- (c) commits any irremediable breach of this Agreement;
- (d) commits any remediable breach of this Agreement and fails to remedy such breach within [\*\*] of receipt of written notice from the other Party requiring it to remedy the breach,

this Agreement may be terminated forthwith by the other Party upon written notice.

- 13.3 Termination of this Agreement (or any Purchase Order) for any reason will be without prejudice to the rights and obligations of the Parties accruing up to and including the date of such termination. For the avoidance of doubt CLIENT shall pay ARRAN all fees for Services rendered to the effective date of termination in accordance with the Purchase Order where there is any termination event referred to in this Section 13. All warranties and other provisions contained in Sections 7, 8, 9, 10, 11, 12, 13, 14 and 15 will survive termination of this Agreement. Further, after any termination or expiration of this Agreement, this Agreement shall remain in full force and effect with respect to any outstanding Services described on any Purchase Orders that are not completed as of the effective date of termination or expiration of this Agreement, unless such Services are specifically cancelled by written consent of both Parties.

- 13.4 In the event of termination of this Agreement due to a breach of this Agreement by ARRAN (but not otherwise), CLIENT shall have the right, but not the obligation to:

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- (a) purchase from ARRAN some or all usable stocks of Product, Raw Materials, components and in-process materials at the contract price in the case of the Product and otherwise at the cost price paid by ARRAN.

- 13.5 In the event of termination of this Agreement (other than as a result of the negligence, wilful default or other breach of the agreement by ARRAN), CLIENT shall be obliged to:

- (a) purchase all usable stocks of Product, Raw Materials, components and in-process materials at the contract price in the case of the Product and otherwise at the cost price paid by ARRAN; and
- (b) accept, at CLIENT's cost, return of all stocks of Raw Materials held by ARRAN.

- 13.6 In the event of termination of this Agreement, in addition to the fees for services rendered to the effective date of termination, ARRAN shall be entitled to charge CLIENT for the costs specified in Section 5.6 hereof.

## 14. **FORCE MAJEURE & SCIENTIFIC/TECHNICAL OBSTACLES**

- 14.1 Neither Party shall be in breach of this Agreement nor liable for delay in performing, or failure to perform, any of its obligations under this Agreement if such delay or failure results from events, circumstances or causes beyond its reasonable control, and in such circumstances the time for performance shall be extended by a period equivalent to the period during which performance of the obligation has been delayed or failed to be performed, provided that if the period of delay or non-performance continues for a period in excess of [\*\*], the Party not affected may terminate this Agreement by giving thirty (30) days' written notice to the other Party. ARRAN will use all reasonable endeavours to mitigate the effects of the force majeure on its performance and delivery of the Products.

- 14.2 If it becomes apparent to either Party at any stage in the provision of the Services that it will not be possible to complete the Services for scientific or technical reasons, the Parties shall agree on a plan for addressing the identified scientific or technical challenges. A thirty (30) day period shall be allowed for good faith discussion and attempts to resolve such problems. If such problems are not resolved within said period, the Parties shall have the right to terminate the applicable Purchase Order and ARRAN shall not be liable for any failure to perform or delay in performing any of its obligations. In the event Client terminates a Purchase Order as detailed above ARRAN's post termination rights as detailed in Section 13.3 shall take effect.

15. **GENERAL**

- 15.1 Neither Party shall assign or otherwise transfer this Agreement or any of its rights and obligations hereunder without the prior written consent of the other Party except to an Affiliate or a successor to its business that assumes all obligations of the assignor hereunder in connection with the transfer or sale of all or substantially all of its assets, or its merger or consolidation with or into any other entity, provided that no such assignment shall release the assignor from its obligations without the consent of the other Party hereto.
- 15.2 If any court or competent authority finds that any provision of this Agreement is invalid, illegal or unenforceable, that provision shall, be deemed to be deleted, and the validity and enforceability of the other provisions of this Agreement shall not be affected.

- 15.3 The Parties to this Agreement expressly agree that the United Nations Convention on the International Sale of Goods shall not apply.
- 15.4 No variation of this Agreement shall be effective unless it is in writing and signed by the Parties (or their authorised representatives).
- 15.5 This Agreement and any dispute or claim arising out of or in connection with it shall be governed by and construed in accordance with the laws of the Republic of Ireland.
- 15.6 The Parties shall attempt in good faith to resolve any controversy, claim, or dispute arising out of or relating to this Agreement, or its interpretation, performance, non-performance or any breach of any respective obligations hereunder through negotiations between their respective Managing Directors (or their designees). If such individuals or their designees are unable to resolve such dispute within [\*\*] of such written notice, either Party may initiate arbitration proceedings pursuant to Section 15.7.
- 15.7 Any dispute arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination shall be submitted to the jurisdiction of the courts of the Republic of Ireland. Each Party irrevocably waives any objection that it may now or hereafter have to the laying of the venue of any suit, action or proceeding brought in such court and any claim that such suit, action or proceeding brought in such court has been brought in an inconvenient forum.
- 15.8 This Agreement, including all of its appendices, contains the entire understanding of the Parties hereto and supersedes all previous agreements between the Parties with respect to the subject matter contained herein. Each Party acknowledges that, in entering into this Agreement, it has not relied on, and shall have no right or remedy in respect of, any statement, representation, assurance or warranty (whether made negligently or innocently) other than as expressly set out in this Agreement.
- 15.9 To the extent that there is a conflict between the terms contained in this Agreement and any Purchase Order, the conflict shall be resolved by interpreting the provisions in the following order of priority: (i) this Agreement (ii) the provisions of the Purchase Order.
- 15.10 Notices shall be given as follows:
- (a) All communications provided for in this Agreement shall be deemed duly given (subject to Section 15.10(b) below) if sent by first class mail, postage prepaid, overnight courier service or facsimile to the address and facsimile number of the respective Parties as set forth below or such other address of which that Party may from time to time notify the other in writing.

To ARRAN: ARRAN CHEMICAL COMPANY LIMITED  
c/o ALMAC GROUP LIMITED  
ALMAC House, 20 Seagoe Industrial Estate  
Craigavon  
BT63 5QD  
United Kingdom  
Attn: [\*\*]  
Fax: [\*\*]

To CLIENT: Nabriva Therapeutics Ireland DAC  
Suite 510, Regus Dublin Airport,

Skybridge House, Dublin Airport,  
Swords, County Dublin, Ireland  
Attn: Robert Crotty, General Counsel  
Email address: [\*\*]

With a copy to:

Nabriva Therapeutics GmbH  
Leberstrasse 20  
1110 Vienna  
Austria  
Attn.: Werner Heilmayer  
Email address: [\*\*]  
Fax: [\*\*]

- (b) All original investigation documents and legal notices as well as a copy of all notices required to be given under this Agreement shall be in writing and sent by certified mail, return receipt requested, or overnight courier to the address provided in Section 15.10(a), to the attention of "LEGAL COUNSEL". Such notices shall be effective on receipt.

15.11 This Agreement may be executed via facsimile or ".pdf" file and in two counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument

**IN WITNESS** whereof this Agreement has been duly executed on the date first above written.

SIGNED by: /s/ Colin Haybum Date: 12 Nov 2018  
Name: Colin Haybum  
Director  
for and on behalf of **ARRAN CHEMICAL COMPANY LIMITED**

SIGNED by: /s/ Michael Murphy Date: 13 Nov 2018  
Name: Michael Murphy  
Director  
for and on behalf of **NABRIVA THERAPEUTICS IRELAND DAC**



## SCHEDULE 1

### FORECASTS

#### A. Ordering

On or before the Effective Date CLIENT shall provide to ARRAN a forecast of CLIENT's anticipated monthly requirement for the Product for the following twelve (12) months (the "**Initial Forecast**"). The first six (6) months of this Initial Forecast shall be considered binding and ARRAN will be permitted to place orders on its suppliers for the Raw Materials in line with the requirements forecast for the first [\*\*].

#### B. Rolling Forecast

CLIENT shall provide to ARRAN, in continuation of the Initial Forecast, an updated forecast of demand for the following twelve (12) months, submitted on a [\*\*] basis (the "**Rolling Forecast**"). The quantities indicated in the Rolling Forecast for the first six (6) calendar months ahead of the current shall be considered binding and ARRAN shall deliver Product in accordance with the forecast and the Purchase Order as set-forth below. The quantities indicated in the Rolling Forecast for the remaining six (6) calendar months shall be considered an estimate of future requirements and shall be non-binding.

#### C. Purchase Orders

CLIENT shall provide ARRAN with Purchase Orders for batches of Product with the binding period of the Rolling Forecast. Upon receipt of the Purchase Orders, ARRAN shall review and confirm in writing acceptance or otherwise of the Purchase Order within [\*\*] from receipt.

Specific arrangements for the volume and timing of supply of the Products may be agreed in advance in writing between the Parties from time to time. Any additional costs to support such arrangements will be agreed in advance with CLIENT.

If for any reason ARRAN believes that it is or is likely to be unable to fulfil any part of the Purchase Order made by CLIENT for the Product, it shall promptly inform CLIENT in writing within [\*\*] of becoming aware that ARRAN is unlikely to be able to fulfil any part of the Purchase Order and the Parties will discuss in good faith a revised delivery date.

**SCHEDULE 2**  
**PRODUCT SPECIFICATION**

PRODUCT: **(R)-3-CYCLOHEXENE-1-CARBOXYLIC ACID**

CAS No: **[5709-98-8]**

Revision: 1  
Revision Date: 29SEP2017



**arran**  
CHEMICAL COMPANY LTD  
A Member of the Almac Group

TEST	SPECIFICATION
APPEARANCE	[**]
IR SPECTRUM	[**]
WATER CONTENT (Karl Fischer)	[**]
HPLC PURITY	[**]
SPECIFIC ROTATION	[**]
CHIRAL PURITY (HPLC)	[**]
<sup>1</sup> H NMR SPECTRUM	[**]
RESIDUAL SOLVENTS (GC)	[**]
RESIDUE ON IGNITION	[**]
HEAVY METALS	[**]

**SCHEDULE 3**

**PRODUCT PRICE**

<b>Description</b>	<b>kg</b>	<b>Price per kg (EUR)</b>	<b>Total price (EUR)</b>
	[**] kg	[**]	[**]
PRODUCT	[**] kg	[**]	[**]
	[**] kg	[**]	[**]

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

#### API SUPPLY AGREEMENT

THIS ACTIVE PHARMACEUTICAL INGREDIENT SUPPLY AGREEMENT (this “**Agreement**”) is made as of this 23<sup>rd</sup> day of November 2018 (“**Effective Date**”), by and between NABRIVA THERAPEUTICS IRELAND DAC (“**NABRIVA**”), with a principal place of business at Suite 510, Regus Dublin Airport, Skybridge House Dublin Airport, Swords, County Dublin, Ireland and HOVIONE LIMITED (“**HOVIONE**”), with a principal place of business at Loughbeg, Ringaskiddy, Co. Cork, Ireland. NABRIVA and HOVIONE shall be individually referred to as a “**Party**” and collectively referred to as the “**Parties**.”

