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, 2020

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 001-38276

APELLIS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**27-1537290**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
100 Fifth Avenue Waltham, MA	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 977-5700

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	**APLS**	**Nasdaq Global Select Market**

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 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 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	☐	Small 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

As of June 30, 2020, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the shares of common stock on the Nasdaq Global Select Stock Market on such date, was $1,953,553,262. The number of shares of the registrant's common stock, par value $0.0001 per share outstanding as of February 22, 2021 was 80,375,365.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A in connection with its 2021 Annual Meeting of Stockholders within 120 days of the end of the registrant's fiscal year ended December 31, 2020. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

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

These forward-looking statements include, among other things, statements about:

- our plans with respect to our ongoing and planned clinical trials for our product candidates, whether conducted by us or Swedish Orphan Biovitrum AB (Publ) or by any future collaborators, including the timing of dosing of patients, enrollment and completion of these trials and of the anticipated results from these trials;
- our plans to develop our current and future product candidates for any additional indications;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- our plans to initiate clinical trials of our current and future product candidates;
- the potential clinical benefits and attributes of our current and future product candidates we may develop and the inhibition of C3;
- our plans to research and develop any current and future product candidates we may develop;
- our current and any future collaborations for the development and commercialization of our current and future product candidates;
- the potential benefits of any collaboration;
- the rate and degree of market acceptance and clinical utility of any products for which we receive marketing approval;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy;
- our ability to identify additional products or product candidates with significant commercial potential;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- developments relating to our competitors and our industry;
- the impact of the COVID-19 pandemic on our clinical trials, business and operations; and
- the impact of government laws and regulations.

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 on Form 10-K, particularly in the "Risk Factors" section, that 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, collaborations, joint ventures or investments that we may make or enter into.

You should read this Annual Report on Form 10-K and the documents that we have filed or incorporated by reference as exhibits to this Annual Report on Form 10-K 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, whether as a result of new information, future events or otherwise, except as required by applicable law.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. All of the market data used in this Annual Report on Form 10-K involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. We believe that the information from these industry publications, surveys and studies is reliable. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors, including those described in the section titled "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us. The Apellis and Apellis Assist names and logos are our trademarks, trade names and service marks.

The other trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners.

RISK FACTOR SUMMARY

Our business is subject to a number of risks that if realized could materially affect our business, financial condition, results of operations, cash flows and access to liquidity. These risks are discussed more fully in the "Risk Factors" section of this Annual Report on Form 10-K. Our principal risks include the following:

- We have incurred significant losses since inception, expect to incur significant and increasing losses for at least the next several years, and may never achieve or maintain profitability. Our net losses were $344.9 million, $304.7 million and $127.5 million for the years ended December 31, 2020, 2019 and 2018, respectively.

- We have not yet successfully obtained marketing approvals nor commercialized any pharmaceutical products, which may make it difficult to evaluate our future prospects. We will need to transition from a company with a development focus to a company capable of supporting commercial activities.

- We will need substantial additional funding, to allow us to support both the systemic and ophthalmological pegcetacoplan programs through commercial launch, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate certain product development programs or commercialization efforts. We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements at least into the second half of 2022.

- If we receive regulatory approval for the use of pegcetacoplan as a treatment for PNH or if our agreement with SFJ Pharmaceuticals Group, or SFJ, is terminated prior to receiving such approval in specified circumstances, we will be required to make substantial payments to SFJ pursuant to our development funding agreement. If we do not have sufficient funding or cash flow from our business to meet our payment obligations under the development funding agreement, SFJ could exercise its remedies as a holder of a first priority security interest in our assets and our business could be materially harmed.

- We are dependent on the successful development and commercialization of pegcetacoplan. If we are unable to develop, obtain marketing approval for or successfully commercialize pegcetacoplan or if we experience significant delays in doing so, our business could be harmed.

- The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaborators such as Swedish Orphan Biovitrum AB (Publ), or Sobi, from obtaining approvals for the commercialization of pegcetacoplan or any of our product candidates that we develop. As a result, we cannot predict when or if, and in which territories, we, or our collaborators, will obtain marketing approval to commercialize pegcetacoplan or any other product candidate that we develop.

- The COVID-19 pandemic may affect our ability to conduct our ongoing clinical trials, delay the initiation of planned and future clinical trials, disrupt regulatory activities, or have other adverse effects on our business and operations. In addition, the COVID-19 pandemic may adversely impact economies worldwide, which could result in adverse effects on our business and operations and ability to raise capital.

- There are no approved therapies that act by inhibiting C3 and only two approved therapies in our target indications that act by inhibiting the complement system. We may not be able to successfully develop and commercialize pegcetacoplan or other product candidates.

- If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, and other regulators, we may incur additional costs or experience delays in completing, or ultimately be able to complete, the development and commercialization of these product candidates.

- We rely on third parties to conduct our clinical trials and to manufacture and distribute our product candidates for our clinical trials. We contract with third parties for the manufacture, storage and distribution of our product candidates for clinical trials as well as in connection with our commercialization efforts. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. If these third parties do not perform satisfactorily, our development or commercialization efforts could be delayed or impaired.

- Our prospects for the development and commercialization of our product candidates will depend in significant part on the success of our collaboration with Sobi for the global co-development and commercialization of systemic pegcetacoplan outside of the United States. Our ability to generate revenues from this collaboration will depend on Sobi.

- If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business, including our patent license agreements with the University of Pennsylvania under which we license patents with claim that recite a class of compounds generically covering our lead product candidates, pegcetacoplan and APL-9, and that specifically recite the active component.

PART I

Item 1. Business.

We are a clinical-stage biopharmaceutical company focused on the development of novel therapeutic compounds to treat disease through the inhibition of the complement system, which is an integral component of the immune system, at the level of C3, the central protein in the complement cascade. We believe that this approach can result in broad inhibition of the principal pathways of the complement system and has the potential to effectively control a broad array of complement-dependent autoimmune and inflammatory diseases.

We have the most advanced clinical programs targeting C3 with Phase 3 clinical trials of our lead product candidate, pegcetacoplan, in multiple indications. We believe that pegcetacoplan has the potential to be a best-in-class treatment that may address the limitations of existing treatment options or provide a treatment option where there currently is none. Pegcetacoplan has already shown activity that we believe is clinically meaningful in clinical trials for several distinct medical conditions, including geographic atrophy in age-related macular degeneration, or GA; paroxysmal nocturnal hemoglobinuria, or PNH; cold agglutinin disease, or CAD; and C3 glomerulopathy, or C3G. We are developing pegcetacoplan and other product candidates, including APL-9, targeting C3 through various routes of administration and plan to conduct clinical trials of these compounds in additional complement-dependent indications.

In October 2020, we entered into a collaboration and license agreement, or the collaboration agreement, with Sobi. Under the collaboration agreement, we agreed to co-develop pegcetacoplan for systemic indications, including PNH, CAD and hematopoietic stem cell transplantation-associated thrombotic microangiopathy, or HSCT-TMA, in hematology; C3G and immune complex membranoproliferative glomerulonephritis, or IC-MPGN, in nephrology; and amyotrophic lateral sclerosis, or ALS, in neurology. Sobi has exclusive ex-U.S. commercialization rights for systemic pegcetacoplan. We retain commercialization rights for systemic pegcetacoplan in the United States and worldwide commercial rights for ophthalmological pegcetacoplan, which includes our GA program in addition to worldwide commercialization rights for APL-9 and other product candidates targeting C3.

Ophthalmological pegcetacoplan

GA. We initiated a Phase 3 clinical program consisting of two Phase 3 clinical trials evaluating ophthalmological administration of pegcetacoplan in patients with GA in September 2018. We refer to these trials as the DERBY and OAKS trials. Both trials are fully enrolled and we expect to announce top-line data from these trials in the third quarter of 2021.

In our Phase 2 clinical trial of pegcetacoplan in patients with GA, treatment with pegcetacoplan resulted in a significant reduction in the rate of GA lesion growth over 12 months.

Additionally, data released in October 2020 from a post hoc analysis of seven patients in our Phase 1b trial of pegcetacoplan in patients with advanced GA and low vision demonstrated a trend in reduced lesion growth in eyes treated with pegcetacoplan versus untreated fellow eyes after 18 months of treatment.

Systemic pegcetacoplan

We are developing pegcetacoplan with Sobi for systemic administration in several indications, including PNH, C3G, IC-MPGN, ALS, CAD and HSCT-TMA.

PNH. In June 2018, we initiated a Phase 3 clinical trial evaluating pegcetacoplan in 80 patients with PNH who exhibited signs of moderate to severe anemia, specifically with an inclusion criterion of hemoglobin level of less than 10.5 g/dL, while being treated with eculizumab, an approved therapy for PNH that is marketed as Soliris. We refer to this trial as the PEGASUS trial.

In January 2020, we announced top-line data from the PEGASUS trial that showed that pegcetacoplan met the trial's primary efficacy endpoint, demonstrating superiority to eculizumab, with a statistically significant improvement in adjusted means of 3.8 g/dL of hemoglobin at week 16 ($p < 0.0001$), and promising results in key secondary endpoints. Additional data from the PEGASUS trial presented in June 2020 and December 2020 demonstrated increased hemoglobin levels, reduced transfusion requirements and improved key markers of hemolysis across the patient population, both in patients with high transfusion requirements and in patients with low or no transfusion requirements, which improvements were sustained through 48 weeks of treatment. In the PEGASUS trial, the safety profile of pegcetacoplan was comparable to that of eculizumab.

In September 2019, we initiated a second Phase 3 clinical trial in patients with PNH who have not been treated with eculizumab within three months before entering the trial. We refer to this trial as the PRINCE trial. The PRINCE trial is fully enrolled and we intend to present top-line data in the second quarter of 2021.

We submitted a new drug application, or NDA, to the FDA and a marketing authorization application, or MAA, to the EMA for pegcetacoplan for the treatment of PNH in September 2020. The FDA accepted the NDA and set the Prescription Drug User Fee Act, or PDUFA, target action date for May 14, 2021. The EMA validated the MAA in October 2020, with the potential for a European Commission decision on the MAA in the second half of 2021.

C3G/IC-MPGN. We have initiated and will continue to lead our registrational program in C3G / IC-MPGN. In October 2020, we reported data from the Phase 2 DISCOVERY trial in five C3G patients treated with pegcetacoplan for 48 weeks. We initiated a Phase 2 randomized, controlled trial in up to 12 patients with post-kidney transplant recurrence of C3G or IC-MPGN, in October 2020 and we expect to dose the first patient in this trial in the first half of 2021. We refer to this trial as the NOBLE trial. We also plan to begin a Phase 3 clinical trial in patients with native kidney or post-transplant recurrence of C3G or IC-MPGN, having reduction of proteinuria as its primary endpoint, in the second half of 2021.

ALS. We have initiated a randomized, placebo-controlled Phase 2 clinical trial of pegcetacoplan in approximately 200 adults with sporadic ALS. We refer to this trial as the MERIDIAN trial. We treated the first patient in the MERIDIAN trial in November 2020 and expect to complete enrollment for the MERIDIAN trial in the second half of 2021.

CAD and HSCT-TMA. Under our collaboration, Sobi will lead development activities for CAD and HSCT-TMA with a Phase 3 clinical trial in CAD and a Phase 2 clinical trial in HSCT-TMA, both planned to begin in 2021. In our Phase 2 clinical trial of pegcetacoplan in patients with CAD, patients achieved increased hemoglobin levels, reduced reticulocytes and bilirubin levels, and reduced LDH levels compared to baseline.

Pipeline

We are developing pegcetacoplan and other product candidates, including APL-9, targeting C3 through various routes of administration. We plan to conduct clinical trials of these compounds in additional complement-dependent indications.

APL-9 is a C3 modulator designed to be intravenously administered for acute use. In May 2020 we initiated a Phase 1/2 randomized, placebo-controlled clinical trial of APL-9 in 66 patients with respiratory failure including acute respiratory distress syndrome, or ARDS, secondary to COVID-19. We expect to report results from this trial in the second quarter of 2021.

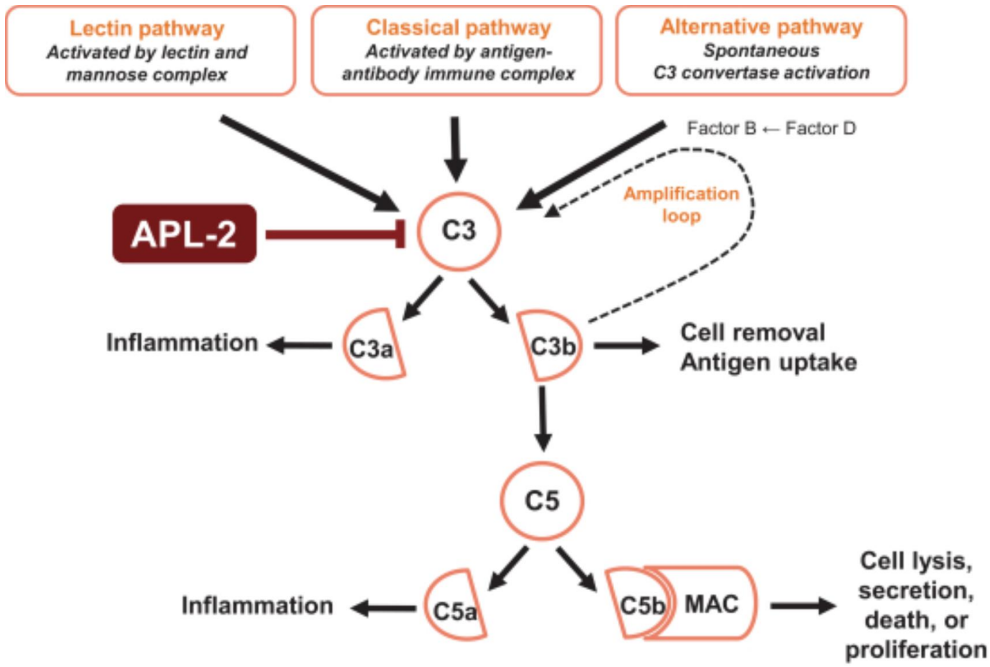
We are also developing APL-9 for the prevention of complement immune system activation coincident with adeno-associated virus, or AAV, vector administration for gene therapies and other indications.

We plan to advance three new product candidates into clinical development by the end of 2022.

Our Approach

The complement system plays a pivotal role in both innate and adaptive immune systems. Complement proteins are produced primarily by the liver and circulate in the blood and through the body's tissues. The complement system may be activated through three principal pathways, known as the classical, lectin and alternative pathways, each of which requires the C3 protein to enable three principal immune responses: opsonization, inflammation and formation of the membrane attack complex, or MAC. When C3 is activated, C3 fragments, such as C3b, tag cell surfaces in a process called opsonization, which marks the cells for removal from tissues or the bloodstream. Two other fragments, C3a and C5a, are released, contributing to inflammation in the surrounding tissues. Further complement activation causes membrane attack complex formation on cell surfaces, piercing holes and causing cells to lyse, or rupture, and others to depolarize or lose membrane potential.

The following figure depicts the complement system, its three principal activation pathways and its principal effects:



Under conditions of excessive or uncontrolled activation, the complement system is believed to play a key role in the incidence and progression of several autoimmune and inflammatory diseases. In these diseases, the complement system acts directly through tissue destruction by the membrane attack complex and indirectly by signaling other elements of the immune system to inappropriately target otherwise healthy tissues. Because the contribution of complement activation to the development and progression of these diseases is not fully understood, it has been difficult to develop therapeutics that ameliorate the conditions contributing to these diseases by targeting only one of the complement activation pathways.

Complement activation and its effects can be inhibited in multiple ways. By targeting complement proteins upstream of C3, one of the three principal activation pathways can be inhibited. For example, inhibition of factor B or factor D results in inhibition of the alternative pathway, but not the classical or lectin pathways. The complement system can also be inhibited by targeting complement proteins downstream of C3, which results in limited inhibition of complement effects. For example, inhibition of C5 leads to inhibition of the formation of the membrane attack complex and C5a-mediated inflammation but does not affect opsonization or C3a-mediated inflammation.

We have designed pegcetacoplan to target complement proteins centrally at the level of C3. We believe that this approach can result in broad inhibition of the complement pathways and has the potential to effectively control complement-dependent diseases. We believe that pegcetacoplan has the potential to be a best-in-class treatment and may address the limitations of existing treatment options or provide a treatment option where there is none.

Our Strategy

We aim to become a leading biopharmaceutical company focused on the discovery, development and commercialization of therapeutics to treat autoimmune and inflammatory diseases through complement inhibition. We hold commercialization rights for systemic pegcetacoplan in the United States and worldwide commercialization rights to ophthalmological pegcetacoplan, which includes our GA program, in addition to worldwide commercialization rights for APL-9 and other novel compounds targeting C3. To achieve our goals, we are pursuing the following strategies:

- ***Complete Phase 3 clinical development and prepare for regulatory submission of pegcetacoplan in GA***. We are developing pegcetacoplan as monotherapy for GA, administered by intravitreal injections. We expect to announce data from the DERBY and OAKS trials in the third quarter of 2021 and to prepare submissions to regulatory authorities for marketing approval of pegcetacoplan as a treatment of geographic atrophy.
- ***Prepare for commercialization of pegcetacoplan in PNH.*** We are developing pegcetacoplan as monotherapy for patients with PNH, administered by subcutaneous injection, and are preparing to commercialize systemic pegcetacoplan in the United States and to support Sobi's commercialization efforts in the rest of the world. We submitted a new drug

application, or NDA, to the FDA and a marketing authorization application, or MAA, to the EMA for pegcetacoplan for the treatment of PNH in September 2020. The FDA accepted the NDA and set the Prescription Drug User Fee Act, or PDUFA, target action date for May 14, 2021.

- ***Continue clinical development of systemic pegcetacoplan in other indications, including ALS and C3G/IC-MPGN.*** We are developing pegcetacoplan for patients with C3G and C3G/IC-MPGN, administered by subcutaneous injection. Sobi has primary responsibility for the clinical development pegcetacoplan for patients with CAD and HSCT-TMA.
- ***Continue development and expansion of our pipeline***. We plan to continue development of treatments for a broad range of complement-dependent autoimmune and inflammatory diseases with pegcetacoplan and additional new product candidates.

Our Programs

Our lead product candidate, pegcetacoplan, is a C3 inhibitor. Pegcetacoplan is a conjugate of a compstatin analogue, formulated both for ophthalmological administration by injections directly into the eye, and systemic administration by subcutaneous injection, which is an injection into the tissue under the skin. We are developing pegcetacoplan and other product candidates, including APL-9, targeting C3 through various routes of administration.

The following table summarizes key information about our ongoing clinical programs:

Program	Clinical Trials	Trial Participants	Estimated Timeline
		Ophthalmological pegcetacoplan	
GA	Phase 3 trials (DERBY/OAKS)	Patients with GA	Top-line data expected 3Q 2021
	Phase 2 trial (FILLY)	Patients with GA	Data reported in Aug 2017
	Phase 1b trial	Patients with low vision GA	Data reported in Apr 2020 and Oct 2020
		Systemic pegcetacoplan	
PNH	Phase 3 trial (PEGASUS)	Eculizumab-treated patients with PNH	Data reported in Jan 2020 and in Dec 2020
	Phase 3 trial (PRINCE)	Treatment-naïve patients with PNH	Top-line data expected 1H 2021
C3G/IC-MPGN	Phase 2 Trial (DISCOVERY)	Patients with glomerular diseases with complement involvement	Data reported Oct 2020
	Phase 2 Trial (NOBLE)	Patients with post-transplant recurrence of C3G or IC-MPGN	First patient treatment expected 1H 2021
	Phase 3 Trial	Patients with native kidney or post-transplant recurrence of C3G or IC-MPGN	Plan to initiate 2H 2021
ALS	Phase 2 Trial (MERIDIAN)	Patients with sporadic ALS	Complete enrollment 2H 2021
CAD	Phase 2 Trial (PLAUDIT)	Patients with CAD and wAIHA	Data reported Jun 2019
	Phase 3 Trial	Patients with CAD	Plan to initiate 2021 (Sobi)
HSCT-TMA	Phase 2 Trial	Patients with HSCT-TMA	Plan to initiate 2021 (Sobi)
		Pipeline	
ARDS	Phase 2 trial	COVID patients	Top-line data reported 2Q 2021

Ophthalmological pegcetacoplan

We are developing pegcetacoplan to be injected intravitreally as a monotherapy for patients with ophthalmological indications, including geographic atrophy, or GA.

Geographic Atrophy

Background

GA is a type of advanced age-related macular degeneration, or AMD. According to the Brightfocus Foundation, over ten million people in the United States have some form of AMD. AMD is a disorder of the central portion of the retina in the eye, known as the macula, which is responsible for central vision and color perception. AMD affects vision in one or both eyes and results in progressive and chronic degeneration of the macula, often resulting in irreversible vision loss. AMD is a disease of aging, typically occurring after

the age of 50. In the early stage of the disease, yellow deposits, or drusen, appear under the retina. Over time, the disease can progress to an intermediate stage where drusen deposits grow larger and other changes reflective of disease progression appear and then to an advanced stage associated with progressive and often severe vision loss which may be characterized as either GA or wet AMD. GA is characterized by a degenerative process resulting in the progressive loss of retinal cells, which over the course of several years results in blindness. Based on published studies, we believe that at least five million people worldwide, including at least one million people in the United States, including have GA.

At the American Academy of Ophthalmology, or AAO, in November 2020, a retrospective study of 69,000 patients diagnosed with GA was presented that analyzed changes in visual acuity and disease progression over two years. The analysis was presented by Verana Health, a data analysis group in retinal diseases under a collaboration with us, and the AAO's IRIS® (Intelligent Research in Sight) Registry, the nation's first comprehensive clinical registry for eye disease. Key findings from the real-world clinical data showed:

- At the first study visit, patients presented with relatively preserved vision, especially in eyes with extrafoveal GA lesions (lesions outside the fovea, which is the central portion of the retina). However, patients with extrafoveal and foveal GA lesions progressively lost vision over time at a rate of approximately five letters on a vision chart per year.
- Progression from GA to new onset wet AMD was observed in 4.7% of patients with bilateral GA (GA in both eyes) and 13.3% of patients with wet AMD in the contralateral eye (AMD in the non-treatment eye) during the first 12 months. The rate at 24 months was 8.2% and 21.6% in bilateral GA and wet AMD in the contralateral eye, respectively.
- A large proportion of GA patients did not return for a follow-up visit after two years. Of the GA patients potentially eligible for inclusion in the analysis, only 40% had a follow-up visit after two years and were ultimately included in the study.

The mechanism by which complement activation is upregulated and can damage the retina is poorly understood. However, we believe that the upregulation of complement activation due to immune dysregulation damages retinal cells in two ways. First, retinal cells are damaged by inflammation caused by increased levels of C3a and C5a. Second, the increased deposition of C3b on the cell surface of retinal cells caused by complement activation, combined with the limited ability of cells to remove C3 activated fragments such as C3b, leads to the accumulation of C3 fragments on the retinal cells. The presence of C3a and C5a, as well as C3 fragment deposition on retinal cells, activates macrophages and microglia. Macrophages are large white blood cells that form part of the immune system that engulf and digest cells, debris and foreign substances. Macrophages also play an important role in modulating other parts of the immune system. Microglia are a type of tissue-residing macrophage located in the brain, spinal cord and retina.

Because pegcetacoplan both blocks the production of C3a and C5a and prevents the accumulation of C3 fragments on retinal cells through the inhibition of C3, we believe that pegcetacoplan may control complement activation in the retinal environment to return it to its quiescent state. We do not believe that selective inhibitors of the alternative pathway, which would only partially block the formation of C3b on the retinal cell surface, or C5 inhibitors, which cannot prevent C3b deposition on retinal cells, can cause the retinal environment to return to its quiescent state.

Current Therapies and Their Limitations

There are no therapies approved to treat GA. There are, however, therapies in development for GA including a number of product candidates in late stages of clinical development.

Benefits of Our Approach

We believe pegcetacoplan, with its inhibition of complement activation at the level of C3 in the retinal environment, may provide the following benefits:

- *Prevention or reduction of the rate of retinal cell death progression*. We believe pegcetacoplan may mitigate or prevent retinal cell death in GA. In our Phase 2 trial of pegcetacoplan in patients with GA, treatment with pegcetacoplan resulted in a significant reduction in the rate of GA lesion growth over 12 months.
- *Potential application to all patients with GA independent of complement pathway causing disease progression.* Pegcetacoplan, by targeting C3, has been designed to inhibit all three principal complement activation pathways and may therefore be effective in a broad patient population. We believe, based on the genetic marker and other data from our analysis of our Phase 2 trial, that the activity of pegcetacoplan does not depend upon the activation of any particular complement pathway.

Clinical Development

We initiated the DERBY and OAKS Phase 3 clinical trials of pegcetacoplan in patients with GA following completion of our Phase 2 clinical trial in patients with GA, which we refer to as the FILLY trial. In August 2017, we completed the primary endpoint analysis for the 12-month treatment period for the Phase 2 FILLY trial and in February 2018 we completed the analysis of data from the six-month monitoring period from that trial. Prior to the FILLY trial, we completed a Phase 1 clinical trial of pegcetacoplan in patients with wet AMD in 2016. In July 2018, we received fast track designation from the FDA for pegcetacoplan in GA.

Phase 3 Clinical Trials

Our ongoing Phase 3 clinical program in GA consists of two 600-patient prospective, multicenter, randomized, double-masked, sham-injection controlled trials (DERBY and OAKS) being conducted at 200 sites worldwide to assess the efficacy and safety of multiple intravitreal injections of pegcetacoplan in patients with GA. Both trials are fully enrolled and we expect to announce top-line data from these trials in the third quarter of 2021.

Patients in each Phase 3 trial receive a dose of 15 mg of pegcetacoplan injected intravitreally in a 0.1 cc volume, monthly or every other month for 24 months. In the sham-injection cohorts, patients receive a simulated injection. As with our Phase 2 clinical trial, the primary endpoint of each trial is the change in total area of GA lesions in the study eye from baseline to month 12 compared to sham. The measurements of change in lesion size will be analyzed at 12 months (primary endpoint, monthly group) and 24 months. We set statistical significance as a p-value of 0.05 or less, meaning that there is a 1 in 20 or less probability that the observed results occurred by chance. Patients who develop new onset exudation in the study eye will continue to be treated with pegcetacoplan along with anti-VEGF injections, the current standard of care for wet AMD.

The observation intervals in pivotal studies in AMD are typically 24 months in total duration to meet regulatory requirements for long-term safety and to demonstrate durability of the treatment effect on anatomical and functional endpoints. However, based on our experience in the Phase 2 FILLY trial, we believe that pegcetacoplan can show treatment effect at 12 months and we therefore plan to analyze the data after all patients have completed 12 months of treatment in the trial in addition to a second assessment after 24 months of treatment. This design is in line with the recommendations of the FDA and the EMA.

We are using a liquid formulation of pegcetacoplan in our Phase 3 trials instead of the freeze-dried formulation that we used in the Phase 2 FILLY trial, which we believe may reduce the incidence of endophthalmitis.

In October 2018, we announced that we voluntarily implemented a pause in dosing in our Phase 3 clinical trials in patients with GA due to observed cases of non-infectious inflammation in patients treated from a single manufacturing lot of pegcetacoplan intravitreal drug product. Four patients in the Phase 3 GA program were treated with pegcetacoplan from this manufacturing lot and each patient developed non-infectious inflammation. Inflammation in all patients completely resolved. We reviewed these events with the data safety monitoring board for our GA trials, conducted a series of non-human studies and introduced improvements to the manufacturing process. Based on these efforts, we believe that the source of inflammation resided in a contaminant or impurity in the active pharmaceutical ingredient. We resumed the trials in March 2019.

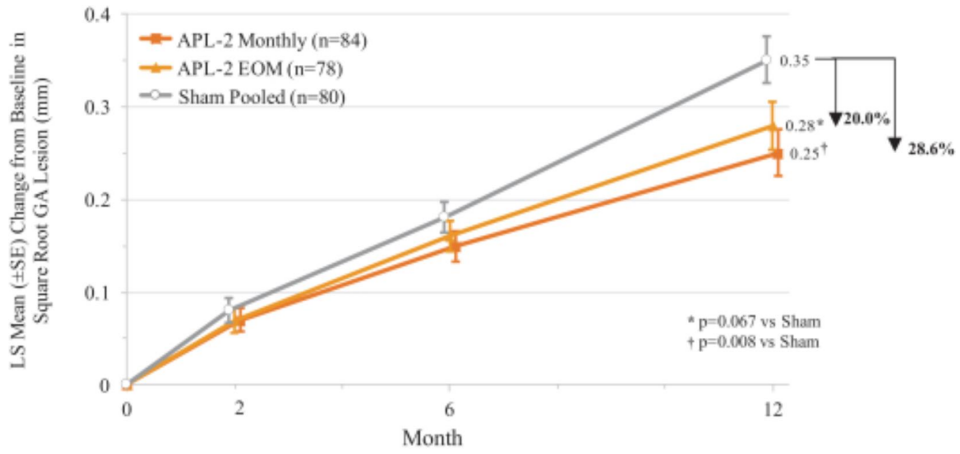
Phase 2 Clinical Trial

In the third quarter of 2015, we initiated a Phase 2 multicenter, randomized, single-masked, sham-controlled clinical trial of pegcetacoplan in patients with GA, which we refer to as the FILLY trial, at more than 40 clinical sites, primarily located in the United States. We enrolled 246 patients in the trial. Patients were randomized in a 2:2:1:1 manner to receive pegcetacoplan monthly, pegcetacoplan every other month, sham injection monthly or sham injection every other month. Patients in the pegcetacoplan arms received a dose of 15 mg of pegcetacoplan injected intravitreally in a 0.1 cc volume, monthly or every other month for 12 months followed by six months of monitoring without treatment. In the sham-injection cohorts, patients receive a simulated injection. Study eyes received up to 13 injections in the monthly arm, and up to seven injections in the every other month arm. Eyes were evaluated for GA at the end of months two, six, 12 and 18.

We conducted this trial to assess the safety, tolerability, pharmacokinetics, or PK, and evidence of activity of multiple intravitreal injections of pegcetacoplan in patients with GA in at least one eye. The primary efficacy endpoint was change in the square root of GA lesion size from baseline to month 12 in each treatment arm when compared to sham in the modified intent to treat population, which included 84 patients receiving administration of pegcetacoplan every month, 78 patients receiving administration of pegcetacoplan every other month and 80 patients in the group receiving sham injections. The primary safety endpoint was the number and severity of local and systemic treatment emergent adverse events. The trial was monitored by a safety monitoring committee.

We announced 12-month results of the Phase 2 trial in August 2017. After 12 months, patients treated monthly with pegcetacoplan showed a 29% reduction in the rate of GA lesion growth compared to sham, with a p-value of 0.008, and patients treated every other month showed a 20% reduction compared to sham, with a p-value of 0.067. The rate of GA lesion growth in the

sham was consistent with the rate of lesion growth in patients with GA in third-party historical studies. These data are shown in the figure below.



EOM = Every other month

We set statistical significance as a p-value of 0.1 or less, meaning that there is a 1-in-10 or less statistical probability that the observed results occurred by chance rather than as a result of a treatment effect. Because the p-value of these results was less than 0.1, they are statistically significant.

After the 12-month treatment period, patients were monitored for a further six months without treatment. During the monitoring period, the GA lesions in the previously treated groups grew at a rate similar to sham but the treatment effect was maintained for the full 18 months. Patients who received monthly pegcetacoplan, and for whom images were available at 12 and 18 months showed a 12% reduction in the growth rate of lesions over the six-month monitoring period compared to sham, while patients who received every other month administration of pegcetacoplan showed a 9% reduction in the growth rate of lesions over the six-month monitoring period compared to sham. These differences are not considered to be statistically significant. In the modified intent to treat population over the full 18-month period, patients who received monthly pegcetacoplan showed a 20% reduction in the growth rate of lesions over the full 18-month period compared to sham, while patients who received every other month administration of pegcetacoplan showed a 16% reduction in the growth rate of lesions over the full 18-month period compared to sham.

The most frequently reported adverse events in the trial were associated with the injection procedure in the study eye. These adverse events included two cases of confirmed endophthalmitis and one case of presumed endophthalmitis where the culture tested negative for bacterial growth. In the latter case, the patient fully recovered visual acuity. In our Phase 2 trial, we observed an incidence rate of endophthalmitis of 0.21% per injection.

In addition, during the 12-month treatment period and the six-month monitoring period, we observed a higher incidence of new onset exudation in the study eyes treated with pegcetacoplan as compared to sham, predominantly in patients with a history of wet AMD in the fellow eye. Specifically, we observed that, after the 12-month treatment period and the six-month monitoring period, 18 patients (21%) receiving administration of pegcetacoplan every month and seven patients (9%) receiving administration of pegcetacoplan every other month showed new onset exudation in the study eye, as compared to one patient (1%) in the sham group.

Patients who experienced new onset exudation in the study eye were discontinued from treatment with pegcetacoplan and, in all but one case, treated with standard of care anti-VEGF injections under supervision. There was no meaningful negative impact on visual acuity resulting from the new onset exudations.

Phase 1b Clinical Trial in Low Vision Geography Atrophy

We are conducting a Phase 1b clinical trial to evaluate the safety of monthly intravitreal treatments with pegcetacoplan in 12 patients with bilateral GA secondary to AMD and with low vision, which we initiated in September 2018. Patients are dosed monthly with pegcetacoplan in one eye using the fellow eye as an untreated control. In April 2020, we reported results in patients demonstrating a trend in reduced GA lesion growth in treated eyes versus the lesion growth in untreated fellow eyes. In October 2020, we reported data from an 18-month post hoc analysis based on the seven study patients for whom data were available for at least 18 months. In this population, the growth rate of GA lesions in the treated eye was on average 52% (mean square root) slower than the untreated fellow eye (p=0.01). It has been shown in third-party studies that lesions in both eyes tend to grow at the same rate in

patients with bilateral GA. Of the 12 enrolled patients, there were no reported cases of inflammation and one patient (8%) developed new-onset exudation at month 12.

Phase 1b/2 Clinical Trial in Wet AMD

We conducted a Phase 1b/2, multi-center, open label clinical trial to evaluate the safety of intravitreal pegcetacoplan therapy when administered in parallel with anti-VEGF treatments in patients with wet AMD in the study eye in the second quarter of 2018. As with our Phase 3 program in GA, we voluntarily implemented a pause in our Phase 1b/2 trial of pegcetacoplan in patients with wet AMD in October 2018. We discontinued the Phase 1b/2 trial of pegcetacoplan in patients with wet AMD.

Phase 1 Clinical Trial

We conducted a Phase 1 open label, ascending single-dose clinical trial of pegcetacoplan administered by intravitreal injection in patients with wet AMD who were receiving anti-VEGF therapy. We conducted the trial at multiple clinical sites both within and outside the United States to assess safety, tolerability and PK of pegcetacoplan. In this trial, patients received a single dose of pegcetacoplan by intravitreal injection followed by 113 days of monitoring. We enrolled eighteen patients in the trial, in three cohorts, at doses of 5 mg (3 patients), 10 mg (3 patients) and 20 mg (12 patients) of pegcetacoplan. Pegcetacoplan was well tolerated, and no serious adverse events were reported. Based on the results, we determined to evaluate a dose of 15 mg in our Phase 2 trial.

Preclinical Studies

We have conducted preclinical studies in monkeys to assess the safety of pegcetacoplan injected intravitreally. A full toxicological review, including histopathological examinations of both eyes and of multiple additional tissues from each monkey revealed no evidence of pegcetacoplan -related toxicity changes at any of the doses tested.

Systemic Pegcetacoplan

We and Sobi plan to jointly advance the clinical development of systemic pegcetacoplan in five parallel registrational programs across hematology, nephrology, and neurology. These include new registrational programs in CAD and HSCT-TMA. We will lead clinical development for PNH, C3G/IC-MPGN and ALS, and Sobi will lead development activities for a Phase 3 trial in CAD and a Phase 2 trial in HSCT-TMA, both planned to start in 2021.

Paroxysmal Nocturnal Hemoglobinuria

Background

PNH is a rare, chronic, debilitating blood disorder that is most frequently acquired in early adulthood and usually continues throughout the life of the patient. Some of the prominent symptoms of PNH include severe anemia, a condition that results from having too few red blood cells, severe abdominal pain, severe headaches, back pain, excessive weakness, fatigue and recurrent infections. If not treated, PNH results in the death of approximately 35% of affected individuals within five years of diagnosis and 50% of affected individuals within ten years of diagnosis, primarily due to the formation of life-threatening blood clots inside the blood vessels, or thrombosis. Based on prevalence data published in an abstract in a peer-reviewed journal, we estimate that there are approximately 4,700 patients with PNH in the United States and approximately15,000 patients with PNH worldwide.

PNH is caused by the presence of mutant stem cells in the bone marrow that lack important proteins on their surface that protect against activation of the complement system. In patients with PNH, an autoimmune response targets and eliminates normal stem cells, enabling mutant cells to become dominant in the bone marrow. These mutant stem cells lead to mutant platelets and red blood cells that, unlike normal cells, are overly susceptible to activation or destruction by the complement system. Mutant platelets, activated by the membrane attack complex, increase the risk of thrombosis, which is the leading cause of mortality in patients with PNH. Mutant red blood cells are susceptible to destruction by intravascular and extravascular hemolysis. Intravascular hemolysis, which involves the destruction of blood cells within the blood vessels, is caused by the formation of the membrane attack complex on the surface of red blood cells causing them to rupture. Intravascular hemolysis causes severe anemia and contributes to the risk of thrombosis. Extravascular hemolysis, which involves the destruction of blood cells outside the blood vessels, is caused by C3-related opsonization on red blood cells leading to removal of the cells from the blood stream by the liver and the spleen. Extravascular hemolysis further contributes to severe anemia and transfusion dependency in patients with PNH.

Current Therapies and Their Limitations

Eculizumab, marketed as Soliris, and ravulizumab, marketed as Ultomiris, both by Alexion Pharmaceuticals, Inc., or Alexion are the only therapies that have been approved for the treatment of PNH. Eculizumab, which is administered every two weeks

intravenously, or directly into the veins, is designed to treat PNH by targeting C5 and preventing the formation of the membrane attack complex and intravascular hemolysis. Many patients with PNH on treatment with eculizumab continue to be anemic. Ravulizumab is administered intravenously every week and subcutaneously once per week and is designed to have a longer half-life and greater inhibition of C5 than eculizumab. Ravulizumab was tested in two Phase 3 non-inferiority trials with eculizumab and was found to be non-inferior to eculizumab.

Retrospective third-party studies have reported that up to 70% of patients with PNH who are on treatment with eculizumab remained anemic and up to 36% of patients on eculizumab continued to require at least one transfusion per year. In these studies, 100% of patients with PNH on eculizumab showed evidence of C3-related opsonization on their red blood cells. We believe that uncontrolled extravascular hemolysis is responsible in part for these continuing complications.

Benefits of Our Approach

We believe that, because pegcetacoplan inhibits complement activation at the level of C3, pegcetacoplan may provide the following benefits in controlling PNH:

- *Prevention of intravascular hemolysis and its consequences*. Pegcetacoplan may prevent the formation of the membrane attack complex on blood cells and may thereby prevent the activation of mutant platelets and intravascular hemolysis, thus reducing the risk of thrombosis, the leading cause of mortality in PNH, as well as reducing anemia.
- *Prevention of extravascular hemolysis and its consequences*. Pegcetacoplan may prevent C3b opsonization, on blood cells, and may thereby prevent extravascular hemolysis, further reducing anemia and transfusion dependency in patients with PNH.
- *Ease and convenience of use*. We believe that the ability to self-administer pegcetacoplan by subcutaneous injection on a regular basis could improve the quality of life for patients with PNH by eliminating the need to travel to a health care facility for intravenous treatment.

Regulatory Matters

We submitted an NDA to the FDA and an MAA to the EMA for pegcetacoplan for the treatment of PNH in September 2020. The FDA accepted the NDA and set the PDUFA target action date for May 14, 2021. The EMA validated the MAA in October 2020, with the potential for a European Commission decision on the MAA in the second half of 2021.

In April 2014, we received orphan drug designation from the FDA for pegcetacoplan for PNH. In February 2019 we received fast track designation from the FDA for pegcetacoplan for patients with PNH, which superseded the fast track designation we received in December 2016 for pegcetacoplan for the subset of patients with PNH who continue to require transfusions despite receiving therapy with eculizumab.

Clinical Development

If we are able to obtain marketing approval for pegcetacoplan for PNH, we plan to allow PNH patients on treatment with eculizumab to assess the benefit of pegcetacoplan in co-treatment with eculizumab for a limited time, before deciding to switch to pegcetacoplan monotherapy or to revert to eculizumab monotherapy.

If pegcetacoplan is approved for the treatment of patients with PNH, we believe that pegcetacoplan could be a best-in-class therapy for PNH, differentiated by mechanism, and that pegcetacoplan has the potential to significantly increase the quality of life of patients with PNH as compared to the current standard of care.

Phase 3 Clinical Trial - PEGASUS

We initiated the Phase 3 PEGASUS trial in patients in June 2018. The PEGASUS trial was an 80-patient randomized head-to-head trial comparing pegcetacoplan monotherapy to eculizumab monotherapy in patients with PNH currently on treatment with eculizumab who have a hemoglobin level of less than 10.5 g/dL, regarding of eculizumab dose or transfusion history. The primary efficacy endpoint of the trial was the change in hemoglobin level from baseline at week 16.

The treatment period of the trial consisted of three parts: a four-week run-in period, a 16-week randomized treatment period and a 32-week open-label pegcetacoplan only period. During the run-in period, all patients received twice-weekly subcutaneous doses of 1,080 mg of pegcetacoplan in addition to patients' then current dose of eculizumab. The run-in period was designed to provide patients with sufficient plasma concentration of pegcetacoplan to provide for what we expected to be adequate complement inhibition before withdrawing eculizumab. Following completion of the run-in period, patients received either 1,080 mg of pegcetacoplan twice per week or their current dose of eculizumab through the duration of the 16-week randomized treatment period. Following completion

of the randomized treatment period with either pegcetacoplan monotherapy or eculizumab monotherapy, all 80 patients had the option to receive pegcetacoplan monotherapy for 32 weeks in an open-label treatment period.

In January 2020, we announced top-line data from the PEGASUS trial that showed that pegcetacoplan met the primary efficacy endpoint, demonstrating superiority to eculizumab with a statistically significant improvement in adjusted means of 3.8 g/dL of hemoglobin at week 16 ($p < 0.0001$). At week 16, pegcetacoplan-treated patients (n = 41) had an adjusted mean hemoglobin increase of 2.4 g/dL from a baseline of 8.7 g/dL, compared to eculizumab-treated patients (n = 39) who had a change of -1.5 g/dL from a baseline of 8.7 g/dL. Additionally, pegcetacoplan showed promising results in key secondary endpoints. Pegcetacoplan met non-inferiority on transfusion avoidance and absolute reticulocyte count. Pegcetacoplan did not meet pre-specified criteria for non-inferiority on mean LDH levels. Pegcetacoplan showed positive trends on LDH and fatigue as measured by the FACIT-fatigue score. The statistical analysis plan for the PEGASUS trial provided for use of the mixed model—repeated measures (MMRM) method. To avoid the effect of transfusions in hemoglobin levels during the 16-week randomization period of the trial, if a patient received a transfusion during the 16-week randomization period, any measurements after the first transfusion were censored from the data used in the MMRM analysis. The treatment effects using observed data from the trial, which included all post-transfusion measurements, were consistent with and supportive of the reported results from the MMRM analysis.

All patients who completed the 16 week randomization period in both groups (77/80) entered the 32-week open-label pegcetacoplan treatment period. At week 48, patients treated with pegcetacoplan during the 16 week randomization period and through the 32 week open-label period sustained increases in hemoglobin levels, with a mean improvement from baseline of 2.7 g/dL, equal to the 2.7 g/dL mean increase seen at week 16 in the same patients. Additionally, patients treated with eculizumab in the randomized period who switched to pegcetacoplan during the open-label period experienced sustained improvements in hemoglobin and other hematological and clinical measures, similar to patients treated with pegcetacoplan monotherapy during the randomized controlled period. In addition to a sustained improvement in hemoglobin, the pegcetacoplan-treated patients group maintained improvements across key secondary endpoints. Throughout the 48-week study, 73% of patients treated with pegcetacoplan during the randomized period remained transfusion free. For comparison, 25% of patients were transfusion free over the year prior to entering the PEGASUS study while on treatment with eculizumab. Improvements across additional markers of disease, such as reticulocyte count, lactate dehydrogenase, or LDH, levels, and the FACIT-fatigue scores, were observed in both groups at week 48 after 32 weeks of open-label treatment with pegcetacoplan.

In the PEGASUS trial, the safety profile of pegcetacoplan was comparable to eculizumab and consistent with previously reported data. After the 48-week study period, twenty-four of 80 pegcetacoplan monotherapy-treated patients (30%) experienced a serious adverse event (SAE). Five of the SAEs (6%) were assessed to be possibly related to study treatment. No cases of meningitis were reported. One death was reported due to COVID-19 and was unrelated to study treatment. The most common adverse events (AEs) reported throughout the study were injection site reactions (36%), hemolysis (24%), and diarrhea (21%). Twelve out of 80 patients (15%) discontinued due to adverse events, with five discontinuations due to hemolysis. Sixty-four of the 67 patients (96%) who completed the open-label period opted to enter the extension study.

Phase 3 Clinical Trial – PRINCE

We initiated the Phase 3 PRINCE trial in September 2019. The PRINCE trial is a 54-patient randomized, multicenter, open-label trial to evaluate the efficacy of pegcetacoplan in treatment-naïve PNH patients. The primary endpoints are avoidance of a greater than 1 g/dL decrease in hemoglobin level from baseline in the absence of transfusion through week 26 and reduction in LDH level from baseline to week 26, in patients with PNH who are currently not being treated with complement inhibitors. Secondary endpoints include hemoglobin response (defined as an increase in hemoglobin levels greater than or equal to 1 g/dL), change in absolute reticulocyte count, change in hemoglobin levels, number of packed red blood cells transfused, change in FACIT score, hemoglobin normalization and LDH normalization. This trial is fully enrolled and we expect to present top-line data in the second quarter of 2021.

Phase 1b Clinical Trials – PHAROAH and PADDOCK

Prior to commencing our two Phase 3 trials, we conducted two clinical trials of pegcetacoplan as part of our PNH program: a Phase 1b clinical trial (PHAROAH) in patients with PNH being treated with eculizumab, which has concluded, and a Phase 1b clinical trial (PADDOCK) in treatment-naïve patients. These trials were designed to assess safety and tolerability and whether pegcetacoplan has the potential to control PNH. In these trials, we measured hemoglobin levels, which are significantly lower in patients with PNH, whether or not treated with eculizumab, and blood reticulocyte count, which is an indicator of overall hemolysis (both intravascular and extravascular) in patients on eculizumab. We also measured intravascular hemolysis based on LDH levels, which can be ten times higher than normal in patients with PNH, bilirubin, which is a breakdown product of hemoglobin and may be higher in patients who experience hemolysis, and the clonal distributions of normal red blood cells and mutant red blood cells unprotected from the membrane attack complex.

PHAROAH was a Phase 1b open-label, single and multiple ascending dose clinical trial of pegcetacoplan in patients with PNH who are receiving eculizumab, conducted at multiple clinical sites in the United States. In the PHAROAH trial, doses of pegcetacoplan

were administered by subcutaneous injection to patients with PNH who were concurrently being treated with eculizumab at varying doses according to the treating physicians' recommendations. We treated a total of nine patients in the PHAROAH trial. Pegcetacoplan was generally well tolerated by the patients in the trial with 12 serious adverse events reported across three patients. Only one of these serious adverse events was noted as possibly related to the administration of pegcetacoplan. We initiated this trial in February 2015 and the last patient transitioned in October 2018 into a long-term extension study that we are conducting.

PADDOCK was a Phase 1b open-label clinical trial of pegcetacoplan in treatment-naïve patients with PNH that we initiated in December 2015 and conducted this trial at multiple clinical sites outside of the United States. In the PADDOCK trial, doses of pegcetacoplan were initially administered by subcutaneous injection during the treatment period. We treated a total of 22 patients in the PADDOCK trial. Pegcetacoplan had been generally well tolerated in these patients with 13 serious adverse events reported across seven patients. Only one of these serious adverse events was noted as possibly related to administration of pegcetacoplan.

Long-Term Extension Study

We are conducting a long-term extension study of pegcetacoplan in patients with PNH who participated in previous clinical trials with pegcetacoplan. This study is an open label, non-randomized, multi-center study to evaluate the long-term safety and efficacy of pegcetacoplan in the treatment of PNH with dosing for a longer period and at doses of 1,080 mg given either twice a week or every three days. We expect to continue the extension study until pegcetacoplan becomes commercially available in the subject's participating country, or until the development program for pegcetacoplan in patients with PNH is terminated.

Phase 1 Clinical Trials—Single and Multiple Ascending Dose in Healthy Volunteers

We have completed both single ascending and multiple ascending dose Phase 1 randomized, double-blind, placebo-controlled clinical trials of pegcetacoplan in a total of 55 healthy volunteers. We conducted the trials at a single site in Australia to assess the safety, tolerability, PK and pharmacodynamics, or PD, of pegcetacoplan. Pegcetacoplan was well tolerated in both trials with no serious adverse events reported, and the PK of pegcetacoplan in humans was in line with our expectations derived from preclinical data, with little inter-subject variability observed. In both trials, we observed a dose-dependent increase in C3 that is indicative of pegcetacoplan binding to C3.

Supporting Clinical Trials and Studies

We conducted a Phase 1 trial to assess the safety and tolerability of pegcetacoplan in patients with renal impairment. The study included one cohort of eight patients with severe renal impairment and a second cohort of eight control patients and will evaluate various PK endpoints, in addition to safety and tolerability endpoints. No significant difference in PK parameters was noted.

We conducted a Phase 1 trial to determine the safety, PK and PD of twice-weekly and once-weekly subcutaneous administration of pegcetacoplan in healthy volunteers. We evaluated whether less frequent administration provides comparable PK and PD profiles to daily subcutaneous administration and may enable less frequent dosing in upcoming clinical trials. We established the dosing regimen in PEGASUS and PRINCE based on this trial.

We conducted a Phase 1 trial to determine the safety, PK and PD of pegcetacoplan in healthy volunteers of Japanese descent. We evaluated whether pegcetacoplan will have comparable PK and PD profiles in this population. No significant difference in PK parameters was noted.

Preclinical Studies

We have conducted numerous preclinical studies of pegcetacoplan in animals and in laboratory samples to assess the safety of pegcetacoplan, including repeat-dose subcutaneous and intravenous toxicity studies of pegcetacoplan in rats, rabbits and monkeys for durations of up to nine months. In these studies, there were no significant macroscopically observable or clinical pathology drug-related changes in any species at any of the doses tested. Similarly, there was no evidence of a potential for adverse effects on myocardial conduction or cardiovascular and respiratory systems in either species, and no genotoxicity potential was observed. In addition, no signs of infection were observed in any of the studies that we conducted. The main toxicity observed at the highest doses tested was microscopic kidney damage, likely resulting from accumulation of pegcetacoplan in the kidney, which is one of the organs we believe to be responsible for its clearance from the body.

While there is no animal model of PNH, pegcetacoplan inhibited both hemolysis of red blood cells by the membrane attack complex and C3 fragment deposition on the surface of these cells in preclinical studies that we conducted *ex vivo* on blood samples from patients with PNH.

Safety

In all trials of pegcetacoplan administered systemically by subcutaneous injection, we have monitored the safety of our targeting of C3 closely. Individuals who lack functional levels of C3 or C5 have been shown to be susceptible to infection by certain bacterial species, including *Neisseria meningitidis* in C5-deficient individuals and *Neisseria meningitidis*, *Streptococcus pneumoniae* and *Haemophilus influenzae* in C3-deficient individuals. As a result, we vaccinate patients in these trials against these three pathogens, which we believe minimizes the risk of infection.

As of February 10, 2021, in our clinical trials of pegcetacoplan using subcutaneous administration in patients with PNH or healthy volunteers, a total of 155 serious adverse events had been reported in 80 of the 279 subjects dosed with pegcetacoplan. Of these 155 serious adverse events, 15 were considered to be at least possibly related to study medication by the investigator. None of these indicated any unexpected safety concerns.

Commercial and Medical Activities for PNH Launch

We are preparing for the launch of pegcetacoplan for patients with PNH in the United States if the FDA approves our NDA submission. We have built commercial and medical organizations focused on addressing the needs of patients at launch. In particular, for PNH we have defined our marketing, disease education, patient support and distribution strategies, identified primary and secondary payers representing a significant percentage of patients with PNH, and have built sales and market access teams in preparation for a commercial launch.