WHEREAS, NABRIVA wishes to purchase from HOVIONE bulk API for use in manufacturing drug product for commercial sale by NABRIVA worldwide and for certain clinical and other purposes;

WHEREAS, HOVIONE has suitable facilities and equipment and sufficient qualified personnel to manufacture API in bulk form, and is willing to provide such API on the terms and conditions set forth below;

WHEREAS, Parties have entered into a Master Services Agreement dated 20 June 2016 and a Novation Agreement in relation thereto dated 22 December 2017 (collectively, the “**MSA**”) and agree that in case of any conflict or inconsistency between the terms of the MSA and the terms of this Agreement, the terms of this Agreement shall prevail; and

WHEREAS, Parties have entered into a Term Sheet dated October 2018, designated as “*Nabriva Lefamulin API Term Sheet*”, in which some terms and conditions of the Agreement have been mutually agreed;

NOW, THEREFORE, the Parties hereto, intending to be legally bound, agree as follows:

#### I. DEFINITIONS

As used in this Agreement:

- 1.1 “**Adverse Experience**” or “**AE**” shall mean any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with any use of a product or of a derivative thereof containing API, whether or not the adverse experience is considered to be related to the use of such product, including but not limited to any of the following: an unexpected side effect, injury, toxicity or sensitivity reaction, which may include an experience of unexpected incidence and severity; an adverse experience occurring in the course of the use of a drug product in professional practice; an adverse experience occurring in clinical studies; an adverse experience occurring from drug overdose, whether accidental or intentional; an adverse experience occurring from drug abuse; an adverse experience occurring from drug withdrawal; and any significant failure of expected pharmacological action.

- 1.2 “**Affiliate**” means any corporation or other business entity which, directly or indirectly, is controlled by, controls, or is under common control with NABRIVA or HOVIONE. For this purpose, “control” shall be deemed to mean direct or indirect ownership of fifty percent (50%) or more of the voting stock or other voting equity of such entity.
- 1.3 “**API**” means CAS 1350636-82-6, molecular formula  $C_{28}H_{45}NO_5S$ , and is more commonly known as lefamulin having those specifications as set forth on Schedule A hereto.
- 1.4 “**Applicable Law**” means all applicable ordinances, rules, regulations, laws, guidelines, guidance, and requirements of any kind whatsoever of FDA and any other Regulatory Bodies, as any of the foregoing may be amended from time to time, including without limitation, cGMP, applicable to the Manufacturing activities of the API in the Territory.
- 1.5 “**Batch**” means a batch of API, which is defined as approximately [\*\*] output.
- 1.6 “**cGMP**” means the current good manufacturing practices regulations applicable to the Manufacture of API as defined by the Q7 Guidance on Good Manufacturing Practices of the International Conference on Harmonization of Technical Requirements of Pharmaceuticals for Human Use (ICH Q7) and as promulgated by a Regulatory Body.
- 1.7 “**Campaign**” means equipment set-up and sanitization, at least [\*\*] Batches, visual cleaning and sanitization between all Batches and a change of line cleaning at the end of such campaign with no idle time included; *provided, however*, for calendar year 2019, a campaign shall consist of [\*\*] Batches.
- 1.8 “**Commercially Reasonable**” and “**Commercially Reasonable Efforts**” shall mean the level of diligence and/or efforts and commitment of resources consistent with the past practice of similarly situated pharmaceutical manufacturers with respect to comparable pharmaceutical products.
- 1.9 “**Confidential Information**” means all information, data, know-how and all other business, technical and financial data disclosed hereunder by one Party or any of its Affiliates to the other Party or any of its Affiliates, except any portion thereof which:
- (a) at the time of disclosure, is generally known to the public;
  - (b) after disclosure, becomes generally known to the public by publication or otherwise, except by breach of this Agreement by the recipient;
  - (c) the recipient can demonstrate by its written records was in the recipient’s possession at the time of such disclosure, and which was not acquired, directly or indirectly, from the disclosing party or its Affiliates;
  - (d) is lawfully disclosed to the recipient on a non-confidential basis by a third party who is not obligated to the disclosing party or any other third party to retain such Confidential Information in confidence;
  - (e) results from research and development by the recipient independent of such disclosure as shown by competent evidence from its written records; or

- (f) is required to be disclosed by applicable law, regulation, the order of a court of competent jurisdiction or by a government authority; provided, in each case the party so disclosing information, to the extent possible and legal, timely informs the other party and uses its reasonable efforts to limit the disclosure and maintain confidentiality to the extent possible and, if possible, permits the other party to attempt by appropriate legal means to limit such disclosure.

The Parties will, to the extent practical, use Commercially Reasonable Efforts to label or identify as confidential, at the time of disclosure all such Confidential Information disclosed orally, visually and/or in another intangible form to the receiving party.

- 1.10 “**Facility**” means the facility of HOVIONE located in [\*\*], or such other Manufacturing facility of HOVIONE as prior approved in writing by NABRIVA.
- 1.11 “**Firm Order**” means NABRIVA’s binding API requirements for a given [\*\*] period, which shall not exceed the Reserve Capacity on a per annum basis.
- 1.12 “**Forecast**” means a rolling [\*\*] forecast provided by NABRIVA of its requirements for API, of which the first [\*\*] shall constitute a Firm Order and the additional [\*\*] period following the period covered by a Firm Order, which is a non-binding forecast; *provided, however*, the forecast for months [\*\*] through [\*\*] shall not vary more than +/- [\*\*]% on an annual basis, unless otherwise agreed to by the Parties in writing. The non-binding portion of the forecast shall represent NABRIVA’s reasonable estimates only to facilitate HOVIONE’s planning.
- 1.13 “**HOVIONE Inventions**” shall mean all Inventions that relate to HOVIONE Technology or Confidential Information of HOVIONE, as well as any Inventions conceived, discovered, invented, developed, created, made or reduced to practice by HOVIONE and/or its agents or contractors in the performance of its obligations under this Agreement that are generally applicable (i.e. not pertaining exclusively to the API) and do not incorporate NABRIVA’s Confidential Information.
- 1.14 “**HOVIONE Technology**” shall mean the Technology developed or obtained by or on behalf of HOVIONE (a) prior to the Effective Date, or (b) independent of this Agreement and without the use of the Confidential Information of NABRIVA.
- 1.15 “**Inventions**” shall mean all discoveries, inventions, developments, modifications, innovations, updates, enhancements or improvements to Technology (whether or not protectable under patent, trademark, copyright or similar laws) that are conceived, discovered, invented, developed, created, made or reduced to practice in the performance of the Parties’ obligations under this Agreement.
- 1.16 “**Latent Defect**” shall mean a failure of the API to comply with Section 9.2 that (a) couldn’t reasonably have been identified through review of the records or the initial testing and inspection of the API, and (b) is the fault of HOVIONE. “Latent Defect” does not include any such failure of API to comply with cGMP or the Specifications that NABRIVA cannot show by Commercially Reasonable evidence was present at the time of delivery by HOVIONE.

- 1.17 “**Manufacture**”, “**Manufactured**” and “**Manufacturing**” means any steps, processes and activities used by HOVIONE to produce API, including without limitation, the manufacturing, processing, quality control testing, release or storage of API.
- 1.18 “**Minimum Annual Commitment**” means NABRIVA’s minimum amount of API that it has agreed to purchase from HOVIONE under this Agreement, which is 750kg per annum for the first year of the Initial Term (as defined in Section 16.1 hereof) and 1,500kg per annum for the remaining years of the Initial Term.
- 1.19 “**Minimum Yield Range**” means for each of the Starting Materials the range of weight by weight (% w/w) conversion into API as agreed to between the Parties according to Section 7.5.
- 1.20 “**NABRIVA Inventions**” means all Inventions other than HOVIONE Inventions.
- 1.21 “**NABRIVA Technology**” means the Technology of NABRIVA developed or obtained by or on behalf of NABRIVA (a) prior to the Effective Date, or (b) independent of this Agreement and without the use of the Confidential Information of HOVIONE.
- 1.22 “**New Drug Filings**” means a new drug application with the U.S. Food and Drug Administration, the marketing authorization application with the European Medicines Agency, or equivalent filings with the applicable Regulatory Bodies in the Territory.
- 1.23 “**Quality Technical Agreement**” means the form of quality assurance/quality control agreement to be entered into by the Parties, as set forth in Schedule B hereto, which sets forth responsibilities and key contacts for API quality and compliance related issues. HOVIONE shall provide NABRIVA with certain production and control information for review prior to release as to be specified in the Quality Technical Agreement. The Quality Technical Agreement also shall address annual product reviews, returned goods, regulatory audits, compliance with cGMP and the Regulatory Bodies, and such other quality related concerns deemed appropriate.
- 1.24 “**Purchase Price**” means the price to be paid by NABRIVA for a Firm Order, as calculated using the pricing set forth in Schedule C hereto.
- 1.25 “**Regulatory Bodies**” means any national agency or any government authority, department, legislature, agency, council, department, or official or public or statutory person (whether autonomous or not) of any country of the Territory that has the power to (a) grant approvals for the performance of Manufacturing services under this Agreement, or (b) issue regulations pertaining to the Manufacture or use of the API in the Territory, or such other jurisdictions as may be agreed by the Parties in this Agreement, including the U.S. Food and Drug Administration and the European Medicines Agency.
- 1.26 “**Reserve Capacity**” means the minimum annual capacity for the API to be reserved by HOVIONE for the Term, which shall be [\*\*]/year, assuming [\*\*]. Upon regulatory approval of lefamulin, NABRIVA, in its sole discretion, may enter into discussions with HOVIONE to increase manufacturing capacity for the API up to [\*\*]/annum, subject to (a) a lead time of at least [\*\*] for procurement, installation and qualification of additional manufacturing equipment, and (b) the Forecast increasing beyond [\*\*]/year.

- 1.27 “**Specifications**” means the specifications for the API, including the minimum shelf life requirements, as set forth in Schedule A hereto.
- 1.28 “**Starting Materials**” means [\*\*] and [\*\*].
- 1.29 “**Technology**” means all methods, techniques, trade secrets, copyrights, know-how, data, documentation, hardware, software and other intellectual property of any kind, whether or not protectable under patent, trademark, copyright or similar laws.
- 1.30 “**Term**” means the Initial Term (as defined in Section 16.1) and any extension thereto.
- 1.31 “**Territory**” means the countries and/or regions set forth in Schedule D hereto, which may be amended upon written agreement of the Parties.
- 1.32 “**Year**” means in the first year of this Agreement, the period from the Effective Date up to and including December 31 of the same calendar year, and thereafter will mean a calendar year.