Our market access team is fully staffed and has engaged with primary and secondary payers representing a significant percentage of PNH patients. We believe that our discussions with primary and secondary payers have yielded positive feedback on the clinical profile of pegcetacoplan. We plan to implement a limited distribution specialty pharmacy model, which we believe will provide patients with a consistent, positive experience at the time of treatment initiation and long-term assistance to the extent needed.

We have established ApellisAssist, a patient-focused program specifically designed to assist patients with onboarding, product training and ongoing support with pegcetacoplan treatment, and we are building a care educator team to connect directly with PNH patients and their caregivers to provide education and training on the use of pegcetacoplan.

We plan to deploy our sales team to cover the health care professionals and key treatment centers, focusing on health care professionals who have patients that continue to experience breakthrough hemolysis, have persistently low hemoglobin, high fatigue, and require transfusions despite being on C5 inhibitors.

We have initiated the commercial manufacturing process for our commercial drug product, obtained required regulatory licenses and executed agreements to establish our warehousing, logistics and distribution networks. Under our collaboration agreement, Sobi will conduct the commercial launch of pegcetacoplan for patients with PNH in jurisdictions outside the United States.

We are developing a custom, on-body drug delivery system that would enable patients to self-administer pegcetacoplan through subcutaneous infusion. While this device is in development, we plan to use one or more commercially available ambulatory infusion pumps in our ongoing and planned clinical trials and for our commercial launch of pegcetacoplan as a treatment for PNH.

Our medical affairs team has engaged with top treating physicians through our virtual presence at medical meetings and in-person engagements when appropriate. In December 2020, we participated in the virtual American Hematology Society, or ASH, annual meeting, and we launched an Apellis medical affairs microsite where the ASH data are available for U.S. healthcare providers. We will continue to leverage this platform for future medical congresses. We have initiated an early access program and have already established multiple U.S. sites for patients. Sobi will conduct medical affairs activities for systemic pegcetacoplan outside the United States.

C3 Glomerulopathy and Immune Complex Membranoproliferative Glomerulonephritis

C3G and IC-MPGN are rare, debilitating kidney diseases that affect approximately 18,000 people in the United States and Europe. There are no approved therapies for the diseases, and symptoms include blood in the urine, dark foamy urine due to the presence of protein, swelling, and high blood pressure. Approximately 50% of people living with IC-MPGN and C3G ultimately suffer kidney failure within five to 10 years of diagnosis. Although IC-MPGN is considered a distinct disease from C3G, the underlying cause and progression of the two diseases are remarkably similar and include overactivation of the complement cascade, with excessive accumulation of C3 breakdown products in the kidney causing inflammation and damage to the organ. There are no medicines currently approved for C3G or IC-MPGN. Pegcetacoplan is designed to prevent C3 activation, and as such, we believe it

has the potential to prevent further deposition of C3 activation products in the glomeruli, which may protect the kidney from further injury.

In February 2018, we initiated a Phase 2 clinical trial of pegcetacoplan in biopsy-proven C3G and other glomerular diseases in which complement has been implicated, including IgA nephropathy, primary membranous nephropathy and lupus nephritis, to evaluate the safety and biologic activity of pegcetacoplan in patients with these glomerular diseases. We refer to this trial as the DISCOVERY trial. Initially each patient received once daily subcutaneous infusions of up to 360 mg of pegcetacoplan for one year but patients could elect to receive twice weekly subcutaneous infusions of 1080 mg after week 24. The primary efficacy endpoint was the reduction in proteinuria, an important market of kidney damage, from baseline to week 48 as quantified by protein-to-creatinine ratio, or uPCR. Based on the scientific literature as well as the underlying pathophysiology of the disease, we believe that a substantial change in proteinuria is reasonably likely to predict a clinical benefit in all four glomerular diseases. Secondary endpoints included analysis of serum C3 and estimated glomerular filtration rate.

In October 2020, we reported data from the DISCOVERY trial in five C3G patients treated with pegcetacoplan for 48 weeks. In those patients, mean (SE) proteinuria decreased from 3.48 (0.82) mg/mg at baseline to 0.93 (0.27) mg/mg at week 48, a decrease of 73.3%, as measured by 24-hour uPCR. Importantly, this reduction in proteinuria was accompanied by a corresponding increase in mean serum albumin. Since albumin is the most abundant protein in serum, its level increases when urinary protein losses are reduced. Other biomarkers improved, including an observed increase in mean serum C3 and stabilization of renal function, as measured by mean serum creatinine. No serious or severe adverse events were reported, and pegcetacoplan was well tolerated overall.

In October 2020, we initiated a registrational program in C3G and IC-MPGN beginning with a randomized, controlled Phase 2 trial in 12 patients with post-transplant disease recurrence that focused on the histopathology of the kidneys. We refer to this trial as the NOBLE trial. Trial participants are randomized in a 3:1 ratio to receive pegcetacoplan or maintain standard of care for 12 weeks and then all patients in the study will receive pegcetacoplan from week 13 to week 52. The primary endpoint of the study is the proportion of patients with reduction in C3c staining on renal biopsy after 12 weeks of treatment with pegcetacoplan. Secondary endpoints include an evaluation of safety, the proportion of patients with reduction in C3c staining on renal biopsy after 52 weeks of treatment, and the proportion of patients achieving at least a 50% reduction in proteinuria. We expect to dose the first patient in the NOBLE trial in the first half of 2021. We plan to begin a Phase 3 trial in patients with C3G and IC-MPGN in the second half of 2021 with reduction in proteinuria as its primary endpoint.

We met with the FDA in October 2017 in a pre-IND meeting and submitted an IND to the FDA in November 2017. In December 2018, we received orphan drug designation from the FDA for the treatment of C3G.

Amyotrophic Lateral Sclerosis

ALS is a devastating neurodegenerative disease that results in progressive muscle weakness and paralysis due to the death of nerve cells, called motor neurons, in the brain and spinal cord. The death of motor neurons leads to the progressive loss of voluntary muscle movement required for speaking, walking, swallowing, and breathing. In individuals with ALS, high levels of C3 are present at the neuromuscular junction where motor neurons communicate directly to muscle cells. Numerous studies suggest that elevated levels of C3 present throughout the motor system of ALS patients are likely to contribute to chronic neuroinflammation and the death of motor neurons. There are currently no approved treatments that stop or reverse the progression of ALS, which impacts approximately 225,000 patients worldwide.

We initiated a randomized, double-blind, placebo-controlled, multicenter Phase 2 clinical trial designed to evaluate the efficacy and safety of pegcetacoplan in approximately 200 adults with sporadic ALS. We refer to this trial as the MERIDIAN trial. Trial participants are randomized in a 2:1 ratio to receive pegcetacoplan or placebo while continuing to receive their existing standard of care treatment for ALS. After 52 weeks of blinded treatment, all patients in the study will receive pegcetacoplan. To reduce the burden on people living with ALS and their caregivers, the study has been designed to minimize the number of in-clinic visits, with approximately six clinic visits in the first year and four in the open-label second year. The primary endpoint of this trial is the Combined Assessment of Function and Survival (CAFS) rank scores at week 52. We treated the first patient in MERIDIAN in November 2020 and expect to complete enrollment in MERIDIAN in the second half of 2021.

Cold Agglutinin Disease

CAD is a severe, chronic, rare blood disorder that impacts about 10,500 people across the United States and Europe. People living with CAD may suffer from chronic anemia, transfusion requirements, and an increased risk of life-threatening thrombotic events such as stroke. In people with CAD, immunoglobin M (IgM) autoantibodies cause red blood cells to agglutinate, or clump together, at temperatures below 30^{o}C or as a result of a compromised immune system or infection This activates the complement cascade to destroy healthy red blood cells through extravascular and intravascular hemolysis. There is no FDA-approved drug

therapy specifically for CAD. The primary and secondary therapies, which include corticosteroids, splenectomy, alkylating agents and immunosuppressive drugs, are associated with low response rates, relapses and clinically significant adverse effects.

We believe that C3 inhibition has the potential to prevent C3-related opsonization and extravascular hemolysis in patients with CAD, and that inhibiting the complement system by targeting C3 may have the same impact, if not greater, as other complement pathway drugs in these diseases. In collaboration with Sobi, we are developing pegcetacoplan as a monotherapy for CAD. In March 2018, we initiated a Phase 2 open label clinical trial of pegcetacoplan administered by subcutaneous injection in patients with CAD, which we refer to as the PLAUDIT trial. In the PLAUDIT trial, doses of pegcetacoplan were initially administered by subcutaneous injection during the treatment period, followed by a long-term extension period. We have treated a total of 13 patients with CAD in the PLAUDIT trial. In December 2018, we announced interim data for the Phase 2 trial at the ASH Conference and further interim data at the European Hematology Association Congress in June 2019. We observed that in the 10 patients with CAD who reached day 168:

- 70% showed a Hb increase of ≥ 2 g/dL, 40% had normalized Hb (≥ 12.0 g/dL) and 80% had Hb ≥ 11.0 g/dL at Day 168
- Mean Hb increased from 8.9 g/dL at baseline to 11.2 g/dL at Day 168, a 2.4 g/dL increase (normal Hb is 12 - 16 g/dL)
- Mean Functional Assessment of Chronic Illness Therapy (FACIT) Fatigue Score increased from 29.4 at baseline to 39.1 at Day 168, an improvement of 9.7 points, where a clinically significant increase is 3 or more points
- Mean absolute reticulocyte count (ARC) decreased from 138.6 X 10^9/L at baseline to 63.6 X 10^9/L at Day 168 (normal ARC is 30 - 100 X 10^9/L)
- Mean indirect bilirubin decreased from 1.9 mg/dL at baseline to 0.4 mg/dL at Day 168 (normal indirect bilirubin is 0.1 -0.75 mg/dL)
- Mean LDH decreased from 486.5 U/L at baseline to 183.2 U/L at Day 168 (normal LDH is 87 - 252 U/L)

Pegcetacoplan has been generally well tolerated in these patients in the PLAUDIT trial, with a safety profile similar to that of other studies of systemic administration of pegcetacoplan.

Sobi will lead development activities for a Phase 3 trial in CAD, planned to start in 2021.

Hematopoietic Stem Cell Transplantation Thrombotic Microangiopathy

Hematopoietic stem cell transplantation thrombotic microangiopathy, or HSCT-TMA, is rare blood disease that can be a fatal complication of a bone marrow transplant or HSCT. In HSCT-TMA, microscopic blood clots form in small blood vessels, leading to organ damage. The kidneys are commonly affected, although any organ may be involved. HSCT-TMA occurs in up to 40% of HSCT recipients; every year, there are approximately 9,000 allogeneic transplants in the United States and approximately 18,000 in the European Union. Excessive complement activation is a high-risk feature in patients with HSCT-TMA, and C3 is believed to play a critical role in TMA based on proinflammatory and procoagulant properties of C3a and C3b.

Sobi will lead development activities for a Phase 2 trial in HSCT-TMA, planned to start in 2021.

Pipeline

We are developing pegcetacoplan and other product candidates, including APL-9, targeting C3 through various routes of administration. We plan to conduct clinical trials of these compounds in additional complement-dependent indications. We plan to advance three new product candidates into clinical development by the end of 2022.

APL-9 is a C3 modulator designed to be intravenously administered for acute use. In May 2020 we initiated a Phase 1/2 randomized, vehicle-controlled clinical trial for APL-9 in 66 patients with respiratory failure including acute respiratory distress syndrome, or ARDS, secondary to COVID-19. We hypothesize that complications of severe COVID-19 infections, including ARDS, are a consequence of complement mediated coagulation and angiopathies. We expect to report results from this trial in the second quarter of 2021. Additionally, we are developing APL-9 for the prevention of complement immune system activation coincident with AAV vector administration for gene therapies and other indications. We believe that targeted control of C3 may prevent the C3-mediated immune response attack on AAV particles, yielding three important potential advantages. First, controlling C3 may significantly increase the efficiency of gene therapy delivery by protecting the AAV particles on their journey from the site of administration to the target tissue. This may reduce the amount of particles needed to be used in gene therapies. Second, control of C3 may minimize the formation of anti-AAV neutralizing antibodies that can complicate subsequent retreatment with the same AAV. Finally, by countering the rapid activation of C3 upon administration of AAV particles, control of C3 may prevent inflammatory reactions that can lead to significant organ damage.

We have conducted a single ascending dose Phase 1 randomized, double-blind, placebo-controlled clinical trials of APL-9 in 20 healthy volunteers to determine the safety, PK and PD of APL-9. In this trial, APL-9 was administered either as a single intravenous

dose infused over 30 minutes or as a slow bolus intravenous loading dose to provide rapid pharmacological complement inhibition followed by a continuous intravenous infusion to maintain pharmacological levels of APL-9 for the desired duration. APL-9 demonstrated control of complement through modulation of C3 within one hour of administration, that lasted up to 12 hours after the end of the infusion. Multiple doses tested achieved complete suppression of the AH50 hemolytic activity. In this Phase I study, APL-9 was well tolerated with no serious adverse events reported. In the study, complement activity resumed shortly after the termination of the intravenous infusion.

Collaboration and License Agreement with Sobi

In October 2020, we entered into a Collaboration and License Agreement with Sobi concerning the development and commercialization of pegcetacoplan and specified other compstatin analogues or derivatives for use systemically or for local non-ophthalmic administration, or Licensed Products. The agreement does not cover pegcetacoplan or other compstatin analogues or derivatives used for non-systemic ophthalmic administration or APL-9.

Under the agreement, we granted Sobi an exclusive (subject to certain rights retained by us), sublicensable license under certain patent rights and know-how to develop and commercialize Licensed Products in all countries outside of the United States.

We retained the right to commercialize Licensed Products in the United States, and, subject to specified limitations, to develop Licensed Products worldwide for commercialization in the United States.

Under the agreement, we and Sobi have agreed to collaborate to develop Licensed Products for the treatment of PNH, CAD, HSCT-TMA, C3G, IC-MPGN and ALS, or the "Initial Indications", and any other indications subsequently agreed upon by the parties, for commercialization by or on our behalf in the United States and by or on behalf of Sobi outside of the United States. If the parties do not agree to jointly pursue any development activities for the Licensed Products (whether for an Initial Indication or otherwise), the party proposing to pursue such activities may conduct such activities at its sole expense (with the non-proposing party having the right to obtain rights to the data generated by such development activities by paying a specified percentage of that expense), subject to agreed-upon exceptions that limit each party's unilateral development rights.

The initial development plan sets forth the initial development activities to be conducted by each of us and Sobi, with us bearing all costs incurred in conducting the activities set forth in such initial development plan, as well as certain specified additional costs that are not included in the initial development plan that may be incurred by the parties in developing Licensed Products for paroxysmal nocturnal hemoglobinuria in the European Union and the United Kingdom.

Each party is obligated to use commercially reasonable efforts to complete the development obligations assigned to it in the development plan. We are obligated to use commercially reasonable efforts to obtain regulatory approval from the FDA for a Licensed Product in each of the Initial Indications, to obtain regulatory approval from the EMA for a Licensed Product in PNH and to assist Sobi to obtain other regulatory and reimbursement approvals for Licensed Products outside of the United States. Sobi is obligated to use commercially reasonable efforts to develop and obtain regulatory approval for, and to commercialize, Licensed Products for each of the Initial Indications in specified major markets.

We have agreed to supply to Sobi, pursuant to a supply agreement to be negotiated by the parties, Licensed Products for development and for commercialization outside of the United States in accordance with the agreement. The agreement granted Sobi the right to perform or have performed drug product manufacturing of Licensed Products for development and for commercialization outside the United States and to manufacture or have manufactured drug substance under certain circumstances.

We and Sobi have formed several governance committees to oversee the development and manufacture, and to review and discuss the commercialization, of Licensed Products.

We have agreed not to, directly or indirectly, alone or with or for any other person or entity, conduct any clinical development or commercialization of APL-9 for any Initial Indication or any other indications subsequently agreed upon by the parties.

Under the terms of the agreement, Sobi paid an upfront payment of $250 million, and agreed to pay us up to an aggregate of $915 million upon the achievement of specified one-time regulatory and commercial milestone events, and to reimburse us for up to $80 million in development costs. We will also be entitled to receive tiered, double-digit royalties (ranging from high teens to high twenties) on sales of Licensed Products outside of the United States, subject to customary deductions and third-party payment obligations, until the latest to occur of: (i) expiration of the last-to-expire of specified licensed patent rights; (ii) expiration of regulatory exclusivity; and (iii) ten (10) years after the first commercial sale of the applicable Licensed Product, in each case on a Licensed Product-by-Licensed Product and country-by-country basis. Under the agreement, we remain responsible for its license fee obligations (including royalty obligations) to the Penn and for our payment obligations to SFJ.

Unless earlier terminated, the agreement will expire upon the expiration of the last royalty term for the last Licensed Product outside of the United States. The agreement may be terminated in its entirety by Sobi upon 90 days' prior written notice at any time after the earlier of (i) October 27, 2022 or (ii) receipt of the first regulatory approval for the first Licensed Product in any of France, Germany, Italy, Spain, or the United Kingdom. Either party may, subject to specified cure periods, terminate the agreement in its entirety in the event of the other party's uncured material breach. In addition, we may, subject to specified cure periods, terminate the agreement in any of China, Japan, Brazil, or Canada if Sobi materially breaches its obligation to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize a Licensed Product for paroxysmal nocturnal hemoglobinuria and amyotrophic lateral sclerosis in such country. Either party may also terminate the agreement under specified circumstances relating to the other party's insolvency. We may terminate the agreement in the event Sobi or its specified affiliates or sublicensees challenges the validity, scope or enforceability of the licensed patent rights under specified circumstances.

Intellectual Property

Our success depends in 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 seek to protect our proprietary position in a variety of ways, including by pursuing patent protection in certain jurisdictions where it is available. For example, we file U.S. and certain foreign patent applications related to our proprietary technology, inventions and improvements that are 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 position.

Pegcetacoplan and APL-9 are analogs of the cyclic peptide compstatin, based on technologies that we have developed internally or have exclusively licensed from the Trustees of the University of Pennsylvania, or Penn.

As of December 31, 2020, we own a total of 13 U.S. patents and 31 pending U.S. patent applications, including original filings, continuations and divisional applications, as well as numerous foreign counterparts of many of these patents and patent applications. Our patents and patent applications include families of US and foreign patent and patent applications relating, for example, to the composition of matter ***of*** certain compstatin analogs with a prolonged *in vivo* half-life, including pegcetacoplan, and/or to methods of treatment and dosing regimens for treating particular complement-dependent diseases. Patents in these families would expire in 2032 or 2033. Our patent applications also include families relating in part to particular doses and dosing regimens for intravitreally or subcutaneously administered pegcetacoplan. Patents based on these applications would expire between 2036 and 2038. Finally, the filings include certain U.S. and foreign patents and patent applications relating to methods of treating eye disorders associated with complement activation, which we acquired in the acquisition of the assets of Potentia Pharmaceuticals, Inc., or Potentia. These acquired Potentia patent rights include issued U.S. patents with claims to methods of treating AMD by administration of compstatin analogs and a granted European patent with claims to a class of compstatin analogs for use in treatment of macular degeneration. These patents have terms that extend into 2026.

In addition to the technology that we developed internally, we hold exclusive licenses from Penn, including a license agreement with Penn that was assigned to us in connection with our acquisition of the Potentia's assets in September 2015. The intellectual property in-licensed under our two license agreements with Penn includes four U.S. patents and numerous foreign counterparts, with claims granted or pending in Europe, Japan and elsewhere. These licensed patent rights include issued patents with claims that recite a class of compounds generically covering our lead product candidates, pegcetacoplan and APL-9, and that specifically recite the active component. These patents have terms that extend to 2026.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. 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 in examining and granting a patent or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. 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 of a U.S. patent as partial compensation for the length of time the drug is under regulatory review while the patent is in force. A patent term 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 extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended.

Similar provisions are available in the European Union and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates, including pegcetacoplan, 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. Expiration dates referred to above are without regard to potential patent term adjustment or extension or other market exclusivity that may be available to us.

We granted worldwide rights to use and license the intellectual property that we hold with respect to pegcetacoplan and APL-9 to our wholly owned subsidiaries, APL DEL Holdings, LLC and Apellis Switzerland GmbH. Our wholly owned subsidiary, Apellis Australia Pty Ltd., holds certain rights to use our intellectual property to manage our clinical trials in Australia and exclusive rights to distribute our product with respect to specific indications within Australia and certain other territories. We granted Sobi an exclusive (subject to certain retained rights), sublicensable license of certain patent rights and know-how to develop and commercialize pegcetacoplan for non-ophthalmological indications in all countries outside of the United States.

We may rely, in some circumstances, on trade secrets to protect our technology. 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, consultants, scientific advisors and contractors. 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.

Patent License Agreement with The Trustees of the University of Pennsylvania (Non-ophthalmic Fields of Use)

In March 2008, Apellis AG entered into an agreement with Penn for an exclusive worldwide license, under specified patent rights controlled by Penn, to develop and commercialize products covered by the licensed patent rights for all fields except the treatment of ophthalmic indications. This license was assigned to us in 2010 in connection with our acquisition of Apellis AG, and we have the right to grant sublicenses under this license.

The patent rights licensed to us by Penn include patents with claims that recite a class of compounds generically covering our lead product candidates, pegcetacoplan and APL-9, and specifically recite the active component.

In exchange for the rights licensed from Penn, Apellis AG transferred to Penn shares of Potentia common stock that it had purchased from Potentia with a $250,000 promissory note in 2008. In 2010, Apellis AG assigned its Penn license to us together with the promissory note. We repaid the promissory note in full in 2013.

Under the license agreement, we are obligated to make a $100,000 annual license maintenance payment to Penn until the first commercial sale of a licensed product, some of which may become creditable against milestone payments under specified circumstances. We may also become obligated to make payments to Penn aggregating up to $1,650,000 based on achieving specified development and regulatory approval milestones and up to $2,500,000 based on achieving specified annual sales milestones with respect to each of the first two licensed products, and to pay low single-digit royalties to Penn based on net sales of each licensed product by us and our affiliates and sublicensees and specified minimum quarterly royalty thresholds. In addition, we are obligated to pay Penn a specified portion of income we receive from sublicensees.

In 2018 we made payments of $375,000, net of a credit for the annual license maintenance payment, for the achievement of milestones under this agreement.

In January 2021 we made payments of $25,050,000 as sublicenses fee under this agreement with respect to the Sobi collaboration and certain other strategic collaborations.

Our royalty obligation with respect to each licensed product in a country extends until the later of the expiration of the last-to-expire patent licensed from Penn covering the licensed product in the country or the expiration of a specified number of years after the first commercial sale of the licensed product in the country.

We have the right to grant sublicenses under the license.

We also are obligated to use commercially reasonable efforts to develop licensed products in accordance with a development plan, which we will update annually, and a development milestone timetable specified in the agreement and to use commercially reasonable efforts to commercialize licensed products.

Penn has the right to terminate the agreement if we breach the agreement and fail to cure our breach within specified cure periods or in the event of specified bankruptcy, insolvency and liquidation events. We have the right to terminate the agreement for our convenience at any time on 60 days' notice to Penn.

Amended and Restated Patent License Agreement with The Trustees of the University of Pennsylvania (Ophthalmic Field of Use)

At the same time that it entered into the agreement with Apellis AG, Penn licensed rights to the same portfolio of cases to Potentia, to develop and commercialize products covered by the licensed patent rights for the treatment of ophthalmic indications. In September 2015, Potentia assigned the license agreement between Potentia and Penn to us in connection with our acquisition of the assets of Potentia pursuant to an asset purchase agreement with Potentia.

Upon Potentia's assignment of the license to us, we became the licensee and are obligated to make a $100,000 annual license maintenance payment to Penn until the first commercial sale of a licensed product. We also became obligated to make payments to Penn aggregating up to $3,200,000 based on achieving specified development and regulatory approval milestones and up to $5,000,000 based on achieving specified annual sales milestones with respect to each licensed product, and to pay low single-digit royalties to Penn based on net sales of each licensed product by us and our affiliates and sublicensees and specified minimum quarterly royalty thresholds. In addition, we are obligated to pay Penn a specified portion of income we receive from sublicensees.

In 2018 we made payments of $650,000, net of a credit for the annual license maintenance payment, for the achievement of milestones under this agreement.

Our royalty obligation with respect to each licensed product in a country will extend until the later of the expiration of the last-to-expire patent licensed from Penn covering the licensed product in the country or the tenth anniversary of the first commercial sale of the licensed product in the country.

We have the right to grant sublicenses under the license.

We also are obligated to use commercially reasonable efforts to develop licensed products in accordance with a development plan, which we will update annually, and a development milestone timetable specified in the agreement and to use commercially reasonable efforts to commercialize licensed products.

Penn has the right to terminate the agreement if we breach the agreement and fail to cure our breach within specified cure periods or in the event of specified bankruptcy, insolvency and liquidation events. We have the right to terminate the agreement for our convenience at any time on 60 days' notice to Penn.

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 and governmental agencies and public and private 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.

There are a number of currently marketed products and product candidates in preclinical research and clinical development by third parties to treat the various diseases that we are targeting. In general, these products and product candidates can be categorized based on their proposed mechanisms of action. The mechanisms of action for these product candidates include inflammation suppression by agents such as complement inhibitors and corticosteroids, as well as immune modulators, visual cycle modulators, anti-amyloid agents, antioxidants, neuroprotectants, cell and gene therapies and vascular and interstitial tissue remodeling agents.

If our lead product candidate is approved for the indications for which we are currently undertaking or planning clinical trials, it will compete with the products and product candidates discussed below.

GA. There are currently no approved treatments for GA. We are aware that there are a number of companies that are actively developing product candidates for the treatment of GA, including the following product candidates that are in clinical development: ANX007, a C1q inhibitor being developed by Annexon Biosciences; GT005, a CFI expression inhibitor being developed by Gyroscope Therapeutics in Phase 2 clinical trials IONIS-FB-L(RX), a complement factor B inhibitor being developed by Genentech/Ionis in Phase 2 clinical trials; Zimura, a C5 inhibitor being developed by Iveric bio (formerly known as Ophthotech Corporation) in Phase 2/3 clinical trials; HMR59, an intravitreal gene therapy being developed by Janssen Pharmaceutical (after acquisition from Hemera Biosciences) in Phase 2 clinical trials; NGM621, a C3 inhibitor being developed by NGM Bio, in Phase 2 clinical trials; and other product candidates that do not target the complement system that are in Phase 2 clinical trials, including therapies being developed by Alcon, Gemini Therapeutics, Genentech, Lineage Cell Therapeutics, Regenerative Patch Technologies, and Stealth BioTherapeutics Inc., or Stealth, which is evaluating elamipretide in a Phase 2b clinical trial in patients with GA. Alexion has announced plans to initiate Phase 2 trials of danicopan in GA in the second half of 2021.

PNH. The principal competitors for PNH, and possibly other indications in our hematology and nephrology programs are eculizumab (marketed as Soliris) and ravulizumab (marketed as Ultomiris), C5 inhibitors developed and marketed by Alexion Pharmaceuticals, or Alexion. Eculizumab and ravulizumab are the only drugs currently approved for the treatment of PNH. In December 2020, AstraZeneca announced that it has agreed to acquire Alexion, with closing expected in the third quarter of 2021, pending regulatory approval.

We are aware of several other companies that are actively developing product candidates using complement inhibition for the treatment of PNH in late-stage clinical development, including nomacopan, a small protein C5 complement inhibitor being developed by Akari Therapeutics, Plc. in Phase 3 clinical trials; BCX9930, a Factor D inhibitor being developed by BioCryst Pharmaceuticals, currently in Phase 1/2 clinical trials; zilucoplan, a cyclic peptide C5 inhibitor developed by UCB S.A., currently in Phase 2 clinical trials, crovalimab, an anti-C5 antibody developed by Roche/Chugai, currently in Phase 3 clinical trials; pozelimab, an anti-C5 antibody developed by Regeneron Pharmaceuticals, currently in Phase 2 clinical trials; and iptacopan (formerly known as LNP-023), a Factor B inhibitor being developed by Novartis currently in Phase 3 clinical trials, as well as other products in early stages of development, including cemdisiran, an RNAi therapeutic targeting C5 developed by Alnylam Pharmaceuticals, Inc. in early clinical trials. Alexion is developing danicopan, formerly ACHN-4471, an orally available complement factor D inhibitor, currently in Phase 3 clinical trials as a cotreatment or combination product with eculizumab, and next generation complement factor D inhibitors ACHN-5528 and ACHN-5548 in early clinical development.

Amgen is developing ABP959, a biosimilar for eculizumab that is in Phase 3 development, and other non-US entities are developing biosimilars for eculizumab in local markets. The approval of a biosimilar or a generic to one of our products or a product with which we compete could have a material impact on our business because it may be significantly less costly to bring to market and may be priced significantly lower than our products or the other products with which we compete.

CAD. There are no currently marketed drug treatments for CAD but treatments in development, include sutimlimab, a C1s monoclonal antibody inhibitor, being developed by Sanofi, has completed Phase 3 clinical trials; and parsaclisib, a PI3K-d inhibitor, being developed by Incyte Corporation, in Phase 2 clinical trials.

C3G. There are no currently marketed drug treatments for C3 glomerulopathy, but treatments in development include narsoplimab (OMS721), a human monoclonal antibody to mannose-binding lectin-associated serine protease-2 (MASP-2) that blocks the lectin pathway, being developed by Omeros Corp., in Phase 2 clinical trials; avacopan, an oral C5aR-inhibitor developed by ChemoCentryx, Inc., in Phase 2 clinical trials; Iptacopan, being developed by Novartis, for C3 glomerulopathy is in Phase 2 clinical trials; and danicopan, being developed by Alexion for C3G, in Phase 2 clinical trials.

ALS. Currently there are four drug treatments approved by the FDA for treatment of ALS or its symptoms, including edaravone marketed as Radicava by Mitsubishi Tanabe Pharma America; riluzole, now generic; thickened riluzole, marketed as Tiglutik by ITF Pharma, and dextromethorphan HBr/quinidine sulfate (marketed as Nuedexta by Avanir Pharmaceuticals. Various companies are conducting clinical trials for symptoms of, or neurological conditions, related to, ALS, with over 50 molecules currently in development that target a broad array of biology, including at least three other anti-complement therapies: Ultomiris by Alexion, in Phase 3 trials, Zilucoplan by UCB/Ra in Phase 2 clinical trials, and ANX005 by Annexon Biosciences. Additionally, Amylyx Pharmaceuticals, Inc. recently reported positive results from their Phase 2 study of AMX0035.

HSCT-TMA. Currently there are three treatments in Phase 3 clinical trials: Ultomiris, developed by Alexion, nomacopan being developed by Akari, and narsoplimab, being developed by Omeros.

ARDS incident to COVID-19. We are aware of various companies conducting clinical trials for treatments of respiratory conditions secondary to COVID-19, including targeted and broad anti-inflammatory approaches being evaluated in phase 2 and phase 3 trials. We are aware of several anti-complement product candidates currently being developed in respiratory conditions secondary to COVID-19, including two C3 inhibition approaches, some of which are in phase 3 development.

Sales and Marketing

Apellis retains U.S. commercialization rights for systemic pegcetacoplan and worldwide commercial rights for ophthalmological pegcetacoplan. We plan to conduct commercial development for systemic pegcetacoplan within the United States. We have developed focused capabilities to commercialize development programs for certain indications where we believe that the medical specialists for the indications are sufficiently concentrated to allow us to effectively promote the product with a targeted sales team. In particular, for PNH we have defined our marketing, disease education, patient support and distribution strategies, identified primary and secondary payers representing a significant percentage of patients with PNH, have built our field market access team, and are building our sales team in preparation for a commercial launch. Sobi received global co-development and exclusive ex-US commercialization rights for systemic pegcetacoplan and will be responsible for the commercial development for systemic pegcetacoplan outside the United States.

For our ophthalmological pegcetacoplan program and for programs involving compounds other than pegcetacoplan, we plan to develop our own capabilities to commercialize our products worldwide. We may seek to enter into collaborations that we believe may contribute to our ability to advance development and ultimately commercialize our product candidates. We may also seek to enter into collaborations where we believe that realizing the full commercial value of our development programs will require access to broader geographic markets or the pursuit of broader patient populations or indications.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates. Although we intend to rely on third-party contract manufacturers to produce our products, we have recruited personnel with experience to manage the third-party contract manufacturers producing our product candidates and other product candidates or products that we may develop in the future.

The process for manufacturing our product candidates consists of chemical synthesis, purification using liquid chromatography, and freeze drying into solid form. The drug substance is then dissolved in solution and aliquoted into small vials for individual dosing. Each of these steps involves a relatively routine chemical engineering process. We expect the costs associated with manufacturing drug product for our product candidates may be comparable to the current manufacturing costs for other similarly sized peptide-based components.

We have engaged a limited number of third-party manufacturers to provide all of our raw materials, drug substances and finished products for use in clinical trials. In particular, we have entered into a commercial supply agreement with Bachem Americas, Inc., or Bachem, to purchase a significant portion of our requirements for the pegcetacoplan drug substance over the next five years. Our raw materials, drug substances and finished 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 raw materials and drug substances based on the volume required and the regulatory requirements at the relevant stage of development. All lots of drug substances and finished products used in clinical trials are manufactured under current good manufacturing practices. Separate third-party manufacturers are for fill and finish services and for labeling and shipment of the final drug products to the clinical trial sites.

We believe that our manufacturing capabilities are sufficient to supply pegcetacoplan at the scale and with the quality required for our ongoing and planned clinical trials, our commercialization efforts and our collaboration with Sobi We continuously review our supply chain risk, including with respect to our manufacturing footprint, and update and implement risk mitigation plans.

Commercial Supply Agreement with Bachem

On December 30, 2020, we entered into a commercial supply agreement, or the Bachem Agreement, with Bachem to supply Company with the drug substance for the finished dosage form of pegcetacoplan.

Under the Supply Agreement, we agreed to purchase from Bachem a significant portion of our requirements for the drug substance during the term of the agreement, and to purchase all of our requirements for drug substance for commercial sale, subject to certain exceptions, for a period after the effective date of the agreement.

Unless earlier terminated, the initial term of the Bachem Agreement continues for five years, or the Initial Term. Thereafter, the Bachem Agreement will automatically renew for an additional two-year term. At least 24 months prior to the end of the Initial Term, Bachem will notify us in writing if it is willing to continue to manufacture and supply the drug substance following the end of the Initial Term. For a period of 12 months after receipt of such notice, we have the right to negotiate pricing terms that would apply during the renewal term, which upon agreement will be finalized in an amendment to the Bachem Agreement. We may terminate the Bachem Agreement in the event any required license, permit or certificate of Bachem related to the manufacturing facility or the drug substance is not approved or issued (or is withdrawn) by the relevant governmental authority. Additionally, each party may terminate the Bachem Agreement upon an uncured material breach of the Bachem Agreement by the other party or upon the other party's insolvency or bankruptcy.

The Bachem Agreement also includes customary provisions relating to, among others, delivery, inspection procedures, warranties, quality, storage, handling and transport, intellectual property, confidentiality and indemnification.

Government Regulation and Product Approvals

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, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, pricing, reimbursement, 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 regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The failure to comply with applicable U.S. requirements at any time during the product development process, approval process or after approval may 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, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice 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:

- 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 IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board 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 NDA;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- 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 user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and post-approval studies required by the FDA.

Preclinical Studies

Before an applicant begins testing a product candidate with potential therapeutic value in humans, the product 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.

Companies usually must complete some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, 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 manufacturing process must be capable of consistently producing quality batches of the product candidate 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 product candidate 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 certain FDA requirements in order to use the study as support for an IND or application for marketing approval. Those requirements provide that such studies must be conducted in accordance with GCP, including review and approval by an independent ethics committee, or IEC, and informed consent from subjects.

In addition to the 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 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 DSMB, or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. Suspension or termination of development during any phase of clinical trials can 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.

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 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.

There is no obligation for a sponsor to make its drug products available for expanded access; however, as required by the 21st Century Cures Act (the "Cures Act"), passed in 2016, if a sponsor has a policy regarding how it responds to expanded access requests, it must make that policy publicly available. This requirement applies upon the earlier of initiation of a Phase 2 or Phase 3 study; or 15 days after the investigational 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

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 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. 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.

Pediatric Studies

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 the Food and Drug Administration Safety and Innovation Act, or FDASIA. The FDA maintains a list of diseases that are exempt from PREA requirements due to low prevalence of disease in the pediatric population. Congress amended the FDA Reauthorization Act of 2017, or FDARA. Previously, drugs that had been granted orphan drug designation were exempt from the requirements of the Pediatric Research Equity Act. Under the amended section 505B, beginning on August 18, 2020, the submission of a pediatric assessment,

waiver or deferral will be required for certain molecularly targeted cancer indications with the submission of an application or supplement to an application.

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, 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 2021 is $2,875,842 for an application requiring clinical data. The sponsor of an approved NDA is also subject to an annual program fee, which for federal fiscal year 2021 is $336,432. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and strives to inform the sponsor by the 74th day after the FDA's receipt of the submission to determine 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. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. The review process 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.

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 comply 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. Under the FDA Reauthorization Act of 2017, or FDARA, the FDA must implement a protocol to expedite review of responses to inspection reports pertaining to certain drug applications, including applications for drugs in a shortage or drugs for which approval is dependent on remediation of conditions identified in the inspection report.

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.

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.

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 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.

Fourth, 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 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 condition 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 IMM 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. There is limited experience with accelerated approvals by the FDA based on intermediate clinical endpoints. However, the FDA 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.

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, or CRL. An approval letter authorizes

commercial marketing of the product with specific prescribing information for specific indications. A CRL generally outlines the deficiencies in the submission and may require substantial additional 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 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 Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product 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 clinical data.

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

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, 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, 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, healthcare 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, the FDA's regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, 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.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, and its implementation regulations, as well as the Drug Supply Chain Security Act, or DSCSA, which regulates the distribution of and tracing of prescription drugs and prescription drug samples at the federal level and sets 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 DSCSA imposes requirements to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market.

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 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 NCE 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. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product. The FDA typically makes decisions about awards of data exclusivity shortly before a product is approved.

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;
- 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.

Pediatric 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. With regard to patents, the six-month pediatric exclusivity period will not attach to any patents for which a generic (ANDA or 505(b)(2) NDA) applicant submitted a paragraph IV patent certification, unless the NDA sponsor or patent owner first obtains a court determination that the patent is valid and infringed by a proposed generic product.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will be receiving orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Those circumstances include instances in which another sponsor's application for the same drug product and indication is shown to be "clinically superior" to the previously approved drug. In this context, clinically superior means that the drug provides a significant therapeutic advantage over and above the already approved drug in terms of greater efficacy, greater safety or by providing a major contribution to patient care. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

Under FDARA, orphan exclusivity will not bar approval of another orphan drug under certain circumstances, including if a subsequent product with the same drug for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously required the FDA to recognize orphan exclusivity regardless of a showing of clinical superiority.

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 is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA 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 drugs for which approval is sought can only be extended in connection with one of the approvals. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Review and Clearance or Approval of Medical Devices in the United States

Medical devices in the United States are strictly regulated by the FDA. Under the FDCA, a medical device is defined as an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component part, or accessory which is, among other things: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. This definition provides a clear distinction between a medical device and other FDA regulated products such as drugs. If the primary intended use of the product is achieved through chemical action or by being metabolized by the body, the product is usually a drug. If not, it is generally a medical device.

Unless an exemption applies, a new medical device may not be marketed in the United States until it has been cleared through filing of a 510(k) premarket notification, or 510(k), or approved by the FDA pursuant to a premarket approval application, or PMA. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices have the lowest level or risk associated with them, and are subject to general controls, including labeling, premarket notification and adherence to the Quality System Regulation, or QSR. Class II devices are subject to general controls and special controls, including performance standards. Class III devices, which have the highest level of risk associated with them, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are subject to most of the aforementioned requirements as well as to premarket approval.

A 510(k) must demonstrate that the proposed device is substantially equivalent to another legally marketed device, or predicate device, that did not require premarket approval. In evaluating a 510(k), the FDA will determine whether the device has the same intended use as the predicate device, and (a) has the same technological characteristics as the predicate device, or (b) has different technological characteristics, and (i) the data supporting substantial equivalence contains information, including appropriate clinical or scientific data, if deemed necessary by the FDA, that demonstrates that the device is as safe and as effective as a legally marketed device, and (ii) does not raise different questions of safety and effectiveness than the predicate device. Most 510(k)s do not require clinical data for clearance, but the FDA may request such data. The FDA seeks to review and act on a 510(k) within 90 days of submission, but it may take longer if the agency finds that it requires more information to review the 510(k). If the FDA concludes that a new device is not substantially equivalent to a predicate device, the new device will be classified in Class III and the manufacturer will be required to submit a PMA to market the product. PMA applications are subject to an application fee. For federal fiscal year 2021, the standard fee is $365,657 and the small business fee is $91,414.

Modifications to a 510(k)-cleared medical device may require the submission of another 510(k) or a PMA if the changes could significantly affect safety or effectiveness or constitute a major change in the intended use of the device. Modifications to a 510(k)-cleared device frequently require the submission of a traditional 510(k), but modifications meeting certain conditions may be candidates for FDA review under a Special 510(k). If a device modification requires the submission of a 510(k), but the modification does not affect the intended use of the device or alter the fundamental technology of the device, then summary information that results from the design control process associated with the cleared device can serve as the basis for clearing the application. A Special 510(k) allows a manufacturer to declare conformance to design controls without providing new data. When the modification involves a change in material, the nature of the "new" material will determine whether a traditional or Special 510(k) is necessary.

A clinical trial is typically required for a PMA application and, in a small percentage of cases, the FDA may require a clinical study in support of a 510(k) submission. A manufacturer that wishes to conduct a clinical study involving the device is subject to the FDA's IDE regulation. The IDE regulation distinguishes between significant and non-significant risk device studies and the procedures for obtaining approval to begin the study differ accordingly. Also, some types of studies are exempt from the IDE regulations. A significant risk device presents a potential for serious risk to the health, safety, or welfare of a subject. Significant risk devices are devices that are substantially important in diagnosing, curing, mitigating, or treating disease or in preventing impairment to human health. Studies of devices that pose a significant risk require both FDA and an IRB approval prior to initiation of a clinical study. Non-significant risk devices are devices that do not pose a significant risk to the human subjects. A non-significant risk device study requires only IRB approval prior to initiation of a clinical study.

Review and Approval of Combination Products in the United States

Certain products may be comprised of components that would normally be regulated under different types of regulatory authorities, and frequently by different Centers at the FDA. These products are known as combination products. Under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products;
- a drug or device packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug or device where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug or device packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a device-drug combination product is attributable to the drug product, the FDA Center responsible for premarket review of the drug product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

Review and Approval of Drug Products in the European Union

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 products. Whether or not it obtains FDA approval for a product, 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.

Procedures Governing Approval of Drug Products in the European Union

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of an E.U. member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent ethics committee has issued a favorable opinion. Clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents.

To obtain marketing approval of a product under European Union regulatory systems, an applicant must submit a marketing authorization application, or MAA, either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all E.U. member states. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the European Medicines Agency, or EMA, is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an

existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to applicants who wish to market a product in various E.U. member states where such product has not previously received marketing approval in any E.U. member states. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state designated by the applicant, known as the reference member state. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

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 clinical trial application 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 European Union adopted a new Clinical Trials Regulation, (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. The new Clinical Trials Regulation will become directly applicable to and binding in all 28 E.U. member states without the need for any national implementing legislation. It will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the new legislation aims at simplifying and streamlining the approval of clinical trials in the European Union. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial will be required to submit a single application for approval of a clinical trial to a reporting E.U. member state (RMS) through a European Union Portal. The submission procedure will be the same irrespective of whether the clinical trial is to be conducted in a single E.U. member state or in more than one E.U. member state.

The Regulation was published on June 16, 2014 but has not yet become effective. In January 2020, the website of the European Commission reported that the implementation of the Clinical Trials Regulation was dependent on the development of a fully functional clinical trials portal and database, which would be confirmed by an independent audit, and that the new legislation would come into effect six months after the European Commission publishes a notice of this confirmation. The website indicated that the audit was expected to commence in December 2020. In late 2020, the EMA indicated that it plans to focus on the findings of a system audit; improving the usability, quality and stability of the clinical trial information system; and knowledge transfer to prepare users and their organizations for the new clinical trial system. The EMA has indicated that the system will go live in December 2021.

As in the United States, similar requirements for posting clinical trial information are present in the European Union (EudraCT) website: https://eudract.ema.europa.eu/ and other countries.

Pediatric Studies in the EU

Prior to obtaining a marketing authorization in the European Union, applicants must demonstrate compliance with all measures included in an EMA-approved 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 laid down in Regulation (EC) No 1901/2006, the so-called Paediatric 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 Paediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine for children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine for children is not needed or is not appropriate, such as for diseases

that only affect the elderly population. Before an MAA 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.

PRIME Designation in the EU

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIority MEdicines, or PRIME, scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises, or SMEs, may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, a dedicated Agency contact and rapporteur from the CHMP or Committee for Advanced Therapies are appointed early in PRIME scheme facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Data and Market Exclusivity in the European Union

In the European Union, new chemical entities qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. 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 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 sponsor is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company can complete a full MAA with a complete database of pharmaceutical tests, preclinical tests and clinical trials and obtain marketing approval of its product.

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 it obtains FDA approval for a product, 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.

Periods of Authorization and Renewals

Marketing authorization is valid for five years in principle 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 European Union 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).

Orphan Drug Designation and Exclusivity

Regulation 141/2000 provides that a drug shall be designated as an orphan drug if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Community when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Community and that without incentives it is unlikely that the marketing of the drug in the European Community would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Community or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Regulation 847/2000 sets out criteria and procedures governing designation of orphan drugs in the European Union. Specifically, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product, demonstration of "clinically relevant superiority" by a similar medicinal product, or, after a review by the Committee for Orphan Medicinal Products, requested by a member state in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs pursuant to Regulation 141/2000 shall be eligible for incentives made available by the European Community and by the member states to support research into, and the development and availability of, orphan drugs.

Pediatric Exclusivity in the EU

If an applicant obtains a marketing authorization in all EU Member States, or a marketing authorization granted in the centralized procedure by the European Commission, and the study results for the pediatric population are included in the product information, even when negative, the medicine is then eligible for an additional six-month period of qualifying patent protection through extension of the term of the Supplementary Protection Certificate, or SPC

Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom (U.K.) voted in favor of leaving the European Union (commonly referred to as "Brexit"). Following protracted negotiations, the United Kingdom left the European Union on January 31, 2020. Under the withdrawal agreement, there is a transitional period until December 31, 2020 (extendable up to two years). On December 24, 2020, the United Kingdom and the European Union entered into a Trade and Cooperation Agreement. The agreement sets out certain procedures for approval and recognition of medical products in each jurisdiction. Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom, as the United Kingdom legislation now has the potential to diverge from European Union legislation. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the UK in the long-term. The MHRA has recently published detailed guidance for industry and organizations to follow from January 1, 2021 now the transition period is over, which will be updated as the UK's regulatory position on medicinal products evolves over time.

Furthermore, while the Data Protection Act of 2018 in the United Kingdom that "implements" and complements the European Union's General Data Protection Regulation, or GDPR, has achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is still unclear whether transfer of data from the European Economic Area, or EEA, to the United Kingdom will remain lawful under GDPR. The Trade and Cooperation Agreement provides for a transitional period during which the United Kingdom will be treated like an European Union member state in relation to processing and transfers of personal data for four months from January 1, 2021. This may be extended by two further months. After such period, the United Kingdom will be a "third country" under the GDPR unless the European Commission adopts an adequacy decision in respect of transfers of personal data to the United Kingdom. The United Kingdom has already determined that it considers all of the EU 27 and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the United Kingdom to the EU/EEA remain unaffected.

General Data Protection Regulation

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU General Data Protection Regulation (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 EU, 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

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products 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, such products. 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, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic, health outcome studies in order to demonstrate the medical necessity, quality of life benefits, and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective in light of cost-benefit analysis. Additionally, a payor's decision to provide coverage for a drug 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 for the drug product. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

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 our net revenue and results. 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 regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the United States, ensuring adequate coverage and payment for our product candidates will face 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 us to conduct studies that compare the cost effectiveness of our product candidates or products to other available therapies. The conduct of such studies could be expensive and result in delays in our commercialization efforts.

Pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug 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 in order to obtain reimbursement. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products but monitor and control company profits and issue guidance to prescribers. 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. In addition, reference pricing and cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

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 regulatory approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease or order 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 penalties 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 or fraudulent or making a false 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 willingly executing, or attempting to execute, a scheme or making false statements in connection with the delivery of or payment for health care benefits, items, or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on covered entities and their business associates that associates that perform certain functions or activities that involve the use or disclosure of protected health information on their behalf;
- 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 collectively the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value to physicians and teaching hospitals and information regarding 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 ACA, which, among other things, includes changes to the coverage and payment for drug products under government health care programs. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2030 under the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These 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.

Since enactment of the ACA, there have been, and continue to be, 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 President Trump 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, became effective in 2019. Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Court of Appeals for the Fifth Circuit court affirmed the lower

court's ruling that the individual mandate portion of the ACA is unconstitutional and it remanded the case to the district court for reconsideration of the severability question and additional analysis of the provisions of the ACA. Thereafter, the U.S. Supreme Court agreed to hear this case. Oral argument in the case took place on November 10, 2020. On February 10, 2021, the Biden Administration withdrew DOJ's support for this lawsuit. A ruling by the Court is expected sometime this year. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

The Trump Administration also took executive actions to undermine or delay implementation of the ACA, including directing 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. On January 28, 2021, however, President Biden rescinded those orders and issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this Order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents.

The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States To date, there have been several recent U.S. congressional inquiries, as well as proposed and enacted 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. To those ends, the Trump Administration issued five executive orders intended to lower the costs of prescription drug products but it is unclear whether, and to what extent, these orders will remain in force under the Biden Administration. Further, on September 24, 2020, the Trump Administration finalized a rulemaking allowing states or certain other non-federal government entities to submit importation program proposals to the FDA for review and approval. Applicants are required to demonstrate that their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. The FDA has issued draft guidance that would allow manufacturers to import their own FDA-approved drugs that are authorized for sale in other countries (multi-market approved products).

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 organizations 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 December 31, 2020, we had 374 full-time or part-time employees, including 5 employees with M.D./Ph.D. degrees, 7 employees with an M.D. degree and 43 employees with Ph.D. degrees. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider the relationship with our employees to be good.

We recognize that attracting, motivating and retaining talented employees is vital to our success. We value the health and wellness of our employees and their families. It is our goal to deliver innovative programs that provide choice, quality, and value. We aim to create an equitable, inclusive and empowering environment in which our employees can grow and advance their careers, with the overall goal of developing, expanding and retaining our workforce to support our current pipeline and future business goals. Our success also depends on our ability to attract, engage and retain a diverse group of employees. Our efforts to recruit and retain a diverse and passionate workforce include providing competitive compensation and benefits packages.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards. We offer a comprehensive benefits program that provides resources to help employees manage their health, finances, and life outside of work.

Corporate Information

Our principal executive office is located at 100 Fifth Avenue, Waltham, Massachusetts and our telephone number is 617-977-5700. Prior to December 31, 2019, our principal executive office was located in Crestwood, Kentucky.

Available Information

We file reports and other information with the Securities and Exchange Commission as required by the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. 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.

Our website address is www.apellis.com. 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 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. In addition, we regularly use our website to post information regarding our business, product development programs and governance, and we encourage investors to use our website, particularly the information in the section entitled "Investors & Media," as a source of information about us.

The foregoing references to our website are not intended to, nor shall they be deemed to, incorporate information on our website into this Annual Report on Form 10-K by reference.

Item 1A. Risk Factors.

Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Annual Report on Form 10-K and in other documents that we file with the SEC, in evaluating our company and our business. Investing in our common stock involves a high degree of risk. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception, expect to incur significant and increasing losses for at least the next several years, and may never achieve or maintain profitability.