## II. PURCHASE AND SALE

- 2.1 Purchase and Sale. HOVIONE agrees to Manufacture and supply to NABRIVA or its Affiliate (or a licensee of the foregoing) those quantities of API ordered pursuant to purchase orders placed by NABRIVA and its Affiliates and/or licensees from time to time in accordance with this Agreement. HOVIONE may not manufacture API for a third party without the prior written consent of NABRIVA. API supplied hereunder may be used by NABRIVA and its Affiliates and/or licensees for all purposes, including manufacturing of drug product for commercial sale or for clinical and other purposes.
- 2.2 Cooperation.
- (a) The Parties shall reasonably cooperate with each other as may be necessary and customary in consideration of industry practice, and shall disclose all material information necessary to enable each other to perform their respective duties hereunder in a timely fashion. NABRIVA shall work with HOVIONE to optimize a Campaign, when possible, to support HOVIONE’s productivity.
- (b) HOVIONE shall consult with NABRIVA regarding all methods, reagents, Starting Materials, protocols and the like used in performing its services hereunder and NABRIVA shall have final approval authority over all material aspects of the specific manufacturing processes for the API and analytical methods used by HOVIONE to fulfil any Firm Order, to the extent these are part of any New Drug Filings or critical for assuring meeting the Specifications. HOVIONE shall consult with NABRIVA at mutually acceptable prearranged times, to keep NABRIVA fully informed of the progress of the Firm Order.
- 2.3 Steering Committee. The Parties shall appoint a Joint Steering Committee comprising senior executive(s) of each Party, who together shall review and monitor planning and execution of the production of the API at regular intervals and resolve any disputes. The Parties also shall develop a joint operating team or supplier relationship management team, which shall work collaboratively to share appropriate information, insure targets and deadlines are met, identify risks and solutions and manage the relationship on behalf of the interests of both Parties, which



may include providing relevant information necessary to support production planning and capacity utilization while protecting company specific confidentiality.

- 2.4 Specific Duties of HOVIONE. In addition to its general obligations relating to the Manufacture and supply of API, HOVIONE shall be responsible for performing the following services:
- (i) Manufacture of API under cGMP;
  - (ii) quality control and testing of all API to monitor compliance with Specifications required by this Agreement;
  - (iii) conducting stability testing of API in accordance with the procedures set forth in the Quality Technical Agreement;
  - (iv) summarizing implemented changes and supplying latest versions of approved critical documentation, and providing other reasonable information necessary for NABRIVA to prepare, submit, obtain and maintain all regulatory filings relating to the API (and/or drug product containing or manufactured using API) under the terms of this Agreement;
  - (v) performing such other services as agreed upon in writing by the Parties; and
  - (vi) if HOVIONE is not able or not willing to provide the requested and forecasted quantities of API, HOVIONE shall reasonably support NABRIVA in transferring the manufacturing process, analytical methods, and materials to an alternate supplier in a timely manner.
- 2.5 Specific Duties of NABRIVA. In addition to its general obligations pursuant to this Agreement, NABRIVA shall be responsible for:
- (i) using Commercially Reasonable Efforts to include in any regulatory filing any re-processing steps to address any Manufacturing deficiencies for which reprocessing is applicable;
  - (ii) providing to HOVIONE the Starting Materials, at no cost, of appropriate quality to Manufacture compliant API according to the filed process, and in time for HOVIONE to start any Manufacture as planned; and
  - (iii) providing HOVIONE with access to knowledgeable NABRIVA personnel for consultation regarding the API, NABRIVA Confidential Information, Starting Materials and the Manufacture;
- 2.6 New Drug Filings. HOVIONE shall neither prepare nor file any New Drug Filings, which shall be NABRIVA's responsibility. NABRIVA shall own the New Drug Filings and shall be responsible for maintaining the New Drug Filings on file with the applicable Regulatory Bodies and making any amendments thereto. During the Term, NABRIVA shall provide copies to HOVIONE of relevant portions of any New Drug Filings relating to HOVIONE's Manufacturing of API for review pursuant to Section 3.3 of this Agreement. For each New Drug Filing, HOVIONE shall have the opportunity to inform NABRIVA that HOVIONE is unable to comply with the obligations required thereunder, and HOVIONE shall not be

deemed in breach of this Agreement for its inability to comply with any obligations in any New Drug Filings provided HOVIONE gives timely notice under Section 3.3 of this Agreement; *provided, however*, the Parties shall cooperate to resolve such non-compliance and to discuss in good faith any appropriate sharing of the costs related thereto based on the relative effort and benefit involved for each Party.

- 2.7 No Subcontracting. HOVIONE shall not subcontract any aspect of the Manufacturing and supply of the API hereunder, except with the prior written consent of NABRIVA.
- 2.8 Periodic Audits. HOVIONE will permit NABRIVA, upon at least [\*\*] prior written notice, and no more than once every second calendar year unless for cause, to have up to [\*\*] NABRIVA employees or representatives who cannot be competitors of HOVIONE and are subject to confidentiality obligations no less restrictive than those set forth in this Agreement accessing the Facility during operational hours to monitor and inspect, as reasonably needed, the Facility and relevant documentation to ascertain compliance by HOVIONE with the terms of this Agreement in the performance of the Manufacture, including cGMP, the Specifications, and Applicable Law. Each such inspection shall be conducted during normal business hours, will be no longer than [\*\*] in duration and will be at no charge. Additional inspections will be at NABRIVA's expense based on HOVIONE's standard fees.
- 2.9 NABRIVA Representatives at the Facility. NABRIVA will have the right to request to have an employee and/or representative present at the Facility during the preparation for or conduct of any manufacturing or production run for manufacture or packaging of the API, and such representative shall be free to inspect and oversee all aspects of such preparation or production run and to comment to HOVIONE thereupon; *provided, however*, HOVIONE's approval of such request shall not be unreasonably withheld. Any NABRIVA employees or representative present at the Facility shall adhere to all applicable HOVIONE policies, safety and security procedures. NABRIVA shall retain full liability and responsibility for the presence and actions of its employees or representatives at HOVIONE's premises. Any information or other matters observed during audits will be construed as HOVIONE's Confidential Information and maintained by NABRIVA as confidential pursuant to Section IV of this Agreement.
- 2.10 Audits for Cause. In addition to the periodic audits referred to in the previous Section, in the event: (a) the Regulatory Bodies schedule a regulatory inspection of the Facility in which the API is Manufactured; (b) HOVIONE receives a "Warning Letter" or Form 483 Observations from the FDA (or a similar correspondence from any applicable Regulatory Bodies) relating to the Manufacture of the API by HOVIONE or compliance with cGMP's at the Facility where the Manufacturing, or other activities related to the API occurs; (c) NABRIVA has rejected a shipment of API for failure to meet Specifications; or (d) NABRIVA otherwise has reasonable concern regarding the quality or Manufacturing of API supplied by HOVIONE, NABRIVA shall have the right to conduct additional audits in respect of API according to the terms specified hereof. The audit for cause shall be subject to at least [\*\*] prior written notice.

### III. API QUANTITY, QUALITY AND MANUFACTURING PROCESSES; TECHNICAL ASSISTANCE

- 3.1 Quantity. HOVIONE shall supply NABRIVA and/or its licensee(s) with quantities of API up to the Reserve Capacity on the terms set forth in this Agreement. HOVIONE shall have

no obligation to supply API in quantities exceeding the Reserve Capacity, but shall use its Commercially Reasonable Efforts to accommodate NABRIVA's demand for such excess quantities. NABRIVA undertakes to purchase from HOVIONE, and shall require its Affiliates and/or licensees to purchase from HOVIONE, not less than [\*\*] percent ([\*\*]%) of API demand for commercial sale in the Territory, subject to the Reserve Capacity (the "HOVIONE Share"). NABRIVA shall be free to obtain from a third party any portion of the HOVIONE Share that HOVIONE is unwilling or unable to supply.

- 3.2 Specification: Quality Standards: Changes. All API Manufactured and sold by HOVIONE to NABRIVA under this Agreement shall meet the Specifications, as well as the quality assurance standards established in the Quality Technical Agreement. Such Specifications, as well as the terms and conditions of the Quality Technical Agreement, are subject to modification from time to time by written agreement of the Parties. Notwithstanding the foregoing, if NABRIVA finds it necessary or desirable to change the Specifications, the Quality Technical Agreement, or any other aspect of the Manufacturing process for API, NABRIVA may deliver a request for such change to HOVIONE and HOVIONE shall use Commercially Reasonable Efforts to make any change identified in such request. Prior to implementation of any such changes, the Parties agree to negotiate in good faith to reach agreement on, if applicable, (a) the new price for any API Manufactured and supplied hereunder by HOVIONE which embodies such changes, based solely on the effect of such changes on HOVIONE's Manufacturing costs for the API (including, but not limited to, the cost of raw materials) and (b) any other amendments to this Agreement which may be necessitated by such changes (*e.g.*, an adjustment to the lead time for purchase orders). NABRIVA's obligation to bear cost increases in the foregoing clause (a) shall be limited to those cost increases that relate solely to the production of the API; costs for other changes affecting cGMP or affecting other products generally (other than the API Manufacturing costs) shall be borne by HOVIONE.
- 3.3 Manufacturing Processes. NABRIVA has provided HOVIONE with its Manufacturing procedures for the API, and HOVIONE shall not materially modify such procedures without the prior written consent of NABRIVA. The Parties shall agree on the equipment to be used to produce the API in the Quality Technical Agreement. Prior to submitting New Drug Filing, NABRIVA shall provide a draft of the relevant section of such New Drug Filing relating to the Manufacture of API to HOVIONE for review and to confirm the accuracy of the information. HOVIONE shall review such draft submitted by NABRIVA under this Section 3.3, preferably within [\*\*] but no later than within [\*\*], and provide any necessary comments accordingly.
- 3.4 Documentation. NABRIVA has provided HOVIONE with analytical methods, product specifications, product impurities, degradation products, and reference standards for the Manufacture of the API as set forth in the Specifications. HOVIONE shall promptly provide NABRIVA, on an ongoing basis, with all available safety data and information concerning the API, process, and related materials, including without limitation, all safety data sheets ("SDSs") as well as any new information developed or learned by HOVIONE in connection with the Manufacturing of API hereunder. In addition, HOVIONE shall provide all the change control and regulatory documentation as required by the Regulatory Bodies to maintain licenses, either by directly disclosing such information to NABRIVA or, where applicable, by filing such information with the Regulatory Bodies and permitting NABRIVA to reference such filing(s).

- 3.5 Communication. Each Party shall make Commercially Reasonable Efforts to respond to requests for support, information and approvals from the other Party within [\*\*]. If a complete response is not possible within such [\*\*] period, the Party owing the response shall communicate within such [\*\*] period the reason for the delay and when the response shall be available.
- 3.6 Quality Technical Agreement. Within [\*\*] of the Effective Date, representatives of the Parties' quality assurance departments shall meet to review and revise, if necessary, and execute the Quality Technical Agreement. The terms contained in the Quality Technical Agreement are intended to complement the terms of this Agreement, and they shall be interpreted as complementary to the extent possible. In the event of a conflict between the terms of the Quality Technical Agreement and the terms of this Agreement, the terms of this Agreement shall control with respect to business, financial and legal matters, and the terms of the Quality Technical Agreement shall control with respect to quality control and quality assurance matters related to the API (including, without limitation, Manufacturing, testing, storage, release, change management and validation activities); *provided, however*, that the inclusion of a particular term or level of detail in the Quality Technical Agreement where such term or level of detail is absent from this Agreement shall not be deemed to constitute a conflict between the two agreements. Only where competing terms in the two agreements conflict in terms of the principal focus of an express prescription or prohibition in the agreements shall a conflict between the two agreements be deemed to exist. Any material breach of the Quality Technical Agreement shall be deemed a breach of this Agreement.