We have incurred significant annual net operating losses in every year since our inception. We expect to continue to incur significant and increasing net operating losses for at least the next several years. Our net losses were $344.9 million, $304.7 million and $127.5 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $926.3 million. We have not generated any revenues from product sales, have not completed the development of any product candidate and may never have a product candidate approved for commercialization. We have financed our operations to date primarily through the sale of our common stock in our initial public offering and subsequent follow-on offerings, the sale of convertible notes, private placements of our preferred stock prior to our initial public offering, the development funding agreement with SFJ Pharmaceuticals Group, or SFJ, the collaboration agreement with Swedish Orphan Biovitrum AB (Publ), or Sobi, borrowings under a term loan facility and the issuance and sale of a promissory note. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and our clinical trials. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue to develop and conduct clinical trials with our lead product candidate, pegcetacoplan, and APL-9;
- initiate and continue research and preclinical and clinical development efforts for any future product candidates;
- seek to identify and develop additional product candidates for complement-dependent diseases;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any;
- establish sales, marketing, distribution and other commercial infrastructure to commercialize any products for which we may obtain marketing approval;
- require the manufacture of larger quantities of product candidates for clinical development and, potentially, commercialization;

- maintain, expand and protect our intellectual property portfolio;
- hire and retain additional personnel, such as clinical, quality control and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and help us comply with our obligations as a public company; and
- add equipment and physical infrastructure to support our research and development programs.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we are, or our collaborators, including Sobi, are able to obtain marketing approval for, and successfully commercialize, one or more of our product candidates. Successful commercialization will require achievement of key milestones, including completing clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we, or any of our collaborators, may obtain marketing approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues, and if or when we might achieve profitability. We and any collaborators may never succeed in these activities and, even if we do, or any collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to 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 pipeline of product candidates or continue our operations. A decline in the value of our company could cause our stockholders to lose all or part of their investment.

We have not yet successfully obtained marketing approvals nor commercialized pharmaceutical products, which may make it difficult to evaluate our future prospects.

Our operations to date have been limited to financing and staffing our company, developing our technology and conducting preclinical research and Phase 1, Phase 2 and Phase 3 clinical trials for our product candidates. However, although we have begun planning commercial activities, we have not yet demonstrated an ability to successfully 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. Accordingly, our stockholders should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by clinical-stage biopharmaceutical companies such as ours. Any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, our stockholders should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We will need substantial additional funding to allow us to support both the systemic and ophthalmological programs through commercial launch, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. We have consumed substantial amounts of cash since our inception. For example, in the years ended December 31, 2020, 2019 and 2018, we used net cash of $160.5 million, $211.1 million and $131.2 million respectively, in our operating activities substantially all of which related to research and development activities. As of December 31, 2020, our cash, cash equivalents and marketable securities were $877.6 million. We expect our expenses to increase in connection with our ongoing activities, particularly as we initiate new clinical trials of, initiate new research and preclinical development efforts for, seek marketing approval for and prepare for commercialization of, our product candidates. In addition, if we obtain marketing approval for pegcetacoplan or any of our other product candidates, we may incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of the collaborator. Furthermore, we continue to incur significant costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations, particularly if we commercialize the ophthalmological program outside the United States without a collaborator or if we fail to establish substantial commercial sales of systemic pegcetacoplan. If we are unable to raise capital when needed or on attractive

terms, we may be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We will be required to expend significant funds in order to advance the development of pegcetacoplan in multiple disease areas, as well as other product candidates we may seek to develop. In addition to our collaboration agreement with Sobi, we may seek one or more additional collaborators for future development of our product candidates for one or more indications. However, we may not be able to enter into an additional collaboration for any of our product candidates for such indications on suitable terms, on a timely basis or at all. Accordingly, we may be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources to achieve our business objectives. We do not have any committed external source of funds other than Sobi's reimbursement obligations under the collaboration agreement. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

We believe that our existing cash, cash equivalents and marketable securities, along with the committed development reimbursement payments from Sobi, will enable us to fund our operating expenses and capital expenditure requirements at least into the second half of 2022. Our estimate as to how long we expect our cash, cash equivalents and marketable securities to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Although we expect that our cash, cash equivalents and marketable securities will be sufficient to allow us to complete the DERBY and OAKS clinical trials, we do not believe they will be sufficient to allow us to support both the systemic and ophthalmological pegcetacoplan programs through commercial launch. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements, will depend on many factors, including:

- the scope, progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for, pegcetacoplan, APL-9 and future product candidates;
- our ability to maintain a productive collaborative relationship with Sobi with respect to pegcetacoplan, including our ability to achieve milestone payments under our agreement with Sobi;
- our ability to identify additional collaborators for any of our product candidates and the terms and timing of any collaboration agreement that we may establish for the development and any commercialization of such product candidates;
- the number and characteristics of future product candidates that we pursue and their development requirements;
- the outcome, timing and costs of clinical trials and of seeking regulatory approvals of pegcetacoplan and other product candidates we may pursue;
- the costs of commercialization activities for any of our product candidates that receive marketing approval to the extent such costs are not the responsibility of our collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of marketing approval, revenue, if any, received from commercial sales of pegcetacoplan and other product candidates;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims;
- the effect of competing technological and market developments;
- the effect of the COVID-19 pandemic on the healthcare system and the economy generally and on our clinical trials and other operations specifically;
- our ability to obtain adequate reimbursement for any product we commercialize; and
- the costs of operating as a public company.

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

We expect our expenses to increase in connection with our planned operations. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, the ownership interest of our then-existing stockholders may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our common stockholders. In addition, additional debt financing, if available,

would result in fixed payment obligations and may involve agreements that include grants of security interests on our assets and restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business.

For example, under our development funding agreement with SFJ, as amended, we have agreed that following regulatory approval by the U.S. Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA, for the use of pegcetacoplan as a treatment for paroxysmal nocturnal hemoglobinuria, or PNH, we will pay to SFJ an initial payment of up to $5.0 million (or up to a total of $10.0 million if regulatory approval is granted by the FDA and the EMA) and then up to an additional $226.0 million in the aggregate (or up to $452.0 million if regulatory approval is granted by the FDA and the EMA) in six additional annual payments with the majority of the payments being made from the third anniversary to the sixth anniversary of regulatory approval. In September 2020, we submitted an NDA, to the FDA and a marketing approval authorization, or MAA, to the EMA for pegcetacoplan for the treatment of PNH. Additionally, we granted a security interest in all of our assets, excluding our intellectual property and license agreements to which we are a party. In connection with the grant of the security interest, we agreed to certain affirmative and negative covenants, including restrictions on our ability to pay dividends, incur additional debt or enter into licensing transactions with respect to our intellectual property other than specified types of licenses.

Future debt securities or other financing arrangements could contain similar or more restrictive negative covenants. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

In January 2021, we closed privately negotiated exchanges with holders of our outstanding convertible notes issued in September 2019, or the 2019 Convertible Notes, under which we issued approximately 3.9 million shares of common stock in exchange for approximately $126.1 million in aggregate principal amount of 2019 Convertible Notes. The effective price per share of the common stock issued in the exchange transactions was lower than the trading price of the Company's common stock on the Nasdaq market at the time of settlement of the exchanges. We may in the future exchange additional principal amount of our Convertible Notes and the effective price per share of the common stock may be lower than the trading price at such time.

If we raise additional funds through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

If we receive regulatory approval for the use of pegcetacoplan as a treatment for PNH or if our agreement with SFJ is terminated prior to receiving such approval in specified circumstances, we will be required to make substantial payments to SFJ pursuant to our development funding agreement. If we do not have sufficient funding or cash flow from our business to meet our payment obligations under the development funding agreement, SFJ could exercise its remedies as a holder of a first priority security interest in our assets and our business could be materially harmed.

We submitted an NDA to the FDA and a MAA to the EMA for pegcetacoplan for the treatment of PNH in September 2020. If we receive regulatory approval for the use of pegcetacoplan as a treatment for PNH, we will be required to make substantial payments to SFJ pursuant to our development funding agreement. In addition, if the agreement is terminated prior to obtaining regulatory approval for the treatment of PNH, under specified circumstances, we also will be required to make substantial payments to SFJ. Our ability to make these required payments depends on our future performance and the future performance of Sobi, which is subject to economic, financial, competitive and other factors beyond our control. Our business may generate cash flow from operations in the future sufficient to meet our obligations under the development funding agreement. If we are unable to generate such cash flow or to obtain additional funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources on acceptable terms or at all, we could default on our payment obligations to SFJ.

Our payment obligations to SFJ could have significant consequences for our security holders and our business, results of operations and financial condition by, among other things:

- limiting our ability to obtain additional financing;
- requiring the dedication of a substantial portion of our cash flow from operations to service our meet our obligations under the development funding agreement, which will reduce the amount of cash available for other purposes; and
- limiting our flexibility to plan for, or react to, changes in our business;

Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due to SFJ, and our cash needs may increase in the future.

We have granted SFJ a first priority security interest in all of our assets other than our intellectual property and the license agreements to which we are a party. If we are unable to meet our payment obligations to SFJ, SFJ may exercise its remedies as a holder of a first priority security interest, which would result in a loss of our assets and our business would be materially harmed.

Our indebtedness could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations and impair our ability to satisfy our obligations under the Convertible Notes.

We incurred an aggregate of $520.0 million of indebtedness as a result of the issuance of convertible notes in September 2019 and May 2020, or the Convertible Notes, of which an aggregate of approximately $393.9 million is outstanding and held by third parties as of the date of this Annual Report on Form 10-K. We issued approximately 3.9 million shares of our common stock in exchange for approximately $126.1 million of 2019 Convertible Notes in January 2021. We may also incur additional indebtedness to meet future financing needs. Our indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the Convertible Notes; and
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under the Convertible Notes, and our cash needs may increase in the future.

Servicing the Convertible Notes will require a significant amount of cash, and we may not have sufficient cash flow from our business to make payments on the Convertible Notes.

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

We may not have the ability to raise the funds necessary to settle conversions of the Convertible Notes in cash or to repurchase the Convertible Notes upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the Convertible Notes.

Holders of the Convertible Notes have the right to require us to repurchase all or a portion of their Convertible Notes upon the occurrence of a fundamental change at a price equal to the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest. In addition, upon conversion of the Convertible Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the Convertible Notes being converted. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Convertible Notes surrendered therefor or Convertible Notes being converted. In addition, our ability to repurchase the Convertible Notes or to pay cash upon conversions of the Convertible Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase Convertible Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the Convertible Notes as required by the indenture would constitute a default under the indenture. A default under the indenture or the fundamental

change itself could also lead to a default under agreements governing our existing or future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Convertible Notes or make cash payments upon conversions thereof.

The conditional conversion feature of the Convertible Notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the Convertible Notes is triggered, holders of Convertible Notes will be entitled to convert the Convertible Notes at any time during specified periods at their option. If one or more holders elect to convert their Convertible Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation in cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Convertible Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal amount of the Convertible Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The accounting method for convertible debt securities could have a material effect on our reported financial results.

In May 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position No. APB 14-1, Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement), which has subsequently been codified as Accounting Standards Codification 470-20, Debt with Conversion and Other Options, or ASC 470-20. Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the Convertible Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the Convertible Notes is that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheet, and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the Convertible Notes. As a result, we will be required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the Convertible Notes to their face amount over the term of the Convertible Notes. We will report lower net income in our financial results because ASC 470-20 will require interest to include both the current period's amortization of the debt discount and the instrument's coupon interest, which could adversely affect our reported or future financial results, the trading price of our common stock and the trading price of the Convertible Notes.

In addition, under certain circumstances, convertible debt instruments (such as the Convertible Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the Convertible Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the Convertible Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the Convertible Notes, then our diluted earnings per share would be adversely affected.

In August 2020, the FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20)* to reduce complexity in applying GAAP to certain financial instruments with characteristics of liability and equity. The Company early adopted this statement effective January 1, 2021. The impact of the adoption of the statement is to increase debt and decrease equity by the amount of the equity component of convertible notes recognized in equity and to decrease the interest expense by the non-cash portion of the discount amortization. Adoption of this statement or other changes to the current accounting standards related to the Convertible Notes could decrease our weighted average basic earnings per share or other financial metrics, but we do not believe that the adoption of this statement will have a materially adverse impact upon our financial statements.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

There are no approved therapies that act by inhibiting C3, and we may not be able to successfully develop and commercialize pegcetacoplan or other product candidates.

Pegcetacoplan is a novel therapeutic compound and its potential benefit in controlling complement-dependent autoimmune and inflammatory diseases has not been established. Pegcetacoplan is designed to control disease through inhibition of C3. There are no approved therapies for our target indications that act by inhibiting C3 and only two approved therapies that act by inhibiting the complement system. As a result, pegcetacoplan may not demonstrate in patients any or all of the pharmacological benefits we believe it may possess. We have not yet obtained marketing approval of any product candidate. We have evaluated pegcetacoplan in preclinical studies and in clinical trials and have advanced pegcetacoplan into Phase 3 clinical development in geographic atrophy, or GA, and PNH. We have submitted an NDA to the FDA and a MAA to the EMA for pegcetacoplan for the treatment of PNH in

September 2020, but we have not obtained regulatory approval to sell pegcetacoplan, APL-9 or any product based on our therapeutic approaches.

If we are unsuccessful in our development efforts, we may not be able to advance the development of pegcetacoplan or any other product candidate, commercialize products, raise capital, expand our business or continue our operations.

The COVID-19 pandemic may affect our ability to initiate and complete preclinical studies and conduct our ongoing clinical trials, delay the initiation of planned and future clinical trials, disrupt regulatory activities, or have other adverse effects on our business and operations. In addition, this pandemic may adversely impact economies worldwide, which could result in adverse effects on our business and operations and ability to raise capital.

The COVID-19 pandemic has caused many governments to implement measures to slow the spread of the outbreak through quarantines, strict travel restrictions, heightened border scrutiny, and other measures. The outbreak and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the pandemic and its effects on our business and operations are uncertain.

A small number of employees of our company, including our chief executive officer, have indicated that they were diagnosed with COVID-19. These employees, including our chief executive officer, have subsequently recovered. We have re-opened our facilities on a limited basis with strict guidelines, but most of our employees continue to work remotely.

We have enrolled, and seek to enroll, patients in our ongoing clinical trials at sites located both in the United States and internationally. We may face difficulties recruiting and retaining patients in our ongoing clinical trials because of logistical effects arising from the pandemic, including increased difficulty for patients and health care providers to travel to or access clinical sites. If patients enrolled in our clinical trials are unable or unwilling to visit clinical trial sites, the data generated by the trials and the timing of completion of our clinical trials may be adversely affected particularly in clinical trials like DERBY and OAKS where patients are expected to travel to clinical sites on a monthly basis over an extended period of time. We may also face disruptions related to the ability to obtain necessary regulatory, institutional review board, or IRB, or other necessary site approvals, as well as other delays at clinical trial sites. In particular, site initiation, participant recruitment and enrollment, participant dosing, availability of drug product or clinical and laboratory supplies, distribution of clinical trial materials, study monitoring, and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. The potential suspension of clinical trial activity at clinical trial sites may have an adverse impact on our clinical trial plans and timelines.

Treatment with complement inhibitors, like pegcetacoplan and APL-9, has immunosuppressive effects. Elderly patients or patients with significantly compromised health, such as those in our clinical trials, could be more susceptible to infections and other complications as a result of treatment with complement inhibitors. The COVID-19 pandemic could lead to delayed enrollment in our trials, more frequent missed visits from ongoing trials and more frequent or severe adverse events during our trials.

We also may face disruptions as a result of the COVID-19 pandemic that affect our ability to procure items that are essential for our research and development activities, including, for example, raw materials used in the manufacturing of our product candidates and laboratory and clinical supplies for our clinical trials. If we experience supply issues, our clinical trial plans and business operations could be adversely affected.

The response to the COVID-19 pandemic may redirect resources with respect to regulatory and intellectual property matters in a way that would adversely impact our ability to progress regulatory approvals and protect our intellectual property. In addition, we may face impediments to regulatory meetings and in obtaining regulatory approvals due to measures intended to limit in-person interactions which could adversely impact the ability of regulatory authorities to take all steps needed to grant regulatory approval and could cause regulatory authorities to defer action on our regulatory submissions, including limitations or delays of inspections of facilities by regulatory authorities, which may impact approval timelines.

Any negative impact that the COVID-19 pandemic has on recruiting or retaining patients in our clinical trials or on the ability of our suppliers to provide materials for our product candidates could cause additional delays to clinical trial activities, which could materially and adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, affect our ability to raise additional capital, and have a material adverse effect on our financial results.

The COVID-19 pandemic has significantly impacted economies worldwide, which could result in adverse effects on our business, operations and ability to raise capital. We cannot be certain what the overall impact of the continuation or worsening of the COVID-19 pandemic may be on our business. It has the potential to adversely affect our business, financial condition, results of operations, and prospects.

We are dependent on the successful development and commercialization of our lead product candidate, pegcetacoplan***. If we are unable to develop, obtain marketing approval for or successfully commercialize pegcetacoplan, either alone or through a collaboration, or if we experience significant delays in doing so, our business could be harmed.***

We currently have no products approved for sale and are investing a significant portion of our efforts and financial resources to fund the development of pegcetacoplan. We submitted an NDA to the FDA and a MAA to the EMA for pegcetacoplan for the treatment of PNH in September 2020. The FDA accepted the NDA and set the PDUFA target action date for May 14, 2021. The EMA validated the MAA in October 2020, with the potential for a European Commission decision on the MAA in the second half of 2021. Pursuant to our agreement with Sobi, we have granted to Sobi the exclusive right to commercialize systemic pegcetacoplan outside the United States. Our prospects are substantially dependent on our ability, or that of Sobi or any future collaborator, to develop, obtain marketing approval for and successfully commercialize pegcetacoplan in one or more disease indications. All of our other product candidates are in early stages of clinical development.

The success of pegcetacoplan will depend on several factors, including the following:

- successful recruitment of patients, enrollment in and completion of our ongoing and planned clinical trials;
- initiation and successful recruitment of patients, enrollment in and completion of additional clinical trials;
- safety, tolerability and efficacy profiles that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval;
- our ability to identify success criteria and endpoints for our clinical trials and otherwise design our clinical trials such that the FDA, EMA, and other regulatory authorities will be able to determine the clinical efficacy and safety profile of any product candidates we may develop;
- timely receipt of marketing approvals from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishment of supply arrangements with third-party suppliers and manufacturers of raw materials and drug intermediates;
- establishment of arrangements with third-party manufacturers to obtain finished products that are appropriately packaged for sale;
- obtaining pegcetacoplan drug product from third-party manufacturers of sufficient quality to be used in our clinical trials and for commercial sale;
- developing, validating and maintaining a commercially viable manufacturing process that is compliant with current good manufacturing practices, or cGMPs;
- the performance of Sobi and any future collaborators;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio;
- successful launch of commercial sales following any marketing approval;
- an acceptable safety profile following any marketing approval;
- commercial acceptance of our products, if approved, by patients, the medical community and third-party payors;
- our ability to compete with other therapies; and
- obtaining and maintaining healthcare coverage and adequate reimbursement.

Many of these factors are beyond our control, including clinical development, the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of our collaborators, including Sobi. If we are unable to develop, receive marketing approval for and successfully commercialize pegcetacoplan on our own or with a collaborator, or experience delays as a result of any of these factors or otherwise, our business could be substantially harmed.

If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the FDA and other regulators, we, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates.

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities, such as the EMA, impose similar requirements. Prior to September 2020, we had not previously submitted or similar drug approval filings to comparable foreign regulatory authorities for any of our product candidates. In September 2020, we submitted an NDA to the FDA and a MAA to the EMA for pegcetacoplan for the treatment of PNH. We may never receive such approvals. We must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our product candidates is susceptible to the risk of failure inherent at any stage of product development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if one or more of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity or intolerability caused by our product candidates, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we cannot be certain that we will not face additional setbacks. It is possible that any of our development programs may be placed on full or partial clinical hold by regulatory authorities at any point, which would delay and possibly prevent further development of our product candidates.

In October 2018, we announced that we voluntarily implemented a pause in dosing in our Phase 3 clinical program in patients with GA due to observed cases of non-infectious inflammation in patients treated from a single manufacturing lot of pegcetacoplan ophthalmological drug product. We also voluntarily implemented a pause in our Phase 1b/2 trial of pegcetacoplan in patients with wet AMD, which we subsequently discontinued. A total of eight patients, four in the Phase 3 GA program and four in our Phase 1b/2 clinical trial of pegcetacoplan in patients with wet AMD, were treated with pegcetacoplan from this manufacturing lot and each patient developed non-infectious inflammation. Inflammation in all eight patients completely resolved. We modified our manufacturing process in order to eliminate an impurity in the active pharmaceutical ingredient and have manufactured sufficient supply of pegcetacoplan utilizing the modified manufacturing process to conduct the Phase 3 GA program. In March 2019, we restarted enrollment of our Phase 3 clinical program in GA, and we announced that we completed enrollment in July 2020.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us and impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. Moreover, if we are required to conduct additional clinical trials or other testing of our product candidates beyond the trials and testing that we contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing or the results of these trials or tests are unfavorable, uncertain or are only modestly favorable, or there are unacceptable safety concerns associated with our product candidates, we may:

- incur additional unplanned costs;
- 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 significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements; or
- be required to remove the product from the market after obtaining marketing approval.

Under our collaboration with Sobi, we are relying on Sobi to conduct certain clinical trials of pegcetacoplan and seek regulatory approval for pegcetacoplan outside the United States. If Sobi or any future collaborator are unable to successfully complete clinical trials of our product candidates and obtain regulatory approvals on a timely basis, or at all, our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties may be materially impaired.

In addition, investigators for our clinical trials and other service providers may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services, including equity awards and option grants, and may have other financial interests in our company. We are required to collect and provide financial disclosure notifications or certifications for our clinical investigators to the FDA. If the FDA concludes that a financial relationship between us and a clinical investigator has created a conflict of interest or otherwise affected interpretation of the trial, the FDA may question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our current and future product candidates.

Our failure to successfully complete clinical trials of our product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our product candidates would significantly harm our business.

Adverse events or undesirable side effects caused by, or other unexpected properties of, any of our product candidates may be identified during development that could delay or prevent their marketing approval or limit their use.

Adverse events or undesirable side effects caused by, or other unexpected properties of, our product candidates could cause us, or any collaborator conducting clinical trials of our product candidates such as Sobi, an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of one or more of our product candidates and could result in a more restrictive label, or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. For example, by design pegcetacoplan has immunosuppressive effects and, in some cases, may be administered to patients with underlying significantly compromised health. Administration of our product candidates could make patients more susceptible to infection.

In addition, in preclinical studies of pegcetacoplan, we observed evidence of minimal to mild kidney toxicity when animals were administered relatively higher doses of pegcetacoplan than the doses we intend to use in the treatment of patients. We believe this kidney toxicity is likely associated with the presence of polyethylene glycol, or PEG, which is a component of pegcetacoplan. If such kidney toxicity, or other adverse effects, were to arise in patients being treated with pegcetacoplan or any other of our product candidates, it could require us to halt, delay or interrupt clinical trials of such product candidate or adversely affect our ability to obtain requisite approvals to advance the development and commercialization of such product candidate.

In our Phase 2 trial of pegcetacoplan in patients with GA, the most frequently reported adverse events were associated with the injection procedure in the study eye. These adverse events included two cases of confirmed endophthalmitis, which is inflammation in the eye typically caused by infection, and one case of presumed endophthalmitis where the culture tested negative for bacterial growth. In addition, during the 12-month treatment period and the subsequent six-month period during which no treatment was administered, we observed a higher incidence of new onset exudation, or fluid leakage in the retinas of eyes in which exudation had not previously been reported, in the study eyes treated with pegcetacoplan, predominantly in patients with a history of wet AMD in the non-study eye, or fellow eye. Specifically, we observed that, after the 12-month treatment period and the six-month monitoring period, 21% of patients who received administration of pegcetacoplan every month and 9% of patients who received administration of pegcetacoplan every other month showed new onset exudation in the study eye as compared to 1% of the sham group. As we continue development of pegcetacoplan for GA, if a significant number of patients develop new onset exudation, then we may need to limit development of ophthalmological pegcetacoplan 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.

In our Phase 3 clinical trial of pegcetacoplan in patients with GA and our Phase 1b/2 clinical trial of pegcetacoplan in patients with wet AMD, several patients treated from a single manufacturing lot of pegcetacoplan ophthalmological drug product experienced non-infectious inflammation. A total of eight patients, four in our Phase 3 GA program and four in our Phase 1b/2 clinical trial of pegcetacoplan in patients with wet AMD, were treated with this pegcetacoplan from this manufacturing lot and each patient developed non-infectious inflammation. Inflammation in these patients has completely resolved.

In our Phase 3 PEGASUS trial, the safety profile observed in the pegcetacoplan was comparable to the safety profile observed in the eculizumab arm and consistent with previously reported data. After the 48-week study period, twenty-four of 80 pegcetacoplan monotherapy-treated patients (30%) experienced a serious adverse event (SAE). Five of the SAEs (6%) were assessed to be possibly related to study treatment. No cases of meningitis were reported. One death was reported due to COVID-19 and was unrelated to study treatment. The most common adverse events (AEs) reported throughout the study were injection site reactions (36%), hemolysis (24%), and diarrhea (21%). Twelve out of 80 patients (15%) discontinued due to adverse events, with five discontinuations due to hemolysis. Sixty-four of the 67 patients (96%) who completed the open-label period opted to enter the extension study.

If any of our product candidates is associated with adverse events or undesirable side effects or has properties that are unexpected, we, or our collaborators, may abandon development or limit development of that product candidate 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 undesirable or unexpected side effects that prevented further development of the compound.

In addition, clinical trials by their nature utilize a sample of the potential patient population. However, with a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered when a significantly larger number of patients are exposed to the product. If safety problems occur or are identified after one of our products reaches the market, the FDA or comparable non-U.S. regulatory authorities may require that we amend the labeling of our product, recall our product, or even withdraw approval for our product.

If we, or any collaborator conducting clinical trials of any of our product candidates such as Sobi, experience any of a number of possible unforeseen events in connection with clinical trials of our product candidates, potential clinical development, marketing approval or commercialization of our product candidates could be delayed or prevented.

We, or our collaborators, may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent clinical development, marketing approval or commercialization of our product candidates, including:

- clinical trials of our product candidates may produce unfavorable or inconclusive results;
- we, or our collaborators, may decide, or regulators may require us or them, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we, or our collaborators, anticipate, patient enrollment in these clinical trials may be slower than we, or our collaborators, anticipate or participants may drop out of these clinical trials at a higher rate than we, or our collaborators, anticipate;
- the cost of planned clinical trials of our product candidates may be greater than we anticipate;
- our third-party contractors or those of our collaborators, including those manufacturing our product candidates or components or ingredients thereof or conducting clinical trials on our behalf or on behalf of our collaborators, may deviate from the trial protocol, fail to comply with regulatory requirements or fail to meet their contractual obligations to us or our collaborators in a timely manner or at all;
- regulators or institutional review boards may not authorize us, our collaborators or our or their investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we, or our collaborators, may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- patients that enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial's duration;
- we, or our collaborators, may have to delay, suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate;
- regulators or institutional review boards may require that we, or our collaborators, or our or their investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their standards of conduct, a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate or findings of undesirable effects caused by a chemically or mechanistically similar product or product candidate;
- the FDA or comparable foreign regulatory authorities may disagree with our, or our collaborators', clinical trial designs or our or their interpretation of data from preclinical studies and clinical trials, including the data from our PEGASUS trial;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we, or our collaborators, enter into agreements for clinical and commercial supplies;
- the supply or quality of raw materials, drug intermediates or manufactured product candidates, other products evaluated in our clinical trials or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient to obtain marketing approval.

Should the COVID-19 pandemic persist, our clinical development plans could be affected, and we may be unable to conduct our clinical trials in the manner or on the timelines that we currently anticipate. Clinical trial participants and clinical investigators may not be able to comply with clinical trial protocols, if for example quarantines or other travel limitations impede participant movement, affect sponsor access to study sites, or interrupt healthcare services. The COVID-19 pandemic could lead to delayed enrollment in our trials, more frequent missed appointments and withdrawals from ongoing trials and more frequent or severe adverse events during our trials.

Product development costs for us will increase if we experience delays in testing or pursuing marketing approvals and we may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any preclinical tests or clinical trials will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we, or our collaborators, may have the exclusive right to commercialize our product candidates or allow our competitors, or the competitors of our collaborators, to bring products to market before we, or our collaborators, do and impair our ability, or the ability of our collaborators, to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that lead to clinical trial delays may ultimately lead to the denial of marketing approval of any of our product candidates.

If we, or any collaborator conducting clinical trials of any of our product candidates such as Sobi, experience delays or difficulties in the enrollment of patients in clinical trials, our or their receipt of necessary regulatory approvals could be delayed or prevented.

We, or our collaborators, may not be able to initiate or continue clinical trials for any of our product candidates if we, or they, are unable to locate and enroll a sufficient number of eligible patients to participate in clinical trials as required by the FDA or comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials, and is affected by many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the proximity of patients to clinical sites;
- the patient referral practices of physicians;
- the eligibility criteria for the trial;
- the design of the clinical trial;
- efforts to facilitate timely enrollment;
- competing clinical trials; and
- clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

Many of the indications for which we are developing product candidates are rare diseases with small patient populations, and many of those patients are treated with other therapies or products. Further, there are only a limited number of specialist physicians that regularly treat patients with these rare diseases and major clinical centers that support such treatment are concentrated in a few geographic regions. In addition, other companies are conducting clinical trials and have announced plans for future clinical trials that are seeking, or are likely to seek, to enroll patients with these rare diseases and patients are generally only able to enroll in a single trial at a time. Both patients and their physicians may be reluctant to forgo, discontinue or otherwise alter existing, approved life-saving therapeutic approaches. Given the severe and life-threatening nature of these indications and the expectation that many patients will be on treatment with other therapies or products, we may encounter difficulty in recruiting a sufficient number of patients for our trials including in particular our planned clinical trials. The small population of patients, competition for these patients, the nature of the disease and limited trial sites may make it difficult for us to enroll enough patients to complete our clinical trials of pegcetacoplan in a timely and cost-effective manner. These difficulties may be exacerbated as a result of the ongoing COVID-19 pandemic.

Our inability, or the inability of our collaborators, to enroll a sufficient number of patients for our, or their, clinical trials could result in significant delays or may require us or them to abandon one or more clinical trials altogether. Enrollment delays in our, or their, clinical trials may result in increased development costs for our product candidates, delay or halt the development of and approval processes for our product candidates and jeopardize our, or our collaborators', ability to commence sales of and generate revenues from our product candidates, which could cause the value of our company to decline and limit our ability to obtain additional financing, if needed.

Results of preclinical studies and Phase 1 and Phase 2 clinical trials may not be predictive of results of later clinical trials.

The outcome of preclinical studies and Phase 1 and Phase 2 clinical trials may not be predictive of the success of later clinical trials, and preliminary or interim results of clinical trials do not necessarily predict final results. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier stages of clinical development, and we could face similar setbacks. Similarly, 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.

In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we, or our collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

Some of the data we present on the use of pegcetacoplan for the treatment of GA is drawn from *post hoc* analyses of data subsets from our Phase 2 clinical trial. While we believe these data were useful in informing the design of future Phase 3 clinical trials for pegcetacoplan, *post hoc* analyses performed after unmasking trial results can result in the introduction of bias and may not be predictive of success in Phase 3 clinical trials.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. For instance, the Phase 3 clinical trials in GA are similar in design to the Phase 2 clinical trial, except that patients will be treated with pegcetacoplan for 24 months rather than 12 months and there will not be a six-month monitoring period following treatment. Additionally, unlike the Phase 2 clinical trial, GA lesion size will be measured by total area rather than mean change in the square root of GA lesion size. In our Phase 3 clinical trials in GA, statistical significance is set at a p-value of 0.05 or less, meaning that there is a 1-in-20 or less probability that the observed results occurred by chance rather than as a treatment effect. In our Phase 2 clinical trial, we set statistical significance as a p-value of 0.1 or less, meaning that there is a 1-in-10 or less probability that the observed results occurred by chance. If we fail to receive positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

If we fail to develop and commercialize other product candidates, we may be unable to grow our business.

Although the development and commercialization of pegcetacoplan is our primary focus, as part of our growth strategy, we are developing a pipeline of product candidates for the treatment of complement-dependent diseases. These other product candidates will require additional, time-consuming and costly development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and/or applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, there can be no assurance that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

We may not be successful in our efforts to develop APL-9 for the treatment of patients with respiratory failure including acute respiratory distress syndrome secondary to COVID-19.

In May 2020, we initiated a Phase 1/2 clinical trial of APL-9 as a potential treatment for patients with respiratory failure including acute respiratory distress syndrome, or ARDS, secondary to COVID-19. ARDS is a serious lung condition that causes low blood oxygen, often resulting in hospitalization and mechanical ventilation or other life-support measures.

The timing and success of our clinical trial of APL-9 for the treatment of these COVID-19 patients will depend on our ability to enroll patients in the trial. Many other companies are pursuing the development of product candidates for the treatment of COVID-19, and patient enrollment may be affected by availability of commercially available treatments and other clinical trials of competing product candidates. Patient enrollment may also be affected by other factors, including the incidence of COVID-19 over time and the perceived risks and benefits of the use of APL-9 as a treatment relative to competing treatments. Our inability to enroll a sufficient number of patients could result in significant delays or could require us to abandon the trial and development of APL-9 for the treatment of these patients altogether.

The COVID-19 pandemic may be effectively contained before we can successfully develop APL-9 as a treatment for these COVID-19 patients and we may not be able to recoup our financial investment in the trial through sales of APL-9. For example, since

December 2020, the FDA has issued the first emergency use authorizations for COVID-19 vaccines developed by Pfizer and BioNTech and Moderna. Additional vaccines may be approved in 2021. The vaccines are being distributed and may be available in sufficient quantities to contain the spread of the SARS-CoV-2 virus before we are able to obtain marketing approval of APL-9 for the treatment of COVID-19. Our commitment of financial resources and personnel to the development of APL-9 for the treatment of these patients may cause delays in or otherwise negatively impact our other development programs and research and discovery efforts with our other product candidates. Various government entities and private foundations are offering incentives, grants and contracts to encourage additional investment into treatments for patients with COVID-19. Such funding may have the effect of increasing the number of competitors and/or providing advantages to competitors working on treatments for COVID-19.

In this trial, we are administering APL-9 as an add-on to the current standard of care. The standard of care for COVID-19 patients may change during our trial or following our trial, and the clinical data that we obtain in our ongoing Phase 1/2 may not translate to supporting the use of APL-9 as an add-on to a new standard of care. To date, patients with ARDS secondary to COVID-19 have experienced high fatality rates and the response of these patients with treatment may differ from the treatment of patients with typical ARDS that is not secondary to COVID-19. Given the severe nature of the indication and limited treatment history of patients with ARDS secondary to COVID-19, we cannot be certain that APL-9 will be able to demonstrate a clinical benefit as a treatment option for these patients.

Given the rapidity of the onset of the COVID-19 pandemic, scientific and medical research on the SARS-CoV-2 virus is ongoing and evolving. We cannot be certain that the evidence that we believe suggests that APL-9 may be beneficial to these patients will be established in a clinical trial. Furthermore, the failure of APL-9 to demonstrate safety and efficacy in these patients could negatively impact the perception of us and APL-9 by investors. Additionally, it is possible that unexpected safety issues could occur in these COVID-19 patients. Any such safety issues could affect our development plans for APL-9 in other indications.

We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our product candidates.

We have never obtained marketing approval for a product candidate. We submitted an NDA to the FDA and a MAA to the EMA for pegcetacoplan for the treatment of PNH in September 2020. The FDA may not approve our NDA and the EMA may not approve or EMA for pegcetacoplan for the treatment of PNH. Although the FDA set the PDUFA target action date and the EMA validated the MAA in Europe, it is possible that the FDA or EMA may refuse to accept for substantive review any NDAs or MAAs that we submit for our product candidates. In addition, the FDA and EMA or may conclude after review of our data that our application is insufficient to obtain marketing approval of pegcetacoplan. If the FDA or EMA does not accept or approve our NDA or MAA for pegcetacoplan, it may require that we conduct additional clinical trials, preclinical studies or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other required trials or studies, approval of any NDA, MAA or application that we submit may be delayed by several years or may require us to expend more resources than we have available. It is also possible that additional trials or studies, if performed and completed, may not be considered sufficient by the FDA or EMA to approve our NDAs or MAAs.

The FDA has advised us that, for the approval of a new treatment for PNH, hemoglobin stabilization in conjunction with change in transfusion dependence constitute accepted clinical benefit, but that a rise in hemoglobin levels may not translate to clinical benefit in patients who entered the trial with high hemoglobin levels, such as permitted by the inclusion criteria of the PEGASUS trial, and who do not require transfusions. We believe that the data from the PEGASUS trial support a finding of clinical benefit. We submitted an NDA to the FDA and an MAA to the EMA for pegcetacoplan for the treatment of PNH in September 2020.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing pegcetacoplan in the United States or EU, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, either to pegcetacoplan or to any future product candidate for which we may seek marketing approval, we may be forced to abandon our development efforts for pegcetacoplan or such future product candidates, which could significantly harm our business.

Even if pegcetacoplan or one of our other product candidates that we develop receives marketing approval, we or others may later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, which could compromise our ability, or that of our collaborators, to market the product.

Clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of our collaborators, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;

- we, or our collaborators, may be required to recall the product, change the way the product is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we, or our collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we, or our collaborators, could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could harm our business and operations and could negatively impact our stock price.

Even if pegcetacoplan or one of our other product candidates that we develop 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, in which case we may not generate significant revenues or become profitable.

We have never commercialized a product, and even if pegcetacoplan or one of our other product candidates that we develop is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies. Eculizumab (marketed as Soliris) and ravulizumab (marketed as Ultomiris) are the only therapies that have been approved for the treatment of PNH, and even if we are able to obtain marketing approval of pegcetacoplan for the treatment of PNH, we may not be able to successfully convince physicians or patients to switch from eculizumab or ravulizumab to pegcetacoplan. This may be particularly true with respect to eculizumab as many in the medical community believe that patients with PNH on eculizumab may experience sudden and excessive blood cell lysis, or rupture, leading to anemia, blood clots and other medical problems, when they stop receiving eculizumab. In addition, even if we are able to demonstrate our product candidates' safety and efficacy to the FDA and other regulators, safety concerns in the medical community may hinder market acceptance.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If pegcetacoplan or any of our other product candidates that we develop is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of pegcetacoplan or our other product candidates that we develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies;
- the prevalence and severity of any side effects;
- the clinical indications for which the product is approved;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- the price at which the product is offered for sale;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- the approval of other new products for the same indications;
- the timing of market introduction of our approved products as well as competitive products;
- adverse publicity about the product or favorable publicity about competitive products;

- potential product liability claims;
- changes in the standard of care for the targeted indications for the product; and
- availability and amount of coverage and reimbursement from government payors, managed care plans and other third-party payors.

In addition, the potential market opportunity for pegcetacoplan in any indication is difficult to precisely estimate. Our estimates of the potential market opportunity for pegcetacoplan include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys. However, no independent source has verified such assumptions. If any of these assumptions proves to be inaccurate, then the actual market for pegcetacoplan could be smaller than our estimates of potential market opportunity. If the actual market for pegcetacoplan is smaller than we expect, our product revenue may be limited, and it may be more difficult for us to achieve or maintain profitability.

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

Because we have limited financial and managerial resources, we intend to focus on developing product candidates for specific indications that we identify as most likely to succeed, in terms of both their potential for marketing approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential.

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

If we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution arrangements with third parties, we may not be successful in commercializing any product candidates if approved.

We are currently developing sales, marketing and distribution infrastructure in the United States to support commercialization of systemic pegcetacoplan for the treatment of PNH and worldwide infrastructure for our other product candidates, including pegcetacoplan as a treatment for GA.

We are building focused capabilities to commercialize development programs for certain indications where we believe that the medical specialists for the indications such as PNH are sufficiently concentrated to allow us to effectively promote the product with a targeted sales team. The development of sales, marketing and distribution capabilities requires substantial resources, is time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we could have prematurely or unnecessarily incurred these commercialization costs. This may be costly, and our investment could be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire or retain a sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we plan to target. If we are unable to establish or retain a sales force and marketing and distribution capabilities, our operating results may be adversely affected. If a potential partner has development or commercialization expertise that we believe is particularly relevant to one of our products, then we may seek to collaborate with that potential partner even if we believe we could otherwise develop and commercialize the product independently.

In certain indications, we may seek to enter into collaborations that we believe may contribute to our ability to advance development and ultimately commercialize our product candidates. We may also seek to enter into collaborations where we believe that realizing the full commercial value of our development programs will require access to broader geographic markets or the pursuit of broader patient populations or indications. As a result of entering into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues may be lower, perhaps substantially lower, than if we were to directly market and sell products in those markets. Furthermore, we may be unsuccessful in entering into the necessary arrangements with third parties or may be unable to do so on terms that are favorable to us. In addition, we may have little or no 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, either on our own or in collaboration with third parties, we will not be successful in commercializing any of our product candidates that receive marketing approval.

We have granted exclusive commercialization rights for systemic pegcetacoplan outside of the United States to Sobi under our agreement with Sobi. If Sobi is unable to meet its contractual obligations, we may be forced to focus our efforts internally to

commercialize systemic pegcetacoplan outside of the United States without the assistance of a commercialization partner or seek another commercialization partner, either of which would result in us incurring greater expenses and could cause a delay in market penetration while we expand our commercial operations or seek an alternative commercialization partner. Such costs may exceed the increased revenues we would receive from direct systemic pegcetacoplan sales outside of the United States, at least in the near term. We would also be forced to declare a breach of the agreement with Sobi and seek a termination of the agreement which could result in an extended and uncertain dispute with Sobi, including arbitration or litigation, any of which would be costly.

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 products is highly competitive, as described in "Competition," above. We expect that we, and our collaborators, will face significant competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to any of our product candidates that we, or our collaborators, may seek to develop or commercialize in the future, including from therapies that act through the complement system and therapies that use different approaches.

Our competitors may succeed in developing, acquiring or licensing technologies and products that are more effective, have fewer side effects or more tolerable side effects or are less costly than any product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete and noncompetitive.

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, or our collaborators, may develop. Our competitors also may obtain FDA or other marketing approval for their products before we, or our collaborators, are able to obtain approval for ours, which could result in our competitors establishing a strong market position before we, or our collaborators, are able to enter the market.

Many of our existing and potential future competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals 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 or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. 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, the development of our product candidates.

If the FDA or comparable foreign regulatory authorities approve generic versions of any of our products that receive marketing approval, or such authorities do not grant our products appropriate periods of data exclusivity before approving generic versions of our products, the sales of our products could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a "reference-listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," or the Orange Book. Manufacturers may seek approval of generic versions of reference-listed drugs through submission of an ANDA in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference-listed drug and that the generic version is bioequivalent to the reference-listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference-listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference-listed drug may be typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference-listed drug has expired. The Federal Food, Drug, and Cosmetic Act, or FDCA, provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity, or NCE. Specifically, 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 that a patent covering the reference-listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference-listed drug. It is unclear whether the FDA will treat the active ingredients in our product candidates as NCEs and, therefore, afford them five years of NCE data exclusivity if they are approved. If any product we develop does not receive five years of NCE exclusivity, the FDA may approve generic versions of such product three years after its date of approval, subject to the requirement that the ANDA applicant certifies to any patents listed for our products in the Orange Book. Manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if we still have patent protection for our product.

Competition that our products may face from generic versions of our products could negatively impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on our investments in those product candidates.

Even if we, or any collaborator that is commercializing any of our product candidates such as Sobi, are able to commercialize any product candidate, the product may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or healthcare reform initiatives, any of which could harm our business.

The commercial success of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by third-party payors, including government health administration authorities and private health coverage insurers. If coverage and reimbursement is not available, or reimbursement is available only to limited levels, we, or our collaborators, may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or our collaborators, to establish or maintain pricing sufficient to realize a sufficient return on our or their investments. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. 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, or our collaborators, might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may 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 or the ability of our collaborators to recoup our or their investment in one or more product candidates, even if our product candidates obtain marketing approval.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Therefore, our ability, and the ability of our collaborators, to commercialize any of our product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors. Third-party payors decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and abroad. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of our collaborators to sell our product candidates profitably. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or those of our collaborators, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost-control initiatives could cause us, or our collaborators, to decrease the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the prices for our products, if any, decrease or if governmental and other third-party payors do not provide coverage or adequate reimbursement, our prospects for revenue and profitability will suffer.

The commercial potential of our products depends in part on reimbursement by government health administration authorities, private health insurers and other organizations. If we, or any collaborator that is commercializing our product candidates such as Sobi are unable to obtain coverage or reimbursement for our products, as monotherapy or in combination with other therapies, including possible combinations with eculizumab or ravulizumab, at the levels anticipated, our financial condition could be harmed. Additionally, if new compounds currently in development by potential competitors, including biosimilars of eculizumab or ravulizumab, obtain marketing approval, there may be downward pressure on reimbursement levels for therapies in our target disease areas, which could have a negative impact on our ability to achieve and maintain profitability.

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for 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. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

In addition, increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we, or any collaborator, including Sobi, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and

adequate payment rates from both government-funded and private payors for any of our product candidates for which we, or our collaborator, obtain marketing approval could significantly harm 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 limit commercialization of any products that we may develop.

We face an inherent risk of product liability claims as a result of the clinical testing of our product candidates despite obtaining appropriate informed consents from our clinical trial participants. We will face an even greater risk if we or our collaborators including Sobi, commercially sell any product that we may develop. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our 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 resulting litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

Although we maintain product liability insurance coverage in the amount of up to $20.0 million in the aggregate and clinical trial liability insurance of up to $20.0 million in the aggregate, this insurance may not fully cover potential liabilities that we may incur. The cost of any litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives marketing approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could harm our business, financial condition, results of operations and prospects.

Our internal information systems, or those of any contractors, consultants, vendors, business partners or other third parties, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

We collect, store and transmit large amounts of confidential information, including personal information and information relating to intellectual property, on internal information systems and through the information systems of our contractors, consultants, vendors, business partners or other third parties.

Despite the implementation of security measures, our internal information systems and those of third parties are vulnerable to damage from computer viruses, malware, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such systems are also vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, our collaborators, contractors, consultants, vendors, business partners and other third parties, or from cyber-attacks by malicious third parties over the Internet or through other mechanisms. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial of service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber-attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient.

While we have not experienced any such material system failure, accident, cyber-attack or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs, clinical trials and business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions, in addition to possibly requiring substantial expenditures of resources to remedy. For example, the loss of clinical trial data from clinical trials could result in delays or termination of our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, as risks with respect to our information systems continue to evolve, we will incur additional

costs to maintain the security of our information systems and comply with evolving laws and regulations pertaining to cybersecurity and related areas. 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, including regulatory fines and other losses with respect to privacy claims, enrollment in our clinical trials could be negatively affected, our competitive position and reputation could be harmed and the further development and commercialization of our product candidates could be delayed.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our clinical trials. If they do not perform satisfactorily, our business could be harmed.

We do not independently conduct clinical trials of our product candidates. We rely, and expect to continue to rely, on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials of pegcetacoplan and any other product candidate that we develop. Any of these third parties may terminate their engagements with us under certain circumstances. We may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, there is a natural transition period when a new contract research organization begins work. As a result, delays would likely occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

Further, although our reliance on these third parties for clinical development activities limits our control over these activities, we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards. For example, notwithstanding the obligations of a contract research organization for a trial of one of our product candidates, 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 current Good Clinical Practices, or cGCPs, 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. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and institutional review boards. If we or our third-party contractors fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our product candidates, which would delay the marketing approval process. We cannot be certain that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. Similar regulatory requirements apply outside the United States, including the International Council for Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use, or ICH. We are also required to register clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. In addition, these contractors may be adversely affected by the COVID-19 pandemic. 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 may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

We contract with third parties for the manufacture, storage and distribution of our product candidates for clinical trials and expect to continue to do so in connection with our future development and commercialization efforts. This reliance on third parties increases the risk that we will not have sufficient quantities of pegcetacoplan or our other product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We currently have no manufacturing facilities, and a relatively small number of personnel with manufacturing experience who can oversee the manufacturing process. We rely on contract manufacturers to manufacture, store and distribute both drug substance and drug product required for our clinical trials. We plan to continue to rely upon contract manufacturers, and, potentially collaboration partners, to manufacture commercial quantities of our products, if approved. We may be unable to establish any

agreements with contract manufacturers or to do so on acceptable terms, or to maintain such agreements as we may enter. Even if we are able to establish agreements with contract manufacturers, reliance on contract manufacturers entails additional risks, including:

- manufacturing delays if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them, or if unforeseen events in the manufacturing process arise;
- the possible termination or nonrenewal of agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the possible breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

We currently rely, and expect to continue to rely, on a small number of third-party contract manufacturers to supply most of our supply of active pharmaceutical ingredients and required finished product for our preclinical studies and clinical trials. In particular, we have entered into a commercial supply agreement with Bachem Americas, Inc., or Bachem, to purchase a significant portion of our requirements for the pegcetacoplan drug substance over the next five years. We have also entered into long-term commercial supply agreements with other suppliers of raw materials, drug substance and drug product. If any of our existing manufacturers should become unavailable to us for any reason, we may incur delays in identifying or qualifying replacements. 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 contract manufacturers or distributors could delay clinical development or marketing approval of our product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue. For example, in the past we experienced issues associated with the manufacturing process for pegcetacoplan that resulted in delays in the supply of pegcetacoplan. These delays resulted in us incurring additional costs and delays in our PNH development program. Additionally, in October 2018, we announced that we voluntarily implemented a pause in dosing in our clinical trials in patients with GA and wet AMD due to observed cases of non-infectious inflammation in patients treated from a single manufacturing lot of pegcetacoplan ophthalmological drug product that we believe occurred due to an impurity in the active pharmaceutical ingredient. If we experience other issues or delays in the future, our development of pegcetacoplan may be materially delayed and our business adversely affected.

Any manufacturing problem, the loss of a contract manufacturer or any loss of storage could be disruptive to our operations, delay our clinical trials and, if our products are approved for sale, result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our product candidates. For example, one company currently produces most of the PEG that is used in pharmaceutical and drug development globally. PEG is a component of pegcetacoplan. If this supplier of PEG experiences manufacturing and supply problems with respect to PEG, then the manufacturers with whom we contract may have difficulty in procuring PEG for the supply and manufacture of pegcetacoplan. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. If we or any third-party parties on which we rely are adversely impacted by restrictions or limitations resulting from the COVID-19 pandemic, our ability to manufacture and supply pegcetacoplan may be disrupted, which would limit our ability to conduct our clinical trials or prepare for our commercial launch. Any unanticipated disruption to our contract manufacturing caused by problems at suppliers could delay shipment of our product candidates, increase our cost of goods sold and result in lost sales with respect to any approved products.

If any of our product candidates are approved by any regulatory agency, we will need to enter into agreements with third-party contract manufacturers for the commercial production and distribution of those products. It may be difficult for us to reach agreement with a contract manufacturer on satisfactory terms or in a timely manner. In addition, we may face competition for access to manufacturing facilities as there are a limited number of contract manufacturers operating under cGMPs that can manufacture our product candidates. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could delay our commercialization efforts.

Third-party manufacturers are required to comply with cGMPs and similar regulatory requirements outside the United States, such as the ICH. Facilities used by our third-party manufacturers must be approved by the FDA after we submit an NDA and before potential approval of the product candidate. Similar regulations apply to manufacturers of our product candidates for use or sale in foreign countries. We do not control the manufacturing process and are completely dependent on our third-party manufacturers for compliance with the applicable regulatory requirements for the manufacture of our product candidates. If our manufacturers cannot successfully manufacture material that conforms to our specifications or the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, they may not be able to meet our supply requirements for clinical and commercial operations and to secure the applicable approval for their manufacturing facilities. If these facilities are not approved for commercial manufacture, we may need to find alternative manufacturing facilities, which could result in delays in obtaining approval for the applicable product candidate.

In addition, our manufacturers are subject to ongoing periodic inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements both prior to and following the receipt of marketing approval for any of our product candidates. Some of these inspections may be unannounced. Failure by any of our manufacturers to comply with applicable cGMPs or other regulatory requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply and criminal prosecutions, any of which could significantly impact the available supplies of our product candidates and harm our business, financial condition and results of operations.

We are developing a custom, on-body drug delivery system that would enable patients to self-administer pegcetacoplan through subcutaneous infusion. While this device is in development, we plan to use one or more commercially available ambulatory infusion pumps in our ongoing and planned clinical trials and for our commercial launch of pegcetacoplan as a treatment for PNH. The development of a custom drug delivery system may be delayed, or we may not be successful in developing a custom drug delivery system and may need to continue to rely on commercially available ambulatory infusion pumps. Any reliance on third-party infusion pumps may involve several risks, including reduced control over costs, delivery schedules, reliability and quality.

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

Our prospects for the development and commercialization of our product candidates will depend in significant part on the success of our collaboration with Sobi and future collaborations.

We have entered into a collaboration with Sobi for the global co-development and commercialization outside of the United States of systemic pegcetacoplan and we may seek to enter into additional collaborations for the development and commercialization of certain of our product candidates. We may have limited control over the amount and timing of resources that our collaborators, including Sobi, will dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, our collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms.

Collaborations involving our product candidates pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may 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 or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- 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 product candidates;
- 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;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product

candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- 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 collaborators and us regarding ownership of or other rights in the intellectual property generated in the course of the collaborations; 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, our agreement with Sobi is subject to early termination in the event of any uncured material breach of the agreement or under specific circumstances relating to insolvency. If we do not maintain a productive collaborative relationship with Sobi or if Sobi is unable to meet its contractual obligations or if there is an early termination of the agreement as described above, we would be forced to either establish a commercial infrastructure outside of the United States so that we could undertake the commercialization efforts which had been theretofore undertaken by Sobi or we would need to seek an alternative collaborator. The establishment of a commercial infrastructure and assumption by us of commercialization activities outside of the United States would require substantial resources, financial and otherwise, and could result in us incurring greater expenses than the increase in revenues from our direct sales of systemic pegcetacoplan. It could also cause a delay in market penetration while we expand our commercial operations. Seeking and obtaining an alternative collaborator outside the United States could also adversely impact sales of systemic pegcetacoplan and market penetration outside of the United States.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If our collaborators, including Sobi are involved in a business combination, it could decide to delay, diminish or terminate the development or commercialization of any product candidate licensed to it by us.

We have in the past established, and in the future, may seek to establish, additional collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

We entered into the collaboration agreement with Sobi in October 2020 concerning the development and commercialization of pegcetacoplan and specified other structurally and functionally similar compstatin analogues or derivatives for use systemically or for local non-ophthalmic administration. We may seek to establish one or more additional collaborators for the development and commercialization of one or more of our product candidates. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In addition, if we are able to obtain marketing approval for product candidates from foreign regulatory authorities, we intend to enter into strategic relationships with international biotechnology or pharmaceutical companies for the commercialization of such product candidates outside of the United States.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration 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 potential differentiation of our product candidates from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Collaborations are complex and time-consuming to negotiate and document. Further, 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.

Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. Our collaboration agreement with Sobi, we agreed not to, directly or indirectly, alone or with or for any other person or entity, conduct any clinical development or commercialization of APL-9 for

PNH, cold agglutinin disease, hematopoietic stem cell transplantation thrombotic microangiopathy, C3 glomerulopathy and immune complex membranoproliferative glomerulonephritis, and amyotrophic lateral sclerosis or any other indications subsequently agreed upon by the parties.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, 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.

Risks Related to Our Intellectual Property

If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to patent license agreements with The University of Pennsylvania under which we license patent rights relating to a family of compounds for use in all fields. The licensed patent rights include issued U.S. and foreign patents with claims that recite a class of compounds generically covering our lead product candidates, pegcetacoplan and APL-9, and that specifically recite the active component. We may enter into additional license agreements in the future. Our license agreements with Penn impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under these licenses, our licensors may have the right to terminate these license agreements, in which event we might not be able to market any product that is covered by these agreements, or our licensors may convert the license to a non-exclusive license, which could negatively impact the value of the product candidate being developed under the license agreement. Termination of these license agreements or reduction or elimination of our licensed rights may also result in our having to negotiate new or reinstated licenses with less favorable terms.

If we are unable to obtain and maintain sufficient patent protection for our product candidates, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates 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 product candidates. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel product candidates that are important to our business; we also license or purchase patent applications filed by others. The patent application and approval process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

Agreements through which we license patent rights may not give us control over patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented and may not be able to secure, maintain, or successfully enforce necessary or desirable patent protection from those patent rights. We have not had and do not have primary control over patent prosecution and maintenance for certain of the patents and patent applications we license, and therefore cannot guarantee that these patents and applications will be prosecuted in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents.

We, or any partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. Moreover, in some circumstances, we might not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering any technology that we may license from third parties in the future. These patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Our license agreements with Penn provide that Penn has the right under certain circumstances to control the preparation, prosecution and maintenance of the underlying patent rights.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or patent term adjustments. If we or our partners, collaborators, licensees, or licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees, or licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications,

such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds commonly involves complex legal and factual questions, which 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.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. 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 be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, we cannot be certain that parties from whom we do or may license or purchase patent rights were the first to make relevant claimed inventions or were the first to file for patent protection for them. If third parties have filed patent applications on inventions claimed in our patents or applications on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or to other patent offices around the world. Alternately or additionally, we may become involved in post-grant review procedures, oppositions, derivations, proceedings, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. An adverse determination in any such challenges may result in loss of exclusivity 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. In addition, 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. Furthermore, while it is our policy to require our employees and contractors who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own. As a result, the inventorship or ownership of our intellectual property may be challenged in the future.

Pending and future patent applications may not result in patents being issued which protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products. Our issued patents or any patents that may issue in the future may be invalidated or interpreted narrowly, such that they fail to provide us with any significant competitive advantage. 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. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does.

Issued patents that we have or may obtain or license may not 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 patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products by submitting ANDAs to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable or find that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Pursuant to the terms of some of our license agreements with third parties, some of our third-party licensors have the right, but not the obligation in certain circumstances to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents. Even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors, and cannot guarantee that we would receive it and on what terms. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. If we cannot obtain patent protection, or enforce existing or future patents against third parties, our competitive position and our financial condition could suffer.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be negatively impacted and our business would be harmed.

In addition to the protection afforded by patents, we also rely on trade secret protection for certain aspects of our intellectual property. 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, consultants, independent contractors, advisors, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. 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. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed.

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 infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may have U.S. and non-U.S. issued patents and pending patent applications relating to compounds and methods of use for the treatment of the disease indications for which we are developing our product candidates or relating to the use of complement inhibition that may cover our product candidates or approach to complement inhibition. For example, we are aware of a U.S. patent with claims that could be construed to cover

pegcetacoplan. Although we believe that these claims, if construed to cover pegcetacoplan, would be invalid due to various prior art disclosures available more than a year before the priority date of the U.S. patent, there are no assurances that a court would agree. If any third-party patents or patent applications are found to cover our product candidates or their methods of use or our approach to complement inhibition, we may not be free to manufacture or market our product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products candidates, including interference proceedings before the USPTO. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate or product. 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; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. 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. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could 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.

Some of our intellectual property that was discovered through government-funded programs may be subject to federal regulation such as "march-in" rights, certain reporting requirements, and a preference for U.S. industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements and limit our ability to contract with foreign manufacturers.

Some of our in-licensed intellectual property with respect to our product candidates has been funded in part by the U.S. government and, therefore, would be subject to certain federal regulations pursuant to the Bayh-Dole Act of 1980, or the Bayh-Dole Act. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act. The "march-in" provisions of the Bayh-Dole Act allow, the U.S. government under strictly limited circumstances to require the patent owners to grant exclusive, partially exclusive or non-exclusive rights to third parties for intellectual property discovered through the government-funded program. The U.S. government can exercise its march-in rights if it determines that action is necessary because the patent owner fails to achieve practical application of the new invention or because action is necessary to alleviate health concerns or address the safety needs of the public. Intellectual property discovered under the government-funded program is also subject to certain reporting requirements, compliance with which may require us or our licensors to expend substantial resources. Such intellectual property is also subject to a preference for U.S. industry, which may limit our ability to contract with foreign product manufacturers for products covered by such intellectual property. Penn has requested a waiver of the U.S. manufacturing requirement, but there can be no assurance that such waiver will be granted.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States, including the Leahy-Smith America Invents Act, or the America Invents Act, could increase those uncertainties and costs. The America Invents Act was signed into law on September 16, 2011, and many of the substantive changes became effective on March 16, 2013. The America Invents Act reformed United States patent law in part by changing the U.S. patent system from a "first to invent" system to a "first inventor to file" system, expanding the definition of prior art, and developing a post-grant review system. This legislation changes United States patent law in a way that may weaken our ability to obtain patent protection in the United States for those applications filed after March 16, 2013.

Further, the America Invents Act created new procedures to challenge the validity of issued patents in the United States, including post-grant review and inter partes review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with an effective filing date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for inter partes review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for inter partes review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas inter partes review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or inter partes review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we or our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent right to us.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our patents. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products. Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Agreements through which we license patent rights may not give us sufficient rights to permit us to pursue enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents (or control of enforcement or defense) of such patent rights in all relevant jurisdictions as requirements may vary. For instance, under the Sobi collaboration, we retain the primary right to prosecute and defend its patent and other intellectual property rights, but Sobi has the primary right to enforce such rights against competitive infringement outside the United States.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond 14 years from the date of product approval, only one patent may be extended and the extension only applies to those claims covering the approved drug, a method for using it, or a method for manufacturing it. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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

Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure, non-competition and non-solicitation agreements, or similar agreements, in connection with such previous employment. 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 third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants 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, which may result in claims by or against us related to the ownership of such 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. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, the failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, which could enable our competitors to obtain access to the same technologies licensed to us.

If we fail to comply with our obligations under license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

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

The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaborators such as Sobi from obtaining approvals for the commercialization of pegcetacoplan or any of our product candidates that we develop. As a result, we cannot predict when or if, and in which territories, we, or our collaborators, will obtain marketing approval to commercialize pegcetacoplan or any other product candidate that we develop.

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. We are not permitted to market our product candidates in the United States or in other countries until we, or they, receive approval of an NDA from the FDA or marketing approval from applicable regulatory authorities outside the United States. Our product candidates are in various stages of development and are subject to the risks of failure inherent in drug development. In September 2020, we submitted an NDA to the FDA and a MAA to the EMA for pegcetacoplan for the treatment of PNH. We have limited experience in conducting and managing the clinical trials necessary to obtain marketing approvals, including FDA approval of an NDA.

The process of obtaining marketing approvals, both in the United States and abroad, is lengthy, expensive and uncertain. It 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. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to regulatory authorities for each therapeutic indication to establish the product candidate’s safety and efficacy. The FDA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. 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.

In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities 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 preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we, or our collaborators, ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. In addition, to the extent that we seek to develop a combination drug-device product for delivery of a product candidate or we rely on a previously cleared device to deliver a product candidate, we will also be dependent on FDA clearance or approval of such products.

Finally, disruptions at the FDA and other agencies may prolong 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, have had to furlough critical 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. The Trump Administration also took several executive actions that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities.

Under our agreement with Sobi, Sobi is responsible for seeking regulatory approval outside the United States for systemic pegcetacoplan. A delay in obtaining or failure to obtain required approvals and clearances could negatively impact our ability or that of our collaborators, including Sobi, to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. Any approval we are granted for our product candidates in the United States would not assure approval of our product candidates in foreign jurisdictions.

In order to market and sell pegcetacoplan or any of our other products in the European Union and other foreign jurisdictions, we, and our collaborators, such as Sobi, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, a product must be approved for reimbursement before the product can be approved for sale in that country. We, and our collaborators, such as Sobi, may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may file for marketing approvals but not receive necessary approvals to commercialize our products in any market.

Additionally, we could face heightened risks with respect to seeking marketing approval in the United Kingdom as a result of the recent withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom withdrew from the European Union, effective December 31, 2020. On December 24, 2020, the United Kingdom and the European Union entered into a Trade and Cooperation Agreement. The agreement sets out certain procedures for approval and recognition of medical products in each jurisdiction. Since the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing any product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for any product candidates, which could significantly and materially harm our business.

We, or our collaborators, may not be able to obtain orphan drug designation or orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. The FDA has granted orphan drug designation to pegcetacoplan for the treatment of PNH and for the treatment of C3 glomerulopathy. We, or our collaborators, may seek orphan drug designations for pegcetacoplan for other indications and for other product candidates and may be unable to obtain such designations.

Even if we, or our collaborators, obtain orphan drug designation for a product candidate, such as is the case for pegcetacoplan for the treatment of PNH, we, or they, may not be able to obtain orphan drug exclusivity for that product candidate. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the EMA will be precluded from approving another marketing application for the same drug for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we, or our collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Fast track designation for one or more of our product candidates may not actually lead to a faster development or regulatory review or approval process.

We have received fast track designations for pegcetacoplan for the treatment of PNH and GA. If a product is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for FDA fast track designation. Even though we have received fast track designation for pegcetacoplan for the treatment of PNH and GA, fast track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with fast rack designation 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.

Even if we, or our collaborators, 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, which could impair our ability to generate revenue.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and our collaborators, must therefore comply with requirements concerning advertising and promotion for any of our product candidates which we or they market. 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 and our collaborators 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 cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, our collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, assuming we, or our collaborators, receive marketing approval for one or more of our product candidates, we, and our collaborators, and our and their 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, and our collaborators, are not able to comply with post-approval regulatory requirements, we, and our collaborators, could have the marketing approvals for our products withdrawn by regulatory authorities and our, or our collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any of our product candidates for which we, or our collaborators, obtain marketing approval in the future could be subject to post-marketing restrictions or withdrawal from the market and we, or our collaborators, may be subject to substantial penalties if we, or

they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products following approval.

Any of our product candidates for which we, or our collaborators, obtain marketing approval, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such product, among other things, will be subject to ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. 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, including the requirement to implement a Risk Evaluation and Mitigation Strategy.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or our collaborators, do not market any of our product candidates for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

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

- 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 letters 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;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Current and future legislation may increase the difficulty and cost for us and our 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 and continue to be 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 our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of our collaborators, to profitably sell any products 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 our 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 of 2010, or collectively the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit

reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2029 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several 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.

Since enactment of the ACA, there have been, and continue to be, 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 (the "TCJA"), Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Court of Appeals for the Fifth Circuit court affirmed the lower court's ruling that the individual mandate portion of the ACA is unconstitutional and it remanded the case to the district court for reconsideration of the severability question and additional analysis of the provisions of the ACA. Thereafter, the U.S. Supreme Court agreed to hear this case. Oral argument in the case took place on November 10, 2020. On February 10, 2021, the Biden Administration withdrew the federal government's support for overturning the ACA. A ruling by the Court is expected sometime this year. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

The Trump Administration also took executive actions to undermine or delay implementation of the ACA, including directing 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. On January 28, 2021, however, President Biden issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this Order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents. This Executive Order also directs the U.S. Department of Health and Human Services to create a special enrollment period for the Health Insurance Marketplace in response to the COVID-19 pandemic.

The prices of prescription pharmaceuticals in the United States and foreign jurisdictions is subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when licensed.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. To date, there have been several recent U.S. congressional inquiries, as well as proposed and enacted 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 products. To those ends, the Trump Administration issued several executive orders intended to lower the costs of prescription drug products. Certain of these orders are reflected in recently promulgated regulations, including an interim final rule implementing the Trump Administration's most favored nation model, but such final rule is currently subject to a nationwide preliminary injunction. It remains to be seen whether these orders and resulting regulations will remain in force during the Biden Administration. Further, on September 24, 2020, the Trump Administration finalized a rulemaking allowing states or certain other non-federal government entities to submit importation program proposals to the FDA for review and approval. Applicants are required to demonstrate that their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. The FDA has issued draft guidance that would allow manufacturers to import their own FDA-approved drugs that are authorized for sale in other countries (multi-market approved products).

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 organizations 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.

In countries outside of the United States, particularly the countries 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. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. 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 harmed, possibly materially.

Our relationships with customers and third-party payors, among others, will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties, including criminal sanctions, civil penalties, contractual damages, reputational harm, fines, disgorgement, exclusion from participation in government healthcare programs, curtailment or restricting of our operations, 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 products for which we obtain marketing approval. Our current and future arrangements with healthcare providers, and third-party payors and customers, if any, will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations. The laws and regulations may constrain the business or financial arrangements and relationships through which we conduct clinical research, market, sell and distribute any products for which we obtain marketing approval. These include the following:

Anti-Kickback Statute. The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), 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, lease or order of a good, facility, item or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

False Claims Laws. The federal false claims and civil monetary penalties laws, including the federal civil False Claims Act, impose 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;

HIPAA. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, executing a scheme, or making materially false statements in connection with the delivery of or payment for health care benefits, items, or services. Additionally, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations on covered entities and their business associates that perform certain functions or activities that involve the use or disclosure of protected health information on their behalf, including mandatory contractual terms and technical safeguards, with respect to maintaining the privacy, security and transmission of individually identifiable health information;

Transparency Requirements. The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or transfers of value made to physicians and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and

Analogous State and Foreign Laws. Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, can apply to sales or marketing arrangements, and claims involving healthcare items or services reimbursed by non-governmental third-party payors, and are generally broad and are enforced by many different federal and state agencies as well as through private actions. 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 require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Additionally, some state and local laws require the registration of pharmaceutical sales representatives in the jurisdiction. 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.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as

Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations and prospects.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union Member States, such as the UK Bribery Act 2010. Violation of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States.

These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Efforts to ensure that our business arrangements with third parties, and our business generally, 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, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, 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. Liabilities they incur pursuant to these laws could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the EU General Data Protection Regulation, or the GDPR, which took effect across all member states of the European Economic Area, or EEA, in May 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 increases our obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to four percent of global revenues or 20 million Euros, whichever is greater, and it 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. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Similar actions are either in place or under way in the United States. There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the California Consumer Privacy Act—which went into effect on January 1, 2020—is creating similar risks and obligations as those created by GDPR, though the Act does exempt certain information collected as part of a

clinical trial subject to the Federal Policy for the Protection of Human Subjects (the Common Rule). Many other states are considering similar legislation. A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

As we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

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.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. As we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

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 harm 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. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations 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 foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. This could include violations of HIPAA, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, including the European Union Data Protection Directive. 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, regulations, guidance or codes of conduct. 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.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain our executive team and to attract, retain and motivate qualified personnel.

We are highly dependent on the pharmaceutical research and development and business development expertise of our executive team, including Cedric Francois, M.D., Ph.D., our President and Chief Executive Officer, and Pascal Deschatelets, Ph.D., our Chief Scientific Officer. The members of our executive team are employed "at will," meaning any of them may terminate his or her employment with us at any time with or without notice and for any reason or no reason. In the future, we may be dependent on other members of our management, scientific and development team.

Our ability to compete in the biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. Our industry has experienced a high rate of turnover of management personnel in recent years. If we lose one or more of our executive officers or other key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

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 other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize our product candidates will be limited.

We expect to continue to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We continue to expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug manufacturing, clinical, regulatory affairs and sales, marketing and distribution. During 2020, the number of our employees increased from 235 on December 31, 2019 to 374 on December 31, 2020. We expect the number of employees to continue to increase significantly in 2021. Our principal office is located in Massachusetts and we maintain additional offices in California, Australia and Switzerland. To manage these growth activities and separation of offices, we must continue to

implement and improve our managerial, operational and financial systems and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of its attention to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates.

We temporarily closed our facilities in March 2020 in response to the COVID-19 pandemic. We have since re-opened our physical facilities on a limited basis, subject to compliance with strict safety guidelines, but most of our employees continue to work remotely. In the event of a renewal of shelter-in-place orders or and mandated local travel restrictions, our employees conducting research and development activities may not be able to access our facilities and our activities may be significantly limited or curtailed, possibly for an extended period of time. Furthermore, it is possible that over the long term our operational efficiency may be decreased if our employees and third-party collaborators are unable to meet and work in the same physical location.

Our employees, independent contractors, consultants, collaborators and contract research organizations 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 that our employees, independent contractors, consultants, collaborators and contract research organizations may engage in fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, to provide accurate information to the FDA or comparable non-U.S. regulatory authorities, to comply with manufacturing standards we have established, to 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, to report financial information or data accurately or to disclose unauthorized activities to us. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter 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. These risks may be particularly acute given the rapid growth in the size of our company. 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 criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

In the future, we may enter into transactions to acquire other businesses, products or technologies. Because we have not made any acquisitions to date, our ability to do so successfully is unproven. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

Risks Related to Ownership of Our Common Stock

An active trading market for our common stock may not be sustainable. If an active trading market is not sustained, our ability to raise capital in the future may be impaired.

Our shares began trading on the Nasdaq Global Select Market on November 9, 2017. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares may not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of stockholders to sell their shares. An inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and impair our ability to acquire other companies or technologies by using our shares as consideration.

The trading price of our common stock is highly volatile, which could result in substantial losses for our stockholders.

The trading price of our common stock has been, and is likely to continue to be, highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price they paid for their common stock. The market price for our common stock may be influenced by many factors, including:

- the timing and results of clinical trials of pegcetacoplan and any other product candidates;
- regulatory developments with respect to pegcetacoplan, including with respect to our efforts to obtain approval with respect to our NDA and MAA related to pegcetacoplan for the treatment of PNH;
- the success of existing or new competitive products or technologies;
- results of discussions with regulatory authorities and regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- the effect of the COVID-19 outbreak on the healthcare system and the economy generally and on our clinical trials and other operations specifically;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- commencement or termination of collaborations for our development programs;
- failure or discontinuation of any of our product candidates or development programs;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results or development timelines;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- short positions, hedging or other transactions in our securities in connection with our Convertible Notes;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- 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.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price

volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and our resources, which could harm our business.

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

Our management will have broad discretion in the application of our cash, cash equivalents and marketable securities and could spend our funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could harm our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our 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 compliance initiatives and corporate governance practices.

As a public company, we incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select 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 devote and will need to continue to devote, a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly.

If we identify a material weakness in our internal control over financial reporting, it could have an adverse effect on our business and financial results and our ability to meet our reporting obligations could be negatively affected, each of which could negatively affect the trading price of our common stock.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains material errors.

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Our system of internal controls, however well-designed and operated, is based in part on certain assumptions and includes elements that rely on information from third parties. Our system can provide only reasonable, not absolute, assurances that the objectives of the system are met. If we, or our independent registered public accounting firm, determine that our internal controls over financial reporting are not effective, or we discover areas that need improvement in the future, these shortcomings could have an adverse effect on our business and financial results, and the price of our common stock could be negatively affected.

If we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements, which could lead to a decline in our stock price. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC, The Nasdaq Stock Market or other regulatory authorities.

A sale of a substantial number of shares of our common stock could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

We have registered all shares of common stock that we may issue under our equity compensation plans. As of December 31, 2020, we had options to purchase an aggregate of 11,735,783 shares of our common stock outstanding, of which options to purchase 6,061,850 shares were vested and 502,373 outstanding unvested restricted stock units that upon vesting would result in the issuance of 502,373 shares of our common stock. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. Moreover, holders of an aggregate of 11,098,982 shares of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Changes in tax laws or in their interpretation could adversely affect our business and financial condition.

Recent changes in tax law could adversely affect our business or financial condition. On December 22, 2017, the U.S. government enacted legislation, commonly referred to as the Tax Cuts and Jobs Act, or the TCJA, that significantly revised the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contained 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 to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks for losses arising in taxable years ending after December 31, 2017 (though any such net operating losses may be carried forward indefinitely), one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits.

As part of Congress' response to the COVID-19 pandemic, the Families First Coronavirus Response Act, or FFCR Act, was enacted on March 18, 2020, and the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, was enacted on March 27, 2020. COVID relief provisions were also included in the Consolidated Appropriations Act, 2021, or CAA, which was enacted on December 27, 2020. The FFCR Act, the CARES Act, and the CAA contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of net operating losses, which was enacted as part of the TCJA. It also provides that net operating losses arising in any taxable year beginning after December 31, 2017, and before January 1, 2021, are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation on the tax deductibility of net interest expense by increasing the limitation from 30% to 50% of adjusted taxable income.

Regulatory guidance under the TCJA, the FFCR Act, the CARES Act, and the CAA is and continues to be forthcoming, and such guidance could ultimately increase or lessen the impact of these laws on our business and financial condition. Congress may enact additional legislation in connection with the COVID-19 pandemic, some of which could have an impact on our company. In addition, it is uncertain if and to what extent various states will conform to the TCJA, the FFCR Act, the CARES Act, or the CAA.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2020, we had both federal and state net operating loss carryforwards of $358.2 million and $405.0 million, respectively, and federal and state research and development tax credit carryforwards of $34.2 million and $6.5 million, respectively. Federal net operating loss carryforward generated post-2017 in the amount of $276.9 million may be carried forward indefinitely. The remaining net operating loss and research and development tax credit carryforwards will begin to expire in 2025. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the TCJA, as modified by the CARES act, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses in 2021 and future years is limited. Certain states have also enacted temporary suspension or limitation of the utilization of net operating loss carryforwards. In addition, under Section 382 of the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We experienced a Section 382 ownership change in September 2015, which imposes annual limitations on our use of pre-change net operating loss carryforwards and other pre-change tax attributes. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. We have determined that our research and development credit carryforwards are also limited. These limitations upon our historical net operating loss and tax credit carryforwards may harm our future operating results by effectively increasing our future tax obligations. Refer to Note 14, "Income Taxes," of our Financial Statements for additional information related to our accounting for income taxes.

Taxing authorities could challenge our historical and future tax positions or our allocation of taxable income among our subsidiaries, and tax laws to which we are subject could change in a manner adverse to us.

We operate through various subsidiaries in a number of countries throughout the world. Consequently, we are subject to tax laws, treaties, and regulations in the countries in which we operate, and these laws and treaties are subject to interpretation. We have taken, and will continue to take, tax positions based on our interpretation of such tax laws. Our transfer pricing arrangements are not generally binding on applicable tax authorities. The price charged for products, services, or the royalty rates and other amounts paid for intellectual property rights, could be challenged by the various tax authorities, resulting in additional tax liability, interest, and/or penalties. There can be no assurance that a taxing authority will not have a different interpretation of applicable law and assess us with additional taxes. If we are assessed with additional taxes, this may result in a material adverse effect on our results of operations and/or financial condition.

Any changes to existing accounting pronouncements or taxation rules or practices may cause adverse fluctuations in our reported results of operations or affect how we conduct our business.

A change in accounting pronouncements or taxation rules or practices can have a significant effect on our reported results and may affect our reporting of transactions completed before the change is effective. New accounting pronouncements, taxation rules and varying interpretations of accounting pronouncements or taxation rules have occurred in the past and may occur in the future. The change to existing rules, future changes, if any, or the need for us to modify a current tax or accounting position may adversely affect our reported financial results or the way we conduct our business.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment.

We have never declared nor paid cash dividends on our capital stock. We currently plan to retain all of our future earnings, if any, to finance the operation, development and growth of our business. In addition, the terms of our development funding agreement with SFJ, precludes us from paying dividends, and any future debt or credit agreements may also preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

Concentration of ownership of our common stock among our executive officers and directors, entities associated with our executive officers and directors and our largest stockholders may allow these stockholders to significantly influence matters submitted to our stockholders for approval, as well as our management and affairs.

As of February 22, 2021, our executive officers and directors, and entities associated or affiliated with our executive officers and directors, in the aggregate, beneficially owned shares representing approximately 24.5% of our outstanding common stock, including our largest stockholder, Morningside Venture Investments, Ltd., which beneficially owned approximately 15.6% of our outstanding common stock. As a result, if these stockholders were to choose to act together, they may have the ability to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, could substantially influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership may:

- delay, defer or prevent a change in control;
- entrench our management or the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

Some of these persons or entities may have interests different than those of our other investors. For example, because many of these stockholders purchased their shares at prices substantially below the price at which other investors purchased shares and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors or they may want us to pursue strategies that deviate from the interests of other stockholders.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management or hinder efforts to acquire a controlling interest in us.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;

- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders. This could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in the best interests of our stockholders. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common stock will likely depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will continue to cover us or provide favorable coverage. Securities or industry analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may negatively impact the market price of our common stock. In the event we do have analyst coverage, if one or more analysts downgrade our stock or change their opinion of our stock, our share price would likely decline. In addition, if one or more analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Our restated certificate of incorporation designates the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against our company and our directors, officers and employees.

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to our company or our stockholders, any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws, or any action asserting a claim against us governed by the internal affairs doctrine. This exclusive forum provision will not apply to actions arising under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended. This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our facilities consist of office space of approximately 77,818 square feet in Waltham, Massachusetts under a lease that expires in December 2026, office space of approximately 9,478 square feet in San Francisco, California under a lease that expires in April 2024; office space of approximately 938 square meters in Zug, Switzerland under a lease that expires in July 2025; lab space of approximately 9,704 square feet in Watertown, Massachusetts under a lease that expires in August 2027; and office space of approximately 241 square meters in Melbourne, Australia under a lease that expires in January 2024. Our lease for 7,125 square feet of office space in Crestwood, Kentucky terminated in January 2021.

Item 3. Legal Proceedings.

We are not currently subject to any material legal proceedings.

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 common stock has been listed on the Nasdaq Global Select Market under the symbol "APLS" since November 9, 2017. Prior to that date, there was no public trading market for our common stock.

Holders of Record

As of February 22, 2021, we had 22 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. In addition, our development agreement with SFJ contains restrictive covenants that prohibit us, subject to certain exceptions, from paying dividends on our common stock, and future debt securities or other financing arrangements could contain similar or more restrictive negative covenants. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors.

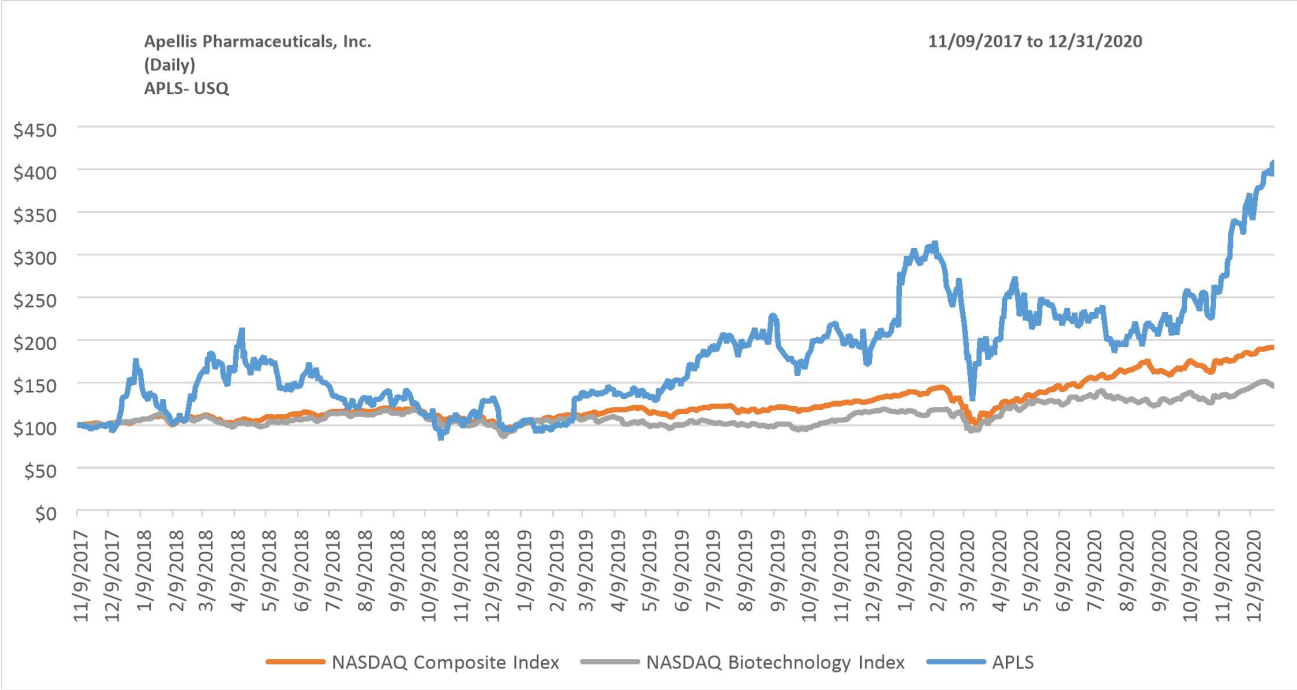
Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated by reference herein to Item 12 of Part III of this Annual Report on Form 10-K.

Stock Performance Graph

The following performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our future filings under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.

The graph below compares the cumulative total stockholder return on our common stock between November 9, 2017 (the first date that shares of our common stock were publicly traded) and December 31, 2020, with the cumulative total return of (a) the Nasdaq Composite Index and (b) the Nasdaq Biotechnology Index over the same period. The graph assumes the investment of $100 after the market close on November 9, 2017 in our common stock and each of the other indices described above. The comparisons are not intended to forecast or be indicative of future performance of our common stock. All amounts shown are based on the closing price of our common stock with the exception of November 9, 2017, which is the opening price based on initial trading of our common stock. Data for the Nasdaq Composite Index and Nasdaq Biotechnology Index assume reinvestment of dividends.


Apellis Pharmaceuticals, Inc.
(Daily)
APLS- USQ
11/09/2017 to 12/31/2020
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$350
$300
$250
$200
$150
$100
$50
$0
11/9/2017
12/9/2017
1/9/2018
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11/9/2020
12/9/2020
NASDAQ Composite Index
NASDAQ Biotechnology Index
APLS

Item 6. Selected Financial Data.

The selected consolidated financial data included in this section are not intended to replace the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We derived the selected consolidated statements of operations data for the years ended December 31, 2020, 2019 and 2018 and the selected consolidated balance sheet data at December 31, 2020 and 2019 from our audited consolidated financial statements included elsewhere in this report. We have derived the consolidated statements of operations data for the years ended December 31, 2017 and 2016 and the consolidated balance sheet data as of December 31, 2018, 2017 and 2016 from our audited financial statements not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the selected historical consolidated financial data below in conjunction with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the audited consolidated financial statements and the related notes included elsewhere in this report.

(In thousands (except per share data))	Year Ended December 31,				
	2020	2019	2018	2017	2016
Consolidated statements of operations data:					
Revenue:					
Licensing revenue	$ 250,494	$ —	$ —	$ —	$ —
Collaboration revenue	152	—	—	—	—
Total revenue:	250,646	—	—	—	—
Operating expenses:					
Research and development (1)	$ 299,921	$ 220,969	$ 105,286	$ 40,304	$ 22,978
License expense (2)	25,050	—	—	—	—
General and administrative (1)	139,401	67,046	22,639	10,463	4,304
Total operating expenses	464,372	288,015	127,925	50,767	27,282
Net operating loss	(213,726)	(288,015)	(127,925)	(50,767)	(27,282)
Loss on extinguishment of debt	—	(1,501)	—	—	—
Loss from remeasurement of development derivative liability	(103,029)	(14,839)	—	—	—
Interest income	4,164	5,108	2,961	278	135
Interest expense (3)	(29,937)	(5,285)	(2,513)	(375)	—
Other income (expense), net	(501)	(175)	(25)	(142)	22
Net loss before taxes	(343,029)	(304,707)	(127,502)	(51,006)	(27,125)
Income tax expense	1,845	—	—	—	—
Net loss	(344,874)	(304,707)	(127,502)	(51,006)	(27,125)
Net loss per common share, basic and diluted (4)	$ (4.59)	$ (4.90)	$ (2.34)	$ (3.68)	$ (3.22)
Weighted-average number of common shares used in net loss per common share, basic and diluted	75,163	62,229	54,396	13,871	8,428

(1) Includes share-based compensation as follows:

(In thousands)	Year Ended December 31,				
	2020	2019	2018	2017	2016
Research and development	$ 21,381	$ 10,683	$ 3,559	$ 2,679	$ 378
General and administrative	23,995	10,461	4,174	2,740	701
Total share-based compensation expense	$ 45,376	$ 21,144	$ 7,733	$ 5,419	$ 1,079

(2) License expense paid to Penn primarily due to revenue received from the Sobi transaction

(3) Includes amortization of debt discount associated with term loan facility, promissory note due to the issuance of warrants and convertible senior notes. See Note 6 to our audited consolidated financial statements included elsewhere in this report.

(4) See Note 15 in the notes to our audited consolidated financial statements appearing at the end of this document for a description of the method used to calculate basic and diluted net loss per common share.

	December 31,				
	2020	2019	2018	2017	2016
Consolidated Balance Sheet Data (in thousands):					
Cash and cash equivalents	$ 565,779	$ 351,985	$ 176,268	$ 175,644	$ 24,863
Working capital	788,865	307,342	185,415	175,461	23,730
Total assets	960,569	389,245	203,534	182,131	27,433
Term loan facility	—	—	20,389	19,807	—
Promissory note	—	—	6,655	6,583	—
Convertible senior notes	358,830	142,567	—	—	—
Development derivative liability	257,868	134,839	—	—	—
Total liabilities	756,012	355,016	42,561	33,188	3,639
Convertible preferred stock	—	—	—	—	92,055
Accumulated deficit	(926,347)	(581,473)	(276,766)	(149,264)	(98,258)
Total stockholders' equity	204,557	34,229	160,973	148,943	23,794

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 consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, 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 clinical-stage biopharmaceutical company focused on the development of novel therapeutic compounds to treat disease through the inhibition of the complement system, which is an integral component of the immune system, at the level of C3, the central protein in the complement cascade. We believe that this approach can result in broad inhibition of the principal pathways of the complement system and has the potential to effectively control a broad array of complement-dependent autoimmune and inflammatory diseases.

We have the most advanced clinical programs targeting C3 with Phase 3 clinical trials of our lead product candidate, pegcetacoplan, in multiple indications. We believe that pegcetacoplan has the potential to be a best-in-class treatment that may address the limitations of existing treatment options or provide a treatment option where there currently is none. Pegcetacoplan has already shown activity that we believe is clinically meaningful in clinical trials for several distinct medical conditions, including geographic atrophy in age-related macular degeneration, or GA; paroxysmal nocturnal hemoglobinuria, or PNH; cold agglutinin disease, or CAD; and C3 glomerulopathy, or C3G. We are developing pegcetacoplan and other product candidates, including APL-9, targeting C3 through various routes of administration and plan to conduct clinical trials of these compounds in additional complement-dependent indications.

In October 2020, we entered into a collaboration and license agreement, or the collaboration agreement, with Swedish Orphan Biovitrum AB (Publ), or Sobi. Under the collaboration agreement, we agreed to co-develop pegcetacoplan for systemic indications, including PNH, CAD and hematopoietic stem cell transplantation-associated thrombotic microangiopathy, or HSCT-TMA, in hematology; C3G and immune complex membranoproliferative glomerulonephritis, or IC-MPGN in nephrology; and amyotrophic lateral sclerosis, or ALS in neurology. Sobi has exclusive ex-U.S. commercialization rights for systemic pegcetacoplan. We retain commercialization rights for systemic pegcetacoplan in the United States and worldwide commercial rights for ophthalmological pegcetacoplan, which includes our GA program in addition to worldwide commercialization rights for APL-9 and other novel compounds targeting C3.

GA. We initiated a Phase 3 clinical program consisting of two Phase 3 clinical trials evaluating pegcetacoplan in patients with GA in September 2018. We refer to these trials as the DERBY and OAKS trials. Both trials are fully enrolled and we expect to announce top-line data from these trials in the third quarter of 2021. In our Phase 2 clinical trial of pegcetacoplan in patients with GA, treatment with pegcetacoplan resulted in a significant reduction in the rate of GA lesion growth over 12 months. Additionally, data released in October 2020 from a post hoc analysis of seven patients in our Phase 1b trial of pegcetacoplan in patients with advanced GA and low vision demonstrated a trend in reduced lesion growth in eyes treated with pegcetacoplan versus untreated fellow eyes after 18 months of treatment.

Systemic Pegcetacoplan. We are developing pegcetacoplan for systemic administration in several indications, including PNH, C3G, IC-MPGN, ALS, CAD and HSCT-TMA.

PNH. In June 2018, we initiated a Phase 3 clinical trial evaluating pegcetacoplan in 80 patients with PNH who exhibited signs of moderate to severe anemia, specifically with an inclusion criterion of hemoglobin level of less than 10.5 g/dL, while being treated with eculizumab, an approved therapy for PNH that is marketed as Soliris. We refer to this trial as the PEGASUS trial.

In January 2020, we announced top-line data from the PEGASUS trial that showed that pegcetacoplan met the trial's primary efficacy endpoint, demonstrating superiority to eculizumab, with a statistically significant improvement in adjusted means of 3.8 g/dL of hemoglobin at week 16 ($p < 0.0001$), and promising results in key secondary endpoints. Additional data from the PEGASUS trial presented in June 2020 and December 2020 demonstrated increased hemoglobin levels, reduced transfusion requirements and improved key markers of hemolysis across the patient population, both in patients with high transfusion requirements and in patients with low or no transfusion requirements, which improvements were sustained through 48 weeks of treatment. In the PEGASUS trial, the safety profile of pegcetacoplan was comparable to that of eculizumab.

In September 2019, we initiated a second Phase 3 clinical trial in patients with PNH who have not been treated with eculizumab within three months before entering the trial. This trial is fully enrolled and we intend to present top-line data in the second quarter of 2021. We refer to this trial as the PRINCE trial.

We submitted an NDA to the FDA, and an MAA to the EMA, for pegcetacoplan for the treatment of PNH in September 2020. The FDA accepted the NDA and set the Prescription Drug User Fee Act, or PDUFA, target action date for May 14, 2021. The EMA validated the MAA in October 2020, with the potential for a European Commission decision on the MAA in the second half of 2021.

C3G/IC-MPGN. We have initiated and will continue to lead our registrational program in C3G / IC-MPGN. We initiated the Phase 2 NOBLE trial in up to 12 patients with post-kidney transplant recurrence of C3G or IC-MPGN in October 2020. We expect to dose the first patient in the NOBLE trial in the first half of 2021. We also plan to begin a Phase 3 clinical trial in patients with native kidney or post-transplant recurrence of C3G or IC-MPGN, having reduction of proteinuria as its primary endpoint, in the second half of 2021.

ALS. We have initiated a randomized, placebo-controlled Phase 2 clinical trial of pegcetacoplan in approximately 200 adults with sporadic ALS. We refer to this trial as the MERIDIAN trial. We treated the first patient in MERIDIAN in November 2020 and expect to complete enrollment in MERIDIAN in the second half of 2021.

CAD and HSCT-TMA. Sobi will lead development activities for a Phase 3 clinical trial in CAD and a Phase 2 clinical trial in HSCT-TMA, both planned to begin in 2021. In our Phase 2 clinical trial of pegcetacoplan in patients with CAD, patients achieved increased hemoglobin levels, reduced reticulocytes and bilirubin levels, and reduced LDH levels compared to baseline.

Pipeline. We are developing pegcetacoplan and other product candidates, including APL-9, targeting C3 through various routes of administration. We plan to conduct clinical trials of these compounds in additional complement-dependent indications. APL-9 is a C3 modulator designed to be intravenously administered for acute use. In May 2020 we initiated a Phase 1/2 randomized, placebo-controlled clinical trial for APL-9 in 66 patients with respiratory failure including acute respiratory distress syndrome (ARDS) secondary to COVID-19. We expect to report results from this trial in the second quarter of 2021. We are also developing APL-9 for the prevention of complement immune system activation coincident with adeno-associated virus, or AAV, vector administration for gene therapies and other indications. We plan to advance three new product candidates into clinical development by the end of 2022.

Since our commencement of operations in May 2010, we have devoted substantially all of our resources to developing our proprietary technology, developing product candidates, undertaking preclinical studies and conducting clinical trials for pegcetacoplan, building our intellectual property portfolio, organizing and staffing our company, business planning, raising capital, preparing for the commercial launch of our products and providing general and administrative support for these operations.

To date, we have financed our operations primarily through $772.1 million in net proceeds from public offerings of our common stock, including our initial public offering, or IPO, $535.8 million in net proceeds from the private offerings of Convertible Notes, a $250.0 million upfront payment and a $25.0 million as a development reimbursement payment from Sobi each pursuant to the Sobi collaboration agreement, $112.6 million in proceeds from the private placement of shares of our convertible preferred stock prior to our IPO, $140.0 million under the SFJ agreement, $20.0 million in proceeds from borrowings under a term loan facility with Silicon Valley Bank, and $7.0 million in proceeds from our issuance and sale of a promissory note. We have repaid the term loan facility and the promissory note in full, and we exchanged $126.1 million of aggregate principal amount of 2019 Convertible Notes for shares of our common stock in January 2021.

We have not generated any revenue from product sales. We have incurred significant annual net operating losses in each year since our inception and expect to continue to incur net operating losses for the foreseeable future. Our net losses were $344.9 million, $304.7 million and $127.5 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $926.3 million. We expect to continue to incur significant expenses and increasing operating losses for the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase significantly if and as we continue to develop and conduct our ongoing and planned clinical trials of pegcetacoplan and APL-9; initiate and continue research and preclinical and clinical development efforts for any future product candidates; seek to identify and develop additional product candidates for complement-dependent diseases; seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any; establish sales, marketing, distribution and other commercial infrastructure to commercialize any products for which we may obtain marketing approval; require the manufacture of larger quantities of product candidates for clinical development and, potentially, commercialization; maintain, expand and protect our intellectual property portfolio; hire and retain additional personnel, such as clinical, quality control and scientific personnel; add operational, financial and management information systems and personnel, including personnel to support our product development and help us comply with our obligations as a public company; and add equipment and physical infrastructure to support our research and development programs.

As of December 31, 2020, we had cash, cash equivalents and marketable securities of $877.6 million. We believe that our cash and cash equivalents and marketable securities as of December 31, 2020, will be sufficient to enable us to fund our current operations at least into the second half of 2022. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "Liquidity and Capital Resources."

We temporarily closed our facilities in March 2020 in respect to the COVID-19 pandemic. We have since reopened our facilities on a limited basis, subject to compliance with strict safety guidelines, but most of our employees continue to work remotely. We do not believe that the COVID-19 pandemic has had a significant impact upon our operations, including our ongoing clinical trials and the manufacture and supply of our product candidates.

SFJ Agreement

On February 28, 2019, we entered into a development funding agreement, which we refer to as the SFJ agreement, with SFJ Pharmaceuticals Group, or SFJ, under which SFJ agreed to provide funding to us to support the development of pegcetacoplan for the treatment of patients with PNH. Pursuant to the agreement, SFJ paid us $60.0 million following the signing of the agreement and agreed to pay us up to an additional $60.0 million in the aggregate in three equal installments upon the achievement of specified development milestones with respect to our Phase 3 program for pegcetacoplan in PNH and subject to our having cash resources at the time sufficient to fund at least 10 months of our operations.

On June 7, 2019, we amended the SFJ agreement, which we refer to as the SFJ amendment. Under the SFJ amendment, SFJ agreed to make an additional $20.0 million funding payment to us to support the development of pegcetacoplan for the treatment of patients with PNH.

On June 27, 2019, we received $40.0 million from SFJ, consisting of $20.0 million as the first installment of the additional $60.0 million upon the achievement of a milestone and the $20.0 million payable under the SFJ amendment.

In September 2019, we received $20.0 million from SFJ, as the second installment of the additional $60.0 million due to the achievement of a milestone and in January 2020 received the remaining $20.0 million installment of the additional $60.0 million upon the announcement of the results of the PEGASUS phase 3 trial.

Convertible Notes

In September 2019, we issued and sold $220.0 million aggregate principal amount of 3.5% convertible senior notes due 2026, or the 2019 Convertible Notes, in a private offering. The net proceeds from the sale of the 2019 Convertible Notes were approximately $212.9 million after deducting the initial purchasers' discounts and commissions and estimated offering expenses payable. We used $28.4 million of the net proceeds from the offering to pay the cost of the capped call transactions in September 2019 described below.

In May 2020, we issued and sold an additional $300.0 million aggregate principal amount of 3.5% convertible senior notes due 2026, or the 2020 Convertible Notes, in a private offering. The aggregate purchase price of the 2020 Convertible Notes was $328.9 million, which amount included accrued interest from March 15, 2020 to, but not including, May 12, 2020. The net proceeds from the sale of the 2020 Convertible Notes were approximately $322.9 million after deducting the initial purchasers' discounts and commissions and offering expenses payable by us. We used $43.1 million of the net proceeds from the offering to pay the cost of the capped call transactions in May 2020 described below. The 2020 Convertible Notes were issued as additional notes under the Indenture and form a single series with, and have the same terms as, the 2019 Convertible Notes, but have a different issue date, issue price, CUSIP number and different restrictions on transfer. We refer to the 2019 Convertible Notes and the 2020 Convertible Notes together as the Convertible Notes.

The Convertible Notes are convertible into shares of our common stock at an initial conversion rate of 25.3405 shares per $1,000 principal amount of notes (equivalent to an initial conversion price of approximately $39.46 per share of common stock). The conversion rate is subject to customary anti-dilution adjustments. In addition, following certain events that occur prior to the maturity date or if we deliver a notice of redemption, we will increase the conversion rate for a holder who elects to convert its Convertible Notes in connection with such corporate event or a notice of redemption, as the case may be, in certain circumstances as provided in the indenture governing the Convertible Notes, or the Indenture.

Prior to March 15, 2026, the Convertible Notes are convertible only upon the occurrence of certain events. On or after March 15, 2026 until the close of business on the second scheduled trading day immediately preceding the maturity date of the Convertible Notes, holders may convert the Convertible Notes at any time. Upon conversion of the Convertible Notes, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of common stock, at our election.

Prior to September 20, 2023, we may not redeem the Convertible Notes. We may redeem for cash all or a portion of the Convertible Notes, at our option, on or after September 20, 2023 if the last reported sale price of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive), including the trading day immediately preceding the date on which we provide a notice of redemption, during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption. The redemption price will be equal to 100% of the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

If we undergo a "fundamental change," as defined in the Indenture, prior to maturity, subject to certain conditions, holders may require us to repurchase for cash all or any portion of their Convertible Notes at a fundamental change repurchase price equal to 100% of the principal amount of the Convertible Notes to be repurchased, plus any accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The Indenture contains customary terms and covenants, including that upon certain events of default occurring and continuing, either the Trustee or the holders of at least 25% in principal amount of the outstanding Convertible Notes may declare 100% of the principal of, and accrued and unpaid interest, if any, on, all the Convertible Notes to be due and payable.

Subsequent to year end, on January 6, 2021, we entered into separate, privately negotiated exchange agreements with certain holders of our 2019 Convertible Notes. Under the terms of these exchange agreements, the holders exchanged approximately $126.1 million in aggregate principal amount of 2019 Convertible Notes held by them for an aggregate of 3,906,869 shares of our common stock. The exchange transactions closed in January 2021.

Capped Call Transactions

In September 2019 and May 2020, concurrently with the pricing of the 2019 Convertible Notes and 2020 Convertible Notes, respectively, we entered into capped call transactions with two counterparties. The capped call transactions are expected generally to reduce the potential dilution to our common stock upon any conversion of Convertible Notes and/or offset any cash payments we are required to make in excess of the principal amount of converted Convertible Notes, as the case may be, in the event that the market price per share of our common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which is initially $39.4625, the conversion price of the Convertible Notes, and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of such Convertible Notes. If, however, the market price per share of our common stock, as measured under the terms of the capped call transactions, exceeds the cap price of the capped call transactions, there would nevertheless be dilution and/or there would not be an offset of such potential cash payments, in each case, to the extent that such market price exceeds the cap price of the capped call transactions.

Collaboration Agreement with Sobi

On October 27, 2020, we entered into the collaboration agreement with Sobi, concerning the development and commercialization of pegcetacoplan and specified other structurally and functionally similar compstatin analogues or derivatives for use systemically or for local non-ophthalmological administration, collectively referred to as the licensed products. See "Business—Collaboration and License Agreement with Sobi" for a description of the key terms of our collaboration agreement with Sobi. We granted Sobi an exclusive (subject to certain rights retained by us), sublicensable license of certain patent rights and know-how to develop and commercialize licensed products in all countries outside of the United States. We retained the right to commercialize licensed products in the United States, and, subject to specified limitations, to develop licensed products worldwide for commercialization in the United States. Under the agreement, Sobi made an upfront payment of $250.0 million in November 2020, and agreed to pay up to an aggregate of $915.0 million upon the achievement of specified one-time regulatory and commercial milestone events, and to reimburse us for up to $80.0 million in development costs. In January 2021 we received a $25.0 million development reimbursement payment from Sobi. We are also entitled to receive tiered, double-digit royalties (ranging from high teens to high twenties) on sales of licensed products outside of the United States, subject to customary deductions and third-party payment obligations, until the latest to occur of: (i) expiration of the last-to-expire of specified licensed patent rights; (ii) expiration of regulatory exclusivity; and (iii) ten (10) years after the first commercial sale of the applicable licensed product, in each case on a licensed product-by-licensed product and country-by-country basis. We remain responsible for our license fee obligations (including royalty obligations) to the University of Pennsylvania and for our payment obligations to SFJ Pharmaceuticals.

Financial Operations Overview

Revenue

We have not generated any revenue from product sales. If we are able to obtain regulatory approval for pegcetacoplan for the treatment of PNH in the United States, we will expect to generate revenue from the sale of products within the next twelve months.

Licensing and Collaboration Revenue

We enter into licensing agreements from time to time in which we receive upfront payments, milestone payments and royalties. In 2020 we entered into a collaboration agreement with Sobi for the development and commercialization of systemic pegcetacoplan, described below, and two license agreements with third parties to use APL-9 in certain research projects.