#### IV. CONFIDENTIAL INFORMATION

- 4.1 The Parties acknowledge that each Party has, prior to the Effective Date, provided its Confidential Information to the other Party in connection with the Manufacture and supply of the API, and further acknowledge that all such Confidential Information (as well as any additional Confidential Information provided by one Party to the other hereunder) shall be subject to the provisions of this Section IV. Notwithstanding anything to the contrary herein, the following shall be deemed to be the Confidential Information of NABRIVA (and not of HOVIONE): (a) any and all information, knowledge, technology, and trade secrets relating directly to or encompassing the API and its Manufacture that is provided by NABRIVA to HOVIONE, whether before, on, or after the Effective Date; and (b) any and all Manufacturing records or other information or documentation delivered to NABRIVA by HOVIONE relating to the Manufacture of API hereunder, other than HOVIONE Confidential Information; and (c) any NABRIVA Inventions. Notwithstanding anything to the contrary herein, HOVIONE Technology and HOVIONE Inventions, whether or not labeled confidential, shall be deemed to be the Confidential Information of HOVIONE (and not of NABRIVA).
- 4.2 During the Term of this Agreement and for [\*\*] thereafter, all Confidential Information shall be held in confidence by the receiving Party, shall not be used by the receiving Party for any purpose except as provided hereunder and shall not be disclosed to third parties except as provided in Section 4.3 or as may otherwise be permitted by the advance written consent of the disclosing Party. Any Affiliate, director, officer, employee, consultant, or agents who receives Confidential Information shall be advised as to the confidential nature thereof and the prohibitions contained herein, and any copies of any portions of any Confidential Information that are disclosed to as provided in this Section shall be identified as confidential.

- 4.3 Notwithstanding Section 4.2, each Party may disclose Confidential Information of the other Party to its Affiliates, directors, officers, employees, agents or consultants who have a need to know exclusively in connection with the performance of their duties in satisfying the obligations of such Party hereunder and who are subject to written obligations of confidentiality and non-use that are no less restrictive than those set forth herein. Any Affiliate, director, officer, employee, agent or consultant who receives Confidential Information shall be advised as to the confidential nature thereof and the prohibitions contained herein. All copies of any portions of any Confidential Information distributed as provided in this Section shall be identified as confidential.
- 4.4 Upon termination of this Agreement, and upon the request of the disclosing Party, the receiving Party shall return or destroy all Confidential Information and any copies thereof in its possession, except that each Party may retain one copy of Confidential Information solely for archival purposes. Termination of this Agreement shall not operate to extinguish either Party's obligation to treat Confidential Information as provided herein, and the same shall continue in effect in accordance with this Section.
- 4.5 Nothing contained herein shall be deemed to grant to either Party, either expressed or implied, a license or other right or interest in the Confidential Information of the other or in any patent, trademark or other similar property of the other.
- 4.6 Neither Party shall use the name of the other in any press releases or other statements to the public (including publicity, promotional materials, or advertising), nor publicly disclose the existence of this Agreement for any purpose (other than as may be required by applicable law or regulation), without the prior written consent of the other, which shall not be unreasonably withheld or delayed.

## V. FORECASTS AND ORDERS

- 5.1 Orders and Forecasts. Upon the execution of this Agreement, NABRIVA shall provide an initial Forecast commencing with the month following the Effective Date. NABRIVA also shall provide HOVIONE with an initial Firm Order. NABRIVA shall purchase API in full Batches. Subject to NABRIVA's full compliance of its obligation to provide to HOVIONE the Starting Materials of appropriate quality to Manufacture compliant API, HOVIONE shall keep a stock of raw materials, intermediate components, and API adequate to meet the requirements of the Firm Order taking into account the Manufacturing schedule and lead times for sourcing the Starting Materials. During the Term, NABRIVA shall place Firm Orders for all Campaigns as soon as any Campaign becomes part of the Firm Order. Purchase orders for API shall be issued by NABRIVA to the Facility. For each additional Campaign requested by NABRIVA beyond those in the Firm Order in a calendar year, HOVIONE shall make Commercially Reasonable Efforts to Manufacture the additional Campaign.
- 5.2 Forecasts Changes and Forecast Updates. On or before the [\*\*] of each calendar year within the Term, NABRIVA shall provide HOVIONE with an additional [\*\*] purchase order to supplement the remaining [\*\*] of the Firm Order, thereby establishing a new Firm Order. NABRIVA also shall provide an updated Forecast for the period following the new Firm Order. Provided a Firm Order does not exceed the Reserve Capacity, HOVIONE shall accept the Firm Order and shall supply NABRIVA in accordance with the Firm Order; *provided, however,* in case of any conflict or inconsistency between the terms of the Firm

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Order and the terms of this Agreement, the terms of this Agreement shall prevail. NABRIVA may increase or decrease the quantities of the Firm Order with HOVIONE's prior written agreement and HOVIONE may adjust its shipping quantities with NABRIVA's prior written agreement. HOVIONE shall use Commercially Reasonable Efforts to execute all Firm Orders received and accepted pursuant to this Section V at the delivery date proposed by HOVIONE on receipt of the Firm Order.

- 5.3 Starting Materials. NABRIVA shall deliver the required Starting Materials from vendors that have been mutually agreed to and approved by the Parties, at no cost and of appropriate quality and quantity to HOVIONE a minimum of [\*\*] in advance of the proposed start date for the Campaign. Where NABRIVA is aware that delivery of the Starting Materials may be delayed, it shall immediately inform HOVIONE and the Parties shall enter good faith discussions to align the delivery of the Starting Materials with the planning for the relevant Campaign. Notwithstanding the forgoing, in case of late delivery and where any good faith discussions between the Parties do not resolve the impact of late delivery of the Starting Materials, and/or in case of quality issues affecting the use of Starting Materials provided by NABRIVA in the Manufacturing of the API, HOVIONE reserves the right to reschedule the start of the relevant Campaign based on available capacity planning and to charge NABRIVA a fee up to [\*\*] percent ([\*\*]%) of the cost of the Campaign as compensation for any idle capacity, with HOVIONE making Commercially Reasonable Efforts to re-allocate idle capacity to other projects and, to the extent successful, reducing or waiving the fee accordingly. The value of any Starting Materials purchased by HOVIONE that cannot be used in a next Campaign and needs to be disposed of, due to shelf life or otherwise and as a direct result of the delayed delivery by NABRIVA, shall be separately invoiced to NABRIVA in addition to the up to the [\*\*] percent ([\*\*]%) mentioned above. HOVIONE shall keep NABRIVA informed of any exposure to import duties and value added tax that are suspended at the time of import in anticipation that the resulting API will be exported. If at any time, this export is not verified and monies for the suspended duties and VAT become due, NABRIVA shall promptly reimburse HOVIONE.
- 5.4 Minimum Annual Commitment. Where the amount of API purchased by NABRIVA in a contract year is less than the Minimum Annual Commitment for such year, NABRIVA shall pay HOVIONE the value of such shortfall, in a lump sum payment and discounted by [\*\*] percent ([\*\*]%), within [\*\*] after HOVIONE invoices NABRIVA for such shortfall. If regulatory approval for API is delayed past [\*\*], the Minimum Annual Commitment for [\*\*] shall be reduced from 1,500kg to 750kg; *provided, however,* if such regulatory approval for API is delayed primarily due to HOVIONE, the Minimum Annual Commitment shall be reduced by [\*\*] for each month or partial month of such delay. In either case, if it is not feasible for HOVIONE to reduce production already scheduled for [\*\*], any production above the reduced Minimum Annual Commitment in [\*\*] shall be used to reduce the Minimum Annual Commitment for [\*\*]. If the Starting Materials supplied by NABRIVA become obsolete due to a delay in regulatory approval for API primarily due to HOVIONE, the cost of replacement materials shall be borne by HOVIONE subject to the limitation of liability herein provided.

## VI. PRICE, SHIPMENT AND PAYMENT

- 6.1 HOVIONE's Responsibilities. HOVIONE shall Manufacture the API so it may be lawfully and safely shipped to NABRIVA or its designee worldwide and shall package the API for shipment in accordance with the Specifications. HOVIONE shall prepare and execute all

reasonably necessary shipping documents, consisting of Packing List, Dangerous Goods

Declaration, and SDS. NABRIVA shall choose the carrier and the designee by indicating both on its purchase order provided to HOVIONE.

6.2 Terms of Shipment.

(i) HOVIONE will ship API FCA (Incoterms 2010) [\*\*] packaged ready for export, including such items required to confirm shipment of goods under controlled condition such as temp tales, documentation suitable for export of the supplied product under controlled conditions and other measures required to satisfy the Quality Technical Agreement, EC Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01), and other Regulatory Bodies' guidance. In amplification of the provisions regarding FCA Incoterms 2010, and not in limitation thereof, HOVIONE shall directly or indirectly through NABRIVA, upon request of NABRIVA and at NABRIVA 's cost and risk, assist in (i) addressing special shipping requirements, (ii) obtaining licenses, official authorizations, clearances, customs, or any other documents and/or information, including security related information that NABRIVA may require for the export, import or transport of the API to the final destination; (iii) making a contract for carriage; and (iv) loading the packed API in any container, collecting vehicle or other means of transport. NABRIVA shall, upon request of HOVIONE, provide information required for taxation or reporting purposes in respect of the export of the API. HOVIONE shall arrange for transportation to its destination in accordance with NABRIVA's written instructions, including use of the common carrier designated by NABRIVA. If NABRIVA does not designate a common carrier, HOVIONE may select the common carrier. Title and risk of loss shall pass from HOVIONE to NABRIVA when the API is delivered to the common carrier. All transport and insurance costs will be borne by NABRIVA.

(ii) NABRIVA will ship Starting Materials DDP (Incoterms 2010) [\*\*].

6.3 Shelf Life. HOVIONE will make Commercially Reasonable Efforts that API when shipped to NABRIVA, assuming it is shipped immediately following full release, will have a remaining shelf life of not less than [\*\*] (based on an assumed registered shelf life of [\*\*]);

6.4 Pricing. HOVIONE shall invoice NABRIVA based on the pricing set forth in Schedule C hereto. Prices may be adjusted annually based on reasonable cost increases, inflation, continuous improvement activities and other factors positively or negatively impacting cost.

6.5 Additional Costs. Additional costs (*e.g.* additional sample testing, long-term storage of starting and/or final materials), as well as any regulatory support over and above that reasonably required to support a stable, robust and reproducible commercial production process, shall be invoiced separately from the commercial manufacturing batches and costs; this shall be handled under the MSA or similar and the Parties shall agree in good faith on any costs related thereto.