We analyze our license and collaboration arrangements pursuant to FASB ASC Topic 808, Collaborative Arrangement Guidance and Considerations to assess whether such arrangements, or transactions between arrangement participants, involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities or are more akin to a vendor-customer relationship. In making this evaluation, we consider whether the activities of the collaboration are considered to be distinct and deemed to be within the scope of the collaborative arrangement guidance and those that are more reflective of a vendor-customer relationship and, therefore, within the scope of the revenue with contracts with customers guidance. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement.

For elements of collaboration arrangements that are not accounted for pursuant to the revenue from contracts with customers guidance, an appropriate recognition method is determined and applied consistently, generally by analogy to the revenue from contracts with customers guidance. Amounts related to transactions with a counterparty in a collaborative arrangement that is not a customer are presented as collaboration revenue and on a separate line item from revenue recognized from contracts with customers, if any, in our consolidated statements of operations.

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, Revenue from Contracts with Customers ("ASC 606"), the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Pursuant to ASC 606, we recorded the $250.0 million non-refundable upfront payment in revenue as the payment was associated with the transfer of the good or services in the form of the license to Sobi. The $80.0 million reimbursement for research and development activities does not constitute a customer/vendor relationship and thus is not in the scope of ASC 606. As ASC 808 does not include recognition guidance, we established an accounting policy to recognize the payments under the reimbursement as a receivable on the balance sheet in an amount that is probable to be reimbursed based upon expense incurred by us, with a contra-research and development expense recognized in the statement of operations.

Under the Sobi collaboration agreement, for the year ended December 31, 2020, we recognized $250.0 million of licensing revenue for the upfront payment in the consolidated statement of operations. For the year ended December 31, 2020, we also recognized in the consolidated statement of operations $43.0 million of contra research and development expense relative to the probable amount to be reimbursed under the $80.0 million for research and development. We recorded a corresponding receivable of $43.0 million on the consolidated balance sheet, with $25.0 million and $18.0 million in current and long-term assets, respectively, as of December 31, 2020.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts, and the development of our product candidates, which include:

- employee-related expenses including salaries, bonuses, benefits and share-based compensation expense related to individuals performing research and development activities;
- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct clinical trials and research and development activities on our behalf, and contract manufacturing organizations that manufacture quantities of drug supplies for both our preclinical studies and clinical trials;
- the cost of consultants, including share-based compensation expense; and
- various other expenses incident to the management of our preclinical studies and clinical trials.

Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed. We have not provided program costs since inception because historically we have not tracked or recorded our research and development expenses on a program-by-program basis.

The successful development of our product candidates is highly uncertain. Accordingly, at this time, we cannot reasonably estimate the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of these product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from pegcetacoplan or any other potential product candidates. This is due to the numerous risks and uncertainties associated with developing therapeutics, including the uncertainties of:

- establishing an appropriate safety profile in preclinical studies;
- successful enrollment in, and completion of clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others; and
- an acceptable safety profile of the products following approval.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs and timing associated with the development of that product candidate.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future as our product candidate development programs progress. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses including salaries, bonuses, benefits and share-based compensation. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters, and fees for accounting and consulting services.

We anticipate that our general and administrative expenses will increase in the future to support continued research and development activities, potential commercialization of our product candidates and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, attorneys and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company including expenses related to services associated with maintaining compliance with exchange listing and SEC requirements, insurance costs and investor relations costs.

Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 in the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, 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.

Licensing Revenue

On October 27, 2020, we entered into the collaboration agreement with Sobi concerning the development and commercialization of pegcetacoplan and specified other compstatin analogues or derivatives for use systemically or for local non-ophthalmic administration, collectively referred to as the Licensed Products. See "Business—Collaboration and License Agreement with Sobi" for a description of the key terms of our collaboration agreement with Sobi.

The Company has determined that the collaboration agreement is within the scope of FASB ASC Topic 808, *Collaborative Arrangements* ("ASC 808") as a contractual arrangement that involves a joint operating activity whereby both parties are (i) active participants in the activity and (ii) exposed to certain significant risks and rewards dependent on the commercial success of the activity. ASC Topic 808 does not address measurement or recognition matters but allows for analogizing to ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). Pursuant to ASC 606, we performed the following five steps: (i) identified the contract with a customer; (ii) identified the performance obligations in the contract; (iii) determined the transaction price; (iv) allocated the transaction price to the performance obligations in the contract; and (v) recognized revenue when the entity satisfied a performance obligation.

We identified the following material promises under the Sobi Agreement: (1) licenses to develop and commercialize pegcetacoplan or, Licenses to IP, and (2) performance of research and development services. We determined the promises to be distinct because Sobi can benefit from each of the license and the development services on their own or with readily available services. We could have provided the license without any development services and Sobi would have been able to benefit from it by obtaining development services from another provider as the Licensed Products products are at a more mature stage in their life cycle.

Under the collaboration agreement, Sobi agreed to pay us

i) a fixed amount of $250.0 million in an upfront payment in November 2020;
ii) a fixed amount of an additional $80.0 million in development reimbursements, payable yearly in four tranches in amounts determined based upon actual expenses incurred by us;
iii) up to an aggregate of $915.0 million upon the achievement of specified one-time regulatory and commercial milestone events; and
iv) tiered, double-digit royalties, ranging from high teens to high twenties, on sales of Licensed Products outside of the United States, subject to customary deductions and third-party payment obligations.

At inception of the collaboration agreement, we considered the $250.0 million non-refundable payment and the $80.0 million fixed proceeds. We also evaluated whether Sobi is a customer for either of the distinct promises in the agreement. Under the Licenses to IP, we determined that Sobi is a customer as the know-how provided and the right granted by us to Sobi are outputs of our business activities for which we will receive consideration. With respect to research and development activity, management determined that there is no vendor relationship as performing research and development activities for others is not a part of our ongoing central operations. Based upon the evaluation of the relative fair values, we allocated the purchase price of $250.0 million and the related milestones and royalties to the license of IP and $80.0 million to performance of research and development activities.

The milestone and royalty payments are subject to activities outside our control. Per ASC 606, we consider this to be a customer/ vendor relationship, therefore, we will include the regulatory milestone payments in the total transaction price when it is probable that a significant reversal of revenue would not occur in a future period. We will recognize commercial milestone and royalty revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which the commercial milestone or royalty has been allocated has been satisfied. In case of commercial milestone or royalty payments, we will recognize revenue in the same period that the sales are completed for which we are contractually entitled to the milestone or percentage-based royalty payment. To date, we have not recognized any commercial milestone or royalty revenue resulting from any of our licensing arrangements. Management will periodically assess the elements of the contract and re-evaluate revenue recognition as necessary.

Pursuant to ASC 606, the $250.0 million non-refundable upfront payment is recognized in revenue as this is the amount allocated to the license. The $80.0 million reimbursement for research and development activities does not constitute a customer/vendor relationship and thus is not in the scope of ASC 606. As ASC 808 does not include recognition guidance we have established an accounting policy to recognize the payments under the reimbursement as a receivable on the balance sheet in an amount that is to be reimbursed based upon expense incurred by us, with a contra- research and development expense recognized in the statement of operations, over time as the expenses are incurred.

Under the Sobi collaboration agreement, for the year ended December 31, 2020, we recognized $250.0 million of licensing revenue in the consolidated statement of operations. For the year ended December 31, 2020, we also recognized in the consolidated statement of operations $43.0 million of contra research and development expense relative to the amount expected to be reimbursed under the $80.0 million for research and development incurred expenses. We also recognized a corresponding receivable of $43.0

million, with $25.0 million in current and $18.0 million in long term assets, respectively, on the consolidated balance sheet as of December 31, 2020.

In addition to the Sobi collaboration agreement, during the year ended December 31, 2020, we entered into two different agreements with third parties to provide APL-9 for use in certain research projects for which $0.6 million was recognized in revenue in the consolidated statement of operations as of December 31, 2020.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing quotations and contracts, identifying 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 the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by CROs and contract manufacturing organizations, or CMOs, in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to CROs and CMOs on our estimates of the services received and efforts expended pursuant to quotes and contracts with CROs and CMOs. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our CROs and CMOs will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting expense amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Convertible Notes

On September 16, 2019, we completed a private offering of the 2019 Convertible Notes with an aggregate principal amount of $220.0 million. On May 12, 2020, we issued the 2020 Convertible Notes with an aggregate principal amount of $300.0 million.

The Convertible Notes are convertible into shares of our common stock at an initial conversion rate of 25.3405 shares per $1,000 principal amount of the Convertible Notes, equivalent to an initial conversion price of approximately $39.46 per share of common stock. The conversion rate is subject to customary anti-dilution adjustments. In addition, following certain events that occur prior to the maturity date or if we deliver a notice of redemption, we are required to increase the conversion rate for a holder who elects to convert its notes in connection with such corporate event or a notice of redemption, as the case may be, in certain circumstances as provided in the Indenture. The Convertible Notes will also be subject to redemption at our option, on or after September 20, 2023, if certain conditions are met. The redemption price is equal to 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

Pursuant to Accounting Standards Codification ("ASC") Subtopic 470-20 *Convertible Debt*, we used an effective interest rate of 10.5% to determine the liability component of the Convertible Notes. This resulted in the recognition of $145.1 million and $204.5 million as the liability component of the 2019 and 2020 Convertible Notes, respectively and the recognition of the residual amount of $74.9 million and $95.5 million as the debt discount with a corresponding increase to additional paid in capital for the equity component of the 2019 and 2020 Convertible Notes, respectively. The 2020 Convertible Notes aggregate debt issuance costs of $6.0 million were allocated to the liability and equity components in the amounts of $3.7 and $2.3 million, respectively. The 2019 Convertible Notes aggregate debt issuance costs of $7.1 million were allocated to the liability and equity components in the amounts of $4.7 million and $2.4 million, respectively.

On January 6, 2021, subsequent to year end, we entered into separate, privately negotiated exchange agreements with certain holders of its 2019 Convertible Notes. Under the terms of these exchange agreements, the holders exchanged approximately $126.1 million in aggregate principal amount of 2019 Convertible Notes held by them for (i) 2,232,808 shares of our common stock, which is equal to 20.7792 shares per $1,000 principal amount of the 2019 Convertible Notes exchanged plus (ii) an additional number of shares of our common stock per $1,000 principal amount of the 2019 Convertible Notes exchanged equal to the quotient of (a) $544.07 divided by (b) the average of the daily volume-weighted average prices of our common stock over the ten consecutive trading days commencing on January 7, 2021. We issued an aggregate of 3,906,869 shares of common stock upon settlement of the exchanges in

January 2021. As of the date of this Annual Report on Form 10-K, we hold the $126.1 million principal amounts of exchanged notes and such notes have not been cancelled.

Capped Call Transactions

On September 11, 2019, and May 6, 2020 concurrently with the pricing of the 2019 Convertible Notes and 2020 Convertible Notes, respectively, we entered into capped call transactions with two counterparties. The capped call transactions are expected generally to reduce the potential dilution to our common stock upon any conversion of notes and/or offset any cash payments we are required to make in excess of the principal amount of the Convertible Notes, as the case may be, in the event that the market price per share of our common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which is initially $39.4625 (the conversion price of the Convertible Notes) and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of such notes. If, however, the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, exceeds the cap price of the capped call transactions, which is initially $63.14 per share, there would nevertheless be dilution and/or there would not be an offset of such potential cash payments, in each case, to the extent that such market price exceeds the cap price of the capped call transactions.

Pursuant to ASC 815-40 *Derivatives and Hedging*, we determined that the capped call transactions should be classified as equity instruments and the capped call premiums paid in the amount of $28.4 million and $43.1 million were recorded as a reduction to additional paid-in capital as of December 31, 2019 and December 31, 2020 for the 2019 Convertible Notes and 2020 Convertible Notes, respectively.

Development Derivative Liability

Following regulatory approval by the FDA or the EMA, for the use of pegcetacoplan as a treatment for PNH we will be obligated to pay SFJ an initial payment of up to $5.0 million (or a total of up to $10.0 million if regulatory approval is granted by the FDA and the EMA) and then up to an additional $226.0 million in the aggregate (or up to $452.0 million if regulatory approval is granted by the FDA and the EMA) in six additional annual payments with the majority of the payments being made from the third anniversary to the sixth anniversary of regulatory approval. Such payments will be proportionately adjusted in the event that the actual funding from SFJ is greater than $120.0 million (including as a result of the payment of the Additional SFJ Funding but excluding the $20.0 million funding payment made under the SFJ amendment).

The SFJ agreement is presented as a derivative liability on the consolidated balance sheet as of December 31, 2020. The liability was initially recorded at the value of the $60.0 million of aggregate cash received pursuant to the contractual terms, which was determined to have been fairly valued as a level 3 derivative. During the years ended December 31, 2020 and 2019, we received an additional $20.0 million and $60.0 million, respectively, as we met certain milestones. The SFJ agreement is remeasured quarterly as a level 3 derivative, with the total change in fair value for the years ended December 31, 2020 and 2019 of $103.0 million and $14.8 million, respectively, recorded in loss from remeasurement of development derivative liability on the consolidated income statement.

The derivative is valued using a scenario-based discounted cash flow method, whereby each scenario makes assumptions about the probability and timing of cash flows, and such cash flows are present valued using a risk-adjusted discount rate. The analysis is calibrated such that the value of the derivative as of the date of the SFJ agreement was consistent with an arm's-length transaction. Key inputs to the level 3 fair value model include (i) the probability and timing of achieving stated development goals to receive the next tranches of funding, (ii) the probability and timing of achieving FDA and EMA approval, (iii) SFJ's cost of borrowing (8.0%), and (iv) our cost of borrowing (12.65%).

SFJ's implied cost of borrowing was 8.0% and our implied cost of borrowing was 12.65% as of the reporting date. These implied costs of borrowing were determined assuming the SFJ agreement was initially executed with arm's-length terms. If the SFJ agreement was instead not determined to be an arm's-length transaction, then implied discount rates could differ.

If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected. See Note 5 to the consolidated financial statements included in Item 15 in this Annual Report on Form 10-K for more information.

Results of Operations

Comparison of Years Ended December 31, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019, together with the dollar increase or decrease and percentage change in those items:

(in thousands)	Year Ended December 31, 2020	2019	Change $	Change %
Revenue:				
Licensing revenue	$ 250,494	$ —	$ 250,494	100%
Collaboration revenue	152	—	152	100
Total revenue:	250,646	—	250,646	100
Operating expenses:				
Research and development	299,921	220,969	78,952	36
License expense	25,050	—	25,050	100
General and administrative	139,401	67,046	72,355	108
Total operating expenses	464,372	288,015	176,357	61
Net operating loss	(213,726)	(288,015)	74,289	(26)
Loss on extinguishment of debt	—	(1,501)	1,501	(100)
Loss from remeasurement of development derivative liability	(103,029)	(14,839)	(88,190)	594
Interest income	4,164	5,108	(944)	(18)
Interest expense	(29,937)	(5,285)	(24,652)	466
Other expense, net	(501)	(175)	(326)	186
Net loss before taxes	(343,029)	(304,707)	(38,322)	13
Income tax expense	1,845	—	1,845	100
Net loss	$ (344,874)	$ (304,707)	$ (40,167)	13

Revenue

Licensing revenue increased $250.5 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019. The increase is primarily due to the Collaboration and Licensing Agreement we entered with Sobi in October 2020 concerning the development and commercialization of pegcetacoplan and specified other compstatin analogues or derivatives for use systemically or for local non-ophthalmic administration. Sobi paid us an upfront payment of $250.0 million in November 2020, which is recognized in licensing revenue in the consolidated statement of operations as of December 31, 2020.

Additionally, during the year ended December 31, 2020, we entered into two different licensing and collaboration agreements with third parties to provide APL-9 for use in certain research project which totaled $0.6 million for the year ended December 31, 2020.

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the years ended December 31, 2020 and 2019, together with the dollar increase or decrease and percentage change in those items:

(In thousands)	Year Ended December 31, 2020	2019	Change $	Change %
Contract manufacturing	$ 112,820	$ 75,767	$ 37,053	49%
Clinical trial costs	102,243	86,684	15,559	18%
Compensation and related personnel costs	76,318	37,536	38,782	103%
Other development costs	30,092	8,350	21,742	260%
Sobi development milestone	(42,975)	—	(42,975)	100%
Research/innovation	16,382	6,280	10,102	161%
Pre-clinical study expenses	4,407	6,360	(1,953)	-31%
Device development expenses	634	(8)	642	-8025%
Research and development expense	299,921	220,969	78,952	36%
License expense	25,050	—	25,050	100%
Total research and development expenses including license expense	$ 324,971	$ 220,969	$ 104,002	47%

Research and development expenses increased by $104.0 million to $325.0 million for the year ended December 31, 2020 from $221.0 million for the year ended December 31, 2019, an increase of 47%. The increase in research and development expenses was primarily attributable to an increase of $37.1 million in manufacturing expenses in connection with the supply of pegcetacoplan for our Phase 3 clinical trials and in preparation for commercial launch, an increase of $15.6 million in clinical trial costs associated with the on-going Phase 3 trials and the preparation for and commencement of our clinical trials in other indications, an increase of $38.8 million in compensation and related personnel costs primarily due to the hiring of additional personnel in 2020, an increase of $21.7 million in research and development supporting activities caused primarily by increased regulatory and quality expenses, an increase of $25.0 million for the licensee fee to Penn related to the Sobi transaction, an increase in research and innovation expense of $10.1 million and an increase of $0.6 million in device development expenses. These increases were offset by a $43.0 million contra research and development expense related to the Sobi transaction and a decrease of $1.9 million related to preclinical study expense. We expect our research and development expenses to continue to increase as the number of patients in our trials increases and the number of ongoing trials increases.

General and Administrative Expenses

General and administrative expenses increased by $72.4 million to $139.4 million for the year ended December 31, 2020, from $67.0 million for the year ended December 31, 2019, an increase of 108%. The increase in general and administrative expenses was primarily attributable to an increase in professional and consulting fees of $35.5 million, an increase in employee related costs of $33.8 million due to the hiring of additional personnel, an increase in directors stock compensation expense of $1.8 million ,an increase in insurance costs of $1.1 million, and an increase in office, travel and related costs of $0.6 million, offset by a decrease of $0.4 million in information technology expenses. The increased professional and consulting fees of $35.5 million primarily consisted of an increase in expenses relating to preparation for commercial launch of $29.3 million, an increase of $4.5 million in accounting and legal fees, and an increase in general consulting fees of $2.6 million, offset by a decrease in communication and public relations fees of $0.9 million. The increased employee related costs of $33.8 million consisted of $21.9 million related to an increase in salaries and benefits primarily due to the hiring of additional personnel and $12.3 million related to stock option expense associated with the grants of stock options and restricted stock units to employees, offset by a decrease of $0.4 million in recruitment expense.

Loss on Extinguishment of Debt

On March 26, 2019, we repaid all outstanding amounts due and owed, including applicable termination fees, under our term loan facility with Silicon Valley Bank. The final payment included the outstanding balance of the term loan as well as (i) a prepayment fee contractually owed of $0.1 million, (ii) a final payment equal to 8% of the original principal amount of the term loan, or $1.6 million, and (iii) per diem interest of $0.1 million, for a total payment of $21.8 million, which resulted in a loss on extinguishment of debt of $1.2 million. On September 16, 2019, we repaid outstanding amounts due and owed on the promissory note with Golda Darty Partners, S.A. or GDP. The remaining discount on the promissory note related to the issuance of warrants in connection with the issuance of the promissory note resulted in a loss on extinguishment of debt of $0.3 million.

Loss from Remeasurement of Development Derivative Liability

On February 28, 2019, we entered into the SFJ agreement under which SFJ agreed to provide funding to us to support the development of pegcetacoplan for the treatment of patients with PNH. The development derivative liability was initially recorded at the value of the $60.0 million aggregate cash received pursuant to the contact terms.

The SFJ agreement was amended on June 7, 2019 to provide for additional funding and we received $20.0 million upon execution of the SFJ amendment in June 2019 and in each of September 2019 and January 2020, we achieved a $20.0 million development milestone under the terms of the agreement, resulting in receipt of an aggregate of $60.0 million of additional funding from SFJ.

We remeasure the fair value of the derivative liability as a level 3 derivative at the end of each quarter. The remeasurements resulted in a change in fair value which resulted in a loss of $103.0 million and $14.8 million recorded in the consolidated statement of operations for the years ended December 31, 2020 and 2019, respectively.

Interest Expense

Interest expense was $29.9 million for the year ended December 31, 2020, an increase of $24.6 million, compared to $5.3 million for the year ended December 31, 2019. The increase in interest expense was primarily attributable to the interest expense on and amortization of the discount on the Convertible Notes offset by the decrease in interest expense attributable to our long-term debt under the term loan facility that we repaid in March 2019 and the promissory note that we repaid in 2019.

Interest Income

Interest income was $4.2 million for the year ended December 31, 2020, a decrease of $.9 million, compared to $5.1 million for the year ended December 31, 2019. The decrease in interest income was primarily attributable to a decline in investment yields and interest rates.

Other Expense, Net

Other expense increased $0.3 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019. The increase was primarily related to corporate franchise taxes and fees.

Income Tax Expense

Income tax expense increased $1.8 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019. The increase was primarily related to foreign and state income tax expense.

Comparison of the Years Ended December 31, 2019 and 2018

A discussion of changes in our results of operations during the year ended December 31, 2019 compared to the year ended December 31, 2018 has been omitted from this Annual Report on Form 10-K but may be found in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on February 27, 2020, which discussion is incorporated herein by reference and which is available free of charge on the SECs website at www.sec.gov.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have financed our operations primarily through $772.1 million in net proceeds from public offerings of our common stock, including our IPO, $535.8 million in net proceeds from offerings of Convertible Notes, a $250.0 million upfront payment and a $25.0 million development reimbursement payment from Sobi each pursuant to the Sobi collaboration agreement, $112.6 million in proceeds from the private placement of shares of our convertible preferred stock prior to our IPO, $140.0 million under the SFJ agreement, $20.0 million in proceeds from borrowings under a term loan facility with Silicon Valley Bank, and $7.0 million in proceeds from our issuance and sale of a promissory note. We have repaid the term loan facility and the promissory note in full, and we exchanged $126.1 million of aggregate principal amount of 2019 Convertible Notes for shares of our common stock in January 2021.

On April 23, 2018, we issued and sold 5,500,000 shares of our common stock in a follow-on public offering at a public offering price of $25.50 per share for net proceeds of $131.2 million, after deducting underwriting discounts and commissions of $8.4 million and offering expenses of $0.5 million.

On March 11, 2019, we issued and sold 6,900,000 shares of our common stock in a follow-on offering at a public offering price of $17.00. We received net proceeds of $109.6 million after deducting underwriting discounts and commissions of $7.0 million and offering costs of $0.7 million.

On September 16, 2019, we completed a private offering of $220.0 million aggregate principal amount of Convertible Notes. We received net proceeds of approximately $212.9 million after deducting the initial purchasers' discounts and commissions and offering costs of $7.1 million.

On January 13, 2020, we issued and sold 10,925,000 shares of our common stock in a follow-on offering at a public offering price of $37.00, including 1,425,000 shares sold pursuant to the underwriters' exercise in full of their option to purchase additional shares of common stock. We received total net proceeds of $381.4 million after deducting underwriting discounts and commissions of $22.2 million and offering costs of $0.5 million.

On May 12, 2020, we completed a private offering of $300.0 million aggregate principal amount of 2020 Convertible Notes. We received net proceeds of approximately $322.9 million, which included accrued interest March 15, 2020 to, but not including May 12, 2020, and the initial purchasers' discounts and commissions and offering costs of $6.0 million.

Subsequent to year end, on January 6, 2021, we entered into separate, privately negotiated exchange agreements with certain holders of our 2019 Convertible Notes. Under the terms of these exchange agreements, the holders exchanged approximately $126.1

million in aggregate principal amount of 2019 Convertible Notes held by them for an aggregate of 3,906,869 shares of our common stock. The exchange transactions closed in January 2021.

In addition to our existing cash, cash equivalents and marketable securities, we expect to receive research and development reimbursements and are eligible to earn development and commercial milestone payments and royalties under our collaboration agreement with Sobi. Our ability to earn these milestone payments and the timing of earning these payments is dependent upon the outcome of our research and development and commercialization activities and is uncertain at this time.

The capped call transactions that we entered into concurrently with the issuance of the Convertible Notes are expected generally to reduce the potential dilution to our common stock upon any conversion of Convertible Notes and/or offset any cash payments we are required to make in excess of the principal amount of converted Convertible Notes, as the case may be, in the event that the market price per share of our common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which is initially $39.4625, the conversion price of the Convertible Notes.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2020 and 2019:

(in thousands)	**Year Ended December 31,**	
	2020	**2019**
Net cash used in operating activities	$ (160,488)	$ (211,135)
Net cash used in investing activities	(316,989)	(1,693)
Net cash provided by financing activities	692,178	388,541
Effect of exchange rate changes on cash and cash equivalents	359	4
Net increase (decrease) in cash and cash equivalents	$ 215,060	$ 175,717

Net Cash Used in Operating Activities

Net cash used in operating activities was $160.5 million for the year ended December 31, 2020 and consisted primarily of a net loss of $344.9 million adjusted for $164.8 million of non-cash items, including a loss from remeasurement of development derivative liability of $103.0 million and share-based compensation expense of $45.4 million, a net increase in operating assets of $35.4 million, an increase in accounts payable and accrued expenses of $55.0 million.

Net cash used in operating activities was $211.1 million for the year ended December 31, 2019 and consisted primarily of a net loss of $304.7 million adjusted for $40.4 million of non-cash items, including share-based compensation expense of $21.1 million, a loss from remeasurement of development derivative liability of $14.8 million, and a loss on early extinguishment of debt of $1.5 million, a net increase in accounts payable, accrued expenses and other liabilities of $48.7 million and a net decrease in operating assets of $4.5 million. The net increase in operating liabilities resulted primarily from an increase in accrued expenses of $50.5 million.

Net Cash Used in Investing Activities

Net cash used in investing activities during the year ended December 31, 2020 was $317.0 million due primarily to the purchase of marketable securities with proceeds from the follow-on common stock offering in January 2020, the issuance of the 2020 Convertible Notes in May 2020 and the $250.0 million from the Sobi agreement offset by the maturities of some of these investments.

Net cash used in investing activities during the year ended December 31, 2019 was $1.7 million due to the purchase of fixed assets for our offices.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $692.2 million during the year ended December 31, 2020 and consisted primarily of proceeds from the follow-on common stock offering in January 2020 of $381.4 million, the proceeds from the issuance of the 2020 Convertible Notes in May 2020 of $322.9 million, the receipt of $20.0 million from the SFJ agreement and $11.0 million upon the exercise of stock options and the employee share purchase plan, offset by the $43.1 million used to purchase the capped call.

Net cash provided by financing activities was $388.5 million during the year ended December 31, 2019 and consisted primarily of proceeds from the issuance of the Convertible Notes in September 2019 of $212.9 million, the issuance of common stock in our March follow-on offering of $109.6 million, the receipt of $120.0 million from the SFJ agreement and $3.1 million upon the exercise

of stock options, offset by $28.7 million for the repayment of our term loan facility and promissory note, and $28.4 million for capped call premiums paid.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. 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 would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We believe that our cash and cash equivalents and marketable securities as of December 31, 2020 will enable us to fund our operating expenses and capital expenditure requirements at least into the second half of 2022. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Although we expect that our cash, cash equivalents and marketable securities will be sufficient to allow us to complete the DERBY and OAKS clinical trials, we do not believe they will be sufficient to allow us to support both the systemic and ophthalmological pegcetacoplan programs through commercial launch. Because of the numerous risks and uncertainties associated with the development of pegcetacoplan and other potential product candidates, and because the extent to which we may enter into collaborations with third parties for the development of these product candidates is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future funding requirements will depend on many factors, including:

- the scope, progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for pegcetacoplan, APL-9 and future product candidates;
- our ability to maintain a productive collaborative relationship with Sobi with respect to pegcetacoplan, including our ability to achieve milestone payments under our agreement with Sobi;
- our ability to identify additional collaborators for any of our product candidates and the terms and timing of any collaboration agreement that we may establish for the development and any commercialization of such product candidates;
- the number and characteristics of future product candidates that we pursue and their development requirements;
- the outcome, timing and costs of clinical trials and of seeking regulatory approvals of pegcetacoplan and other product candidates we may pursue;
- the costs of commercialization activities for any of our product candidates that receive marketing approval to the extent such costs are not the responsibility of any collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of marketing approval, revenue, if any, received from commercial sales of pegcetacoplan and our other product candidates;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims;
- the effect of competing technological and market developments;
- the effect of the COVID-19 pandemic on the healthcare system and the economy generally and on our clinical trials and other operations specifically;
- our ability to obtain adequate reimbursement for any product we commercialize; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical testing and 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. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of medicines that we do not expect to be commercially available for many

years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

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, strategic alliances and licensing arrangements. We currently do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Debt financing, if available, would result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through collaborations, strategic alliances 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.

Contractual Obligations

The following table summarizes our significant contractual obligations as of payment due date by period at December 31, 2020:

(In thousands)	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Convertible notes (1)	$ 623,892	$ 18,200	$ 36,400	$ 36,400	$ 532,892
Non-cancellable purchase commitments (2)	13,650	13,650	—	—	—
Operating leases (3)	22,489	4,962	9,668	6,483	1,376
Total	$ 660,031	$ 36,812	$ 46,068	$ 42,883	$ 534,268

(1) Amounts include interest on long-term debt represents obligations under the debt outstanding as of December 31, 2020, applying contractual fixed interest rate and assuming scheduled payments are paid as contractually required through maturity. Subsequent to year end, in January 2021, we entered into an agreement to exchange $126.1 million of our 2019 Convertible Notes for shares of common stock. See Note 20 to the consolidated financial statements included in Item 15 in this Annual Report on Form 10-K for more information.

(2) Equals the non-cancellable purchase commitments under the Bachem Agreement signed with Bachem on December 30, 2020,

(3) Represents future minimum lease payments under our non-cancelable operating leases. The minimum lease payments above do not include any related common area maintenance charges or real estate taxes.

On February 28, 2019, we entered into the SFJ agreement. Under the SFJ agreement, following regulatory approval by the FDA or the EMA of the use of pegcetacoplan as a treatment for PNH, we will be obligated to pay SFJ an initial payment of up to $5.0 million (or up to a total of $10 million if regulatory approval is granted by the FDA and the EMA) and then up to an additional $226.0 million in the aggregate (or up to $452.0 million if regulatory approval is granted by the FDA and the EMA) in six additional annual payments with the majority of the payments being made from the third anniversary to the sixth anniversary of regulatory approval. The timing and likelihood of such payments are not currently known.

During the third quarter of 2019, we entered into contracts to conduct research and development activities with third parties which commit us to pay future milestone payments up to $15.0 million or to pay royalty fees ranging from 3-6% if any of the research results in regulatory approval or commercial revenue for a product. The scope of the services under the research and development contracts can be modified and the contracts cancelled by us upon written notice. In some instances, the contracts may be cancelled by the third party upon written notice. If we were to cancel these contracts, we would be required only to pay for activities incurred through termination date. We have not included any of these potential payments in the contractual obligations table above, as we cannot reasonably estimate whether, when and in what amount any of such payments shall be made.

We are party to two license agreements with Penn under which we license specified intellectual property from Penn. The patent rights licensed to us by Penn include patents with claims that recite a class of compounds generically covering pegcetacoplan. Each license agreement requires us to pay ongoing annual maintenance payments of $100,000 per year until the first commercial sale of a licensed product. With respect to the license for the nonophthalmic field of use, we have agreed to make milestone payments to Penn aggregating up to $1.7 million based on achieving specified development and regulatory approval milestones, and up to $2.5 million based on achieving specified annual sales milestones with respect to each of the first two licensed products. In 2018 we made one milestone payment of $0.4 million under the nonophthalmic license. With respect to the license for the ophthalmic field of use, we have agreed to make milestone payments to Penn aggregating up to $3.2 million based on achieving specified development and regulatory milestones, and up to $5.0

million based on achieving specified annual sales milestones. In 2018 we made one milestone payment, net of credits for the annual maintenance payment, of $0.7 million under the ophthalmic license. The license agreements also require that we pay low single-digit royalties to Penn based on net sales of each licensed product by us and our affiliates and sublicensees and specified minimum quarterly royalty thresholds. In addition, we are obligated to pay Penn a specified portion of income we receive from sublicensees. In January 2021 we paid Penn $25.0 million as a sublicensee fee under these agreements relating to the Sobi agreement. We have not included any of these potential payments in the contractual obligations table above, as we cannot reasonably estimate whether, when and in what amount any of such payments shall be made.

We enter into agreements in the normal course of business with CROs for clinical trials and clinical supply manufacturing and with vendors for preclinical research studies and other services and products for operating purposes. We have not included these payments in the table of contractual obligations above since either the contracts are cancelable at any time by us, generally upon 30 days prior written notice to the CRO, or the noncancelable minimum purchase commitments under such contracts have already been satisfied, and therefore we believe that our non-cancelable obligations under these agreements are not material. Under these agreements, as of December 31, 2020, we are obligated to pay up to $2.8 million to these vendors.

We have certain non-cancelable purchase obligations related to the manufacturing of drug substance and drug product, primarily with Bachem Americas, Inc, and Bachem AG, for the drug substance for the finished dosage form of pegcetacoplan.

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 applicable SEC rules.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of December 31, 2020, we had cash, cash equivalents and marketable securities of $877.6 million, consisting primarily of money market funds and U.S. treasury securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio. We have the ability to hold our marketable securities until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

Item 8. Financial Statements and Supplementary Data.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Apellis Pharmaceuticals, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Apellis Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 25, 2021, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Development Derivative Liability — Refer to Notes 4 and 10 to the financial statements.

Critical Audit Matter Description

On February 28, 2019, the Company entered into a development funding agreement with SFJ Pharmaceuticals Group ("SFJ") under which SFJ agreed to provide funding to the Company to support the development of one the Company's clinical trials ("SFJ Agreement"). The SFJ Agreement is presented as a derivative liability whose fair value is based on unobservable inputs. The liability is initially recorded at the value of the aggregate cash received pursuant to the contractual terms and is subsequently remeasured at each quarter with the change in fair value recorded in loss from remeasurement of development derivative liability on the income statement.

We identified the valuation of the development derivative liability as a critical audit matter. The development derivative liability is valued using a scenario-based discounted cash flow method, whereby each scenario makes assumptions about the probability and timing of cash flows, and such cash flows are present valued using a risk-adjusted discount rate. This model includes unobservable inputs including the probability and timing of achieving U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) approval and Company's cost of borrowing. This required a high degree of auditor judgment and an increased extent of effort, including the need to involve our fair value specialists.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the development derivative liability model and unobservable inputs used by management to estimate the fair value of the development derivative liability included the following, among others:

- We tested the effectiveness of controls over management's valuation of the development derivative liability such as those related to management's assumptions over the probability and timing of achieving FDA and EMA approval and the review of the discount rate.

- We evaluated the reasonableness of management's assumptions over the probability and timing of achieving FDA and EMA approval by comparing the assumptions within the model to:

    - Internal communications to management and the Board of Directors.
    - Information included in Company press releases as well as in analyst reports for the Company.
    - Inquiries with those responsible for clinical affairs regarding the progress of ongoing trials.

- With the assistance of our fair value specialists, we evaluated the reasonableness of the valuation methodology including the discount rate used by testing the source information and the mathematical accuracy of the calculation.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
February 25, 2021

We have served as the Company's auditor since 2019.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Apellis Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows of Apellis Pharmaceuticals, Inc. (the Company) for the year ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the results of the Company's operations and its cash flows for the year ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We served as the Company's auditor from 2015 to 2019.

Boston, Massachusetts

February 26, 2019

APELLIS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except per share amounts)

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 565,779	$ 351,985
Marketable securities	311,869	—
Prepaid assets	11,400	19,802
Restricted cash	1,266	—
Other current assets	26,878	1,308
Total current assets	917,192	373,095
Non-current assets:		
Right-of-use assets	17,719	14,110
Property and equipment, net	6,803	1,655
Other assets	18,855	385
Total assets	$ 960,569	$ 389,245
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,477	$ 8,361
Accrued expenses	111,935	54,783
Current portion of development derivative liability	4,230	—
Current portion of right-of-use liabilities	3,685	2,609
Total current liabilities	128,327	65,753
Long-term liabilities:		
Convertible senior notes	358,830	142,567
Development derivative liability	253,638	134,839
Right-of-use liabilities	15,217	11,857
Total liabilities	756,012	355,016
Commitments and contingencies (note 15)	—	—
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000 shares authorized and zero shares issued and outstanding at December 31, 2020 and 2019	—	—
Common stock, $0.0001 par value; 200,000 shares authorized at December 31, 2020 and 2019; 76,130 and 63,938 shares issued and outstanding at December 31, 2020 and 2019, respectively	8	6
Additional paid-in capital	1,131,013	615,850
Accumulated other comprehensive loss	(117)	(154)
Accumulated deficit	(926,347)	(581,473)
Total stockholders' equity	204,557	34,229
Total liabilities and stockholders' equity	$ 960,569	$ 389,245

See accompanying notes to consolidated financial statements

APELLIS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Amounts in thousands, except per share amounts)

	Year Ended December 31,		
	2020	2019	2018
Revenue:			
Licensing revenue	$ 250,494	$ —	$ —
Collaboration revenue	152	—	—
Total revenue:	250,646	—	—
Operating expenses:			
Research and development	299,921	220,969	105,286
License expense	25,050	—	—
General and administrative	139,401	67,046	22,639
Operating expenses:	464,372	288,015	127,925
Net operating loss	(213,726)	(288,015)	(127,925)
Loss on extinguishment of debt	—	(1,501)	—
Loss from remeasurement of development derivative liability	(103,029)	(14,839)	—
Interest income	4,164	5,108	2,961
Interest expense	(29,937)	(5,285)	(2,513)
Other expense, net	(501)	(175)	(25)
Net loss before taxes	(343,029)	(304,707)	(127,502)
Income tax expense	1,845	—	—
Net loss	(344,874)	(304,707)	(127,502)
Other comprehensive income/(loss):			
Unrealized loss on marketable securities	(8)	—	—
Foreign currency gain/(loss)	45	(31)	(123)
Total other comprehensive income/(loss)	37	(31)	(123)
Comprehensive loss, net of tax	(344,837)	(304,738)	(127,625)
Net loss per common share, basic and diluted	$ (4.59)	$ (4.90)	$ (2.34)
Weighted-average number of common shares used in net loss per common share, basic and diluted	75,163	62,229	54,396

See accompanying notes to consolidated financial statements

APELLIS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Amounts in thousands, except per share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Outstanding Shares	Amount				
Balance at January 1, 2018	50,334	$ 5	$ 298,201	$ —	$ (149,264)	$ 148,942
Issuance of common stock in follow-on offering, net of offering costs	5,500	1	131,194	—	—	131,195
Issuance of common stock upon exercise of stock options	445	—	728	—	—	728
Share-based compensation expense	—	—	7,733	—	—	7,733
Net loss	—	—	—	—	(127,502)	(127,502)
Foreign currency loss	—	—	—	(123)	—	(123)
Balance at December 31, 2018	56,279	6	437,856	(123)	(276,766)	160,973
Issuance of common stock in follow-on offering, net of offering costs	6,900	—	109,581	—	—	109,581
Issuance of common stock upon exercise of stock options or warrants	759	—	3,129	—	—	3,129
Recognition of equity component of convertible notes	—	—	72,520	—	—	72,520
Purchase of capped call transactions and associated costs	—	—	(28,380)	—	—	(28,380)
Share-based compensation expense	—	—	21,144	—	—	21,144
Net loss	—	—	—	—	(304,707)	(304,707)
Foreign currency loss	—	—	—	(31)	—	(31)
Balance at December 31, 2019	63,938	6	615,850	(154)	(581,473)	34,229
Issuance of common stock in follow-on offering, net of offering costs	10,925	1	381,422	—	—	381,423
Issuance of common stock upon exercise of stock options	1,208	1	9,417	—	—	9,418
Recognition of equity component of convertible notes	—	—	120,485	—	—	120,485
Purchase of capped call transactions and associated costs	—	—	(43,112)	—	—	(43,112)
Share-based compensation expense	—	—	45,376	—	—	45,376
Issuance of common stock to employee stock purchase plan	59	—	1,575	—	—	1,575
Unrealized loss on available-for-sale investments	—	—	—	(8)	—	(8)
Net loss	—	—	—	—	(344,874)	(344,874)
Foreign currency gain	—	—	—	45	—	45
Balance at December 31, 2020	76,130	$ 8	$ 1,131,013	$ (117)	$ (926,347)	$ 204,557

See accompanying notes to consolidated financial statements

APELLIS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands, except per share amounts)

	Year Ended December 31,		
	2020	2019	2018
Operating Activities			
Net loss	$ (344,874)	$ (304,707)	$ (127,502)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation expense	45,376	21,144	7,733
Loss on early extinguishment of debt	—	1,501	—
Loss from remeasurement of development derivative liability	103,029	14,839	—
Non-cash lease expense	222	356	—
Depreciation expense	637	240	—
Amortization of debt discounts	—	52	—
Amortization of discounts for promissory note	—	—	72
Amortization of term loan facility discounts	—	104	582
Amortization of discounts for convertible notes, net of financing costs	15,536	2,186	—
Changes in operating assets and liabilities:			
Prepaid assets	8,738	4,531	(299)
Other current assets	(26,284)	287	(19,275)
Other assets	(17,860)	(323)	(309)
Accounts payable	(54)	(1,641)	(978)
Accrued expenses	55,046	50,454	6,587
Other liabilities	—	(158)	2,148
Net cash used in operating activities	(160,488)	(211,135)	(131,241)
Investing Activities			
Purchase of property and equipment	(5,422)	(1,693)	—
Purchase of available-for-sale securities	(879,067)	—	—
Proceeds from maturity of available-for-sale securities	567,500	—	—
Net cash used in investing activities	(316,989)	(1,693)	—
Financing Activities			
Deferred issuance costs	—	—	(18)
Proceeds from issuance of common stock, net of issuance costs	381,423	109,581	131,194
Proceeds from development derivative liability	20,000	120,000	—
Payments for capped call transactions and associated costs	(43,112)	(28,380)	—
Proceeds from issuance of convertible notes, net of issuance costs	322,874	212,912	—
Proceeds from exercise of stock options and warrants	9,418	3,129	727
Proceeds from issuance of common stock under employee share purchase plan	1,575	—	—
Repayment of promissory note	—	(7,000)	—
Repayment of term loan facility	—	(21,701)	—
Net cash provided by financing activities	692,178	388,541	131,903
Effect of exchange rate changes on cash and cash equivalents	359	4	(38)
Net increase in cash and cash equivalents	215,060	175,717	624
Cash, cash equivalents and restricted cash at beginning of period	351,985	176,268	175,644
Cash, cash equivalents and restricted cash at end of period	$ 567,045	$ 351,985	$ 176,268

See accompanying notes to consolidated financial statements

APELLIS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands, except per share amounts)
(Cont'd)

	Year Ended December 31,		
	2020	2019	2018
Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets:			
Cash and cash equivalents	$ 565,779	$ 351,985	$ 176,268
Restricted cash	1,266	—	—
Total cash, cash equivalents, and restricted cash	$ 567,045	$ 351,985	$ 176,268
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 12,929	$ 987	$ 1,816
Equity component of convertible notes	$ 120,485	$ 72,520	$ —

See accompanying notes to consolidated financial statements

1. Nature of Organization and Operations

Apellis Pharmaceuticals, Inc. (the "Company") is a clinical-stage biopharmaceutical company focused on the development of novel therapeutic compounds to treat disease through the inhibition of the complement system, which is an integral component of the immune system, at the level of C3, the central protein in the complement cascade.

The Company was incorporated in September 2009 under the laws of the State of Delaware. The Company's principal executive offices are located in Waltham, Massachusetts, effective January 1, 2020.

The Company's operations since inception have been limited to organizing and staffing the Company, acquiring rights to product candidates, business planning, raising capital and developing its product candidates.

The Company is subject to risks common in the biotechnology industry including, but not limited to, raising additional capital, development by its competitors of new technological innovations, its ability to successfully complete preclinical and clinical development of product candidates and receive timely regulatory approval of products, market acceptance of the Company's products, protection of proprietary technology, healthcare cost containment initiatives, and compliance with governmental regulations, including those of the U.S. Food and Drug Administration ("FDA"). Additionally, the Company is subject to risks arising from the Coronavirus Disease 2019 (COVID-19) pandemic, which could have adverse effects upon its business and operations, including on its ability to initiate, conduct and complete clinical trials, and could disrupt regulatory activities.

Collaboration and License Agreement

On October 27, 2020, the Company and its wholly-owned subsidiaries Apellis Switzerland GmbH and APL DEL Holdings, LLC entered into a Collaboration and License Agreement with Sobi, concerning the development and commercialization of pegcetacoplan and specified other structurally and functionally similar compstatin analogues or derivatives for use systemically or for local non-ophthalmological administration (collectively referred to as the "Licensed Products").

Under the collaboration agreement, the Company granted Sobi an exclusive (subject to certain retained rights of the Company), sublicensable license of certain patent rights and know-how to develop and commercialize Licensed Products in all countries outside of the United States. The Company retained the right to commercialize Licensed Products in the United States, and, subject to specified limitations, to develop Licensed Products worldwide for commercialization in the United States.

Sobi paid the Company an upfront payment of $250.0 million in November 2020 and has agreed to pay up to an aggregate of $915.0 million upon the achievement of specified one-time regulatory and commercial milestone events, and to reimburse the Company for up to $80.0 million in development costs. The Company will also be entitled to receive tiered, double-digit royalties (ranging from high teens to high twenties) on sales of Licensed Products outside of the United States, subject to customary deductions and third-party payment obligations, until the latest to occur of: (i) expiration of the last-to-expire of specified licensed patent rights; (ii) expiration of regulatory exclusivity; and (iii) ten (10) years after the first commercial sale of the applicable Licensed Product, in each case on a Licensed Product-by-Licensed Product and country-by-country basis. Under the collaboration agreement, the Company remains responsible for its license fee obligations (including royalty obligations) to the University of Pennsylvania as a licensor of the Company and for its payment obligations to SFJ Pharmaceuticals. See note 11, License and Collaboration Agreements, for further discussion related to the Sobi collaboration agreement.

Convertible Notes Offering

On May 12, 2020, the Company completed a private offering of $300.0 million aggregate principal amount of 3.5% convertible senior notes due 2026 (the "2020 Convertible Notes"). The aggregate purchase price of the 2020 Convertible Notes was $328.9 million, which amount includes accrued interest from March 15, 2020 to, but not including, May 12, 2020.

The net proceeds from the sale of the Convertible Notes were approximately $322.9 million after deducting the initial purchasers' discounts and commissions and offering expenses paid by the company. The Company used $43.1 million of the net proceeds from the sale of the Convertible Notes to pay the cost of the capped call transactions described below.

The 2020 Convertible Notes form a single series with, and have the same terms as, the Company's $220.0 million aggregate principal amount of 3.500% convertible senior notes due 2026 issued on September 16, 2019, (the "2019 Convertible Notes", and together with the 2020 Convertible Notes, the "Convertible Notes"), but have a different issue date, issue price, CUSIP number and different restrictions on transfer. The 2020 Convertible Notes were issued as additional notes under the indenture (the "Indenture"), dated as of September 16, 2019, by and between the Company and U.S. Bank National Association, as trustee (the "Trustee"), under which the 2019 Convertible Notes were issued. The 2020 Convertible Notes rank equal in right of payment to the 2019 Convertible Notes.

The 2020 Convertible Notes are senior unsecured obligations of the Company and bear interest at a rate of 3.5% per year payable semiannually in arrears on March 15 and September 15 of each year, beginning on March 15, 2020. The Convertible Notes will mature on September 15, 2026, unless converted earlier, redeemed or repurchased in accordance with the terms of the Convertible Notes. See Note 6 – Long-term Debt for additional information.

Subsequent to year end, on January 6, 2021, the Company entered into separate, privately negotiated exchange agreements with certain holders of its 2019 Convertible Notes. Under the terms of these exchange agreements, the holders exchanged approximately $126.1 million in aggregate principal amount of 2019 Convertible Notes held by them for an aggregate of 3,906,869 shares of common stock. The exchange transactions closed on January 26, 2021. As of the date of this Annual Report on Form 10-K, the Company holds the $126.1 million principal amounts of exchanged notes and such notes have not been cancelled.

Capped Call Transactions

On May 6, 2020, concurrently with the pricing of the 2020 Convertible Notes, the Company entered into capped call transactions with two counterparties. The capped call transactions are expected generally to reduce the potential dilution to the Company's common stock upon any conversion of the 2020 Convertible Notes and/or offset any cash payments the Company is required to make in excess of the principal amount of converted 2020 Convertible Notes, as the case may be, in the event that the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which is initially $39.4625 (the conversion price of the 2020 Convertible Notes) and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of such 2020 Convertible Notes.

Follow-on Public Offerings

On January 13, 2020, the Company issued and sold 10,925,000 shares of its common stock at a price per share to the public of $37.00 in a follow-on public offering including an additional 1,425,000 shares of its common stock that were sold at the follow-on public offering price of $37.00 per share pursuant to the underwriters' in full exercise of their option to purchase additional shares of common stock. The Company received net proceeds of approximately $381.4 million after deducting underwriting discounts and commissions of approximately $22.2 million and offering costs of $0.5 million for these transactions.

On March 11, 2019, the Company issued and sold 6,900,000 shares of its common stock at a price per share of $17.00 in a follow-on public offering. The Company received net proceeds of approximately $109.6 million after deducting underwriting discounts and commissions of approximately $7.0 million and offering costs of $0.7 million.

Liquidity and Going Concern

The accompanying consolidated financial statements have been prepared on the basis of the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. As of February 25, 2021, the date of issuance of these consolidated financial statements, the Company believes that its cash and cash equivalents and marketable securities as of December 31, 2020 of $877.6 million, will be sufficient to fund its operations and capital expenditures for at least the next twelve months from the date of issuance of these consolidated financial statements. The Company's future viability beyond that point is dependent on its ability to raise additional capital to finance its operations.

The Company is subject to risks common to other life science companies in the development stage including, but not limited to, uncertainty of product development and commercialization, lack of marketing and sales history, development by its competitors of new technological innovations, dependence on key personnel, market acceptance of products, product liability, protection of proprietary technology, ability to raise additional financing, and compliance with FDA and other government regulations. If the Company does not successfully commercialize any of its product candidates, it will be unable to generate recurring product revenue or achieve profitability. Management's plans in order to meet its short-term and longer-term operating cash flow requirements include obtaining additional funding.

There are uncertainties associated with the Company's ability to (1) obtain additional debt or equity financing on terms that are favorable to the Company, (2) enter into collaborative agreements with strategic partners, and (3) succeed in its future operations. If the Company is not able to obtain the required funding for its operations, or is not able to obtain funding on terms that are favorable to the Company, it could be forced to delay, reduce or eliminate its research and development programs or future commercialization efforts and its business could be materially harmed.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Apellis Australia Pty Ltd, Apellis Bermuda Limited, Apellis Germany GmbH, Apellis Ireland Ltd, Apellis Netherlands B.V., Apellis Switzerland GmbH, Apellis UK Limited, APL DEL Holdings LLC, APL Sales Corp I, LLC, APL PRG I, Corp. and Apellis MA Securities Corp. All intercompany balances and transactions have been eliminated in consolidation. The consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") and following the requirements of the Securities and Exchange Commission (the "SEC").

Licensing and Collaboration Revenue

The Company analyzes license and collaboration arrangements pursuant to FASB ASC Topic 808, *Collaborative Arrangement Guidance and Considerations,* ("ASC 808") to assess whether such arrangements, or transactions between arrangement participants, involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities or are more akin to a vendor-customer relationship. In making this evaluation, the Company considers whether the activities of the collaboration are considered to be distinct and deemed to be within the scope of the collaborative arrangement guidance or if they are more reflective of a vendor-customer relationship and, therefore, within the scope of FASB ASC Topic 606, *Revenue from Contracts with Customer, (*"ASC 606"). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement.

For elements of collaboration arrangements that are not accounted for pursuant to guidance in ASC 606, an appropriate recognition method is determined and applied consistently, generally by analogy to the revenue from contracts with customers guidance. Amounts related to transactions with a counterparty in a collaborative arrangement that is not a customer are presented as collaboration revenue and in a separate line item from revenue recognized from contracts with customers, if any, in our consolidated statements of operations.

Pursuant to ASC 606, for arrangements or transactions between arrangement participants determined to be within the scope of the contracts with customers guidance, the Company performs the following steps to determine the appropriate amount of revenue to be recognized as we fulfill our obligations: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

We evaluate the performance obligations promised in the contract that are based on goods and services that will be transferred to the customer and determine whether those obligations are both (i) capable of being distinct and (ii) distinct in the context of the contract. Goods or services that meet these criteria are considered distinct performance obligations. The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration or variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of potential transaction price and the likelihood that the transaction price will be received. The Company utilizes either the most likely amount method or expected value method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration that is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. We assess if these options provide a material right to the customer and, if so, these options are considered performance obligations. The Company has not currently identified any such material rights.

Revenue is recognized when, or as, the Company satisfies a performance obligation by transferring a promised good or service to a customer. An asset is transferred when, or as, the customer obtains control of that asset. For performance obligations that are satisfied over time, the Company recognizes revenue using an input or output measure of progress that best depicts the satisfaction of the relevant performance obligation.

After contract inception, the transaction price is reassessed at every period end and updated for changes such as resolution of uncertain events. Any change in the overall transaction price is allocated to the performance obligations on the same methodology as at contract inception.

See note 11, License and Collaboration Agreements, for further discussion related to the Sobi collaboration agreement.

Offering Costs

Offering costs represent underwriting, legal, accounting and other direct costs related to the Company's follow-on offerings and filing of a registration statements on Form S-3 in 2019, and related to the Company's offering of Convertible Notes in 2020 and 2019. Costs were deferred until completion of the follow-on offerings and offering of Convertible Notes, at which time they were reclassified to additional paid-in capital as a reduction of the proceeds.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: development derivative liability, accrued expenses, prepaid expenses, convertible debt and taxes.

Fair Value of Financial Instruments

The Company is required to disclose information on the fair value of financial instruments and inputs that enable an assessment of the fair value. The three levels of the fair value hierarchy prioritize valuation inputs based upon the observable nature of those inputs as follows:

Level 1 – Quoted prices 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 or indirectly;

Level 3 – Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability.

The Company's financial instruments, in addition to those presented in Note 6, Long-term Debt, Note 8, Marketable Securities, and Note 10, Fair Value Measurements, include cash and cash equivalents, the Australian research and development credit, accounts payable and accrued liabilities. Management believes that the carrying amounts of cash and cash equivalents, the Australian research and development credit, accounts payable and accrued expenses approximate the fair value due to the short-term nature of those instruments.

Cash and Cash Equivalents

Cash and cash equivalents are defined as cash in banks and investment instruments having maturities of three months or less from their acquisition date. The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents are valued at cost, which approximates the fair value. See Note 10, Fair Value Measurements, for additional information.

Foreign Currency

The financial position and results of operations of the Company's Australian, Irish and German subsidiaries are measured using the foreign subsidiary's local currency. Revenues and expenses of the subsidiaries have been translated into U.S. dollars at average

exchange rates prevailing during the respective periods. Assets and liabilities have been translated at the rates of exchange on the balance sheet date. The resulting translation gain and loss adjustments are recorded directly as a separate component of stockholders' equity. The financial position and results of operations of the Company's Swiss subsidiary are measured and reported in U.S. dollars and transactions are translated to U.S. dollars at the end of the period.

Research and Development

Costs incurred in connection with research and development activities are expensed as incurred. Research and development expenses include (i) employee-related expenses, including salaries, benefits, travel and share-based compensation expense; (ii) external research and development expenses incurred under arrangements with third parties, such as contract research and contract manufacturing organizations, investigational sites and consultants, including share-based compensation expense for consultants; (iii) the cost of acquiring, developing and manufacturing clinical study materials; and (iv) costs associated with preclinical and clinical activities and regulatory operations.

The Company enters into consulting, research and other agreements with commercial entities, researchers, universities and others for the provision of goods and services. Such arrangements are generally cancellable upon reasonable notice and payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided by the Company's clinical sites and vendors. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on behalf of the Company.

Depending upon the timing of payments to the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses are based on management's estimates of the work performed under service agreements, milestones achieved and experience with similar contracts. The Company monitors each of these factors and adjusts estimates accordingly.

Included in research and development is a refundable Australian research and development credit. The credit is recognized as a reduction of clinical trial costs over the periods necessary to match the benefit of the credit with the costs for which it is intended to compensate.

Patents

Costs incurred in connection with the application for and issuance of patents are expensed as incurred.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. As of December 31, 2020 and 2019, the Company did not have any significant uncertain tax positions.

Concentrations of Credit Risk

Cash and cash equivalents are the only financial instruments that potentially subject the Company to concentrations of credit risk. Cash and cash equivalents are held at financial institutions in the United States, Switzerland, Australia, Ireland and Germany. The Company is exposed to credit risk in the event of default by the financial institution to the extent that cash and cash equivalent balances recorded in the balance sheets are in excess of the amounts that are insured by the Federal Deposit Insurance Corporation. The Company has not experienced any losses on its deposits since inception, and management believes that minimal credit risk exists with respect to these financial institutions.

Net Loss per Share

Basic net loss per common share is calculated by dividing net loss by the weighted-average shares outstanding during the period. For purposes of the diluted net loss per share calculation, convertible notes and common stock options are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented.

Comprehensive Loss

The Company's components of comprehensive loss other than its net loss, are the foreign currency gains/losses recorded from the remeasurement of the long term intra-entity loan transaction to the Company's wholly owned subsidiaries as well as the foreign currency gain/ loss from the translation of the Company's wholly owned subsidiaries into U.S. dollars in 2020 and 2019.

Recent Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20)* to reduce complexity in applying GAAP to certain financial instruments with characteristics of liability and equity. The ASU removes the guidance that requires entities to account for beneficial conversion features and cash conversion features in equity, separately from the host convertible debt or preferred stock. The ASU further revises the guidance to require entities to calculate diluted earnings per share for convertible instruments by using the if-converted method. In addition, entities must presume share settlement for purposes of calculating diluted EPS when an instrument may be settled in cash or shares. The new standard is effective for annual reporting periods beginning after December 15, 2021, for public companies, including interim periods within that reporting period. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company early adopted this statement effective January 1, 2021. The impact of the adoption of the statement is to increase debt and decrease equity by the amount of the equity component of convertible notes recognized in equity. Additionally, interest expense is expected to decrease by the non-cash portion of the discount amortization. Weighted average basic earnings per share amounts are not expected to be materially affected.

3. Common Stock

The Company has reserved the following shares of common stock for future issuance (in thousands):

	December 31,		
	2020	2019	2018
Shares reserved under 2010 Equity Incentive Plan	—	—	5,013
Shares reserved under 2017 Equity Incentive Plan	8,613	6,319	4,033
Shares reserved under 2017 Employee Stock Purchase Plan	913	972	972
Common stock warrants	—	—	14
Total	9,526	7,291	10,032

4. Development Derivative Liability

On February 28, 2019, the Company entered into the SFJ agreement under which SFJ agreed to provide funding to the Company to support the development of pegcetacoplan for the treatment of patients with PNH. Pursuant to the agreement, SFJ paid the Company $60.0 million following the signing of the agreement, and agreed to pay the Company up to an additional $60.0 million in the aggregate in three equal installments upon the achievement of specified development milestones with respect to the Company's Phase 3 program for pegcetacoplan in PNH and subject to the Company having cash resources at the time sufficient to fund at least 10 months of the Company's operations.

On June 7, 2019, the Company and SFJ amended the development funding agreement. Under the SFJ amendment, SFJ agreed to make an additional $20.0 million funding payment to the Company to support the development of pegcetacoplan for the treatment of patients with PNH.

In the years ended December 31, 2020 and 2019, the Company received $20.0 million and $120.0 million, respectively, from SFJ, as the Company met milestones as identified in the SFJ Agreement.

Under the SFJ agreement following regulatory approval by the FDA or EMA for the use of pegcetacoplan as a treatment for PNH the Company will be obligated to pay SFJ an initial payment of up to $5.0 million (or a total of $10.0 million if regulatory approval is granted by the FDA and the EMA) and then up to an additional $226.0 million in the aggregate (or up to $452.0 million if regulatory approval is granted by the FDA and the EMA) in six additional annual payments with the majority of the payments being made from the third anniversary to the sixth anniversary of regulatory approval.

The SFJ agreement is presented as a derivative liability on the consolidated balance sheet and is considered a level three derivative and, as such is remeasured each quarter. The liability was initially recorded at the value of the $60.0 million aggregate cash received pursuant to the contractual terms. During the years ended December 31, 2020 and 2019, the Company received an additional $20.0 million and $60.0 million respectively under the SFJ agreement as the Company met additional milestones in the agreement. The derivative liability was remeasured quarterly at fair value, with the total change in fair value of $103.0 million and $14.8 million recorded for the years ended December 31, 2020 and 2019, respectively in loss from remeasurement of development derivative liability on the consolidated income statement. The remeasurement of the development derivative liability resulted in a remeasured fair value of $257.9 million and $134.8 million as of December 31, 2020 and 2019, respectively on the consolidated balance sheet. At December 31, 2020, $4.2 million of the $257.9 million of the development derivative liability fair market value is included in current liabilities.

The following table presents a rollforward of the liability (in thousands):

	For the Year Ended December 31,	
	2020	2019
Balance at fair market value, January 1,	$ 134,839	$ —
Amounts received under the SFJ agreement and SFJ amendment	20,000	120,000
Loss recorded in loss from remeasurement of development derivative liability	103,029	14,839
Balance at fair market value, December 31,	$ 257,868	$ 134,839

The derivative is valued using a scenario-based discounted cash flow method, whereby each scenario makes assumptions about the probability and timing of cash flows, and such cash flows are present valued using a risk-adjusted discount rate. The analysis is calibrated such that the value of the derivative as of the date of the SFJ agreement was consistent with an arm's-length transaction. Key inputs to the level 3 fair value model include (i) the probability and timing of achieving stated development milestones to receive the next tranches of funding, (ii) the probability and timing of achieving FDA and EMA approval, (iii) SFJ's cost of borrowing (8.0%), and (iv) the Company's cost of borrowing (12.65%).

SFJ's implied cost of borrowing was 8.0% and the Company's implied cost of borrowing was 12.65% as of the reporting date. These implied costs of borrowing were determined assuming the SFJ agreement was initially executed with arm's-length terms. If the SFJ agreement was instead not determined to be an arm's-length transaction, then implied discount rates could differ.

5. Accrued Expenses and Prepaid Assets

Accrued expenses are as follow (in thousands):

	December 31,	
	2020	2019
Accrued research and development	$ 47,879	$ 36,449
Accrued license fee	25,050	—
Accrued payroll liabilities	22,896	11,443
Other	16,110	6,891
Total	$ 111,935	$ 54,783

Prepaid assets include $8.0 million and $18.1 million of prepaid research and development costs as of December 31, 2020 and 2019, respectively.

6. Long-term Debt

Convertible Senior Notes

On September 16, 2019, the Company completed a private offering of the 2019 Convertible Notes with an aggregate principal amount of $220.0 million issued pursuant to an indenture (the "Indenture") with U.S. Bank National Association, as trustee (the "Trustee").

The net proceeds from the sale of the 2019 Convertible Notes were approximately $212.9 million after deducting the initial purchasers' discounts and commissions of $6.6 million and offering expenses of $0.5 million paid by the Company. The Company used $28.4 million of the net proceeds from the sale of the Convertible Notes to pay the cost of the capped call transactions described below.

On May 12, 2020, the Company issued the 2020 Convertible Notes with an aggregate principal amount of $300.0 million. The net proceeds from the sale of the 2020 Convertible Notes were approximately $322.9 million after deducting the purchasers' discounts and commission of $5.7 million and offering expenses of $0.3 million. The Company used $43.1 million of the net proceeds from the sale to pay the cost of the additional capped call transactions in May 2020 described below.

The Convertible Notes are senior unsecured obligations of the Company and bear interest at a rate of 3.5% per year payable semiannually in arrears on March 15 and September 15 of each year, beginning on March 15, 2020. The Convertible Notes will mature on September 15, 2026, unless converted earlier, redeemed or repurchased in accordance with the terms of the Convertible Notes.

The Convertible Notes are convertible into shares of the Company's common stock at an initial conversion rate of 25.3405 shares per $1,000 principal amount of Convertible Notes (equivalent to an initial conversion price of approximately $39.4625 per share of common stock). The conversion rate is subject to customary anti-dilution adjustments. In addition, following certain events that occur prior to the maturity date or if the Company deliver a notice of redemption, the Company will increase the conversion rate for a holder who elects to convert its Convertible Notes in connection with such corporate event or a notice of redemption, as the case may be, in certain circumstances as provided in the indenture.

Prior to March 15, 2026, the Convertible Notes are convertible only upon the occurrence of certain events. On or after March 15, 2026 until the close of business on the second scheduled trading day immediately preceding the maturity date of the Convertible Notes, holders may convert the Convertible Notes at any time. Upon conversion of the Convertible Notes, the Company will pay or deliver, as the case may be, cash, shares of the Company's common stock or a combination of cash and shares of common stock, at the Company's election.

Prior to September 20, 2023, the Company may not redeem the Convertible Notes. The Company may redeem for cash all or a portion of the Convertible Notes, at its option, on or after September 20, 2023 if the last reported sale price of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive), including the trading day immediately preceding the date on which the Company provides a notice of redemption, during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption. The redemption price will be equal to 100% of the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

If the Company undergoes a "fundamental change," as defined in the Indenture, prior to maturity, subject to certain conditions, holders may require the Company to repurchase for cash all or any portion of their Convertible Notes at a fundamental change repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus any accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The Company used an effective interest rate of 10.5% to determine the liability component of the 2019 and 2020 Convertible Notes. This resulted in the recognition of $145.1 million and $204.5 million as the liability component of the 2019 and 2020 Convertible Notes, respectively, and the recognition of the residual amount of $74.9 million and $95.5 million as the debt discount with a corresponding increase to additional paid in capital for the equity component of the 2019 and 2020 Convertible Notes, respectively. The 2020 aggregate debt issuance costs of $6.0 million were allocated to the liability and equity components in the amounts of $3.7 million and $2.3 million, respectively. The 2019 Convertible Notes aggregate debt issuance costs of $7.1 million were allocated to the liability and equity components in the amounts of $4.7 million and $2.4 million, respectively.

Interest expense for the Convertible Notes was $29.9 million for the year ended December 31, 2020 and $4.4 million from inception through December 31, 2019. For the year ended December 31, 2020, interest expense included the amortization of the discount on the Convertible Notes of $15.0 million, accrued semi-annual coupon payable of $14.4 million and amortization of debt issuance costs of $0.5 million. From inception through December 31, 2019, interest expense included amortization of the discount on

the Convertible Notes of $2.1 million, accrued semi-annual coupon payable of $2.2 million and amortization of debt issuance costs of $0.1 million. As of December 31, 2020 and 2019, $7.8 million and $4.6 million, respectively of debt issuance costs was recorded on the consolidated balance sheet as a reduction to the carrying amount of the Convertible Notes.

The aggregate balance of the Convertible Notes, net of unamortized debt issuance costs, as of December 31, 2020 and 2019 was $358.8 million and $142.6 million, respectively. See note 20 "Subsequent events" for discussion on the exchange of $126.1 million of 2019 Convertible Notes to shares of common stock.

Capped Call Transactions

On September 11, 2019, and May 6, 2020 concurrently with the pricing of the 2019 Convertible Notes and the 2020 Convertible Notes, the Company entered into capped call transactions with two counterparties. The capped call transactions are expected generally to reduce the potential dilution to the Company's common stock upon any conversion of Convertible Notes and/or offset any cash payments the Company is required to make in excess of the principal amount of converted Convertible Notes, as the case may be, in the event that the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which is initially $39.4625 (the conversion price of the Convertible Notes) and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of such Convertible Notes. If, however, the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, exceeds the cap price of the capped call transactions, which is initially $63.14 per share, representing a premium of 100% above the last reported sale price of $31.57 per share of its common stock on The Nasdaq Global Select Market on September 11, 2019, there would nevertheless be dilution and/or there would not be an offset of such potential cash payments, in each case, to the extent that such market price exceeds the cap price of the capped call transactions.

Pursuant to ASC 815-40 *Derivatives and Hedging*, the Company determined that the capped call transactions should be classified as equity instruments and the capped call premium paid in the amount of $28.4 million and $43.1 million were recorded as reductions to additional paid-in capital upon the issuance of the Convertible Notes.

Term Loan Facility

On October 20, 2017, the Company entered into a loan and security agreement with Silicon Valley Bank ("SVB") to provide for a $20.0 million term loan facility (the "term loan facility"). Borrowings under the term loan facility accrued interest at a floating rate per annum equal to the WSJ prime rate plus 1.50%. Under the agreement, the Company was required to make monthly interest-only payments through November 1, 2019 and to make 24 equal monthly payments of principal, plus accrued interest, thereafter from November 1, 2019 through October 1, 2021, when all unpaid principal and interest would become due and payable.

On March 26, 2019, the Company voluntarily repaid all outstanding amounts due and owed, including applicable termination fees, under the term loan facility. The final payment of $21.8 million totaled per diem interest of $0.1 million and $21.7 million for the outstanding balance of the term loan facility which included (i) a final payment equal to 8% of the original principal amount of the term loan facility of $1.6 million, and (ii) a prepayment fee contractually owed of $0.1 million plus other fees which resulted in a total loss on extinguishment of debt of $1.2 million.

In connection with the Company's entry into the term loan facility, the Company issued to SVB a warrant to purchase 14,064 shares of the Company's common stock with an exercise price per share of $5.484. The warrant had a ten-year term and included a put option pursuant to which, in the event of an acquisition, change in control or dissolution or winding up of the Company or the expiration of the warrant, SVB could require the Company to repurchase the warrant for a total aggregate purchase price of $250 thousand. The warrants were exercised in November 2019.

Promissory Note

On October 19, 2017, the Company issued and sold an unsecured promissory note in the principal amount of $7.0 million to Golda Darty Partners S.A. ("GDP"). The promissory note accrued interest at a rate per annum of 8.0%, and was due and payable quarterly in arrears on the 19th day of each April, July, October and January. The promissory note had a maturity date of October 19, 2022 when the $7.0 million would be due and payable in its entirety. The promissory note was contractually subordinated to the Company's obligations to SFJ under the SFJ agreement.

On September 16, 2019, the Company voluntarily repaid all outstanding amounts due and owed under the promissory note, except for a small amount of interest subsequently repaid. The payment of $7.1 million reflected per diem interest of $0.1 million and $7.0 million for the outstanding principal balance of the promissory note.

In connection with the issuance and sale of the above promissory note, the Company issued to GDP a warrant to purchase 93,764 shares of the Company's common stock at a price per share of $5.484, which was exercised in whole in October 2017. The

Company recorded the fair value of the warrant in the aggregate amount of $0.4 million as a discount to the promissory note. This amount was being accreted as additional interest expense over the term of the promissory note. Upon the repayment of the promissory note, the Company recorded a loss on extinguishment of debt of $0.3 million due to the remaining discount.

The contractual maturities of the Company's long-term debt obligations due subsequent to December 31, 2020 consist of the $520.0 Convertible Senior Notes which mature in September 2026.

7. Leases

On January 1, 2019, the Company adopted ASU 2016-02 *Leases (Topic 842)* using a modified retrospective method. The Company recognized $5.5 million of lease assets and liabilities. There was no impact to retained earnings upon adoption of Topic 842. The underlying assets of the Company's leases primarily relate to office space leases, but also include some equipment leases. The Company determines if an arrangement qualifies as a lease at its inception. During 2019, the Company leased additional office space resulting in an initial recognition value of $9.8 million of lease assets and liabilities.

As a practical expedient permitted under Topic 842, the Company has elected to account for the lease and non-lease components as a single lease component for all leases of which it is the lessee. Lease payments, which may include lease and non-lease components, are included in the measurement of the Company's lease liabilities to the extent that such payments are either fixed amounts or variable amounts that depend on a rate or index as stipulated in the lease contract. When the Company cannot readily determine the rate implicit in the lease, the Company determines its incremental borrowing rate by using the rate of interest that it would have to pay to borrow on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment.

The Company enters into lease agreements with terms generally ranging from 2-7 years. Some of the Company's lease agreements include Company options to extend the lease on a month-to-month basis or for set periods for up to five years. Many leases also include options to terminate the leases within one year or per other contractual terms. Renewal and termination options were generally not included in the lease term for the Company's existing operating leases.

As of December 31, 2020 and 2019, all leases were classified as operating lease assets and liabilities. Additional information related to the operating lease assets and liabilities is as follows (in thousands):

	2020	2019
Operating lease assets	$ 17,719	$ 14,110
Operating lease liabilities	$ 18,902	$ 14,466
Weighted average remaining term in years	4.66	5.01
Weighted average discount rate used to measure outstanding lease liabilities	7.74%	8.19%

For the years ended December 31, 2020 and 2019, the total lease cost for operating lease expense was approximately $4.4 million and $2.4 million, respectively.

Supplemental cash flow information related to operating leases for the years ended December 31, 2020 and 2019 is as follows (in thousands):

	2020	2019
Operating cash flows from operating leases	$ 4,732	$ 2,013
Operating lease assets obtained in exchange for lease obligations	$ 7,237	$ 10,201

The maturity of the Company's operating lease liabilities as of December 31, 2020 are as follows (in thousands):

2021	$ 4,962
2022	4,842
2023	4,826
2024	4,114
2025 and thereafter	3,745
Total future minimum lease payments	22,489
Less imputed interest	(3,587)
Total operating lease liabilities	$ 18,902

8. Marketable Securities

The amortized cost, gross unrealized holding losses and fair value of available-for-sale debt securities by type of security as of December 31, 2020 were as follows (in thousands):

	As of December 31, 2020			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
U.S. Government-related obligations	$ 311,877	$ 11	$ (19)	$ 311,869

All available-for-sale securities mature in one year or less. The Company did not hold available-for-sale securities as of December 31, 2019.

9. Other Comprehensive Income and Accumulated Other Comprehensive Income

The following tables summarize the changes in accumulated other comprehensive income/(loss), by component for the years ended December 31, 2020 and 2019 (in thousands):

	Unrealized Gains (Losses) from Marketable Securities	Foreign Currency Translation Adjustment	Total Accumulated Other Comprehensive Income (Loss)
Balances, December 31, 2019	$ —	$ (154)	$ (154)
Net other comprehensive income (loss)	(8)	45	37
Balances, December 31, 2020	$ (8)	$ (109)	$ (117)

	Unrealized Gains (Losses) from Marketable Securities	Foreign Currency Translation Adjustment	Total Accumulated Other Comprehensive Income (Loss)
Balances, December 31, 2018	$ —	$ (123)	$ (123)
Net other comprehensive income (loss)	—	(31)	(31)
Balances, December 31, 2019	$ —	$ (154)	$ (154)

10. Fair Value Measurements

The Company is required to disclose information on the fair value of financial instruments and inputs that enable an assessment of the fair value. The three levels of the fair value hierarchy prioritize valuation inputs based upon the observable nature of those inputs as follows:

Level 1 – Quoted prices 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 or indirectly;

Level 3 – Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability.

The following table presents the fair value of financial instruments recorded originally at amortized cost or fair value and not re-measured on a recurring basis (in thousands):

		December 31, 2020			
Balance Sheet Classification:	Type of Instrument	Level 1	Level 2	Level 3	Total
Financial Assets:					
Cash and cash equivalents:	Money market funds	$ 427,515	$ —	$ —	$ 427,515
	Bank certificates of deposit	43,577	—	—	43,577
Total Financial Assets		$ 471,092	$ —	$ —	$ 471,092

		December 31, 2019			
Balance Sheet Classification:	Type of Instrument	Level 1	Level 2	Level 3	Total
Financial Assets:					
Cash and cash equivalents:	Money market funds	$ 281,314	$ —	$ —	$ 281,314
Total Financial Assets		$ 281,314	$ —	$ —	$ 281,314

The Company's Convertible Notes fall into the Level 2 category within the fair value level hierarchy. The fair value was determined using broker quotes in a non-active market for valuation. As of December 31, 2020 and 2019, the debt component of the Company's Convertible Notes had a fair value of approximately $676.2 million and $149.5 million, respectively. The Convertible Notes accrue a semi-annual coupon at an annual rate of 3.5%, which was included in accrued expenses in the consolidated balance sheet at December 31, 2020 and 2019.

The following table presents the fair value of financial instruments recorded at fair value at inception and remeasured on a recurring basis (in thousands):

		December 31, 2020			
Balance Sheet Classification:	Type of Instrument	Level 1	Level 2	Level 3	Total
Financial Assets:					
Cash and cash equivalents:	US government obligations	$ 89,990	$ —	$ —	$ 89,990
Marketable securities:	US government obligations	311,869	—	—	311,869
Total Financial Assets		$ 401,859	$ —	$ —	$ 401,859
Financial Liabilities:					
Development derivative liability	Development derivative liability	$ —	$ —	$ 257,868	$ 257,868
Total Financial Liabilities		$ —	$ —	$ 257,868	$ 257,868

		December 31, 2019			
Balance Sheet Classification:	Type of Instrument	Level 1	Level 2	Level 3	Total
Financial Liabilities:					
Development derivative liability	Development derivative liability	$ —	$ —	$ 134,839	$ 134,839
Total Financial Liabilities		$ —	$ —	$ 134,839	$ 134,839

The fair value of the SFJ agreement is presented as a development derivative liability based on level 3 inputs. The derivative is valued using a scenario-based discounted cash flow method, whereby each scenario makes assumptions about the probability and timing of cash flows, and such cash flows are present valued using a risk-adjusted discount rate. The analysis is calibrated such that the value of the derivative as of the date of the SFJ agreement was consistent with an arm's-length transaction. Key inputs to the level 3 fair value model include (i) the probability and timing of achieving stated development milestones to receive the next tranches of

funding, (ii) the probability and timing of achieving FDA and EMA approval, (iii) SFJ's cost of borrowing (8.0%), and (iv) the Company's cost of borrowing (12.65%). A 10% change in the key inputs of i) the probability and timing of payment and ii) the discount rate utilized would result in a change in fair value of the development derivative liability of approximately 5.0% or $12.9 million.

SFJ's implied cost of borrowing was 8.0% and the Company's implied cost of borrowing was 12.65% as of the reporting date. These implied costs of borrowing were determined assuming the SFJ agreement was initially executed with arm's-length terms.

11. License and Collaboration Agreements

Sobi Transaction

On October 27, 2020, the Company and its subsidiaries Apellis Switzerland GmbH and APL DEL Holdings, LLC entered into a Collaboration and License Agreement with Sobi, concerning the development and commercialization of pegcetacoplan and specified other structurally and functionally similar compstatin analogues or derivatives for use systemically or for local non-ophthalmological administration (collectively referred to as the "Licensed Products").

Under the collaboration agreement, the Company granted Sobi an exclusive (subject to certain retained rights of the Company), sublicensable license of certain patent rights and know-how to develop and commercialize Licensed Products in all countries outside of the United States. The Company retains the right to commercialize Licensed Products in the United States, and, subject to specified limitations, to develop Licensed Products worldwide for commercialization in the United States.

Under the collaboration agreement, the Company and Sobi have agreed to collaborate to develop Licensed Products for the treatment of paroxysmal nocturnal hemoglobinuria, cold agglutinin disease, hematopoietic stem cell transplantation-associated thrombotic microangiopathy, C3 glomerulopathy and immune complex membranoproliferative glomerulonephritis, and amyotrophic lateral sclerosis, and any other indications subsequently agreed upon by the parties, for commercialization by or on behalf of the Company in the United States and by or on behalf of Sobi outside of the United States. If the parties do not agree to jointly pursue any development activities for the Licensed Products (whether for an Initial Indication or otherwise), the party proposing to pursue such activities may conduct such activities at its sole expense (with the non-proposing party having the right to obtain rights to the data generated by such development activities by paying a specified percentage of that expense), subject to agreed-upon exceptions that limit each party's unilateral development rights.

The initial development plan sets forth the initial development activities to be conducted by each of the Company and Sobi, with the Company bearing all costs incurred in conducting the activities set forth in such initial development plan, as well as certain specified additional costs that are not included in the initial development plan that may be incurred by the parties in developing Licensed Products for paroxysmal nocturnal hemoglobinuria in the European Union and the United Kingdom. The Company and Sobi will form several governance committees to oversee the development and manufacture, and to review and discuss the commercialization, of Licensed Products.

The Company shall supply Licensed Products to Sobi for development and for commercialization outside of the United States in accordance with a supply agreement to be negotiated by the parties. The collaboration agreement grants Sobi the right to perform or have performed drug product manufacturing of Licensed Products for development and for commercialization outside the United States and to manufacture or have manufactured drug substance under certain circumstances.

Sobi paid the Company an upfront payment of $250.0 million in November 2020 and has agreed to pay up to an aggregate of $915.0 million upon the achievement of specified one-time regulatory and commercial milestone events, and to reimburse the Company for up to $80.0 million in development costs. The Company will also be entitled to receive tiered, double-digit royalties (ranging from high teens to high twenties) on sales of Licensed Products outside of the United States, subject to customary deductions and third-party payment obligations, until the latest to occur of: (i) expiration of the last-to-expire of specified licensed patent rights; (ii) expiration of regulatory exclusivity; and (iii) ten (10) years after the first commercial sale of the applicable Licensed Product, in each case on a Licensed Product-by-Licensed Product and country-by-country basis. Under the collaboration agreement, the Company remains responsible for its license fee obligations (including royalty obligations) to the University of Pennsylvania as a licensor of the Company and for its payment obligations to SFJ Pharmaceuticals.

Accounting Analysis

The Company has determined that the agreement is within the scope of ASC 808 as a contractual arrangement that involves a joint operating activity whereby both parties are (i) active participants in the activity and (ii) exposed to certain significant risks and rewards dependent on the commercial success of the activity. ASC Topic 808 does not address measurement or recognition matters

but allows for analogizing to ASC 606. Pursuant to ASC 606, the Company performed the following five steps: (i) identified the contract(s) with a customer; (ii) identified the performance obligations in the contract; (iii) determined the transaction price; (iv) allocated the transaction price to the performance obligations in the contract; and (v) recognized revenue when (or as) the entity satisfies a performance obligation.

The Company identified the following material distinct promises under the Sobi Agreement: (1) licenses to develop and commercialize pegcetacoplan or, Licenses to IP, and (2) performance of research and development services. The Company determined the promises to be distinct because Sobi can benefit from each of the license and the development services on their own or with readily available services. The Company could have provided the license without any development services and Sobi would have been able to benefit from it by obtaining development services from another provider as the Licensed Products are at a more mature stage in their life cycle.

Under the agreement, Sobi agreed to pay the Company

i) a fixed amount of $250.0 million in an upfront payment in November 2020;
ii) a fixed amount of an additional $80.0 million in development reimbursements, payable yearly in four tranches in amounts determined based upon actual expenses incurred by the Company;
iii) up to an aggregate of $915.0 million upon the achievement of specified one-time regulatory and commercial milestone events; and
iv) tiered, double-digit royalties, ranging from high teens to high twenties, on sales of Licensed Products outside of the United States, subject to customary deductions and third-party payment obligations.

At contract inception, the $250.0 million non-refundable payment and the $80.0 million reimbursements were fixed proceeds. The Company evaluated whether Sobi is a customer for either of the distinct promises in the agreement. Under the Licenses to IP, the Company determined that Sobi is a customer as the know-how provided and the right granted by the Company to Sobi are outputs of the Company's business activities for which the Company will receive consideration. With respect to research and development activity, management determined that there is no vendor relationship as performing research and development activities for others is not a part of the Company's ongoing central operations. Based upon the evaluation of the relative fair values, the Company allocated the purchase price of $250.0 million and the related milestones and royalties to the license of IP and $80.0 million to performance of research and development activities.

The milestone and royalty payments are subject to activities outside the control of the Company. Per ASC 606, the Company considers this to be a customer/ vendor relationship, therefore, the Company will include the regulatory milestone payments in the total transaction price when it is probable that a significant reversal of revenue would not occur in a future period. The Company will recognize commercial milestone and royalty revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which the commercial milestone or royalty has been allocated has been satisfied. In case of commercial milestone or royalty payments, the Company will recognize revenue in the same period that the sales are completed for which the Company is contractually entitled to the milestone or percentage-based royalty payment. To date, the Company has not recognized any commercial milestone or royalty revenue resulting from any of our licensing arrangements. Management will periodically assess the elements of the contract and re-evaluate revenue recognition as necessary.

Pursuant to ASC 606, the Company has recognized the $250.0 million in revenue as this is the amount allocated to the license. The $80.0 million reimbursement for research and development activities does not constitute a customer/vendor relationship and thus is not in the scope of ASC 606. As ASC 808 does not include recognition guidance, the Company has established an accounting policy to recognize the payments under the reimbursement as a receivable on the balance sheet in an amount that is to be reimbursed based upon expense incurred by the Company, with a contra- research and development expense recognized in the statement of operations, over time as the expenses are incurred.

Under the Sobi collaboration agreement, for the year ended December 31, 2020, the Company recognized $250.0 million of licensing revenue in the consolidated statement of operations. For the year ended December 31, 2020, the Company also recognized in the consolidated statement of operations $43.0 million of contra research and development expense relative to the probable amount to be reimbursed under the $80.0 million for research and development. The Company recorded a corresponding receivable of $43.0 million on the consolidated balance sheet, with $25.0 million and $18.0 million in current and long-term assets, respectively, as of December 31, 2020.

Other agreements

In addition, to the Sobi collaboration agreement, during the year ended December 31, 2020, we entered into two different agreements with third parties to provide APL-9 for use in certain research projects for which $0.6 million was recognized in revenue in the consolidated statement of operations as of December 31, 2020.

12. License Agreements

In connection with its purchase of assets from Potentia in September 2014, the Company became party to a license agreement with the Trustees of the University of Pennsylvania ("Penn") as a result of an agreement to purchase substantially all the assets of Potentia Pharmaceuticals, Inc, for an exclusive, worldwide license to specified patent rights. The Company is required to pay annual maintenance fees of $0.1 million until the first sale of a licensed product. The Company is also required to make milestone payments aggregating up to $3.2 million based upon the achievement of specified development and regulatory milestones and up to $5.0 million based upon the achievement of specified annual sales milestones with respect to each licensed product, and to pay low single-digit royalties based on net sales of each licensed product and with minimum quarterly royalty thresholds. In addition, the Company is obligated to pay a specified portion of income it receives from sublicensees.

In addition, the Company is also party to a license agreement with Penn for an exclusive, worldwide license to specified patent rights for the development and commercialization of products in fields of use, as defined therein. The Company is required to pay annual maintenance fees of $0.1 million until the first sale of a licensed product. The Company is required to make milestone payments aggregating up to $1.7 million, based upon the achievement of development and regulatory approval milestones, and up to $2.5 million, based upon the achievement of annual sales milestones with respect to each of the first two licensed products. The license agreement also requires the Company to pay low single digit royalties based on net sales of each licensed product, subject to minimum quarterly royalty thresholds. In addition, the Company is obligated to pay a specified portion of income it receives from sublicensees.

In 2018, the Company made payments to Penn of $1.0 million net of a credit for the annual license maintenance payment, for the achievement of milestones under these agreements. In 2020, the Company owed payments to of $25.0 million for royalty expense related to the Sobi Agreement and another licensing transaction. This was paid in early January 2021.

In addition to the license agreement with Penn, the Company contracts to conduct research and development activities with third parties. Certain of these contracts commit the Company to pay future milestone payments up to $15.0 million or to pay royalty fees ranging from 3-6% if any of the research results in regulatory approval or commercial revenue for a product.

13. 401(k) Profit Sharing Plan and Trust

In July 2010, the Company adopted an employee profit-sharing plan (the "401(k) Plan"), qualified under Section 401(k) of the Internal Revenue Code (the "IRC"). All of the Company's full-time employees who have attained the age of 21 are eligible to participate in the 401(k) Plan immediately upon employment. Pursuant to the 401(k) Plan, employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit and have the amount of the reduction contributed to the 401(k) Plan. In 2020, 2019 and 2018, the Company recorded $2.1 million, $0.8 million and $0.3 million respectively, for employer contributions made to the 401(k) Plan.

14. Income Taxes

The components of loss from continuing operations before provision for income taxes are as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Domestic	$ (118,839)	$ (297,127)	$ (122,900)
Foreign	(224,190)	(7,580)	(4,602)
Total	$ (343,029)	$ (304,707)	$ (127,502)

The provision for income taxes for the year ended December 31, 2020 is as follows (in thousands):

	Year Ended December 31, 2020
Current income tax expense:	
U.S. Federal	$ —
U.S. State and Local	57
Foreign	1,788
Total current income tax expense	1,845
Deferred income tax expense:	
U.S. Federal	—
U.S. State and Local	—
Foreign	—
Total deferred income tax expense	—
Total tax expense	$ 1,845

For the years ended December 31, 2019 and 2018, the Company did not report any current or deferred income tax expense or benefit.

The Company's effective income tax provision differs from the amount calculated using the statutory U.S. federal income tax rate, principally due to the following (in thousands):

	Year Ended December					
	2020		2019		2018	
	Amount	Percentage of income before income taxes	Amount	Percentage of income before income taxes	Amount	Percentage of income before income taxes
Statutory U.S. federal income tax	$ (72,036)	21.0%	$ (63,988)	21.0%	$ (26,775)	21.0%
Foreign tax rate differential	22,760	(6.6)	—	—	—	—
State income taxes, net of federal benefit	(14,107)	4.1	(16,424)	5.4	(6,398)	5.0
Change in valuation allowances	240,065	(69.9)	90,300	(29.6)	38,157	(29.9)
Intellectual property transfer	(162,000)	47.2	—	—	—	—
Tax credits	(11,696)	3.4	(6,113)	2.0	(6,149)	4.8
Change in state apportionment, Kentucky tax reform and other	93	—	(17)	—	873	(0.7)
Permanent and other including share based payments excess deductions	(1,234)	0.3	(3,758)	1.2	292	(0.2)
Effective income tax provision	$ 1,845	(0.5)	$ —	—%	$ —	—%

The Company's effective rate for the year ended December 31, 2020 compared to the year ended December 31, 2019 increased primarily as a result of subsidiary operations in foreign jurisdictions and state income taxes.

During the year ended December 31, 2020, in connection with a corporate reorganization, the Company transferred intellectual property between tax jurisdictions, resulting in deferred tax benefit on basis difference on our intangible assets. The additional deferred tax asset was offset by valuation allowance, resulting in no net impact on our effective tax rate

The Company accounts for income taxes in accordance with ASC Topic 740. Deferred income tax assets and liabilities are determined based upon temporary differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

The following table presents the principal components of the Company's deferred tax assets and liabilities (in thousands):

	December 31,	
	2020	2019
Deferred tax assets:		
Intangible assets	$ 162,011	$ 16
Share-based compensation	11,827	6,625
Deferred interest expense	—	—
Contribution carryforwards	—	41
Net operating loss carryforwards	122,731	102,623
Research and development credits	24,992	14,476
Orphan drug credits	14,372	9,380
Development derivative liability	68,883	35,875
Accruals	4,520	2,259
Other	207	11
Total deferred tax assets	409,543	171,306
Deferred tax liabilities:		
Fixed assets	(23)	—
Convertible debt	(10,473)	(11,480)
481(a) adjustment	(1,935)	(2,891)
Total deferred tax liabilities	(12,431)	(14,371)
Net deferred tax assets before allowance:	397,112	156,935
Less valuation allowance	(397,112)	(156,935)
Net deferred tax assets	$ —	$ —

ASC Topic 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, the Company has recorded full valuation allowances against its domestic and foreign deferred tax assets at December 31, 2020, because management has determined that is it more likely than not that these assets will not be realized. The valuation allowance increased by $240.2 million from December 31, 2019 to December 31, 2020, primarily due to increases in operating losses, development derivative liability, and the step-up in fair value of intellectual property transfer.

At December 31, 2020, the Company had approximately $358.2 million and $405.0 million of Federal and state net operating loss carryforward, respectively. At December 31, 2019, the Company had approximately $392.9 million and $358.3 million of Federal and state net operating loss carryforwards, respectively. The Company also had federal and state research and development tax credit carryforwards $34.2 million and $6.5 million, respectively of as of December 31, 2020. Federal net operating loss carryforward in the amount of $276.9 million may be carried forward indefinitely. The remaining federal and state net operating loss, research and development tax credit carryforwards begin to expire in 2025. The Company also has foreign net operating loss carryforwards of $240.9 million which will begin to expire in 2026.

Under the provisions of the IRC, the net operating loss ("NOL"), and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the IRC, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed several financings since its inception that it believes may have resulted in a change in control as defined by Sections 382 and 383 of the IRC.

The Company does not have any unrecognized tax benefits during any periods presented and does not expect this to significantly change in the next twelve months. There were no interest and penalties recorded in the statement of operations during any period and no amounts accrued for interest and penalties at December 31, 2020 or 2019.

The Company and its subsidiaries file income tax returns in the United States, as well as various state and foreign jurisdictions. Generally, the tax years 2017 through 2019 remain open and subject to examination by the major taxing jurisdictions to which the

Company is subject. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service, or state or foreign tax authorities, to the extent utilized in a future period.

15. Commitments and Contingencies

The Company has entered into a leasing agreement to amend the current office space leases in Waltham, Massachusetts (the "Amended Waltham office space lease"). The Amended Waltham office space lease adds additional office space in Waltham, Massachusetts with a commencement date of January 1, 2021. The Amended Waltham office space lease amends all prior leasing arrangements for the Waltham office space, has a term of 72 months, and includes leasing an additional 16,401 square feet of office space for a total of 77,818 leased square feet of office space. The Amended Waltham office space lease provides for initial monthly lease payments of $0.3 million per month which is approximately a 20% increase to the existing per month rent payment. The base rent payable over the lease period is $19.4 million.

The Company contracts to conduct research and development activities with third parties. The scope of the services under the research and development contracts can be modified and the contracts cancelled by the Company upon written notice. In some instances, the contracts may be cancelled by the third party upon written notice. If the Company were to cancel these contracts as of December 31, 2019, the Company would be required to pay certain termination costs and other fees of approximately $2.8 million that would be incurred in future periods.

The Company has certain non-cancelable purchase obligations related to the manufacturing of drug substance and drug product, primarily with Bachem Americas, Inc, and Bachem AG, collectively ("Bachem") for the drug substance for the finished dosage form of pegcetacoplan. As of December 31, 2020, the Company has non-cancellable purchase commitments for 2021 with Bachem in the amount of approximately $13.7 million.

Following regulatory approval by the FDA or EMA of pegcetacoplan for the treatment of PNH, the Company has certain payment and other obligations under the SFJ agreement, which are discussed above in Note 5.

Indemnifications—In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend indemnified parties for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has not incurred any cost to defend lawsuits or settle claims related to these indemnification provisions.

Legal—During the normal course of business, the Company may be a party to legal claims that may not be covered by insurance. Management does not believe that any such claims would have a material impact on the Company's consolidated financial statements.

16. Equity Incentive Plans

Share-based Compensation

The Company's Board of Directors adopted, and its stockholders approved, an equity incentive plan in 2010 (as amended, the "2010 Plan"). The Board of Directors and stockholders amended the 2010 Plan in August 2017 to increase the number of shares of common stock reserved for issuance thereunder to 6,188,466. The 2010 Plan allowed for the grant of incentive stock options and non-qualified stock options to purchase common stock for employees, directors and consultants under terms and conditions established by the Board of Directors. Incentive stock options and nonqualified stock options were granted at exercise prices that were no less than 100% of the estimated fair value per share of the common stock on the date of grant. If an individual owns capital stock representing more than 10% of the voting shares, the price of each share was at least 110% of the fair value on the date of grant. The Board of Directors determined the fair value of common stock with the assistance of a third-party specialist. Options expire 10 years from the issuance date. Following the adoption of the 2017 Stock Incentive Plan, the Company no longer grants stock options or other awards under the 2010 Plan.

In October 2017, the Company's Board of Directors adopted, and its stockholders approved, the 2017 Stock Incentive Plan (the "2017 Plan"), which became effective on November 8, 2017. The 2017 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, awards of restricted stock, restricted stock units and other stock-based awards. The number of shares of common stock reserved for issuance under the 2017 plan is the sum of (i) 1,359,587 shares of common stock, plus (ii) an additional number of shares of common stock equal to the sum of (a) the number of shares of common stock reserved for

issuance under the 2010 equity incentive plan that remained available for future issuance immediately prior to the effectiveness of the 2017 Plan, which was 299,568 shares, and (b) the number of shares of common stock subject to outstanding awards under the 2010 equity incentive plan upon effectiveness of the 2017 plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right plus (iii) an annual increase, to be added the first day of each fiscal year, beginning with the fiscal year ending December 31, 2018 and continuing until, and including, the fiscal year ending December 31, 2027, equal to the lowest of 4,219,409 shares of common stock, 4.0% of the number of shares of common stock outstanding on the first day of the fiscal year and an amount determined by the board of directors.

As of December 31, 2020, a total of 8,613,049 shares of common stock were reserved for issuance under the 2017 Plan. In January 2021, the shares available for future issuance under the 2017 plan were increased by 3,045,189 shares pursuant to the annual increase described above.

Additionally, during 2019 and thereafter, the Company has granted equity awards as equity inducement awards material to entry into employment with the Company to certain newly hired employees outside of the Company's existing plans in accordance with Nasdaq listing rule 5635(c)(4). In February 2020 the Board of Directors adopted the 2020 Inducement Stock Incentive Plan (the "2020 Plan"), which permitted the Company to grant equity awards to newly hired employees in accordance with Nasdaq listing rule 5635(c)(4). The aggregate number of shares reserved for issuance under the 2020 Plan was initially 750,000 shares but was increased to 1,050,000 shares in January 2021.

In October 2017, the Company's board of directors adopted and the Company's stockholders approved the 2017 Employee Stock Purchase Plan ("ESPP"), which became effective upon the IPO and provides participating employees with the opportunity to purchase up to an aggregate of 468,823 shares of common stock. The number of shares of common stock reserved for issuance under the 2017 ESPP will automatically increase on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2018 and continuing until, and including, the fiscal year ending December 31, 2027, equal to the lowest of (i) 937,646 shares of common stock, (ii) 1.0% of the number of shares of common stock outstanding on the first day of the fiscal year and (iii) an amount determined by the board of directors. The board of directors initiated the first offering under ESPP in October 2019.

Total share-based compensation expense related to the various plans during the years ended was as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Research and development	$ 21,381	$ 10,683	$ 3,559
General and administrative	23,995	10,461	4,174
Total share-based compensation expense	$ 45,376	$ 21,144	$ 7,733

Stock Options—Options granted generally vest over 48 months. Options granted to employees on or after December 5, 2013 generally vest in installments of (i) 25% at the one-year anniversary and (ii) in either 36 equal monthly or 12 equal quarterly installments beginning in the thirteenth month after the initial vesting commencement date (as defined) subject to the employee's continuous service with the Company. Options granted before December 5, 2013 vest over four years in equal annual installments of 25% at each anniversary of the grant date.

Under the Executive Separation Benefits and Retention Plan and by resolutions adopted by the Compensation Committee in October 2019, the stock options granted to the Company's executives and employees will become fully vested upon the occurrence of a change in control, as defined in the Executive Separation Benefits and Retention Plan, if such executive or employee is terminated without cause or resigns for good reason within 12 months after such change in control.

The following table summarizes the Company's stock option activity:

	Shares (in thousands)	Weighted - Average Exercise Price Per Share	Weighted - Average Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2019	10,855	$ 13.52		
Granted	2,884	37.93		
Exercised	(1,208)	7.80		
Forfeited	(795)	28.03		
Outstanding, December 31, 2020	11,736	$ 19.13		
Options exercisable, December 31, 2020	6,062	$ 10.96	6.22	$ 280,290
Expected to vest, December 31, 2020	5,674	$ 27.85	8.62	$ 166,527

The aggregate intrinsic values of options outstanding, exercisable, vested and expected to vest were calculated as the difference between the exercise price of the options and the fair value of the common stock as of December 31, 2020.

During the years ended December 31, 2020, 2019 and 2018, the Company granted stock options to purchase an aggregate of 2.9 million, 4.4 million and 2.1 million shares of its common stock, respectively with weighted average grant date fair values of $27.52, $17.31 and $13.13, respectively.

The aggregate intrinsic value of options exercised during the years ended December 31, 2020, 2019 and 2018 were $38.0 million, $15.7 million, and $5.0 million respectively calculated as the difference between the exercise price of the underlying options and the estimated fair value of the common stock for the options on the respective date of exercise.

The fair market value of options vested during the years ended December 2020, 2019 and 2018 was $33.6 million, $12.9 million and $5.1 million, respectively.

At December 31, 2020, unrecognized compensation expense related to unvested options, was $100.1 million, which the Company expects to recognize over an estimated weighted-average period of 2.84 years.

The assumptions used in the Black-Scholes model to estimate the grant date fair value are as follows:

	Year Ended December 31,		
	2020	2019	2018
Risk-free interest rate	0.32 - 1.76%	1.42 - 2.56%	2.68 - 2.99%
Dividend yield	0%	0%	0%
Volatility	84.4 - 87.8%	102.6 - 111.2%	87.0 - 110.9%
Expected terms (years)	5.31 - 6.08	5.31 - 6.08	5.94 - 6.25

Restricted Stock Units— The fair value of RSU's is estimated based upon the closing market price of the Company's common stock on the date of grant. RSUs generally vest annually over a four-year period:

	Number of Stock Units (in thousands)	Weighted Average Grant Date Fair Value Per Share
Unvested Balance at December 31, 2019	—	$ —
Granted	546	38.97
Vested	—	—
Forfeited	(44)	40.43
Unvested Balance at December 31, 2020	502	38.84

At December 31, 2020, there was approximately $16.2 million of related unrecognized compensation cost which the Company expects to recognize over a remaining weighted average period of 3.4 years.

Employee Stock Purchase Plan—At December 31, 2020, 913,226 shares of common stock remained available for issuance pursuant to the ESPP. Eligible employees who elect to participate in an offering under the ESPP may have up to 15 percent of their earnings withheld, subject to certain limitations, to purchase shares of common stock pursuant to the ESPP. The price of common stock purchased under the ESPP is equal to 85 percent of the lower of the fair market value of the common stock at the commencement date of each offering period or the relevant purchase date. During the year ended December 31, 2020, a total of 58,938 shares of common stock *were* issued under the ESPP at average per share price of $26.71. During the year ended December 31, 2020, the Company recorded cash received from the issuance of stock to the ESPP of $1.6 million and recorded $0.8 million of stock-based compensation expense related to the ESPP.

17. Net Loss per Common Share

The following table presents the calculation of basic and diluted net loss per common share (amounts in thousands except per share amounts):

	Year Ended December 31,		
	2020	2019	2018
Numerator:			
Net loss	$ (344,874)	$ (304,707)	$ (127,502)
Denominator:			
Weighted-average number of common shares used in net loss per common share -- basic and diluted	75,163	62,229	54,396
Net loss per common share -- basic and diluted	$ (4.59)	$ (4.90)	$ (2.34)

Shares outstanding presented below were excluded from the calculation of diluted net loss per share, prior to the use of the treasury stock method, as their effect is anti-dilutive (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Convertible notes	13,177	—	—
Common stock under option	11,736	10,854	7,498
Restricted stock units	502	—	—
Common stock warrants	—	—	14
Total	25,415	10,854	7,512

18. Related Party Transaction

Effective as of May 1, 2018, the Company entered into a subscription license agreement and a services agreement with Revon Systems, Inc. (“Revon”). Under the subscription license agreement, Revon granted the Company an exclusive license to use the Revon software platform and applications for any purpose with respect to the Company's programs in age-related macular degeneration, hemolytic diseases and complement-dependent nephropathies for an annual license fee of $0.2 million and an option to obtain a perpetual, exclusive license thereafter for $0.4 million. Under the services agreement, Revon provided development services with respect to the Revon software to the Company for $0.3 million during the first year. Prior to the acquisition of Revon by an unrelated third party in July 2019, the Company paid the remainder of the annual license fee due for the second year, exercised the option for the perpetual license and discontinued the services agreement. For the year ended December 31, 2019, the Company paid Revon a total of $0.7 million. There were no payments under the agreement during the year ended December 31, 2020.

Each of Cedric Francois, the Company’s chief executive officer, Pascal Deschatelets, the Company’s chief operating officer, and Alec Machiels, a member of the board of directors, was an affiliate of Revon. The Board approved the Revon agreements after review by a subcommittee of the disinterested members of the Board and determination by the full Board that the terms of the Revon agreements were fair, reasonable and in the best interests of the Company. The exercise of the option for the perpetual license was approved in accordance with the Company’s related party transaction policy.