6.6 Taxes. Any use, sales, excise or value added tax, duty, custom, inspection or testing fee, or any other tax, fee or charge of any nature whatsoever imposed by any governmental authority on or measured by a transaction between the Parties, shall be paid by NABRIVA in addition to the prices quoted or invoiced by HOVIONE. In the event HOVIONE is

required to pay any such tax, fee, or charge, NABRIVA shall reimburse HOVIONE for such payment, or *in lieu* of such payment, NABRIVA shall provide HOVIONE at the time the order is submitted an exemption certificate or other document acceptable to the authority imposing the tax, fee or charge.

- 6.7 Import and Export. Without limiting the generality of any other provisions of this Agreement, and in addition to any other amounts due to HOVIONE under this Agreement, NABRIVA shall be responsible for all costs or liabilities incurred by HOVIONE in connection with the import or export of Starting Materials including, but not limited to, the costs of any bank or other guaranties required of HOVIONE by customs authorities, any penalties or fines levied against HOVIONE that are related to such import or export, and any costs incurred by HOVIONE in connection with any claims or proceedings relating to the foregoing. If applicable, HOVIONE shall provide customary export documentation, as specified by NABRIVA in writing or by separate delivery and shipment documentation instructions, together with each shipment of API (or such other deliverables). HOVIONE also shall provide NABRIVA with all relevant shipping information (*e.g.*, carrier, shipment details, scheduled arrival date, quantity) prior to or coincident with shipping any API (or such other deliverables) under this Agreement.
- 6.8 Terms of Payment. Prior to the start of a scheduled Campaign, HOVIONE shall invoice NABRIVA upon issuance of a purchase order for [\*\*] percent ([\*\*]%) of the Purchase Price to allow for raw material sourcing. On the start of a scheduled campaign, HOVIONE shall invoice NABRIVA an additional [\*\*] percent ([\*\*]%) of the Purchase Price as an advance on manufacturing costs. HOVIONE shall invoice NABRIVA for the remaining [\*\*] percent ([\*\*]%) of the Purchase Price upon the issuance of the Certificate of Analysis, together with copies of all documentation required for release of the API as provided in the Quality Technical Agreement, unless otherwise agreed between the Parties in writing. With the issuance of the last invoice HOVIONE confirms that API is released and ready for shipment.
- 6.9 Invoicing and Payment. NABRIVA shall pay HOVIONE the amounts owed under an invoice within [\*\*] after the date of the invoice from HOVIONE. Late payments shall bear interest at the then-current United States prime rate as reported in the Wall Street Journal Europe Edition, or if less, the highest rate permitted under Applicable Law.
- 6.10 Cost Improvement Program. The Parties agree to share cost improvement measures related to the Manufacturing of API. All cost improvement investments specific for such API shall require consent of both Parties. HOVIONE shall be entitled to receive reimbursement for reasonable costs which it incurred in developing such cost improvements measures. Cost improvement benefits concerning such improvements to the Manufacturing of API shall be allocated equitably between the parties and reflected in the Purchase Price.

## VII. INSPECTION AND ANALYSIS

- 7.1 Inspection by HOVIONE. HOVIONE shall analyze each API lot for compliance with the Specifications set forth in Schedule A. HOVIONE shall send to NABRIVA a Certificate of Analysis and a Certificate of Compliance, together with any other documentation required under the Quality Technical Agreement prior to, or together with, each shipment of API. In this regard, HOVIONE agrees to retain all records and documents necessary to fulfill the requirements established by Applicable Law.



7.2 Inspection by NABRIVA. NABRIVA or its authorized representative shall visually inspect all shipments upon their receipt and shall report any reasonably discernible defects in the API to HOVIONE within [\*\*] of its receipt of the API and related records (the “**Inspection Period**”). Prior to the expiration of the Inspection Period for a shipment of API, NABRIVA will provide prompt written notice to HOVIONE if any such API does not comply with the warranties set forth in Section 9.2. Such notice will specify the nature of the API’s non-compliance. Except in case of a Latent Defect, failure by NABRIVA to provide such notice within the applicable Inspection Period will be deemed an acceptance of such API by NABRIVA. Any Latent Defects shall be reported to HOVIONE by NABRIVA within [\*\*] of NABRIVA’s discovery of the same. Section 7.3 will only be applicable to a Latent Defect if and to the extent (i) the Latent Defect is reported to HOVIONE no later than [\*\*] after NABRIVA’s acceptance of a batch of API and (ii) the notice states in a reasonably sufficient detail the reason for the Latent Defect.

7.3 Non-Conforming API.

- (a) When due primarily to HOVIONE’s fault or omission, if any API does not meet the warranties set forth in Section 9.2 as determined by NABRIVA’s testing and inspection of the API and/or review of the documentation provided by HOVIONE, then HOVIONE shall re-process or re-work such non-conforming API into conforming API. If re-processing or re-working is not possible, due to regulatory or other reasons, then solely at its option NABRIVA may, as its sole remedy, require that HOVIONE either (i) replace said API at no charge to NABRIVA and pay all round-trip shipping charges to and from the destination of the original shipment, (ii) refund to NABRIVA the Purchase Price for the rejected API and any applicable shipping costs (including customs duties), or (iii) credit NABRIVA’s account in an amount equal to the Purchase Price for the rejected API and any applicable shipping costs (including customs duties). HOVIONE shall reimburse NABRIVA for the reasonable costs incurred by NABRIVA in properly disposing of any non-conforming API. Any notice given hereunder shall specify the manner in which the API fails to conform to the purchase order or fails to meet such warranty or the Specifications. HOVIONE shall not re-work or re-process such non-conforming API without prior written notice to NABRIVA.
- (b) If during a Campaign the quality of API is not compliant with the Quality Technical Agreement and/or the Specifications, and if such non-compliance is attributable to HOVIONE, HOVIONE shall compensate NABRIVA for the cost of the Starting Materials used and supplied by NABRIVA, calculated on the basis of USD [\*\*] per kg of [\*\*] and USD [\*\*] per kilogram of [\*\*] and shall not invoice the service cost for any such Campaign or relevant part thereof.
- (c) The remedies set forth in this Section 7.3 are NABRIVA’s sole remedies under this Agreement with respect to non-conforming API.

7.4 Independent Testing. When due primarily to HOVIONE’s fault or omission, if NABRIVA notifies HOVIONE that any API does not meet the warranties in Section 9.2, and HOVIONE does not agree with NABRIVA’s position, the Parties shall attempt to reach a mutually acceptable resolution of the dispute. If they are unable to do so after a reasonable period (such period not to exceed [\*\*] from the date of original notification), the matter shall be submitted to an independent testing laboratory acceptable to both Parties. Such testing laboratory shall use the testing methods contained in the Specifications. Both

Parties shall accept the judgment of the independent laboratory. The cost of such testing shall be borne by the party whose position is determined to have been in error.

7.5 Expected Yield and Yield Review. Within [\*\*] of January 1<sup>st</sup> 2020, following the first year of commercial Manufacture under this Agreement, the Parties will jointly define the initial Minimum Yield Range for each of the Starting Materials, based on yield data provided by HOVIONE for all relevant Batches of API Manufactured during calendar year 2019. Following this, within [\*\*] of each January 1<sup>st</sup> during the Term, the Parties will in good faith discuss reasonable adjustments to the Minimum Yield Range for each of the Starting Materials based on the previous year's actual API yield performance (the "**Actual Annual Yield**"). The Parties will at such time agree upon the appropriate Minimum Yield Range for each of the Starting Materials for the subsequent period. The updated Minimum Yield Ranges will be defined based on yield data provided by HOVIONE for all relevant Batches of API Manufactured during the last 12-month period, or any other period as mutually agreed between the Parties. If the Parties are unable to agree on such period or the revised Minimum Yield Range for any of the Starting Materials, then such dispute will be resolved in accordance with Section 17 hereof. For the avoidance of doubt, increases due to changes in Batch size or Campaign size are not considered yield improvements, nor will Batches with established root causes for unusually high or low yields be considered in determining a revised Minimum Yield Ranges.

7.6 Reconciliation of Yield and Credits.

- (a) Within [\*\*] of each January 1<sup>st</sup> during the Term, the Parties shall perform a yield analysis for each of the Starting Materials using the calculations set forth in Schedule E hereto, which may be revised on mutual written agreement between the Parties from time to time. The results of the yield analysis for each of the Starting Materials shall be added together to determine the Actual Annual Yield.
- (b) If the Actual Annual Yield is less than the lower end of the Minimum Yield Range, then there is a shortfall for the efficient use of the Starting Materials that Year. If even after offsetting this shortfall with any remaining Surplus according to Section 7.6(c) below, there is a remaining shortfall for that Year (the "**Shortfall**"), then HOVIONE will deduct the corresponding amount of the Shortfall from the next invoice to be issued to NABRIVA.
- (c) If the Actual Annual Yield is more than the higher end of the Minimum Yield Range, then there is a surplus for the efficient use of the Starting Materials that Year (the "**Surplus**"). If there is a Surplus, then HOVIONE shall have the right to offset that Surplus against any future Shortfall for the Starting Materials.
- (d) Upon expiration or termination of this Agreement, any remaining Shortfall credit amount owing under this Section 7.6 will be deducted from any remaining invoice(s) pending to be issued to NABRIVA or otherwise paid into NABRIVA's account within [\*\*] of the date of termination or expiration.

VIII. REGULATORY MATTERS; REGULATORY FILINGS AND APPROVALS

8.1 General.

- (a) HOVIONE shall be responsible for obtaining and maintaining all site licenses for the Manufacture of the API and shall comply with other applicable regulations promulgated by the Regulatory Bodies in connection with the Manufacture of the API.
- (b) NABRIVA shall be responsible for obtaining and maintaining, at its expense, all regulatory licenses and approvals necessary for NABRIVA to use and sell the API provided under this Agreement, including, without limitation, all submissions filed with the FDA or other Regulatory Bodies.