19. Selected Quarterly Financial Data (Unaudited)

The following interim financial information presents the Company's 2020 and 2019 results of operations on a quarterly basis (amounts in thousands except per share amounts):

	Quarter Ended			
	March 31, 2020	June 30, 2020	September 30, 2020	December 31, 2020
Operating income/ (loss)	$ (98,786)	$ (115,508)	$ (129,552)	$ 130,120
Net income/(loss)	(168,822)	(118,617)	(135,700)	78,265
Net income/(loss) per common share, basic (1)	(2.29)	(1.57)	(1.79)	1.03
Net income/(loss) per common share, diluted (1)	(2.29)	(1.57)	(1.79)	0.93

	Quarter Ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Operating Loss	$ (48,651)	$ (63,476)	$ (69,948)	$ (105,940)
Net Loss	(50,574)	(71,090)	(69,825)	(113,218)
Net Loss per common share, basic and diluted (1)	(0.87)	(1.12)	(1.10)	(1.77)

(1) The sum of the four quarters of earnings per share for 2020 and 2019 may not add to the full year earnings per share amount due to rounding and/or the use of quarter-to-date weighted average shares to calculate the earnings per share amount in each respective quarter. For the quarter ended December 31, 2020, diluted net income per common share was calculated using the if-converted method, which adjusts both the numerator by removing the interest expense associated with the Convertible Notes and the denominator by increasing the share count.

20. Subsequent Events

On January 6, 2021, the Company entered into separate, privately negotiated exchange agreements with certain holders of its 2019 Convertible Notes. Under the terms of these exchange agreements, the holders exchanged approximately $126.1 million in aggregate principal amount of 2019 Convertible Notes held by them for an aggregate of 3,906,869 shares of common stock issued by the Company. The exchange transactions closed in January 2021.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of the Company's chief executive officer and chief financial officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of as of December 31, 2020. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, 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 Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC'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 Exchange Act 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. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of the Company's disclosure controls and procedures as of December 31, 2020, the Company's chief executive officer and chief financial officer concluded that, as of such date, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) or 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's 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:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the Company; and
- 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.

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

The company's management assessed the effectiveness of the company's internal control over financial reporting as of December 31, 2020. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013).

Based on our assessment, management concluded that, as of December 31, 2020, the Company's internal control over financial reporting is effective based on those criteria.

Deloitte & Touche LLP, the Company's independent auditors have issued an audit report on our assessment of the company's internal control over financial reporting, which is included below.

Changes in Internal Control over Financial Reporting

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the year ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded no such changes during the year ended December 31, 2020 materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

As a result of the COVID-19 pandemic, beginning in March 2020, certain of our employees began working remotely. We have not identified any material changes in the Company's internal control over financial reporting as a result of these changes to the working environment. We are continually monitoring and assessing the COVID-19 situation to determine any potential impacts on the design and operating effectiveness of our internal controls over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Apellis Pharmaceuticals, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Apellis Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2020, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects,

effective internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.
We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2020, of the Company and our report dated February 25, 2021, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting 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 the assets of the company; (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 receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; 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.
Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.
/s/ Deloitte & Touche LLP
Boston, Massachusetts
February 25, 2021

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission on Schedule 14A in connection with our 2021 Annual Meeting of Stockholders, or the Proxy Statement, which we intend to file not later than 120 days after the end of our fiscal year ended December 31, 2020, under the headings "Information about our Executive Officers," "Election of Directors," "Corporate Governance," and " Delinquent Section 16(a) Reports," and is incorporated in this Annual Report on Form 10-K by reference.

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, which is available on our website at www.apellis.com. The Code of Business Conduct and Ethics is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose the nature of any amendment to our Code of Business Conduct and Ethics or any waiver from our Code of Business Conduct and Ethics granted to any officer or director on our website or in a current report on Form 8-K.

Item 11. Executive Compensation.

The information required by this item regarding executive compensation will be set forth in the sections titled "Executive Compensation" and "Director Compensation" in our Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item regarding security ownership of certain beneficial owners and management will be set forth in the sections titled "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in our Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item regarding certain relationships and related transactions and director independence will be set forth in the sections titled "Certain Relationships and Related Party Transactions," "Election of Directors," and "Corporate Governance," respectively, in our Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item regarding principal accountant fees and services will be set forth in the section titled "Principal Accountant Fees and Services" in our Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed as a part of this Report:

(1) Financial Statements—Included in Item 8 of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

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 the required information is otherwise included in our consolidated financial statements or notes thereto.

(3) Index to Exhibits.

Exhibit Index

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit Number	
2.1*	Asset Purchase Agreement	S-1	333-220941	10/13/2017	2.1	
3.1	Restated Certificate of Incorporation of the Registrant	8-K	001-38276	11/13/2017	3.1	
3.2	Amended and Restated By-Laws of the Registrant	8-K	001-38276	11/13/2017	3.2	
4.1	Specimen Stock Certificate evidencing the shares of common stock	S-1/A	333-220941	10/27/2017	4.1	
4.2	Investors' Rights Agreement dated as of August 7, 2017, among the Registrant and the other parties thereto	S-1	333-220941	10/13/2017	4.2	
4.3	Indenture (including form of Note), dated as of September 16, 2019, by and between Apellis Pharmaceuticals, Inc. and U.S. Bank National Association, as trustee	8-K	001-38276	9/16/2019	4.1	
4.4	Description of Securities Registered Under Section 12 of the Exchange Act					X
10.1+	2010 Equity Incentive Plan, as amended	S-1	333-220941	10/13/2017	10.1	
10.2+	Form of Incentive Stock Option Grant Notice and Agreement under 2010 Equity Incentive Plan	S-1	333-220941	10/13/2017	10.2	
10.3+	Form of Nonstatutory Stock Option Grant Notice and Agreement under 2010 Equity Incentive Plan	S-1	333-220941	10/13/2017	10.3	
10.4+	2017 Stock Incentive Plan	S-1/A	333-220941	10/30/2017	10.4	
10.5+	Form of Incentive Stock Option Agreement under 2017 Stock Incentive Plan	S-1/A	333-220941	10/27/2017	10.5	
10.6+	Form of Nonstatutory Stock Option Agreement under 2017 Stock Incentive Plan	S-1/A	333-220941	10/27/2017	10.6	
10.7+	Form of Director and Officer Indemnification Agreement	S-1/A	333-220941	10/27/2017	10.7	
10.8†	Patent License Agreement, dated as of March 28, 2008, by and between Apellis AG and The Trustees of the University of Pennsylvania, as assigned to the Registrant	S-1/A	333-220941	10/13/2017	10.8	
10.9†	Amended and Restated Patent License Agreement, dated as of March 28, 2008, by and between Potentia Pharmaceuticals, Inc. and The Trustees of the University of Pennsylvania, as amended by the First Amendment to the Amended and Restated Patent License Agreement, dated as of October 14, 2009 and as assigned to the Registrant	S-1/A	333-220941	10/13/2017	10.9	
10.10	Summary of Non-Employee Director Compensation Program	S-1/A	333-220941	10/30/2017	10.11	
10.11	Lease, dated as of April 27, 2017, by and between the Registrant and NWALP PHOP Property Owner, LLC	S-1/A	333-220941	10/13/2017	10.13	
10.12+	2017 Employee Stock Purchase Plan	S-1/A	333-220941	10/30/2017	10.15	
10.13+	Offer Letter, dated as of October 9, 2017, by and between the Registrant and Timothy Sullivan	S-1/A	333-220941	10/20/2017	10.16	
10.14	First Amendment to Lease, dated July 25, 2018, by and between Registrant and NWALP PHOP Property Owner LLC.	10-Q	001-38276	7/31/2018	10.2	
10.15	Second Amendment to Lease, dated June 5, 2019, by and between Registrant and NWALP PHOP Property Owner LLC.	10-Q	001-38276	7/31/2019	10.2	
10.16	Third Amendment to Lease, dated September 25, 2019, by and between Registrant and NWALP PHOP Property Owner LLC.	10-Q	001-38276	11/5/2019	10.1	
10.17	Fourth Amendment to Lease, dated November 13, 2020, by and between Registrant and NWALP PHOP Property Owner LLC.					X

10.18	Equity Distribution Agreement, dated December 28, 2018, by and between the Registrant and Citigroup Capital Markets, Inc.	S-3	333-299091	12/28/2018	1.2	
10.19	Development Funding Agreement, dated as of February 28, 2019, by and between the Registrant and SFJ Pharmaceuticals XI, L.P.	10-Q	001-38276	5/7/2019	10.1	
10.20	Amendment, dated as of June 7, 2019, to the Development Funding Agreement, dated as of February 28, 2019 by and between the Registrant and SFJ Pharmaceuticals XI, L.P.	10-Q	001-38276	7/31/2019	10.1	
10.21	Standard Office Lease, dated as of March 29, 2019, by and between the Registrant and Geary-Market Investment Company, Ltd.	10-Q	001-38276	5/7/2019	10.2	
10.22	Form of Capped Call Transaction Confirmation	8-K	001-38276	5/7/2020	10.1	
10.23+	Amendment No. 1 to 2017 Employee Stock Purchase Plan	10-Q	001-38276	11/2/2020	10.1	
10.24	Form of Exchange Agreement	8-K	001-38276	1/7/2021	10.1	
10.25††	Collaboration and License Agreement, dated October 27, 2020, by and among, the Registrant, Apellis Switzerland GmbH, APL DEL holdings, LLC and Swedish Orphan Biovitrum AB (publ)					X
10.26††	Commercial Supply Agreement, dated December 30, 2020, by and between the Registrant and Bachem Americas, Inc.					X
21.1	Subsidiaries of the Registrant					X
23.1	Consent of Deloitte & Touche, LLP					X
23.2	Consent of Ernst & Young LLP					X
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					
101.SCH	Inline XBRL Taxonomy Extension Schema Document					
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					

* Pursuant to Item 601(b)(2) of Regulation S-K, the Registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the Asset Purchase Agreement to the Securities and Exchange Commission upon request.
† Confidential treatment has been granted as to certain portions, which portions have been omitted and separately filed with the Securities and Exchange Commission.
†† Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.
+ Management contract or compensatory plan or arrangement.

Filed herewith.

Item 16. Form 10-K Summary.

Not applicable

SIGNATURES

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

Apellis Pharmaceuticals, Inc.

Date: February 25, 2021

By: /s/ Cedric Francois
Cedric Francois
President, Chief Executive Officer and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Cedric Francois **Cedric Francois**	President, Chief Executive Officer and Director (Principal Executive Officer and Duly Authorized Officer)	February 25, 2021
/s/ Timothy E. Sullivan **Timothy E. Sullivan**	Chief Financial Officer and Treasurer (Principal Financial Officer and Duly Authorized Officer)	February 25, 2021
/s/ Nicole D. Perry **Nicole D. Perry**	Vice President, Accounting and Treasurer (Principal Accounting Officer)	February 25, 2021
/s/ Gerald Chan **Gerald Chan**	Director	February 25, 2021
/s/ A. Sinclair Dunlop **A. Sinclair Dunlop**	Director	February 25, 2021
/s/ Alec Machiels **Alec Machiels**	Director	February 25, 2021
/s/ Stephanie M. O'Brien **Stephanie M. O'Brien**	Director	February 25, 2021
/s/ Paul Fonteyne **Paul Fonteyne**	Director	February 25, 2021

DESCRIPTION OF SECURITIES REGISTERED UNDER SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of the common stock, par value $0.0001 per share (the "Common Stock"), of Apellis Pharmaceuticals, Inc. ("us," "our," "we" or the "Company"), which is the only security of the Company registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), summarizes certain information regarding the Common Stock in our restated certificate of incorporation, our amended and restated bylaws and applicable provisions of Delaware corporate law, and is qualified by reference to our restated certificate of incorporation and amended and restated bylaws, which are incorporated by reference as Exhibit 3.1 and Exhibit 3.2, respectively, to the Annual Report on Form 10-K.

Our authorized capital stock consists of 200,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

Common Stock

Voting Rights. Holders of our Common Stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders will be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Any matter other than the election of directors to be voted upon by the stockholders at such meeting will be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter, except when a different vote is required by law, our certificate of incorporation or our bylaws.

Dividends. Holders of Common Stock are entitled to receive proportionately any dividends as may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by our board of directors, subject to any preferential dividend rights of any outstanding preferred stock.

Liquidation and Dissolution. In the event of our liquidation or dissolution, whether voluntary or involuntary, the holders of Common Stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock.

Other Rights. Holders of Common Stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of Common Stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future. Outstanding shares of our Common Stock are non-assessable. Holders of our Common Stock are not, and will not be, subject to any liability as stockholders.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Delaware law contains, our restated certificate of incorporation and our amended and restated bylaws contain, provisions that could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors.

Staggered Board; Removal of Directors. Our restated certificate of incorporation and amended and restated bylaws divide our board of directors into three classes with staggered three-year terms. In addition, a director may be removed only for cause and only by the affirmative vote of the holders of at least 75% of the votes that all of our stockholders would be entitled to cast in an annual election of directors. Any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office. The classification of our board of directors and the limitations on the removal of directors and filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of us.

Stockholder Action by Written Consent; Special Meetings. Our restated certificate of incorporation provides that any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of such holders and may not be effected by any consent in writing by such holders. Our restated certificate of incorporation and amended and restated bylaws also provide that, except as otherwise required by law, special meetings of our stockholders can only be called by our chairman of the board, our chief executive officer or our board of directors.

Advance Notice Requirements for Stockholder Proposals. Our amended and restated bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of persons for election to our board of directors. Stockholders at an annual meeting may consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a stockholder of record on the

record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities.

Issuance of Preferred Stock. Our board of directors is authorized, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, and to fix the designations, powers, preferences and the relative, participating, optional or other special rights, and any qualifications, limitations and restrictions of the shares of each series of preferred stock. The issuance of preferred stock could impede the completion of a merger, tender offer or other takeover attempt.

Delaware Business Combination Statute. We are subject to Section 203 of the General Corporation Law of the State of Delaware. Subject to certain exceptions, Section 203 prevents us from engaging in a "business combination" with any "interested stockholder" for three years following the date that the person became an interested stockholder, unless the interested stockholder attained such status with the approval of our board of directors or unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger or consolidation involving us and the "interested stockholder" and the sale of more than 10% of our assets. In general, an "interested stockholder" is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person.

Amendment of Certificate of Incorporation and Bylaws. The General Corporation Law of the State of Delaware provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless a corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Our amended and restated bylaws may be amended or repealed by a majority vote of our board of directors or by the affirmative vote of the holders of at least 75% of the votes that all of our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes that all of our stockholders would be entitled to cast in any annual election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our restated certificate of incorporation described above under "—Staggered Board; Removal of Directors" and "—Stockholder Action by Written Consent; Special Meetings."

Exclusive Forum Selection. Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (1) any derivative action or proceeding brought on behalf of the Company, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to the Company or our stockholders, (3) any action asserting a claim against the Company arising pursuant to any provision of the General Corporation Law of the State of Delaware or our restated certificate of incorporation or amended and restated bylaws, or (4) any action asserting a claim against the Company governed by the internal affairs doctrine. Although our restated certificate of incorporation contains the choice of forum provision described above, it is possible that a court could rule that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

FOURTH AMENDMENT TO LEASE

This FOURTH AMENDMENT TO LEASE (this "**Amendment**") is entered into this 13th day of November, 2020 (the "**Effective Date**") by and between NWALP PHOP Property Owner LLC, a Delaware limited liability company (the "**Landlord**"), and Apellis Pharmaceuticals, Inc., a Delaware corporation (the "**Tenant**").

W I T N E S S E T H:

WHEREAS, the Landlord and the Tenant entered into that certain Lease dated as of April 27, 2017 (the "**Original Lease**"**)**, regarding premises consisting of approximately 6,126 rentable square feet (the "**Original Premises**") and situated in that certain building located at 200 Fifth Avenue, Waltham, Massachusetts;

WHEREAS, the Landlord and the Tenant entered into that certain First Amendment to Lease dated July 25, 2018 (the "**First Amendment**") pursuant to which the Landlord and the Tenant amended the Original Lease so as to relocate the Tenant from the Original Premises to certain space in the Building located at 100 Fifth Avenue, Waltham, Massachusetts on the third (3rd) floor thereof consisting of approximately 22,600 rentable square feet (the "**New Premises**");

WHEREAS, the Landlord and Tenant entered into that certain Second Amendment to Lease dated June 5, 2019 (the "**Second Amendment**") pursuant to which the Landlord and Tenant agreed to expand the Premises so as to rent certain space located on the sixth (6th) floor of the Building consisting of 8,821 rentable square feet of space (the "**Expansion Premises**");

WHEREAS, the Landlord and the Tenant entered into that certain Third Amendment to Lease dated September 25, 2019 (the "**Third Amendment**") pursuant to which the Landlord and Tenant agreed to expand the Premises so as to rent (i) certain space located on the seventh (7th) floor of the Building consisting of 18,140 rentable square feet of space, and (ii) certain space located on the fifth (5th) floor of the Building consisting of 11,856 rentable square feet of space (together, the "**Second Expansion Premises**") (the New Premises, the Expansion Premises and the Second Expansion Premises, collectively, the "**Current Premises**") (the Original Lease, as amended by the First Amendment, the Second Amendment and the Third Amendment, is referred to in this Amendment as the "**Lease**");

WHEREAS, the Landlord and Tenant desire to expand the Premises so as to rent (i) certain space located on the sixth (6th) floor of the Building consisting of 12,179 rentable square feet of space, as described in ***Exhibit A-(iv)*** attached to this Amendment (the "**Sixth Floor Expansion Premises**"), (ii) certain space located on the lower level of the Building consisting of 3,315 rentable square feet of space, and (iii) certain space located on the lower level of the Building consisting of 907 rentable square feet of space (items (ii) and (iii), each described in ***Exhibit A-(v)*** attached to this Amendment, and together, the "**Lower Level Expansion Premises**") (the Sixth Floor Expansion Premises and the Lower Level Expansion Premises, collectively, the "**Third Expansion Premises**"); and

WHEREAS, the Landlord and the Tenant mutually desire to amend the Lease to provide for Tenant's leasing of the Third Expansion Premises and to make other modifications to the terms and condition of the Lease, all as further provided for below.

NOW, THEREFORE, in consideration of the mutual covenants contained in this Amendment, the Lease and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Landlord and the Tenant hereby agree as follows effective as of the Effective Date:

1. **Rent**. The Basic Rent Table set forth in the Definition of "Basic Rent" shall be amended by adding the following:

"As of the Third Expansion Premises Rent Commencement Date, the Basic Rent due from Tenant to Landlord pursuant to Section 3.1 for the Premises is payable as set forth in the following rent table:

Third Expansion Premises Rent Commencement Date - 9/30/2021	$250,083.50/month	$3,001,002.00/year
10/1/2021 - 9/30/2022	$256,097.50/month	$3,073,170.00/year
10/1/2022 - 9/30/2023	$262,582.33/month	$3,150,988.00/year
10/1/2023 - 9/30/2024	$269,067.17/month	$3,228,806.00/year
10/1/2024 - 6/30/2025	$275,395.06/month	$3,304,740.67/year
7/1/2025 - 6/30/2026	$285,332.67/month	$3,423,992.00/year
7/1/2026 - 12/31/2026	$291,817.50/month	$3,501,810.00/year

2. **Premises**. As of the Third Expansion Premises Term Commencement Date, the following definitions set forth in Section 1.1 of the Lease are deleted in their entirety and replaced with the following:

(a) **Premises**: Agreed to include (i) The Original Premises from the Term Commencement Date until the New Premises Substantial Completion Date, (ii) the New Premises from the New Premises Substantial Completion Date (i.e., January 1, 2019) until the Expiration Date, (iii) the Expansion Premises, from the Expansion Premises Term Commencement Date (i.e., June 5, 2019) to the Expiration Date, (iv) the Second Expansion Premises, from the Second Expansion Premises Term Commencement Date (i.e., October 1, 2019) to the Expiration Date, and (v) the Third Expansion Premises, from the Third Expansion Premises Term Commencement Date to the Expiration Date.

(b) **Premises Rentable Area**: Agreed to be (i) 6,126 rentable square feet from the Term Commencement Date until the New Premises Substantial Completion Date; (ii) 22,600 rentable square feet from the New Premises Substantial Completion Date until the Expansion Premises Term Commencement Date; (iii) 31,421 rentable square feet from the Expansion Premises Term

Commencement Date to the Second Expansion Premises Term Commencement Date; (iv) 61,417 rentable square feet from the Second Expansion Premises Term Commencement Date to the Third Expansion Premises Term Commencement Date; and (v) 77,818 rentable square feet from the Third Expansion Premises Commencement Date to the Expiration Date.

(c) **Tenant's Proportionate Share:** Agreed to be (i) three and sixty five one hundredths percent (3.65%) from the Term Commencement Date until the New Premises Substantial Completion Date; (ii) fourteen and forty one hundredths percent (14.41%) from the New Premises Substantial Completion Date until the Expansion Premises Term Commencement Date; (iii) twenty percent (20%) from the Expansion Premises Term Commencement Date to the Second Expansion Premises Term Commencement Date; (iv) thirty six and fifty hundredths percent (36.5%) from the Second Expansion Premises Term Commencement Date until the Third Expansion Premises Term Commencement Date; and (v) forty nine and six hundredths percent (49.6%) from the Third Expansion Premises Rent Commencement Date to the Expiration Date (which is based on the ratio of the agreed upon (a) Premises Rentable Area to (b) Building Rentable Area).

(d) **Expiration Date:** December 31, 2026.

3. **Definitions**. In addition, the following definition shall be added to Section 1.1 of the Lease:

(a) **Third Expansion Premises Term Commencement Date**: shall be the first (1st) day following the date of the NRT Termination Satisfaction Notice (as hereinafter defined).

(b) **Third Expansion Premises Term:** The period of time commencing on the Third Expansion Premises Term Commencement Date and expiring on the Expiration Date.

(c) **Third Expansion Premises Rent Commencement Date**: The later of (i) January 1, 2021, or (ii) the date that the Third Expansion Premises are delivered to Tenant in the condition required by Section 5 of this Amendment.

4. **Exhibits**: As of the Third Expansion Premises Term Commencement Date:

The Enumeration of Exhibits as set forth in Section 1.2 of the Lease shall be updated to add the following:

"Exhibit A-(iv)	Plan of the Sixth Floor Expansion Premises
Exhibit A-(v)	Plan of the Lower Level Expansion Premises"

5. **Condition of Third Expansion Premises**. Subject to the terms of this Section 5, the Third Expansion Premises are being leased by Tenant in their condition as of the Third Expansion Premises Term Commencement Date, in their "As Is" condition as of the Effective Date, without representation or warranty by Landlord, except that the Third Expansion Premises shall be delivered to Tenant vacant (and all existing leases or occupancy agreements terminated), broom clean, with all furniture, fixtures and equipment removed, other than the furniture located on the Lower Level Expansion Premises, and in compliance with all applicable laws. Tenant acknowledges and agrees that Tenant inspected the Third Expansion Premises prior to the execution of this Amendment and is satisfied with the condition of the Third Expansion Premises. With respect to the furniture located on the Lower Level Expansion Premises, Landlord hereby conveys its interest in the same, if any, to Tenant without warranty, representation or recourse of any kind. There is no warranty relating to title, possession, quiet enjoyment, or the like in this disposition.

6. **Landlord's Third Expansion Contribution**. Landlord shall provide to Tenant a contribution in the amount of $410,025 (the "**Landlord's Third Expansion Contribution**") to be used towards Tenant's improvements to the Third Expansion Premises (including both hard and soft costs of construction, as well as the purchase and installation of Tenant's cabling, wiring, furniture, fixtures and equipment), subject to the provisions stated in this Section 6 of this Amendment.

(a) Tenant shall prepare, at its sole cost and expense (against which the Landlord's Third Expansion Contribution may be applied), plans (the "**Third Expansion Plans**") for the interior finish and layout of the initial improvements (the "**Third Expansion Initial Work**") which Tenant desires to have performed in the Third Expansion Premises. The Third Expansion Plan **s**hall be submitted to Landlord, together with a construction budget setting forth the anticipated costs for the Third Expansion Initial Work (the "**Third Expansion Estimated Initial Work Budget**"), and Landlord shall approve or disapprove of the Third Expansion Plans, in its reasonable discretion, within ten (10) Business Days of receiving them. No work shall be conducted by or on behalf of Tenant until the Third Expansion Plans have been fully approved in writing by Landlord. At Tenant's sole cost and expense (against which the Landlord's Third Expansion Contribution may be applied), Tenant shall cause the Third Expansion Plans to be revised in a manner sufficient to remedy the Landlord's objections and/or respond to the Landlord's concerns and for such revised Third Expansion Plans to be redelivered to Landlord, and Landlord shall approve or disapprove Tenant's revised Third Expansion Plans within five (5) Business Days following the date of resubmission, unless such revised Third Expansion Plans involve structural alterations to the Building or the HVAC, in which case Landlord shall approve or disapprove such revised Third Expansion Plans within ten (10) Business Days. Landlord's failure to timely respond to Tenant's

submitted Third Expansion Plans or revised Third Expansion Plans shall be deemed to be an approval thereof.

(b) The Third Expansion Plans shall be stamped by a Massachusetts registered architect and engineer, such architect and engineer and Tenant's general contractor, being subject to Landlord's prior reasonable approval, and shall comply with Applicable Law and the requirements of the Rules and Regulations and shall be in a form satisfactory to appropriate governmental authorities responsible for issuing permits, approvals and licenses required for such Third Expansion Initial Work.

(c) All of the Third Expansion Initial Work shall be completed in accordance with the requirements set forth in the Rules and Regulations for Tenant Alterations.

(d) Landlord shall reimburse Tenant for the costs incurred by the Tenant with respect to the design and performance of the Third Expansion Initial Work (the "**Cost of Third Expansion Initial Work**") up to the amount of Landlord's Third Expansion Contribution, subject to the provisions hereof. To the extent that the Cost of Third Expansion Initial Work exceeds the Landlord's Third Expansion Contribution, Tenant shall be entirely responsible for such excess. Landlord's Third Expansion Contribution shall be payable by Landlord to Tenant (or, at Landlord's election, directly to Tenant's general contractor or subcontractors) in installments according to Landlord's construction disbursement procedures set forth below, as the Third Expansion Initial Work progresses. Prior to payment of any such installment, Tenant shall deliver to Landlord a written request, to be submitted no more frequently than once every thirty (30) days, for such disbursement, which request shall be accompanied by: (i) invoices for the Third Expansion Initial Work covered by such requisition; (ii) copies of partial lien waivers or final lien waivers (in the case of a final installment) from (I) all contractors and subcontractors holding contracts in excess of $10,000 whose work is covered by such requisition or (II) in the event that the aggregate amount of Tenant's contracts in connection with the Third Expansion Initial Work exceeds $25,000, from any contractors and subcontractors whose work is covered by such requisition; and (iii) a certificate signed by the Architect certifying that the Third Expansion Initial Work represented by the aforementioned invoices has been completed substantially in accordance with the Third Expansion Plans. Landlord shall make each such payment, as set forth above, within forty-five (45) days of Landlord's receipt of the documentation described above. If at any time the amount of Landlord's Third Expansion Contribution remaining is insufficient to pay for the remaining amount of the Third Expansion Initial Work, then Tenant shall pay from its own funds all amounts required to accomplish lien free completion of the Third Expansion Initial Work. In the event that Landlord fails to pay all or any portion of Landlord's Third Expansion Contribution to Tenant when due, and such failure continues for thirty (30) days after written notice is delivered to Landlord from Tenant, Tenant may

offset the amount of the unpaid Landlord's Third Expansion Contribution against rent due until all of such unpaid Landlord's Third Expansion Contribution has been recouped by Tenant.

7. **Offset to Basic Rent**. Tenant may, at Tenant's option, use up to one hundred percent (100%) of the Landlord's Third Expansion Contribution to offset Base Rent next coming due, with the balance carried forward and applied towards each of the next rental payments until Landlord's Third Expansion Contribution has been fully used.

8. **Landlord's Current Space Contribution**. In addition to the Landlord's Third Expansion Contribution, Landlord shall provide to Tenant a contribution in the amount of $245,688 (the "**Landlord's Current Premises Contribution**") to be used towards Tenant's improvements to the Current Premises, subject to the condition that the provisions described in Section 6 of this Amendment shall also apply to Landlord's Current Space Contribution and any references to Landlord's Third Expansion Premises Contribution, Third Expansion Plans, Third Expansion Initial Work, Third Expansion Estimated Initial Work Budget and Cost of Third Expansion Initial Work shall be deemed to refer instead to "Landlord's Current Premises Contribution" and the plans and specifications, work and budget therefor.

9. **Initial Access**. Upon the Third Expansion Premises Term Commencement Date, Tenant shall have full use and access of the Third Expansion Premises and all of Tenant's obligations hereunder shall commence, provided that Tenant shall deliver to Landlord certificates of insurance evidencing the coverages required by the Lease. Notwithstanding the foregoing, Tenant's obligations to pay Basic Rent, Additional Rent and electric fees in relation to the Third Expansion Premises shall not commence until the Third Expansion Premises Rent Commencement Date.

10. **Yield-Up and Surrender of Premises**. Tenant shall yield-up and surrender the Current Premises and the Third Expansion Premises on or prior to the Expiration Date in strict accordance with Article 16 of the Lease. Failure to yield-up and surrender the Current Premises and Third Expansion Premises in accordance with this Section 10 shall constitute a Default of Tenant under the Lease and entitle Landlord to exercise any and all of the remedies to which Landlord is entitled under the Lease, at law or in equity.

11. **Brokers**. Each of Landlord and Tenant hereby represents that such party has not dealt with any brokers with respect to the transactions contemplated by this other than Jeremy Hood and CBRE (together, the "**Broker**"). Each of Landlord and Tenant hereby agrees to defend, indemnify and hold harmless the other, and its successors and assigns, against and from all claims, losses, liabilities and expenses including, without limitation, reasonable attorney's fees, arising out of any claim by any broker, consultant, finder or like agent, which are based upon

alleged dealings by such party with respect to this Amendment other than the Broker. Provided that this Amendment is executed by the Landlord and the Tenant, the Landlord shall pay to the Broker a commission fee per a separate agreement.

12. **NRT Termination Agreement**. Landlord and Tenant acknowledge and agree that all the rights and obligations of each party pursuant to this Amendment are contingent upon the following (i) the full execution of that certain Termination of Lease Agreement by and between NRT New England LLC, a Delaware limited liability company ("**NRT**"), and Landlord, to be signed and dated simultaneously herewith (the "**NRT Termination Agreement**"); (ii) the satisfaction by NRT of all of the terms and conditions of the NRT Termination Agreement no later than five (5) business days following the execution date of said agreement, including, without limitation, the payment by NRT of any amounts due pursuant to the NRT Termination Agreement. Following Landlord's confirmation that the conditions of items (i) and (ii) above are satisfied, Landlord shall certify of the same to Tenant (the "**NRT Termination Satisfaction Notice**"), and this Section 12 shall be of no further force and effect. For the avoidance of doubt, in the event that the NRT Termination Agreement is not fully executed and dated by Landlord and NRT as of the date of this Amendment and/or the terms and conditions of the NRT Termination Agreement are not fully satisfied within five (5) business days following its execution date, Landlord shall promptly (and in any event within seven (7) Business Days following the Effective of this Amendment) deliver written notice thereof to Tenant and this Amendment shall be null and void.

13. **Capitalized Terms**. Capitalized terms that are not otherwise defined herein shall have the meaning set forth in the Lease.

14. **Ratification of Existing Lease Terms**. Other than as expressly set forth herein, the terms and provisions of the Lease are hereby ratified, confirmed and shall remain unmodified and in full force and effect.

15. **Governing Law**. This Amendment shall be governed by the laws of the Commonwealth of Massachusetts without regard to its conflict of law provisions.

16. **Counterpart Signatures**. This Amendment may be executed in counterparts, each of which shall constitute an original document and all of which, together, shall constitute one and the same instrument, and computer-scanned image signatures hereon shall be binding. Facsimile, electronic or scanned signatures shall be deemed originals for all purposes.

[Signatures Appear on the Following Page]

IN WITNESS WHEREOF, the Landlord and the Tenant have each caused this Amendment to be executed as of the date first above written.

LANDLORD:

NWALP PHOP PROPERTY OWNER LLC, a Delaware limited liability company

By: ALP PHOP Manager, LLC, a Massachusetts limited liability company, its appointed representative

By: Andrew Maher
Name: Andrew Maher
Title: Manager

TENANT:

APELLIS PHARMACEUTICALS, INC., a Delaware corporation

By: /s/ Nur Nicholson
Name: Nur Nicholson
Title: Chief Technical Officer

EXHIBIT A-(iv)

The Sixth Floor Expansion Premises

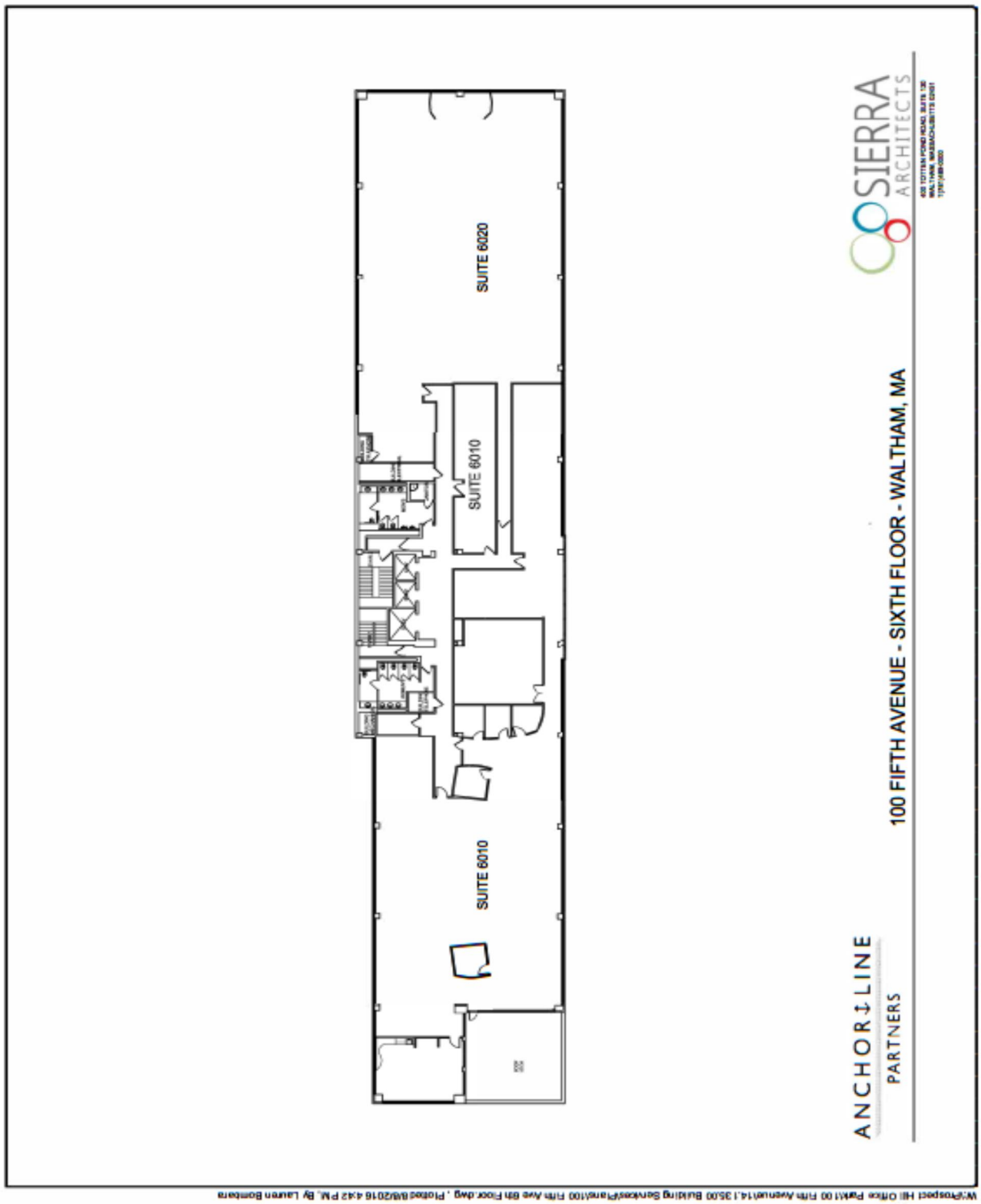

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EXHIBIT A-(v)

The Lower Level Expansion Premises

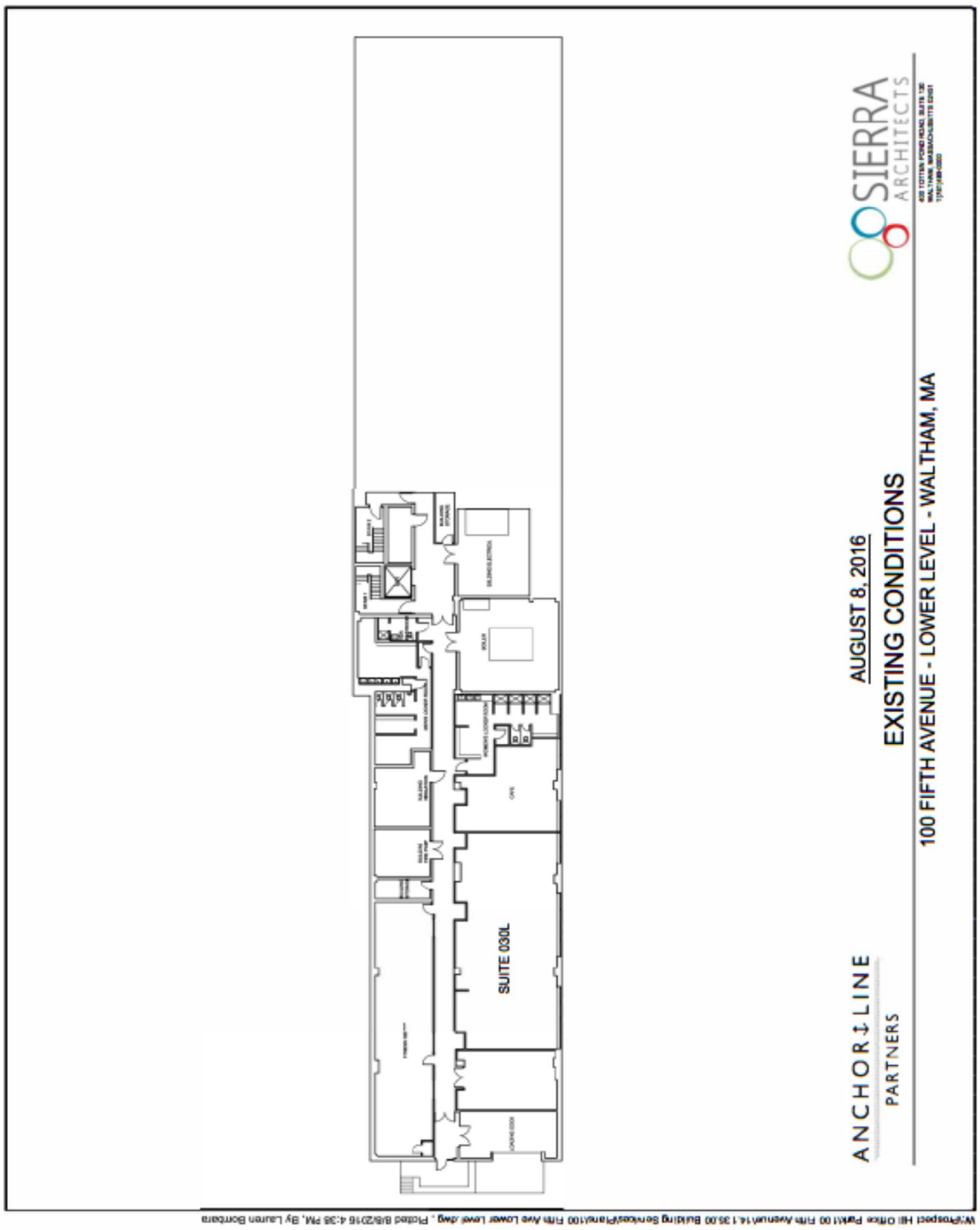

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Exhibit 10.25

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

COLLABORATION AND LICENSE AGREEMENT

BY AND AMONG

APELLIS SWITZERLAND GMBH

APELLIS PHARMACEUTICALS, INC.

APL DEL HOLDINGS, LLC

AND

SWEDISH ORPHAN BIOVITRUM AB (PUBL)

October 27, 2020

TABLE OF CONTENTS

List of Schedules:

COLLABORATION AND LICENSE AGREEMENT

This COLLABORATION AND LICENSE AGREEMENT (this "**Agreement**"), dated as of October 27, 2020 (the "**Effective Date**"), is made by and among Apellis Switzerland GmbH, a company with limited liability (*Gesellschaft mit beschränkter Haftung*) registered under the laws of Switzerland and having its registered office at Zählerweg 10, 6300 Zug, Switzerland ("**Apellis GmbH**"), Apellis Pharmaceuticals, Inc., a Delaware corporation with a principal place of business at 100 5th Avenue, Waltham, MA 02451 USA ("**Apellis US**") and APL DEL Holdings, LLC, a company organized and existing under the laws of Delaware with its registered agent located at c/o Vcorp Services, LLC, 1013 Centre Road, Suite 403-B, in the City of Wilmington, County of New Castle, Delaware, 19805 ("**Apellis LLC**") (Apellis GmbH, Apellis US and Apellis LLC together referred to as "**Apellis**") and Swedish Orphan Biovitrum AB (publ), a Swedish public company having its principal place of business at SE-112 76 Stockholm, Sweden ("**Sobi**"). Sobi and Apellis are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

Whereas, Apellis is a biopharmaceutical company that owns or otherwise Controls the Compound;

Whereas, Sobi is a biopharmaceutical company that has expertise and capabilities in the Development, performance of Medical Affairs, Manufacturing, and Commercialization of human therapeutic products; and

Whereas, Sobi and Apellis desire to Develop and Commercialize the Products worldwide in accordance with the terms and conditions set forth in this Agreement.

Now Therefore, the Parties hereby agree as follows.

ARTICLE 1
DEFINITIONS

As used in this Agreement, the following capitalized terms will have the meanings set forth in this Article 1 (Definitions) or as otherwise defined elsewhere in this Agreement:

1.1. "**Accounting Standards**" means with respect to Apellis and its Affiliates and sub/licensees, GAAP, with respect to Sobi and its Affiliates, IFRS, and, with respect to Sublicensees and Functional Sublicensees, IFRS or GAAP, as applicable, in each case as generally and consistently applied throughout the Party's, Affiliate's, sub/licensees, Sublicensee's, or Functional Sublicensee's organization. Each Party will promptly notify the other Party if such Party or any of its Affiliates, Sublicensees, Functional Sublicensees, or sub/licensees changes the Accounting Standards pursuant to which its records relating to this Agreement are maintained; provided, however, that each Party and its Affiliates and each Sublicensee and Functional Sublicensee and each sub/licensee may only use internationally recognized accounting principles (e.g., IFRS or GAAP).

1.2. "**Additional Global Development Activities**" has the meaning set forth in Section 4.4.4(a)(i) (JEC Approval).

1.3. "**Additional Development**" has the meaning set forth in Section 4.4.4 (Additional Development).

1.4. "**Additional Development Activities**" has the meaning set forth in Section 4.4.4 (Additional Development).

1.5. "**Additional Development Proposal**" has the meaning set forth in Section 4.4.4 (Additional Development).

1.6. "**Additional Third Party IP**" has the meaning set forth Section 2.3 (New In-Licenses).

1.7. "**Adverse Event**" has the meaning set forth in 21 C.F.R. § 312.32, or any equivalent Applicable Law in any relevant country or region, and generally means any untoward medical occurrence associated with the use of a product in human subjects, whether or not considered related to such product. An Adverse Event does not necessarily have a causal relationship with a product, but rather can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of such product.

1.8. "**Affiliate**" of a Person means any other Person that (directly or indirectly) is Controlled by, Controls, or is under common Control with such Person.

1.9. "**Agreement**" has the meaning set forth in the Preamble.

1.10. "**Alliance Manager**" has the meaning set forth in Section 3.1.1 (Alliance Managers).

1.11. "**ALS**" means amyotrophic lateral sclerosis.

1.12. "**Alternate Supplier**" has the meaning set forth in Section 8.3.2(a) (Manufacturer Know-How).

1.13. "**[**]**" means [**].

1.14. "**[**] APL-1 Agreement**" means the [**] Agreement by and between Apellis US and [**], dated as of [**].

1.15. "**[**] APL-2 Agreement**" means the [**] Agreement by and between Apellis US and [**], dated as of [**].

1.16. "**Apellis**" has the meaning set forth in the Preamble.

1.17. "**Apellis Know-How**" means any and all Know-How, including, for clarity, the Manufacturing Know-How, that is (a) Controlled by Apellis or any of its Affiliates as of the Effective Date or during the Term, including Apellis' interest in the Joint Know-How, and (b) necessary or useful for the Exploitation of any Compound or Product in the Sobi Territory. Notwithstanding anything in this Agreement to the contrary, Apellis Know-How shall not include (x) any Know-How licensed by Apellis or any of its Affiliates from [**], including pursuant to the [**] Agreement, except to the extent that the Parties agree to incorporate any such Know-How into any Product Developed under the Global Development Plan, (y) any Additional Third Party IP in-licensed by Apellis or any of its Affiliates under an agreement that Sobi does not agree to make a Collaboration In-License pursuant to Section 2.3 (New In-Licenses), or (z) any Know-How to the extent Controlled by any Person that acquires all or any part of Apellis or an Affiliate of Apellis, or any Affiliate of such Person, except to the extent that, following such acquisition, the Parties specifically agree to incorporate such Know-How into any Product Developed under the Global Development Plan, in each case (i) that is Controlled, immediately prior to the effective date of the acquisition, by such Person or any of its Affiliates (other than Apellis or any of its Affiliates immediately prior to the effective date of the acquisition) or (ii) that is Controlled by such Person or any of its Affiliates (other than Apellis or any of its Affiliates immediately prior to the

effective date of the acquisition) on or after the effective date of acquisition but (A) is not Controlled by Apellis or any Person that was an Affiliate of Apellis immediately prior to the effective date of the acquisition, (B) is made, invented, created, designed, conceived, produced, or otherwise developed or obtained without the use of or reliance on any Apellis Confidential Information or Sobi Confidential Information, and (C) is not utilized by or on behalf of Apellis or its Affiliates in connection with the Exploitation of a Product. For clarity, subject to clauses (x)-(z) above, the Apellis Know-How shall include Know-How Controlled by Apellis or any of its Affiliates related to any Non-Systemic Ophthalmology Product to the extent such Know-How is necessary or useful to the Exploitation of any Compound or Product in the Sobi Territory.

1.18. "**Apellis' Knowledge**" means, for the purposes of Sections 11.3.10 (Additional Representations and Warranties of Apellis), 11.3.11 (Additional Representations and Warranties of Apellis), and 11.3.22 (Additional Representations and Warranties of Apellis) only, to the knowledge of any or all of [**] after making reasonable enquiries of such persons' direct reports.

1.19. "**Apellis Patent Right**" means any Patent Right that (a) is Controlled by Apellis or any of its Affiliates as of the Effective Date or during the Term, including Apellis' interest in the Joint Patent Rights, and (b) Covers the Exploitation of any Compound or Product. As of the Effective Date, the Apellis Patent Rights include those Patent Rights identified on Schedule 1.19 (Apellis Patent Rights), but any Patent Right that meets the definition of Apellis Patent Rights will constitute an Apellis Patent Right under this Agreement, notwithstanding any failure to identify such Patent Right on Schedule 1.19 (Apellis Patent Rights). Notwithstanding anything in this Agreement to the contrary, Apellis Patent Rights shall not include (x) any Patent Rights licensed by Apellis or any of its Affiliates from [**], including pursuant to the [**] Agreement, except to the extent that the Parties agree to incorporate any Know-How Covered by any such Patent Right into any Product Developed under the Global Development Plan, (y) any Additional Third Party IP in-licensed by Apellis or any of its Affiliates under an agreement that Sobi does not agree to make a Collaboration In-License pursuant to Section 2.3 (New In-Licenses), or (z) any Patent Right to the extent Controlled by any Person that acquires all or any part of Apellis or an Affiliate of Apellis, or any Affiliate of such Person, except to the extent that, following such acquisition, the Parties specifically agree to incorporate any technology or invention Covered or claimed by such Patent Right into any Product Developed under the Global Development Plan, in each case (i) that is Controlled, immediately prior to the effective date of the acquisition, by such Person or any of its Affiliates (other than Apellis or any of its Affiliates immediately prior to the effective date of the acquisition) or (ii) that is Controlled by such Person or any of its Affiliates (other than Apellis or any of its Affiliates immediately prior to the effective date of the acquisition) on or after the effective date of acquisition but is not Controlled by Apellis or any Person that was an Affiliate of Apellis immediately prior to the effective date of the acquisition and Covers or claims an invention that was invented without the use of or reliance on any Apellis Confidential Information or Sobi Confidential Information. For clarity, subject to clauses (x)-(z) above, the Apellis Patent Rights shall include Patent Rights Controlled by Apellis or any of its Affiliates related to any Non-Systemic Ophthalmology Product to the extent such Patent Rights Cover the Exploitation of a Compound or Product.

1.20. "**Apellis Readiness Activities**" has the meaning set forth in Section 4.3.6 (Development Diligence Obligations).

1.21. "**Apellis Retained Rights**" has the meaning set forth in Section 2.1.2(c) (No Implied Licenses; Retained Rights).

1.22. "**Apellis Supply Agreement(s)**" means the Manufacture and supply agreement(s) entered into by Apellis (or its applicable Affiliate(s)) and a Third Party contract manufacturer(s), pursuant to which such manufacturer(s) will Manufacture and supply to Apellis commercial quantities of Compounds or Products.

1.23. "**Apellis Technology**" means all Apellis Patent Rights and Apellis Know-How.

1.24. "**Apellis Territory**" means the U.S.

1.25. "**Apellis Territory Regional Development Activities**" means all Development activities, other than the Global Development Activities, conducted by or on behalf of Apellis to support Regulatory Approval of any Product in the Apellis Territory.

1.26. "**Apellis Territory Regional Development Plan**" has the meaning set forth in Section 4.4.2 (Apellis Territory Regional Development Plan).

1.27. "**APL-9**" means any compound composed of two (2) symmetric pentadecapeptide, combining a cyclic tridecapeptide active C3-inhibiting moiety and a 2-amino acid linker, covalently bound to the ends of a linear PEG10 molecule, as further described in Schedule 1.27. The average molecular weight of APL-9 is approximately 13.8kDa.

1.28. "**Applicable Law**" means all applicable laws, statutes, rules, regulations, and other pronouncements having the effect of law of any Governmental Authority that may be in effect from time to time, including any applicable securities or market abuse rules or regulations or any applicable rules, regulations, guidances, and other requirements of any Regulatory Authority that may be in effect from time to time, including, for clarity, all applicable Data Protection Laws.

1.29. "**Assigned Manufacturer IP**" means (a) under the [**] Agreement, all technology, Apellis Supplied Materials (as defined in the [**] Agreement), know-how, inventions, discoveries, ideas, concepts, trade-secrets, improvements, processes, process improvements, information, Specifications (as defined in the [**] Agreement), analytical test methods, CMC Documentation (as defined in the [**] Agreement), Drug Master Files (as defined in the [**] Agreement) or data, whether patentable or not, which is specifically related to the Drug Substance or Drug Product (each as defined in the [**] Agreement), or arise from the Services (as defined in the [**] Agreement), and is not generally applicable to the field of peptide manufacturing, and any Apellis intellectual property rights therein; (b) under the [**] Agreement, all technology, know-how, inventions, discoveries, ideas, concepts, trade-secrets, improvements, processes, process improvements, information, or data, whether patentable or not, which are related to the Drug Substance or Drug Product (each as defined in the [**] Agreement), including those that arise from the Services (as defined in the [**] Agreement), and any intellectual property rights therein; (c) under the [**] Agreement, any intellectual property discovered or developed by [**] or jointly with Apellis US in the performance of the Services (as defined in the [**] Agreement), that is specific to and not severable from the Product (as defined in the [**] Agreement); (d) under the [**] APL-1 Agreement, all technology, know-how, inventions, discoveries, ideas, concepts, trade secrets, improvements, processes, process improvements, information, or data, whether patentable or not, which are related to the API or Drug Product (each as defined in the [**] APL-1 Agreement), or arise from the Services (as defined in the [**] APL-1 Agreement); and (e) under the [**] APL-2 Agreement, all technology, know-how, inventions, discoveries, ideas, concepts, trade secrets, improvements, processes, process improvements, information, or data, whether patentable or not, which are related to the API or Drug Product (each as defined in the [**] APL-2 Agreement), provided by Apellis under the [**] APL-2 Agreement, and any intellectual property rights therein.

1.30. "**[**]**" means [**].

1.31. "**[**] Agreement**" means the [**] Agreement for APL-2 by and between Apellis US and [**], dated as of [**].