IX. REPRESENTATIONS AND WARRANTIES

9.1 General.

- (a) Either Party represents and warrants one to the other that (i) it is, and will remain, a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of organization; and (ii) the execution and delivery of this Agreement has been authorized by all requisite corporate action. This Agreement is and will remain a valid and binding obligation of the executing Party, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors.
- (b) HOVIONE represents and warrants to NABRIVA that (i) it has and shall maintain throughout the term of this Agreement, the expertise, with respect to personnel and equipment, to fulfill the obligations established hereunder, and has obtained all requisite material licenses, authorizations and approvals required by Applicable Law to Manufacture the API in accordance with this Agreement; (ii) the Facility, equipment and personnel to be employed shall be qualified to Manufacture API according to current cGMP at the time each such batch of API is produced, and that the production facility to be employed is in compliance with Applicable Law; (iii) there are no pending or uncorrected citations or adverse conditions noted in any inspection of the Facility to be employed which would cause the API to be misbranded or adulterated within the meaning of the United States Federal Food, Drug and Cosmetic Act, as amended, or other Applicable Law; (iv) the execution, delivery and performance of this Agreement by HOVIONE does not conflict with, or constitute a breach of any order, judgment, agreement, or instrument to which HOVIONE is a party; (v) the execution, delivery and performance of this Agreement by HOVIONE does not require the consent of any person or the authorization of (by notice or otherwise) any governmental or regulatory authority; and (vi) HOVIONE has not been debarred by the FDA under the Generic Drug Enforcement Act of 1992 (or by any analogous agency or under any analogous law or regulation), and neither it nor, to its knowledge, any of its officers or directors has ever been convicted of a felony under the laws of the United States for conduct relating to the development or approval of a drug product or relating to the marketing or sale of a drug product, and further, to its knowledge, that no individual or firm debarred by any governmental authority shall participate in the performance, supervision, management or review of the production of API supplied to NABRIVA under this Agreement.
- (c) NABRIVA represents and warrants to HOVIONE that (i) the execution, delivery and performance of this Agreement by NABRIVA does not conflict with, or

constitute a breach of any order, judgment, agreement, or instrument to which NABRIVA is a party; (ii) the execution, delivery and performance of this Agreement by NABRIVA does not require the consent of any person or the authorization of (by notice or otherwise) any governmental or regulatory authority (other than those relating to the granting of approval to commercialize the product containing the API); (iii) to the best of NABRIVA's knowledge, the use of NABRIVA Confidential Information as contemplated in the Services will not infringe the intellectual property rights of any third party and NABRIVA will promptly notify HOVIONE in writing should it become aware of any claims asserting such infringement; and (iv) NABRIVA will comply with all Applicable Law in its use of the API.

9.2 Manufacturing Warranty. HOVIONE represents and warrants that at all times during the term of this Agreement:

- (a) the Facility shall remain in compliance with, and the API shall be Manufactured and delivered in compliance with all cGMPs, Applicable Laws, the Specifications; and the Quality Technical Agreement in effect at the time of Manufacture;
- (b) all API Manufactured by HOVIONE, at the time of delivery to the common carrier, (i) will not be adulterated or misbranded, and (ii) will be free and clear of any lien, security interest or encumbrance;
- (c) each document provided with or in a connection with the shipment of the API is accurate.

9.3 Warranty Disclaimer. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS ANY WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

#### X. QUALITY CONTROL, RECORDS AND INSPECTIONS

10.1 Samples. HOVIONE shall maintain samples of API as required by Applicable Law or as otherwise mutually agreed by NABRIVA and HOVIONE in writing. HOVIONE shall be responsible for maintaining retention samples of the API as may be required by Applicable Law.

10.2 Validation. HOVIONE shall qualify or validate all process, methods, equipment, utilities, facilities and computers used in the Manufacturing, storage, testing and release of API in conformity with all Applicable Laws. NABRIVA shall have the right to review the results of said qualification or validation upon request.

10.3 Quality Compliance. As stipulated in the Quality Technical Agreement, HOVIONE shall provide NABRIVA with timely notification of all significant deviations, notes to file, and other deficiencies that may reasonably be expected to impact the quality of the API, as well as all FDA or other applicable Regulatory Bodies reports regarding testing, Manufacture, bulk packaging or labeling of the API.

10.4 Manufacturing Records. HOVIONE shall maintain complete and accurate records relating to the API and the Manufacture, bulk packaging, labeling and testing thereof for the period required by the applicable Regulatory Bodies, and HOVIONE shall provide copies thereof

to NABRIVA upon NABRIVA's reasonable request. The records shall be subject to audit and inspection under this Section X.

- 10.5 Batch Records. Records which include the information relating to the Manufacturing, bulk packaging and quality operation for each lot of API shall be prepared by HOVIONE at the time such operations occur. HOVIONE shall prepare such records in accordance with cGMP's, the Specifications and the Quality Technical Agreement.
- 10.7 Regulatory Inspections. HOVIONE shall promptly inform NABRIVA of any contact, inspection or audit by any Regulatory Bodies related to or affecting the API. HOVIONE shall promptly provide NABRIVA with copies of any Regulatory Bodies-issued inspection observation reports (including without limitation FDA Form 483s and equivalent forms from other regulatory bodies) and agency correspondence that may reasonably be expected to adversely affect the API or HOVIONE's ability to supply API hereunder. HOVIONE and NABRIVA shall cooperate in resolving any concerns with any Regulatory Bodies. HOVIONE shall also inform NABRIVA of any action taken by any Regulatory Bodies against HOVIONE or any of its officers and employees which may reasonably be expected to adversely affect the API or HOVIONE's ability to supply API hereunder within [\*\*] after the action is taken.

XI. COMPLAINTS, ADVERSE EVENTS AND RECALLS

- 11.1 API Complaints and AEs. NABRIVA shall maintain complaint files with respect to the pharmaceutical product containing API in accordance with cGMPs. If HOVIONE should receive any complaints and or AE notices with respect to the pharmaceutical product containing API, HOVIONE shall promptly notify NABRIVA by facsimile transmission or equivalent within [\*\*] of its receipt thereof. All such notices shall be sent to the attention of the:

To NABRIVA: Chief Medical Officer  
Fax No. [\*\*]

General Counsel  
E-mail: [\*\*]

NABRIVA shall promptly provide HOVIONE with copies of any complaints received by NABRIVA relating to the pharmaceutical product containing API if such complaints relate to the Manufacture or bulk packaging of the API. NABRIVA shall have the exclusive responsibility for responding to all complaints, and for promptly providing HOVIONE with a copy of any responses to complaints relating to the pharmaceutical product containing the API if such complaints relate to the Manufacture or bulk packaging of the API. NABRIVA or its Affiliates shall have responsibility for reporting all complaints relating to the pharmaceutical product containing API to the FDA and any other regulatory authorities, including, but not limited to, complaints relating to the Manufacture or bulk packaging of the API as well as adverse experience (AE) reports. NABRIVA shall correspond with complainants as to any complaints associated with pharmaceutical product containing API, whether received during or after the term hereof. HOVIONE shall assist NABRIVA in investigating complaints relating to the pharmaceutical product containing API if such complaints relate to the Manufacture or bulk packaging of the API, by analyzing API and Manufacturing processes to determine the nature and cause of an alleged API Manufacturing defect or alleged API failure. HOVIONE shall also reasonably assist

NABRIVA, if so expressly required by NABRIVA from time to time, in the investigation of any Adverse Experience (AE) reported to either party when such AEs are reasonably believed to be attributable to the Manufacture or bulk packaging of the API. If NABRIVA determines that any reasonable physical, chemical, biological or other evaluation should be conducted in relation to an AE or complaint relating to the Manufacture or bulk packaging of the API, HOVIONE shall reasonably conduct the evaluation and use its Commercially Reasonable Efforts to provide NABRIVA with a written report of such evaluation within [\*\*] from receipt of NABRIVA's written request for same, together with samples of the API from the relevant lot. The obligations and responsibility in connection with such AEs and the management of the same shall pertain to NABRIVA exclusively.

- 11.2 Recall Action. If NABRIVA should elect or be required to initiate a recall of pharmaceutical product containing or manufactured using API supplied hereunder, or a withdrawal or field correction of such pharmaceutical product, HOVIONE shall assist NABRIVA (and/or its Affiliate(s)) in connection with such recall, withdrawal, or field correction, including, without limitation, by conducting an investigation to determine the extent to which the API contributed to the need for such recall, withdrawal, or field correction. All regulatory authority contacts and coordination of any recall activities shall be initiated by, and shall be the sole responsibility of, NABRIVA.
- 11.3 Recall Expenses. If a recall or a withdrawal of any pharmaceutical product containing or manufactured using API is necessary for any reason, HOVIONE and NABRIVA shall each bear the costs of the recall in proportion to each Party's responsibility, if any, for the error necessitating the recall or withdrawal. Such recall costs include, but are not limited to, all reasonable costs and expenses of NABRIVA and HOVIONE associated with implementing any such recall or withdrawal, including notification, packaging, shipping, distribution, and destruction costs and required reimbursements to third parties, and all costs and expenses associated with obtaining replacement product (including API).
- 11.4 Recall Records. HOVIONE shall maintain complete and accurate records for such periods as may be required by Applicable Law.

## XII. INSURANCE

- 12.1 During the term of this Agreement, HOVIONE shall maintain in full force and effect valid and effective insurance policies relating to its property, plant, equipment, obligations, liabilities, representations and warranties as contemplated herein. HOVIONE's coverage shall be not less than USD [\*\*] (or the equivalent amount in other currency) per loss occurrence and per aggregated loss occurrences per year, with the exception of Employer's liability/workers' compensation, where HOVIONE's coverage shall not be less than USD [\*\*]. HOVIONE shall provide to NABRIVA, upon NABRIVA's written request, evidence of adequate liability insurance coverages and the amounts thereof. Such coverage shall be with an insurance company having an A.M. Best rating of at least A-VII (or its equivalent) and shall have to be maintained for as long as HOVIONE has obligations under this Agreement.
- 12.2 During the term of this Agreement, NABRIVA agrees to maintain in full force and effect valid and effective insurance policies that are reasonably sufficient to cover its obligations, liabilities, representations and warranties as contemplated herein. NABRIVA's coverage shall be not less than USD [\*\*] (or the equivalent amount in other currency) per loss occurrence and per aggregated loss occurrences per year.

### XIII. INVENTIONS

- 13.1 Background Technology. All rights to and interest in NABRIVA Technology will remain the exclusive property of NABRIVA, and all rights to and interest in HOVIONE Technology will remain the exclusive property of HOVIONE. NABRIVA grants HOVIONE the right to use NABRIVA Technology and NABRIVA Improvements for the limited purpose of fulfilling HOVIONE's obligations under this Agreement.
- 13.2 NABRIVA Inventions. NABRIVA shall own all right, title, and interest in and to any NABRIVA Inventions, along with all intellectual property rights, with respect thereto. HOVIONE agrees to communicate all NABRIVA Inventions promptly to NABRIVA. HOVIONE hereby assigns and transfers to NABRIVA all right, title, and interest in the NABRIVA Inventions, and HOVIONE agrees to take all further acts reasonably required to evidence such assignment and transfer to NABRIVA at NABRIVA's expense. All NABRIVA Inventions shall be automatically considered as Confidential Information of NABRIVA under the terms of Section IV.
- 13.3 HOVIONE Inventions. It is expressly agreed that Section 13.1 above is not applicable to HOVIONE Inventions (and relevant intellectual property rights). In this case, therefore, any HOVIONE Inventions, and the relevant intellectual property rights, shall belong to HOVIONE, and such HOVIONE Inventions are and will be assigned to HOVIONE or its designee without additional compensation to NABRIVA. NABRIVA will take such steps as HOVIONE may reasonably request and at HOVIONE's expense to vest in HOVIONE or HOVIONE's designee ownership of the HOVIONE Improvements.
- 13.4 Patents. NABRIVA will have the exclusive right to prepare, file, prosecute, maintain and defend, at its sole expense, any patent applications and/or patents that claim NABRIVA Inventions. HOVIONE will have the exclusive right to prepare, file, prosecute, maintain and defend, at its sole expense, any patent applications and/or patents that claim HOVIONE Inventions.

### XIV. INDEMNIFICATION

- 14.1 By HOVIONE. HOVIONE shall indemnify and hold NABRIVA, its Affiliates, directors, officers, employees, agents, successors, and assigns harmless from any and all liability, damage, loss, cost, or expense (including reasonable attorneys' fees) ("**Losses**"), to the extent arising out of or resulting from any third party claim, suit or action ("**Claim**") related to gross negligence or willful misconduct by HOVIONE or its Affiliates, or any breach by HOVIONE of any covenant, representations and/or warranties hereunder, except, in each case, to the extent NABRIVA is obligated to indemnify HOVIONE under Section 14.2.
- 14.2 By NABRIVA. NABRIVA shall indemnify and hold HOVIONE, its Affiliates, directors, officers, employees, agents, successors, and assigns harmless from any and all Losses, to the extent arising out of or resulting from any Claim related to (i) any pharmaceutical products containing or manufactured using the API, to the extent such products are sold by or on behalf of NABRIVA or its Affiliates, or (ii) any gross negligence or willful misconduct by NABRIVA or its Affiliates, or (iii) any breach by NABRIVA of any of its covenants, representations and/or warranties hereunder in each case, except to the extent such Losses or Claims result from the matters contemplated in Section 14.1.

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- 14.3 By Each Party. If gross negligence or willful misconduct of both HOVIONE and NABRIVA contribute to any Loss, HOVIONE and NABRIVA shall each indemnify and hold harmless the other with respect to that portion of the Loss attributable to its negligence or willful misconduct.
- 14.4 Procedures. If one Party receives notice of a Claim for which it is entitled to indemnification by the other party, the party receiving notice shall give prompt notification to the indemnifying party. The party being indemnified shall cooperate fully with the indemnifying party throughout the pendency of the Claim, and the indemnifying party shall have complete control over the conduct and disposition of the Claim including the retention of legal counsel engaged to handle such matter. The indemnifying party hereunder shall not be liable for any costs associated with the settlement of any Claim brought against it or the other party unless it has received prior notice of the settlement negotiations and has agreed to the settlement.

### XV. LIMITATION OF LIABILITY

- 15.1 NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, IN NO EVENT SHALL HOVIONE OR NABRIVA BE LIABLE TO THE OTHER FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR INDIRECT DAMAGES HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS OR REVENUES, ARISING OUT OF OR IN ANY WAY RELATED TO THIS AGREEMENT. THIS LIMITATION WILL APPLY EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE
- 15.2 SUBJECT TO SECTION 15.3 HEREOF, IN NO EVENT SHALL HOVIONE'S TOTAL LIABILITY HEREUNDER EXCEED THE LESSER OF \$[\*] OR [\*].
- 15.3 NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION XV IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY WITH RESPECT TO ANY THIRD-PARTY CLAIMS UNDER SECTION 14.1 OR 14.2 OR THE DAMAGES AVAILABLE FOR BREACH OF THE CONFIDENTIALITY OBLIGATIONS IN SECTION IV.

### XVI. TERMINATION

- 16.1 Term. This Agreement shall become effective and remain in effect for a period of seven (7) years from the Effective Date (the "**Initial Term**") and, unless either of the Parties gives written notice of non-renewal at least two (2) years prior to the end of the Initial Term (or any renewal term), this Agreement shall be renewed for consecutive terms of two (2) years.
- 16.2 Breach. If either Party hereto commits a material breach of any of its obligations under this Agreement or the Quality Technical Agreement,

the other Party may, at its option, terminate this Agreement by giving the breaching party at least [\*\*] prior written notice of its intent to terminate this Agreement, which notice shall specify the breach and the termination date, unless the breaching Party cures said breach prior to the specified termination date.



- 16.3 Insolvency. Either party may terminate this Agreement immediately in its entirety if the other Party files a petition of bankruptcy, is adjudged bankrupt, takes advantage of any insolvency act, or executes a bill of sale, deed of trust, or assignment for the benefit of creditors.
- 16.4 Survival. The rights and obligations contained in Sections covering representations and warranties, indemnification and confidentiality shall survive termination of this Agreement, as will any rights to payment or other rights or obligations that have accrued under this Agreement prior to termination. Termination shall not affect the liability of either Party by reason of any act, default, or occurrence prior to said termination.
- 16.5 Transfer. If either party terminates this Agreement, HOVIONE shall upon request and for a period of no more than [\*\*], and at NABRIVA's expense, provide reasonable assistance in transferring manufacturing of API to a facility owned by NABRIVA or a third party selected by NABRIVA.
- 16.6 Return of Materials. Upon termination or expiration of this Agreement, HOVIONE shall return to NABRIVA or NABRIVA's nominee all materials in its stock and belonging to NABRIVA and shall deliver to NABRIVA, against payment of the applicable price, any remaining API.
- 16.7 Other Obligations Upon Termination. Upon termination or expiration of this Agreement, HOVIONE will suspend work as early as possible and will invoice NABRIVA and NABRIVA shall promptly reimburse HOVIONE for:
- (i) the reasonable, documented costs and expenses related to the termination of this Agreement which are not ordinarily planned as close-out of Manufacture, including, but not limited to: (a) the disposal of API, samples, and raw materials directly related to HOVIONE's obligations hereunder; and (b) staff time and related costs necessary to transfer any API relevant know-how or other information to NABRIVA;
  - (ii) any outstanding, unpaid invoices issued by HOVIONE;
  - (iii) any amount not yet invoiced but owed by NABRIVA under this Agreement for (a) work in process to Manufacture the API; and (b) API that is in HOVIONE's Facilities to fulfill purchase orders placed by NABRIVA prior to the notice date of termination; and
  - (iv) reimbursement for any materials purchased (that cannot be cancelled) and/or held by HOVIONE for a Firm Order, or as otherwise agreed by the Parties in writing, as of the notice date of termination; and
  - (v) the Minimum Annual Commitment as defined in Section 16.8 below.
- 16.8 Termination upon Non-Approval. If NABRIVA has no need for the API because API is (i) not approved by the Regulatory Bodies; (ii) market approval is withdrawn in the Territory; or (iii) NABRIVA and any licensees decide not to file for approval or withdraw API from the market, within [\*\*] of such cancellation news, NABRIVA may terminate this Agreement by paying HOVIONE immediately for the value of the Minimum Annual

Commitment, minus [\*\*] percent ([\*\*]%), for (i) the next [\*\*] if this Agreement is terminated prior to receiving any regulatory approval; (ii) the next [\*\*] if terminated after receiving the first regulatory approval; or (iii) the remaining Term, whichever is the shorter. Notwithstanding the foregoing, HOVIONE shall make Commercially Reasonable Efforts to re-allocate any released resources to other projects and, to the extent successful at the date termination becomes effective shall accordingly reduce or waive such charge. The value of any Starting Materials purchased by HOVIONE to meet the Firm Order or otherwise on the direction of NABRIVA that cannot be used for another HOVIONE customer and need to be disposed of, due to shelf life or otherwise, as a result of not meeting the Minimum Annual Commitment, shall be deducted from the [\*\*] percent ([\*\*]%) discount.

## XVII. GOVERNING LAW AND ALTERNATIVE DISPUTE RESOLUTION

- 17.1 This Agreement shall be governed by and construed in accordance with the laws of England and Wales, without regard to any choice of law principle that would dictate the application of the law of another jurisdiction. The Parties agree that the provisions of the United Nations Convention on Contracts for the International Sale of Goods will not apply to this Agreement, and are hereby expressly excluded.
- 17.2 Both Parties understand and appreciate that their long term mutual interest shall be best served by effecting a rapid and fair resolution of any claims or disputes which may arise out of services performed under this contract or from any dispute concerning contract terms. Therefore, both Parties agree to use their best efforts to resolve all such disputes as rapidly as practicable on a fair and equitable basis. Toward this end both Parties agree to develop and follow a process for presenting, rapidly assessing, and settling claims on a fair and equitable basis.
- 17.3 If any dispute or claim arising under this contract cannot be readily resolved by the Parties pursuant to the process described in Section 17.2, the Parties agree to refer the matter to a panel consisting of [\*\*] employed by each Party who is not directly involved in the claim or dispute for review and resolution. A copy of the contract terms, agreed upon facts (and areas of disagreement), and concise summary of the basis for each side's contentions shall be provided to both such senior executives who shall review the same, confer, and attempt to reach a mutual resolution of the issue.
- 17.4 If the matter has not been resolved utilizing the process set forth in this Article XVII, and the Parties are unwilling to accept the non-binding decision of the panel, any said dispute shall be submitted to binding arbitration for final decision.
- 17.5 It is expressly agreed that arbitration shall be held in English language in London, England in accordance with the Rules of Arbitration of the International Chamber of Commerce ("**ICC Rules**"), except where those rules conflict with these provisions, in which case this provision controls. The arbitration shall be conducted by a single arbitrator appointed in accordance with the ICC Rules. The arbitrator may engage an independent expert with experience in the subject matter of the dispute to advise the arbitrator. Within [\*\*] of initiation of arbitration, the Parties shall reach agreement upon and thereafter follow procedures, including limits on discovery, assuring that the arbitration will be concluded and the award rendered within no more than [\*\*] from selection of the arbitrator or, failing agreement, procedures meeting such time limits will be designed by the arbitrator and

adhered to by the Parties. The arbitrator shall decide the merits of any dispute in accordance with the law governing this Agreement, without application of any principle of conflict of laws that would result in reference to a different law. The decision and/or award rendered by the arbitrator shall be written, final and non-appealable and may be entered and enforced in any court of competent jurisdiction. Unless otherwise agreed by the Parties in writing, the costs of any arbitration, including administrative fees and fees of the arbitrator, shall be borne by the non-prevailing Party, but each Party shall bear its own attorney and expert fees. The Parties agree that, notwithstanding any provision of applicable law, they will not request, and the arbitrator shall have no authority to award, punitive or exemplary damages against either Party. Pending the selection of the arbitrator or pending the arbitrator's determination of the merits of any dispute, either Party may seek appropriate interim or provisional relief from any court of competent jurisdiction as necessary to protect the rights or property of that Party.

#### XVIII. MISCELLANEOUS

- 18.1 Headings. The headings and captions used herein are for the convenience of the Parties only and are not to be construed to define, limit or affect the construction or interpretation hereof.
- 18.2 Severability. If any provision of this Agreement is found to be invalid or unenforceable, then the offending provision shall not render any other provision of this Agreement invalid or unenforceable, and all other provisions shall remain in full force and effect and shall be enforceable, unless the provisions which have been found to be invalid or unenforceable, to the fullest extent permitted by law. If any such affected provision materially affects the commercial basis of this Agreement, the Parties shall negotiate in good faith to amend the provisions of this Agreement to preserve and afford to each Party the full extent of benefits that this Agreement is intended to provide.
- 18.3 Entire Agreement. This Agreement, including all those Schedules appended hereto, contains the entire agreement of the Parties regarding the subject matter hereof and supersedes all prior agreements, understandings or conditions (whether oral or written) regarding the same. Further, this Agreement may not be changed, modified, amended or supplemented except by a written instrument signed by the duly authorized representatives of the Parties. Neither Party has relied on any representation except as may be expressly set forth herein.
- 18.4 Assignability. Without the prior written consent of the other Party, neither Party shall assign or otherwise transfer this Agreement or any of its rights and obligations hereunder except to an Affiliate or a successor to its business that assumes all obligations of the assignor hereunder in connection with the transfer or sale of all or substantially all of its assets, corporate reorganization, or its merger or consolidation with or into any other entity, provided that no such assignment shall release the assignor from its obligations without the consent of the other Party hereto.
- 18.5 Further Assurances. Each Party hereto agrees to execute, acknowledge and deliver such further instruments, and to take such other actions, as may be necessary or appropriate to carry out the purposes and intent of this Agreement.

- 18.6 Waiver. The waiver by either Party of a breach of any provisions contained herein shall be effective only if made in writing and shall in no way be construed as a waiver of any succeeding breach of such provision or the waiver of the provision itself.
- 18.7 Force Majeure. A Party shall not be liable for nonperformance or delay in performance (other than of obligations regarding confidentiality) caused by any event reasonably beyond the control of such Party including, without limitation, hostilities, revolutions, wars, riots, civil disturbances, national emergencies, strikes, lockouts, unavailability of supplies, epidemics, fires, floods, earthquakes, other forces of nature, explosions, embargoes, or any other Acts of God, or any laws, proclamations, regulations, ordinances, or other acts or orders of any court, government or governmental agency. Any occurrence of force majeure shall be reported promptly to the other Party. The Party claiming force majeure must demonstrate that such event directly impacts its ability to perform its obligation under this Agreement in a timely manner and take commercially reasonable efforts to mitigate such force majeure. A Party whose performance has been excused shall perform such obligation as soon as is reasonably practicable after the termination or cessation of such event or circumstance. The other Party has no right to demand indemnity for damage; provided, however, in the event force majeure preventing performance shall continue for more than six (6) months, either Party may terminate this Agreement with a written notice to the other without any liability hereunder, except the obligation to make payments due to such date.
- 18.8 Remedies. Each Party agrees and acknowledges that its disclosure of Confidential Information in breach of this Agreement may cause irreparable harm to other Party, and therefore that any such breach or threatened breach may entitle such Party to seek injunctive relief, in addition to any other legal remedies available in a court of competent jurisdiction.
- 18.9 Good Faith. The Parties agree to perform this Agreement in a spirit of good faith and fair dealing, and each shall seek to avoid intentionally doing anything that would deprive the other of the full benefits contemplated hereunder. Neither Party shall use any affiliate or third party as a means of avoiding its responsibilities under this Agreement. The Parties agree to communicate openly and in a spirit of co-operation to insure all services are rendered in accordance with the highest degree of professional competence, cGMPs and any other applicable law, regulation or regulatory requirement.
- 18.10 Independent Contractors. The Parties are independent contractors under this Agreement. Nothing contained in this Agreement is to be construed so as to constitute NABRIVA and HOVIONE as partners, agents or employees of the other, including with respect to this Agreement. Neither Party hereto shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party or to bind the other Party to any contract, agreement or undertaking with any third party unless expressly so authorized in writing by the other Party.
- 18.11 Publicity. Each Party undertakes to the other that it shall keep the existence and nature of this Agreement confidential and not use this Agreement or the name of the other Party in any press release, publicity, advertisement, promotional materials, or other disclosure with regard to this Agreement without the prior written consent of the other Party, except as may be required by applicable laws or regulations or the rules of a recognized stock exchange.

- 18.12 Drafting. This Agreement was negotiated at arm's-length and entered into freely by the Parties and upon the advice of their respective counsel. All Parties hereto are to be deemed the drafters of this Agreement. No provision hereof shall be construed in favor of or against any Party hereto based upon principles of *contra proferentem* or any other presumption as to inequality of bargaining power or otherwise.
- 18.13 Counterparts. This Agreement shall be executed by the duly authorized officers of the Parties. This Agreement may be executed in one (1) or more counterparts, including by facsimile or other electronic transmission, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 18.14 Notices. Except as otherwise expressly stated herein, all notices, consents or approvals required by this Agreement shall be in writing and sent by overnight courier service, certified or registered air mail, postage prepaid, or by facsimile or email (confirmed by such certified or registered mail) to the Parties at the following addresses or such other addresses as may be designated in writing by the respective Parties. Notices shall be deemed effective on the date of mailing.

If to NABRIVA: Nabriva Therapeutics Ireland DAC,  
Suite 510, Regus Dublin Airport,  
Skybridge House Dublin Airport,  
Swords, County Dublin, Ireland  
Attention: General Counsel  
E-mail: [\*\*]  
Fax No.: [\*\*]

With copy to: Nabriva Therapeutics GmbH  
Leberstrasse 20  
1110 Vienna  
Austria  
Attn.: Werner Heilmayer  
Email address: [\*\*]  
Fax: [\*\*]

All HOVIONE invoices and/or charges in billing should be directed to the Accounting Department at:

Nabriva Therapeutics Ireland DAC  
Attention: VP of Technical Operations  
E-mail: ap-ic@nabriva.com

If to HOVIONE: Hovione FarmaCiencia SA  
Estrada do Paço do Lumiar,  
Campus do Lumiar, Edificio R,  
1649-038 Lisboa  
Portugal  
Attention: VP Sales & Marketing

With copy to: Hovione FarmaCiencia SA  
Estrada do Paço do Lumiar,  
Campus do Lumiar, Edificio R,  
1649-038 Lisboa

Portugal  
Attention: General Counsel  
E-mail: [\*\*]

All NABRIVA purchase orders shall be sent to:

HOVIONE LIMITED  
[\*\*]  
Attention: General Manager  
Fax: [\*\*]

- 18.15 Solicitation of Employees. Except with the other Party's written approval, during the Term, a Party shall not actively solicit for employment the employees of the other Party who are involved in the relationship of the Parties under this Agreement and further, any employees possessing intrinsic technical, analytical or manufacturing know-how. This Section does not preclude: (a) solicitations made by a recruiting firm on behalf of a Party, provided the firm was not instructed to specifically hire employees of the other Party, and (b) employees of the other Party proactively enquiring for or responding to publicized job opportunities with the Party. In the event a Party hires an employee of the other Party in breach of this Section 18.15, the other Party may recover stipulated damages in the amount of [\*\*] percent ([\*\*]%) of that employee's annualized W-2 earnings, or equivalent, at the time the Party hires the employee.

IN WITNESS WHEREOF, the undersigned Parties have caused this Agreement to be executed as of the date first above written.

NABRIVA THERAPEUTICS IRELAND DAC

By: /s/ Michael Murphy  
Name: Michael Murphy  
Title: Director

HOVIONE LIMITED

By: /s/ Guy Villax  
Name: Guy Villax  
Title: CEO

By: /s/ Frédéric Kahn  
Name: Frédéric Kahn  
Title: VP Marketing & Sales

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**Schedule A**

**API Specifications**

The parties have agreed upon all those applicable specifications for the API as set forth hereunder. The parties shall agree upon any modifications to the specifications here below in writing.

- Include packaging specifications
- Include minimum shelf life
- Include analytical methods, product specifications, product impurities, degradation products, and reference standards provided by Nabriva

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**Schedule B**

**Form of Quality Technical Agreement**

The Quality Technical Agreement shall be revised, if necessary, within [\*\*] from the execution date of this Agreement.



**Schedule C**

**Purchase Price**

The pricing in the table below, dependent on the total number of batches per campaign, shall apply:

<b>Routine commercial manufacture</b>	<b>Lefamulin (**) / batch</b>	<b>Yearly regulatory maintenance fee</b>
<b>Campaign size</b>	<b>Price (EUR/kg)</b>	
[**]	[**]	
[**]	[**]	
[**]	[**]	[**]
[**]	[**]	
[**]	[**]	
- Assumptions:	[**]	
[**].		

**Schedule D**

**Territory**

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**Schedule E-1**

**SAMPLE YIELD CALCULATION FOR [\*\*]**

Reporting Year ending:

To be agreed between the Parties during the first year of the Term.

**Schedule E-2**

**SAMPLE YIELD CALCULATION FOR [\*\*]**

Reporting Year ending:

To be agreed between the Parties during the first year of the Term.

SUBSIDIARIES OF NABRIVA THERAPEUTICS plc

<b>Nabriva Therapeutics GmbH</b>	<b>Austria</b>
<b>Nabriva Therapeutics Ireland Designated Activity Company</b>	<b>Ireland</b>
<b>Zavante Therapeutics, Inc.</b>	<b>United States</b>
<b>Nabriva Therapeutics US, Inc.</b>	<b>United States</b>

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**Consent of Independent Registered Public Accounting Firm**

The Board of Directors  
Nabriva Therapeutics plc:

We consent to the incorporation by reference in the registration statements (Nos. 333-208097, 333-222003, 333-226330 and 333-228094) on Forms S-8 and the registration statements (Nos. 333-219567 and 333-223739) on Forms S-3 of Nabriva Therapeutics plc of our report dated March 12, 2019, with respect to the consolidated balance sheets of Nabriva Therapeutics plc and subsidiaries as of December 31, 2017 and 2018, and the related consolidated statements of operations and comprehensive income (loss), changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2018, and the related notes (collectively, the "consolidated financial statements"), which report appears in the December 31, 2018 annual report on Form 10-K of Nabriva Therapeutics plc.

/s/ KPMG LLP

Philadelphia, Pennsylvania  
March 12, 2019

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## CERTIFICATIONS

I, Theodore Schroeder, certify that:

1. I have reviewed this Annual Report on Form 10-K of Nabriva Therapeutics plc;
2. Based on my knowledge, this 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 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 internal 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 in accordance 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.

/s/ Theodore Schroeder

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Theodore Schroeder  
Chief Executive Officer  
(Principal Executive Officer)

Dated: March 12, 2019

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## CERTIFICATIONS

I, Gary Sender, certify that:

1. I have reviewed this Annual Report on Form 10-K of Nabriva Therapeutics plc;
2. Based on my knowledge, this 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 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 internal 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 in accordance 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.

/s/ Gary Sender

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Gary Sender  
Chief Financial Officer  
(Principal Financial Officer)

Dated: March 12, 2019

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**CERTIFICATION  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Nabriva Therapeutics plc (the "Company") for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Theodore Schroeder, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Theodore Schroeder

Theodore Schroeder  
*Chief Executive Officer*  
*(Principal Executive Officer)*

Dated: March 12, 2019

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**CERTIFICATION  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Nabriva Therapeutics plc (the "Company") for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Gary Sender, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Gary Sender

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Gary Sender  
*Chief Financial Officer*  
*(Principal Financial Officer)*

Dated: March 12, 2019

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