1.32. "**[**] IP**" means all intellectual property (including trademarks), including all data, information, reports, manufacturing know-how and any and all related documentation, which are (a) developed, generated or derived, directly or indirectly by or on behalf of [**] prior to the effective date of the [**] Agreement or (b) any manufacturing know-how developed or generated by [**] during the term of the [**] Agreement that is generally applicable to the field of peptide manufacturing and not specific to the Drug Substance or Drug Product (each as defined in the [**] Agreement) or Apellis' Confidential Information (as defined in the [**] Agreement).

1.33. "**Business Day**" means any day other than a Saturday, Sunday, or bank or other public holiday in Boston, Massachusetts or in Stockholm, Sweden.

1.34. "**C3G**" means C3 glomerulopathy and IC-MPGN (Immune complex Membranoproliferative glomerulonephritis).

1.35. "**CAD**" means cold agglutinin disease.

1.36. "**Calendar Quarter**" means the respective periods of three consecutive calendar months ending on March 31st, June 30th, September 30th, or December 31st in any Calendar Year; *except that* (a) the first Calendar Quarter shall begin on the Effective Date and end on December 31, 2020, and (b) the final Calendar Quarter shall end on the last day of the Term.

1.37. "**Calendar Year**" means any calendar year beginning on January 1st and ending on December 31st; *except that* (a) the first Calendar Year shall begin on the Effective Date and end on December 31, 2020, and (b) the final Calendar Year shall end on the last day of the Term.

1.38. "**Change of Control**" of a Party means any of the following, in a single transaction or a series of related transactions: (a) the sale or disposition of all or substantially all of the assets of such Party to a Third Party, (b) the direct or indirect acquisition by a Third Party (other than an employee benefit plan (or related trust) sponsored or maintained by such Party or any of its Affiliates) of beneficial ownership of more than fifty percent (50%) of the then-outstanding common shares or voting power of such Party or any direct or indirect entity which holds, directly or indirectly, beneficial ownership of more than fifty percent (50%) of the then-outstanding common shares or voting power of such Party (a "**Parent Entity**"), (c) the merger or consolidation of such Party or any Parent Entity with or into a Third Party, unless, following such merger or consolidation, the stockholders of such Party or Parent Entity immediately prior to such merger or consolidation beneficially own directly or indirectly more than fifty percent (50%) of the then-outstanding common shares or voting power of the entity resulting from such merger or consolidation or (d) a change in the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract, or otherwise. With respect to a Change of Control of Apellis, a Change of Control shall refer to a Change of Control of any of Apellis US, Apellis GmbH or Apellis LLC.

1.39. "**Challenge**" has the meaning set forth in Section 14.3 (No Patent Challenge).

1.40. "**Clinical Trial**" means any clinical trial for a compound or product in humans that is designed to generate data in support or maintenance of a Drug Approval Application or Regulatory Approval,

including any post-approval clinical trial in humans, but excluding any investigator-sponsored clinical trial.

1.41. "**CMC**" means Chemistry, Manufacturing, and Controls.

1.42. "**Collaboration In-License**" has the meaning set forth in Section 2.3 (New In-Licenses).

1.43. "**Collaboration Know-How**" means any Know-How that is made, invented, conceived, discovered, developed, or otherwise generated in the performance of activities under this Agreement during the Term, including, for clarity, activities under the Global Development Plan, the Apellis Territory Regional Development Plan, the Sobi Territory Regional Development Plan, or otherwise.

1.44. "**Collaboration Patent Right**" means any Patent Right Covering or claiming any Collaboration Know-How.

1.45. "**Combination Product**" means a Product that is regulated or sold in the form of a combination that contains or comprises a Compound together with one (1) or more other therapeutically active pharmaceutical agents (whether coformulated or copackaged or otherwise sold for a single price).

1.46. "**Combination Therapy Data**" has the meaning set forth in Section 4.8.1(b)(ii) (Combination Therapy Data).

1.47. "**Combination Therapy Development**" has the meaning set forth in Section 4.8.1 (Combination Therapy Proposal).

1.48. "**Combination Therapy Development Activities**" has the meaning set forth in Section 4.8.1 (Combination Therapy Proposal).

1.49. "**Combination Therapy Development Proposal**" has the meaning set forth in Section 4.8.1 (Combination Therapy Proposal).

1.50. "**Combination Therapy Global Development Activities**" has the meaning set forth in Section 4.8.1(a)(i) (Combination Therapy Proposal).

1.51. "**Commercial Milestone Event**" has the meaning set forth in Section 9.4 (Commercial Milestones).

1.52. "**Commercial Milestone Payment**" has the meaning set forth in Section 9.4 (Commercial Milestones).

1.53. "**Commercialization**," means any and all activities directed to the launch, marketing, promotion, detailing, distribution, offering for sale, sale, having sold, importing, or exporting (including having imported or having exported) for purposes of commercialization, or other commercialization, of a pharmaceutical product, including interacting with Governmental Authorities regarding any of the foregoing and seeking Reimbursement Approval (as applicable); but excluding activities directed to Manufacturing, Development, or Medical Affairs (except that sponsorships may be conducted as Commercialization activities or Medical Affairs activities). "**Commercialize**," "**Commercializing**," "**Commercialization**" and "**Commercialized**" will be construed accordingly.

1.54. "**Commercially Reasonable Efforts**" means, with respect to efforts and resources to be expended by a Party to achieve an agreed objective, such reasonable, diligent, and good faith efforts and resources as such Party would normally use to accomplish a similar objective under similar circumstances taking into account the responsible allocation of such Party's resources under the circumstances, including, with respect to a Party's obligation to Develop or Commercialize a Product, those efforts and resources consistent with the exercise of prudent scientific and business judgment as applied by an entity of similar size and resources to such Party to the Development or Commercialization (as applicable) of its own products that are at a similar stage of Development or Commercialization and have similar market potential, taking into account performance of other products, competitiveness of Third Party products, efficacy, safety, patent and regulatory exclusivity, anticipated or approved labelling, present and future market potential, competitive market conditions and the profitability of the product in light of pricing and reimbursement issues. Commercially Reasonable Efforts shall be determined on a market-by-market and Indication-by-Indication basis, and it is anticipated that the level of efforts required may be different for different markets and Indications and may change over time, reflecting changes in the status of the Product and markets involved.

1.55. "**Committee**" means the JEC and each subcommittee thereof, including the JDC, JMSC, JMC, and JCC.

1.56. "**Competitive Infringement**" has the meaning set forth in Section 10.3.1 (Notice).

1.57. "**Compound**" means the compound known as APL-2 (pegcetacoplan) or any compstatin analogue or derivative, in each case with systemic half-life (*i.e.*, terminal half-life of a dose administered by IV) in humans greater than or equal to that of APL-2 as further described in Schedule 1.57. For the avoidance of doubt, "Compound" excludes APL-9.

1.58. "**Confidential Information**" has the meaning set forth in Section 13.1 (Confidential Information).

1.59. "**Control**" or "**Controlled**" means: (I) with respect to any Intellectual Property, the possession by a Party or any of its Affiliates (whether by ownership, license, or otherwise, other than pursuant to this Agreement) of (a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms set forth herein, or (b) with respect to Patent Rights, Regulatory Approvals, Reimbursement Approvals, Regulatory Submissions, Reimbursement Submissions, intangible Know-How, or other Intellectual Property, the legal authority or right to assign, or grant a license, sublicense, access, authorization, or right to use (as applicable) to the other Party under, such Patent Rights, Regulatory Approvals, Reimbursement Approvals, Regulatory Submissions, Reimbursement Submissions, intangible Know-How, or other Intellectual Property on the terms set forth herein, in each case ((a) and (b)), without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such assignment, access, authorization, right to use, license, or sublicense; and (II) (including, with correlative meanings, the terms "Controlled by" and "under common Control with"), as used with respect to a Person in the definitions of "Affiliate," means the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract, or otherwise, and "Control" will be presumed to exist if either of the following conditions is met: (a) in the case of a corporate entity, direct or indirect ownership of voting securities entitled to cast at least fifty percent (50%) of the votes in elections of directors, or (b) in the case of a non-corporate entity, direct or indirect ownership of at least fifty percent (50%) of the equity interests with the power to direct the management and policies of such entity.

1.60. "**Cover**," "**Covering**," or "**Covered**" means, with respect to a product, technology, process, method, or mode of administration that, in the absence of ownership of, or a license granted under, a particular claim in a patent or patent application, the manufacture, use, offer for sale, sale, or importation of such product, or the practice of such technology, process, method, or mode of administration, would infringe such claim or, in the case of a claim that has not yet issued, would infringe such claim if it were to issue.

1.61. "**CTA**" means a Clinical Trial Application in the countries that are officially recognized as member states of the European Union.

1.62. **"Data Protection Laws"** means all Applicable Laws related to data protection and privacy, including the EU Data Protection Laws, the Health Insurance Portability and Accountability Act of 1996, and any supranational, federal, state, or national legislation relating to Personally Identifiable Information or privacy that is applicable to a Party relating to the processing of Personally Identifiable Information.

1.63. "**Debarred**" has the meaning set forth in Section 11.1.6 (Mutual Representations and Warranties of the Parties).

1.64. "**Defending Party**" has the meaning set forth in Section 10.2.2(c) (Defense of Patent Rights).

1.65. "**Deliverables**" means any and all deliverables to be generated or provided by or on behalf of a Party in connection with the performance of any activities set forth in the Global Development Plan.

1.66. "**Develop**" or "**Development**" means all internal and external research, development, and regulatory activities related to pharmaceutical products, including (a) research, toxicology, non-clinical, and preclinical testing and activities, Clinical Trials, drug substance and drug product process development, product and process characterization, product and process qualification and validation, qualification and validation and stability testing of product from development, qualification, or validation batches, quality assurance and quality control of development, qualification, or validation batches, clinical studies, statistical analysis, and report writing and (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials or to obtain, support, or maintain Regulatory Approval of a pharmaceutical product, and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or region for such pharmaceutical product regarding the foregoing, including all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval, but expressly excluding activities directed to Manufacturing, Medical Affairs, or Commercialization. Development will include any Clinical Trials to be conducted after receipt of Regulatory Approval (such as post-marketing studies and observational studies) and development and regulatory activities for additional forms, formulations, or Indications for a pharmaceutical product after receipt of Regulatory Approval of such product (including label expansion). Further, Development will include importing or exporting (including having imported or having exported) pharmaceutical products for purposes of development. "**Developing**," "**Development**" and "**Developed**" will be construed accordingly.

1.67. "**Development FTE Costs**" means, for a given period, the Development FTE Rate multiplied by the number of FTEs actually expended to conduct Development activities under this Agreement during such period. FTEs will be pro-rated on a daily basis if necessary.

1.68. "**Development FTE Rate**" means [**] dollars ($[**]) per FTE for the Calendar Year 2020. The Development FTE Rate shall be adjusted for each Calendar Year commencing with the Calendar Year 2021 and, unless otherwise agreed in writing by the Parties, shall be the prior year's rate, increased or decreased by the relevant percentage increase or decrease based on the Employment Cost Index provided by the U.S. Department of Labor (Series ID: CIU 1010000000000A); except that the Development FTE Rate in any given Calendar Year may not increase by an amount more than [**] percent ([**]%) of the prior year's Development FTE Rate.

1.69. "**Development Milestone Event**" has the meaning set forth in Section 9.3 (Development Milestones).

1.70. "**Development Milestone Payment**" has the meaning set forth in Section 9.3 (Development Milestones).

1.71. "**Development Reimbursement Payments**" has the meaning set forth in Section 9.2 (Development Reimbursement Payments).

1.72. "**Disclosing Party**" has the meaning set forth in Section 13.1 (Confidential Information).

1.73. "**Disputes**" has the meaning set forth in Section 16.3 (Resolution by Executive Officers).

1.74. "**Dollar**" means the U.S. dollar, and "$" or "USD" will be interpreted accordingly.

1.75. "**Drug Approval Application**" means any marketing authorization application, in each case, filed with the applicable Regulatory Authority in a country or other regulatory jurisdiction, which application is required to market or sell a pharmaceutical product in such country or jurisdiction (and any amendments thereto), including all NDAs and any analogous application or submission with any Regulatory Authority outside of the U.S., including, with respect to the European Union, MAAs.

1.76. "**DTPA**" means that certain Data Transfer and Processing Agreement entered into by the Parties on the Effective Date.

1.77. "**Effective Date**" has the meaning set forth in the Preamble.

1.78. "**EMA**" means the European Medicines Agency and any successor agency thereto and, with respect to any Regulatory Approval in the European Union, includes the European Commission.

1.79. "**EMA PNH Regulatory Approval**" means the first Drug Approval Application (and associated orphan drug designation and pediatric investigation plan) filed with the EMA for the first Product in PNH.

1.80. "**[**]**" means [**].

1.81. "**[**] Agreement**" means the [**] Agreement by and between Apellis US and [**], dated as of [**].

1.82. "**[**]**" means [**].

1.83. "**[**] Agreement**" means that certain [**] Agreement, dated as of [**], by and between Apellis and [**], as amended from time to time.

1.84. "**[**]**" means [**].

1.85. "**[**] Agreement**" means the [**] Agreement for Activated PEG by and between Apellis US and [**] dated as of [**].

1.86. "**Executive Officer**" has the meaning set forth in Section 3.7.2 (Escalation to JEC).

1.87. "**Existing Agreements**" means (a) the SFJ Agreement and (b) the Penn Other Fields License Agreement.

1.88. "**Existing CDA**" means the Confidentiality Agreement by and between Apellis Pharmaceuticals, Inc. and Sobi, dated as of [**], as amended by Amendment No. 1 to Confidentiality Agreement, dated as of [**].

1.89. "**Existing Manufacturing Agreement**" means each of (a) the [**] Agreement, (b) the [**] Agreement, (c) the [**] Agreement, (d) the [**] Agreement, (e) the [**] APL-1 Agreement, and (f) the [**] APL-2 Agreement.

1.90. "**Exploit**" means to Develop, have Developed, make, have made, use, have used, perform Medical Affairs, have performed Medical Affairs, offer for sale, have offered for sale, sell, have sold, export, have exported, import, have imported, Manufacture, have Manufactured, Commercialize, have Commercialized, or otherwise exploit. "**Exploitation**" and "**Exploiting**" will be construed accordingly.

1.91. "**EU Data Protection Law**" means the EU General Data Protection Regulation 2016/679 ("**GDPR**") (and its derivatives), Directive 2002/58/EC (as transposed into domestic legislation of each European Union Member State or Member State of the EEA) and any other applicable data protection laws, regulations, codes of practice, codes of conduct, guidance issued by any relevant Supervisory Authority in the relevant European Union Member State or Member State of the EEA relating to the protection of natural persons with regard to Personal Data, privacy, or amending, implementing, replacing, or superseding any of the foregoing and including, for clarity, the UK Data Protection Act 2018 and any implementing, replacing or superseding laws of the United Kingdom as a result of the exit by the United Kingdom from the European Union, or, and to the extent applicable, the applicable data protection or privacy laws of any other country including, without limitation, Switzerland.

1.92. "**Failure to Supply**" means (a) Apellis' (i) failure to deliver under the Supply Agreement at least [**] percent ([**]%) of Compound or Product in a Purchase Order on at least [**] occasions or (ii) delivery delays beyond the applicable Delivery Date(s) under the Supply Agreement for Purchase Orders of at least [**] in the aggregate, in each case ((i) and (ii)) in any consecutive [**] period in a Calendar Year or (b) an interruption in the supply of Compound or Product to Sobi under the Supply Agreement that directly results in an outage of Compound or Product in the Sobi Territory of at least [**] through no breach by Sobi of its obligations under the Supply Agreement that causes, or directly results in, such outage.

1.93. "**FD&C Act**" means the U.S. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended from time to time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.94. "**FDA**" means the U.S. Food and Drug Administration and any successor thereto.

1.95. "**Field**" means any and all uses, applications, and Indications.

1.96. "**Finished Form**" means a Product supplied in finished form, ready for distribution in an applicable country in compliance with all Applicable Law in such country at the relevant time, including all applicable primary, secondary, or tertiary packaging and labeling of such Product (in its commercial packaging presentation) for sale or use in the applicable country, including: (a) the Regulatory Authority-approved full prescribing information for such Product in the applicable country; (b) the Regulatory Authority-approved labels and other written, printed, or graphic materials on any container, wrapper, or any package insert that is used with or for such Product in such country; and (c) insertion of materials such as patient inserts, patient medication guides, and professional inserts, and any other written, printed, or graphic materials accompanying such Product, including any additional information and materials necessary to comply with serialization requirements in the applicable country, and any brand security or anti-counterfeiting measures included in the packaging elements for such Product considered to be part of the finished packaged Product, and all testing and release thereof.

1.97. "**First Commercial Sale**" means, with respect to a Product in a country, the first sale of such Product by a Party, its Affiliates, sub/licensees, or Sublicensees to a Third Party (other than a sub/licensee or Sublicensee) for sale to, or use or consumption by, an end user in such country following Regulatory Approval and, to the extent required, Reimbursement Approval of such Product in such country, excluding any such sales of a Product to Third Parties for any expanded access program or compassionate sales or use program (including any named patient program or single patient program), and excluding any transfers of a Product to Third Parties for the performance of Clinical Trials.

1.98. "**FTE**" means a qualified full time person, or more than one person working the equivalent of a full-time person, where "full time" is based upon a total of [**] working hours per Calendar Year of Development or Manufacturing work carried out by one (1) or more duly qualified employees of a Party. Overtime, and work on weekends, holidays, and the like will not be counted with any multiplier (*e.g.*, time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution. The Parties may agree to utilize fractions of FTEs, if applicable.

1.99. "**Functional Sublicensee**" means, on a Product-by-Product and country-by-country basis in the Sobi Territory, a Subcontractor appointed as distributor by Sobi or any of its Affiliates or Sublicensees of a Product in such country where (a) such Subcontractor is primarily responsible for Commercialization activities with respect to such Product in such country and (b) the gross amount invoiced to such Subcontractor by Sobi or any of its Affiliates or Sublicensees with respect to such Product in such country is less than [**] percent ([**]%) of the gross amount invoiced by such Subcontractor to Third Parties for such Product in such country (but, if such amount is not available to Sobi despite Sobi having used Commercially Reasonable Efforts to obtain it, and the Parties are unable to agree upon such amount, the Parties shall submit such dispute for resolution to a mutually agreed independent accounting expert, whose decision will be final and binding on the Parties).

1.100. "**GAAP**" means U.S. generally accepted accounting principles, which principles are used at the relevant time and consistently applied by the applicable Person.

1.101. "**GDPR**" shall mean Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

1.102. "**Global Branding Strategy**" means the global messaging and branding strategy established in accordance with this Agreement for each Product throughout the world for at least the following [**], including with respect to positioning, messaging, branding, packaging, and labeling (including logo, colors, and other visual branding elements).

1.103. "**Global Development Activities**" means all Development activities conducted under the Global Development Plan. For clarity, Global Development Activities do not include the Apellis Territory Regional Development Activities or the Sobi Territory Regional Development Activities.

1.104. "**Global Development Budget**" has the meaning set forth in Section 4.4.1 (Global Development Plan).

1.105. "**Global Development Plan**" has the meaning set forth in Section 4.4.1 (Global Development Plan).

1.106. "**GLP Toxicology Study**" means a toxicology study (a) that is conducted using applicable GLP, (b) that is conducted in a species that satisfies applicable regulatory requirements, and (c) the data and results from which are intended to meet the standards necessary for submission as part of, or otherwise to enable the submission of, an IND, CTA, or Drug Approval Application with an applicable Regulatory Authority.

1.107. "**Good Clinical Practices**" or "**GCP**" means all applicable current good clinical practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of Clinical Trials, including, as applicable, (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other applicable guidelines for good clinical practice for trials on medicinal products anywhere in the world, (b) the Declaration of Helsinki (2013) as last amended at the 64th World Medical Association in October 2013 and any further amendments or clarifications thereto, (c) C.F.R. Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), and 312 (Investigational New Drug Application), as may be amended from time to time, and (d) any equivalent Applicable Law in any relevant country, each as may be amended and applicable from time to time, and, in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate, and protect the rights, integrity, and confidentiality of trial subjects.

1.108. "**Good Laboratory Practices**" or "**GLP**" means all applicable current good laboratory practice standards, including, as applicable, as set forth in the then-current good laboratory practice standards promulgated or endorsed by the FDA, as defined in 21 C.F.R. Part 58, and any equivalent Applicable Law in any relevant country or region, each as may be amended and applicable from time to time.

1.109. "**Good Manufacturing Practices**" or "**GMP**" means all applicable current good manufacturing practices, including, as applicable, the principles detailed in (a) the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) the International Conference on Harmonization's Q7 guidelines, and (d) any equivalent Applicable Law in any relevant country or region, in each case, as may be amended and applicable from time to time.

1.110. "**Good Pharmacovigilance Practices**" or "**GVP**" means all applicable current good pharmacovigilance practice practices promulgated or endorsed by any applicable Regulatory

Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be amended and applicable from time to time.

1.111. "**Governmental Authority**" means any court, tribunal, arbitrator, agency, commission, department, ministry, official, authority, or other instrumentality of any national, supra-national, federal, state, county, city, or other political subdivision.

1.112. "**Government Official**" is broadly defined as, and includes, (a) any elected or appointed government official (*e.g.*, a member of a ministry of health), (b) any employee or Person acting for or on behalf of a government official, agency, or enterprise performing a governmental function, (c) any non-U.S. political party officer, employee, or Person acting for or on behalf of a non-U.S. political party or candidate for public office, (d) any employee or Person acting for or on behalf of a public international organization, (e) all government employees and employees of state-owned enterprises, or (f) any Person otherwise categorized as a government official under local Applicable Laws, where "government" is meant to include all levels and subdivisions of non-U.S. governments (*i.e.*, local, regional, or national, and administrative, legislative, or executive).

1.113. "**Gross Sales**" has the meaning set forth in Section 1.149 (Net Sales).

1.114. "**ICH**" means International Conference on Harmonization.

1.115. "**IFRS**" means international financial reporting standards, which standards are used at the relevant time and consistently applied by the applicable Person.

1.116. "**IND**" means an Investigational New Drug application required pursuant to 21 C.F.R. Part 312 or any comparable filings (other than any CTA) outside of the U.S. required to commence Clinical Trials in such country or region, and all supplements or amendments that may be filed with respect to the foregoing.

1.117. "**Indemnification Claim Notice**" has the meaning set forth in Section 12.3.1 (Notice of Claim).

1.118. "**Indemnified Party**" has the meaning set forth in Section 12.3.1 (Notice of Claim).

1.119. "**Indemnifying Party**" has the meaning set forth in Section 12.3.1 (Notice of Claim).

1.120. "**Indemnitee**" and "**Indemnitees**" have the meanings set forth in Section 12.3.1 (Notice of Claim).

1.121. "**Indication**" means a separate and distinct disease or pathological condition for which a Product can be used to diagnose, treat, or prevent, which use is the subject of a separate Regulatory Approval for a distinct labelling supported by data from at least one (1) Clinical Trial not previously submitted to the applicable Regulatory Authority in a country for approval to use the Product to diagnose, treat, or prevent the disease or pathological condition. For clarity, subpopulations or patients with a primary disease, disorder, or condition, however stratified, shall not be deemed to be separate.

1.122. "**Initial Indications**" means the following Indications: PNH, CAD, C3G, TMA and ALS.

1.123. "**Intellectual Property**" means all Patent Rights, copyrights, design rights, trademarks, trade secrets, Know-How, Patent Term Extensions, and all other intellectual property rights (whether registered or unregistered) and all applications and rights to apply for any of the foregoing, anywhere in the world.

1.124. "**JCC**" or "**Joint Commercialization Committee**" has the meaning set forth in Section 3.2.4 (Subcommittees).

1.125. "**JDC**" or "**Joint Development Committee**" has the meaning set forth in Section 3.2.4 (Subcommittees).

1.126. "**JEC**" or "**Joint Executive Committee**" has the meaning set forth in Section 3.2.1 (Formation).

1.127. "**JMC**" or "**Joint Medical Committee**" has the meaning set forth in Section 3.2.4 (Subcommittees).

1.128. "**JMSC**" or "**Joint Manufacturing and Supply Committee**" has the meaning set forth in Section 3.2.4 (Subcommittees).

1.129. "**Joint Know-How**" means any Collaboration Know-How made, invented, conceived, discovered, developed, or otherwise generated jointly by a Party's or any of its Affiliates', sub/licensees', Sublicensees', or Subcontractors' employees, agents, or independent contractors, or any Person contractually required to assign or license such Collaboration Know-How to such Party or any Affiliate of such Party, on the one hand, and the other Party's or any of its Affiliates', sub/licensees', Sublicensees', or Subcontractors' employees, agents, or independent contractors, or any Person contractually required to assign or license such Collaboration Know-How to such Party or any Affiliate of such Party, on the other hand.

1.130. "**Joint Patent Right**" means any Patent Right that Covers or claims any Joint Know-How.

1.131. "**Joint Technology**" means the Joint Know-How and the Joint Patent Rights.

1.132. "**Know-How**" means (a) any commercial, technical, scientific, or other know-how or information, knowledge, practices, instructions, skills, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, records, improvements, modifications, techniques, assays, physical, chemical or biological materials, designs, protocols, formulas, data (including physical data, chemical data, toxicology data, animal data, raw data, clinical data, analytical and quality control data, Manufacturing data and know how, regulatory data, study designs, and protocols), dosage regimens, control assays, assay standards and references, cells, cell lines, animal models, product specifications, marketing, pricing and distribution costs, inventions, processes, methods, utilities, formulations, compositions of matter, articles of Manufacture, creations, discoveries, findings, algorithms, technology, forecasts, profiles, strategies, plans, results in any form whatsoever, know-how, and trade secrets (in each case, whether or not patentable, copyrightable, or otherwise protectable), and (b) any physical embodiments of any of the foregoing.

1.133. "**License**" has the meaning set forth in Section 2.1.1 (License Grants to Sobi).

1.134. "**Licensed Manufacturer IP**" means (a) under the [**] Agreement, any [**] IP that [**] incorporates into the Services (as defined in the [**] Agreement) or any deliverable under the [**] Agreement; (b) under the [**] Agreement, any intellectual property discovered or developed by [**] or jointly with Apellis US in the performance of the Services (as defined in the [**] Agreement), that is not specific to or is severable from the Product; and (c) under the [**] APL-1 Agreement, any [**] Pre-Existing IP (as defined in the [**] APL-1 Agreement) that [**] incorporates into the Services (as defined in the [**] APL-1 Agreement) or deliverables under the [**] APL-1 Agreement.

1.135. "**Losses**" has the meaning set forth in Section 12.1 (Indemnification by Apellis).

1.136. "**MAA**" means, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the Centralized Approval Procedure or with the applicable Regulatory Authority of a country in Europe pursuant to the mutual recognition, de-centralised, or any other national approval procedure.

1.137. "**Major European Countries**" means France, Germany, Italy, Spain, and the United Kingdom.

1.138. "**Major Market**" means each of [**].

1.139. "**Manufacture**" means activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, release (according to Product specifications, Regulatory Approvals, and Applicable Law), shipping, or storage of any pharmaceutical product (or any components or process steps involving any pharmaceutical product or any companion diagnostic), placebo, or comparator agent, as the case may be, including stability testing, but excluding activities directed to Development, Medical Affairs, or Commercialization. "**Manufacturing**" and "**Manufactured**" will be construed accordingly.

1.140. "**Manufacturing and Supply Chain Plan**" has the meaning set forth in Section 8.1 (Manufacturing and Supply Chain Plan).

1.141. "**Manufacturing Costs**" means (i) the actual price paid by Apellis to any Third Party manufacturer, on the terms of the applicable Apellis Supply Agreement, and (ii) fully allocated Manufacturing overhead and any reasonable internal and external costs or expenses incurred by Apellis in contracting with, managing, and overseeing such Third Party manufacturer, at the Manufacturing FTE Costs, in each case of subclauses (i) and (ii) to the extent attributable for Manufacturing and supply activities for Compounds and Products for supply to Sobi or its Affiliates or Sublicensees for Commercialization in the Sobi Territory or clinical Development pursuant to this Agreement (which, for clarity, with respect to the actual price paid by Apellis to any Third Party manufacturer, includes any discounts or cost reductions received by Apellis from such Third Party, including *pro rata* portions of such discounts or such cost reductions received with respect to Apellis' general Manufacture and supply relationship with such Third Party that are attributable to such Compounds and Products in or for the Sobi Territory), and *pro rata* portions of costs of storage, packaging, and shipping of such Compounds and Products, including *pro rata* portions of the costs listed below to the extent related to Manufacturing and supply activities for Compounds and Products for supply to Sobi or its Affiliates or Sublicensees for Commercialization in the Sobi Territory or clinical Development pursuant to this Agreement:

(a) any pass-through acquisition costs charged by such Third Party, together with any mark-up charged by such Third Party in relation thereto, for the purchase of raw materials;

(b) costs of loss of Drug Substance or activated PEG resulting from any failed batches to the extent actually incurred or written off by Apellis;

(c) any fees charged by such Third Party for forfeited reservations for unused slots due to failed batches;

(d) any fees charged by such Third Party relating to quality control (including stability), quality assurance, compliance, analytical, or other testing of such Product or any raw materials used in the Manufacture of such Product;

(e) any fees charged by any Third Party relating to storage, packaging, handling, transportation, shipping, insurance, and disposal;

(f) any fees charged by such Third Party relating to an allocation of idle or reserved capacity, but only to the extent such capacity was mutually agreed by the Parties;

(g) the cost of validation batches produced in the course of Manufacturing process validation that are used in clinical or commercial supply by or on behalf of Sobi or any of its Affiliates or Sublicensees;

(h) any costs of process development or capital investments in facilities or equipment that are incurred by an applicable Third Party manufacturer and passed through to Apellis or its Affiliates through an increase in the costs of Compounds or Products (or raw materials) purchased, directly or indirectly, by Apellis or its Affiliates from such Third Party manufacturer to the extent such costs are approved pursuant to Section 8.9.1 (Cost Sharing) or deemed approved by Sobi pursuant to Section 8.9.1(a)(i) (Cost Sharing);

(i) importation and exportation duties, fees, VAT, and other taxes, net of refunds and other offsets; and

(j) all fees charged by such Third Party relating to Product and raw material testing and yield loss costs (to the extent within typical yield loss, as agreed by the Parties and set forth in the Supply Agreement),

in each case to the extent actually incurred for the Manufacture and supply of Compounds and Products for Sobi or its Affiliates or Sublicensees for Commercialization in the Sobi Territory or clinical Development pursuant to this Agreement.

For the purposes of this definition, Article 8 (Manufacturing), and Schedule 8.6 (Supply Agreement Material Terms), "*pro rata*" shall have the meaning given to it in the Supply Agreement or, with respect to the period prior to execution of the Supply Agreement, as may be determined in accordance with Section 8.9 (Manufacturing Process Costs).

1.142. "**Manufacturing FTE Costs**" means [**] dollars ($[**]) per FTE for the Calendar Year 2020 (the "**Manufacturing FTE Rate**") (which shall be adjusted for each Calendar Year commencing with the Calendar Year 2021 and, unless otherwise agreed in writing by the Parties, shall be the prior year's rate, increased or decreased by the relevant percentage increase or decrease based on the Employment Cost Index provided by the U.S. Department of Labor (Series ID: CIU 1010000000000A); except that the Manufacturing FTE Rate in any given Calendar Year may not increase by an amount more than [**] percent ([**]%) of the prior year's Manufacturing FTE Rate) multiplied by the number of FTEs actually expended to conduct Manufacturing activities under this Agreement during such period. FTEs will be pro-rated on a daily basis if necessary

1.143. "**Manufacturing Know-How**" has the meaning set forth in Section 8.3 (Manufacturing Technical Transfer).

1.144. "**Manufacturing Process Costs**" has the meaning set forth in Section 8.9 (Manufacturing Process Costs).

1.145. "**Medical Affairs**" means activities conducted by a Party's medical affairs department (or, if a Party does not have a medical affairs department, the equivalent thereof), including communications with key opinion leaders and other healthcare providers, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), activities performed in connection with patient registries, expanded access programs, including early access programs, named patient programs, and compassionate use, real world evidence generation (excluding Clinical Trials), health economics and outcomes research, medical information, publications, advocacy, and other medical programs and communications, including educational grants and sponsorships, research grants (including conducting investigator-initiated studies), and charitable donations, in each case to the extent related to medical affairs and not to other activities that involve the promotion, marketing, sale, or other Commercialization of pharmaceutical products and are not conducted by a Party's medical affairs (or equivalent) departments; but excluding activities directed to Manufacturing, Development, or Commercialization (except that sponsorships may be conducted as Commercialization activities or Medical Affairs activities).

1.146. "**Medical Affairs Strategy**" has the meaning set forth in Section 7.1 (Medical Affairs Strategy).

1.147. "**Medical Education Materials**" means all written medical education materials relating to any condition treated with a Product, and other printed, graphic, electronic, audio, video, or other media and materials, in each case used to educate patients, healthcare professionals, payers, and the public regarding a Product or any Indication treated with a Product.

1.148. "**NDA**" means a New Drug Application, as defined in the FD&C Act, submitted to the FDA in the U.S. in accordance with the FD&C Act with respect to a pharmaceutical product.

1.149. "**Net Sales**" means, with respect to a Product and country, (x) the gross amount invoiced in a country by Sobi or any of its Affiliates or Sublicensees or (y) if such Product is sold by a Functional Sublicensee on behalf of Sobi or any of its Affiliates or Sublicensees, (i) in any of Canada, Japan, China, Australia, the United Kingdom, or any country in the European Union, the gross amount invoiced in such country by such Functional Sublicensee or (ii) in any country not listed in clause (i), the greater of (A) the gross amount invoiced to such Functional Sublicensee by Sobi or any of its Affiliates or Sublicensees or (B) [**] percent ([**]%) of the gross amount invoiced in such country by such Functional Sublicensee (but, if such amount is not available to Sobi despite Sobi having used Commercially Reasonable Efforts to obtain it, and the Parties are unable to agree upon such amount, the Parties shall submit such dispute for resolution to a mutually agreed independent accounting expert, whose decision will be final and binding on the Parties) (Sobi and each of its Affiliates, Sublicensees, and Functional Sublicensees, a "**Selling Party**," as applicable) for the sale, use, lease, transfer, or other disposition of such Product in such country to Third Parties (excluding any milestones or payments not linked to the sale, use, lease, transfer, or other disposition of such Product) ("**Gross Sales**"), in each case ((x) and (y)) less the following accrued costs and expenses that are directly attributable to the applicable disposition, specifically identified on an invoice or other documentation, indefeasibly paid to a Third Party, net of any refunds or offsets specific to Products, and actually borne by the applicable Selling Party (collectively, "**Sales Returns and Allowances**"):

(a) trade, cash, and quantity discounts (*e.g.*, discounts for prompt or timely payment);

(b) inventory management fees paid to wholesalers and distributors, not to exceed [**] percent ([**]%) of Net Sales;

(c) credits, chargebacks, retroactive price reductions, rebates, refunds, returns that do not exceed the original invoice amount;

(d) outbound transportation and insurance expenses;

(e) sales and use taxes, tariffs, customs duties, excises, and other taxes and fees imposed by a Governmental Authority on the sale, transportation, or delivery of a Product (other than taxes on income);

(f) negotiated payments made to private sector and government Third Party payors (*e.g.*, PBMs, HMOs, PPOs) and purchasers or providers (*e.g.*, staff model HMOs, hospitals, clinics), regardless of the payment mechanism, including rebate, chargeback, and credit mechanisms;

(g) discounts under discount prescription drug programs and reductions for coupon and voucher programs; and

(h) bad debts calculated in accordance with Accounting Standards, except that any reductions to bad debts previously deducted from Gross Sales will become an add back to Net Sales in the Calendar Quarter in which the reduction in bad debt is recognized.

Such amounts will be determined consistent with the applicable Selling Party's customary practices and Accounting Standards. All deductions will be applied on a non-duplicative basis.

Notwithstanding anything to the contrary in the foregoing, "Net Sales" will only include sales of Products to a Third Party for any expanded access program or compassionate sales or use program (including any named patient program or single patient program) to the extent such sales are above cost.

For the purposes of calculating and reporting the Net Sales in any country in which the Product is Commercialized via a Functional Sublicensee under Section 1.149(y) (Net Sales), Sobi will use Commercially Reasonable Efforts to provide reasonable estimates of such Net Sales for such country at the end of each Calendar Quarter, *provided that*, at the end of the fourth (4th) Calendar Quarter in each year in the Term, Sobi shall use Commercially Reasonable Efforts to procure the actual amounts of such Net Sales in such country in such Calendar Year and, if such actual amounts are obtained by Sobi, Sobi shall perform a true-up of such quarterly estimates of Net Sales for such country, following which the Parties shall coordinate in good faith to implement any required adjustment to the Net Sales for such country for such period for the purposes of this Agreement.

Notwithstanding anything to the contrary in the foregoing, "Net Sales" will not include any sales at or below cost for test marketing, pre-clinical or clinical studies, or disposition of samples in customary quantities.

If non-monetary consideration is received by a Selling Party for any Product, Net Sales for such transaction will be calculated based on the fair market value of such non-monetary consideration (calculated as the cash consideration that the applicable Selling Party would realize

from an unrelated buyer in arm's length sale of an identical item sold in the same quantity and at the same time and place of the transaction), as determined by the Parties in good faith. If the Parties are unable to agree on the fair market value, then the dispute will be resolved in accordance with Article 16 (Dispute Resolution).

Except as expressly set forth in Section 1.149(y)(ii)(A) (Net Sales), Sales or transfers of Products between any of the Selling Parties will not result in any Net Sales, with Net Sales to be based only on any subsequent sales or dispositions to a non-Selling Party.

In the case of a Combination Product containing a given Compound, Net Sales for purposes of determining payments hereunder attributable to the Product from the sale, use, lease, transfer, or other disposition of such Combination Product shall be determined by multiplying Net Sales of the Combination Product by the fraction A/(A+B), where A is the weighted (by sales volume) average sales price of a Product containing, as its sole active ingredient, such Compound when sold separately in Finished Form (the "**Non-Combination Product**") and B is the weighted average sale price of the other active ingredient(s) sold separately in finished form, in each case during the applicable royalty reporting period or, if sales of both the Non-Combination Product and the other active ingredient(s) did not occur in such period, then in the most recent royalty reporting period in which sales of both occurred; *provided that* the value attributed to the Non-Combination Product as a component of the Combination Product resulting from such calculation shall never be less than the weighted (by sales volume) average sales price of the Non-Combination Product when sold separately in Finished Form. In the event that such average sales price cannot be determined for both the Non-Combination Product and the other active ingredient(s) in combination, Net Sales for purposes of determining payments hereunder shall be mutually agreed by the Parties based on the relative value contributed by each component, and such agreement shall not be unreasonably withheld, provided if the Parties are unable to agree, the same shall be subject to the baseball arbitration procedure set forth in Section 16.5.1 (Baseball Arbitration).

1.150. "**Neutral Safety Committee**" has the meaning set forth in Section 16.4 (Neutral Safety Committee).

1.151. "**[**]**" means [**].

1.152. "**[**] Agreement**" means the [**] Agreement by and between Apellis US and [**], dated as of [**].

1.153. "**Non-Proposing Party**" has the meaning set forth in Section 4.4.4(b)(i) (Unilateral Development Activities) or Section 4.8.1 (Combination Therapy Development), as applicable.

1.154. "**Non-Systemic Ophthalmology Product**" means any product in any form, formulation, or presentation containing, incorporating, consisting of, or comprising a Compound as an active ingredient that is (a) formulated, approved, or marketed for diseases that have, as their primary association, an association to the eye and (b) not administered systemically.

1.155. "**Out-of-Pocket Costs**" means, with respect to activities conducted in accordance with this Agreement, direct *bona fide* costs, fees, or expenses paid by a Party or its Affiliates to Third Parties (or payable to Third Parties and accrued in accordance with Accounting Standards) and specifically identifiable and incurred to conduct such activities, including any such payments to Subcontractors.

1.156. "**Party**" and "**Parties**" has the meaning set forth in the Preamble.

1.157. "**Party Vote**" has the meaning set forth in Section 3.7.1 (Voting; Consensus).

1.158. "**Patent Rights**" means any and all (a) patents, (b) patent applications, including all provisional and non-provisional applications, priority applications, patent cooperation treaty (PCT) applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patents granted thereon, (c) all patents-of-addition, confirmation patents or registration patents, reissues, re-examinations, utility models or designs, renewals, and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates and equivalents thereof, (d) inventor's certificates or letters patent, or (e) other substantially equivalent forms of government-issued rights substantially similar to any of the foregoing described in subsections (a) through (d) above, anywhere in the world.

1.159. "**Patent Term Extension**" means any patent term extension under 35 U.S.C. §156 or any non-U.S. counterpart or equivalent of the foregoing, including supplementary protection certificates and any other extensions that are available as of the Effective Date or become available during the Term.

1.160. "**Penn**" means The Trustees of the University of Pennsylvania.

1.161. "**Penn Other Fields License Agreement**" means that certain Patent License Agreement, dated as of March 28, 2008, by and between Apellis (as successor to Apellis AG) and Penn, as amended on September 11, 2009 and as further amended from time to time.

1.162. "**Person**" means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, Governmental Authority, association, or other entity.

1.163. "**Personally Identifiable Information**" means any information relating to an identified or, in combination with other information, identifiable person or persons captured in an electronic or hardcopy format, including such information as it relates to clinical study or Clinical Trial subjects (including key-coded patient data), physicians, clinicians, healthcare professionals, consultants, or other persons participating in any clinical study or Clinical Trial, and any equivalent definition in any Applicable Law to the extent that such definition is broader than that provided here, including, solely with respect to individuals afforded protections under the EU Data Protection Laws, the definition of "personal data" under the GDPR.

1.164. "**Phase III Clinical Trial**" means a human clinical trial of a pharmaceutical product in any country that would satisfy the requirements of 21 C.F.R. § 312.21(c), as amended (or the non-United States equivalent thereof).

1.165. "**PNH**" means paroxysmal nocturnal hemoglobinuria.

1.166. "**PNH Phase III Clinical Trial**" means each of the following Phase III Clinical Trials: (a) APL2-308: "A Phase III Study to Evaluate the Efficacy and Safety of APL-2 in Patients with PNH" (NCT04085601) and (b) APL2-302: "Study to Evaluate the Efficacy and Safety of APL-2 in Patients with PNH" (NCT03500549).

1.167. "**Product**" means any pharmaceutical product in any form, formulation, or presentation containing, incorporating, consisting of, or comprising a Compound as an active ingredient; *but excluding* all Non-Systemic Ophthalmology Products.

1.168. "**Product Trademarks**" has the meaning set forth in Section 6.9 (Product Trademarks).

1.169. "**Promotional Materials**" means all marketing materials, grants, sponsorships, and all written, printed, graphic, electronic, audio or video media, or other materials, including journal advertisements, sales visual aids, leave-behind items, formulary binders, reprints, direct mail, direct-to-consumer advertising, internet postings and sites, and broadcast advertisements intended for use or used by or on behalf of either Party or their Affiliates to market or promote any Product or educate the public regarding any Product or any Indication treated with any Product; *but excluding* all Medical Education Materials.

1.170. "**Proposing Party**" has the meaning set forth in Section 4.4.4 (Additional Development) or Section 4.8.1 (Combination Therapy Development), as applicable.

1.171. "**Prosecute**" has the meaning set forth in Section 10.2.1(b) (Prosecution Rights).

1.172. "**Prosecuting Party**" has the meaning set forth in Section 10.2.1(d) (Prosecution Rights).

1.173. "**Qualified Safety Expert**" means any scientist (a) with at least [**] of applicable pharmaceutical safety experience, (b) who has not worked for or been engaged by any Party or any of either Party's Affiliates in the [**] period immediately prior to the formation of the applicable Neutral Safety Committee, and (c) who does not own more than [**] percent ([**]%) of the outstanding equity in any Party or any of either Party's Affiliates.

1.174. "**Receiving Party**" has the meaning set forth in Section 13.1 (Confidential Information).

1.175. "**Regional Development Activities**" means, as applicable, the Apellis Territory Regional Development Activities and the Sobi Territory Regional Development Activities.

1.176. "**Regulatory Approval**" means, with respect to a particular country or other regulatory jurisdiction, all approvals, product or establishment licenses, registrations, or authorizations (including approval of a Drug Approval Application or any label update or other modification to an existing Regulatory Approval) of all applicable Regulatory Authorities in such country or jurisdiction necessary for the commercial marketing or sale of a pharmaceutical product in such country or other regulatory jurisdiction for one (1) or more Indications, excluding Reimbursement Approval.

1.177. "**Regulatory Authority**" means any applicable Governmental Authority with jurisdiction or authority over the Development, Manufacture, Commercialization, or other Exploitation (including Regulatory Approvals) of pharmaceutical products, and any corresponding national or regional regulatory authorities.

1.178. "**Regulatory Data**" means any and all research data, pharmacology data, CMC data, preclinical and nonclinical data, and clinical data, and all other documentation submitted, or required to be submitted, to Regulatory Authorities to support, obtain, or maintain any Regulatory Approval for a pharmaceutical product or administration device, or otherwise included in any Regulatory Submissions for a pharmaceutical product or administration device, including clinical studies' and Clinical Trials' final protocols, final study reports, statistical analysis plans, and results thereof.

1.179. "**Regulatory Exclusivity**" means, with respect to a Product in a country, any exclusive marketing right, data protection, or other exclusive right, other than a Patent Right, conferred by any Governmental Authority with respect to such Product in such country, including any new drug exclusivity, new indication or use exclusivity, pediatric exclusivity, or orphan drug exclusivity.

1.180. "**Regulatory/Reimbursement Responsible Party**" means, with respect to a given Product in a given country or regulatory jurisdiction, the Party responsible for regulatory and reimbursement activities and obligations with respect to such Product in such country or regulatory jurisdiction, including, for clarity, applicable regulatory and reimbursement activities for a Product after receipt of Regulatory Approval or Reimbursement Approval for such Product.

1.181. "**Regulatory Submission**" means any filing, application, or submission with any Regulatory Authority or other applicable Government Authority in support of the Development, Manufacture, Commercialization, or other Exploitation of a pharmaceutical product (including to obtain, support, or maintain Regulatory Approval from such Regulatory Authority or other Governmental Authority), and all formal and informal, written or electronic correspondence or communications with or from the relevant Regulatory Authority or other Governmental Authority, as well as minutes of any material meetings, telephone conferences, or discussions with the relevant Regulatory Authority or other Governmental Authority. Regulatory Submissions include all INDs, CTAs, Drug Approval Applications, other applications for Regulatory Approval.

1.182. "**Reimbursement Approval**" means any approval, agreement, determination, or other decision by the applicable Governmental Authority in a given country or other regulatory jurisdiction that establishes prices charged to end-users for a given pharmaceutical product at which such pharmaceutical product will be reimbursed by the applicable Governmental Authorities in such country or regulatory jurisdiction.

1.183. "**Reimbursement Submission**" means any filing, application, or submission with any applicable Government Authority to obtain, support, or maintain Reimbursement Approval from such Governmental Authority, and all formal and informal, written or electronic correspondence or communications with or from the relevant Governmental Authority, as well as minutes of any material meetings, telephone conferences, or discussions with the relevant Governmental Authority.

1.184. "**Results**" means all (a) results, information, data, presentations, summaries, and analyses that are generated pursuant to, or prepared as a result of, or in connection with the performance of, the Global Development Activities and are required to be provided to the other Party pursuant to the Global Development Plan, and (b) Collaboration Know-How that relate to any of the foregoing.

1.185. "**Reversion Technology**" has the meaning set forth in Section 15.2.2(a) (Reversion License).

1.186. "**Royalty Term**" has the meaning set forth in Section 9.5.2 (Royalty Term).

1.187. "**Sales Returns and Allowances**" has the meaning set forth in Section 1.149 (Net Sales).

1.188. "**SDEA**" has the meaning set forth in Section 5.4.1 (SDEA; Responsibilities).

1.189. "**Second Source**" has the meaning set forth in Section 8.2 (Sobi Right to Manufacture Drug Product).

1.190. "**Selling Party**" has the meaning set forth in Section 1.149 (Net Sales).

1.191. "**Serious Adverse Event**" has the meaning set forth in 21 C.F.R. § 312.32, and generally means any Adverse Event that (a) results in death, (b) is life-threatening, (c) requires inpatient hospitalization or prolongation of existing hospitalization, (d) results in persistent or significant disability or incapacity, (e) is a congenital anomaly or birth defect, or (f) based upon appropriate

medical judgment, is considered an important medical event that may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

1.192. "**SFJ**" means SFJ Pharmaceuticals XI, L.P.

1.193. "**SFJ Agreement**" means that certain Development Funding Agreement, dated as of February 28, 2019, by and between Apellis and SFJ, as amended on June 7, 2019 and further amended from time to time.

1.194. "**Shared Development Costs**" has the meaning set forth in Section 4.6.3 (Shared Development Costs).

1.195. "**Sobi**" has the meaning set forth in the Preamble.

1.196. "**Sobi Know-How**" means any and all Collaboration Know-How that is (a) Controlled by Sobi or any of its Affiliates during the Term (for the avoidance of doubt, including Sobi's interest in the Joint Know-How) and (b) necessary or useful for the Exploitation of any Compound or Product Developed under the Global Development Plan. Notwithstanding anything in this Agreement to the contrary, Sobi Know-How shall not include (x) any Additional Third Party IP in-licensed by Sobi or any of its Affiliates under an agreement that Apellis does not agree to make a Collaboration In-License pursuant to Section 2.3 (New In-Licenses) or (y) any Know-How to the extent Controlled by any Person that acquires all or any part of Sobi or an Affiliate of Sobi, or any Affiliate of such Person, except to the extent that, following such acquisition, the Parties specifically agree to incorporate such Know-How into any Product Developed under the Global Development Plan, in each case (i) that is Controlled, immediately prior to the effective date of the acquisition, by such Person or any of its Affiliates (other than Sobi or any of its Affiliates immediately prior to the effective date of the acquisition) or (ii) that is Controlled by such Person or any of its Affiliates (other than Sobi or any of its Affiliates immediately prior to the effective date of the acquisition) on or after the effective date of acquisition but (A) is not Controlled by Sobi or any Person that was an Affiliate of Sobi immediately prior to the effective date of the acquisition, (B) is made, invented, created, designed, conceived, produced, or otherwise developed or obtained without the use of or reliance on any Sobi Confidential Information or Apellis Confidential Information, and (C) is not utilized by or on behalf of Sobi or its Affiliates in connection with the Exploitation of a Product.

1.197. "**Sobi Patent Right**" means any Collaboration Patent Right that is (a) Controlled by Sobi or any of its Affiliates during the Term (for the avoidance of doubt, including Sobi's interest in any Joint Patent Right) and (b) Covers the Exploitation of any Compound or Product Developed under the Global Development Plan. Notwithstanding anything in this Agreement to the contrary, except to the extent necessary or useful for the Exploitation of any Compound or Product Developed under the Global Development Plan, Sobi Patent Right shall not include (x) any Additional Third Party IP in-licensed by Sobi or any of its Affiliates under an agreement that Apellis does not agree to make a Collaboration In-License pursuant to Section 2.3 (New In-Licenses) or (y) any Patent Right to the extent Controlled by any Person that acquires all or any part of Sobi or an Affiliate of Sobi, or any Affiliate of such Person, except to the extent that, following such acquisition, the Parties specifically agree to incorporate any technology or invention Covered or claimed by such Patent Right into any Product Developed under the Global Development Plan, in each case (i) that is Controlled, immediately prior to the effective date of the acquisition, by such Person or any of its Affiliates (other than Sobi or any of its Affiliates immediately prior to the effective date of the acquisition) or (ii) that is Controlled by such Person or any of its Affiliates (other than Sobi or any

of its Affiliates immediately prior to the effective date of the acquisition) on or after the effective date of acquisition but is not Controlled by Sobi or any Person that was an Affiliate of Sobi immediately prior to the effective date of the acquisition and Covers or claims an invention that was invented without the use of or reliance on any Sobi Confidential Information or Apellis Confidential Information.

1.198. "**Sobi Technology**" means all Sobi Patent Rights and Sobi Know-How.

1.199. "**Sobi Territory**" means the entire world except for the Apellis Territory.

1.200. "**Sobi Territory Regional Development Activities**" means all Sobi activities, other than the Global Development Activities, conducted by or on behalf of Apellis to support Regulatory Approval of any Product in the Sobi Territory.

1.201. "**Sobi Territory Regional Development Plan**" has the meaning set forth in Section 4.4.3 (Sobi Territory Regional Development Plan).

1.202. "**Subcontractor**" means a Third Party engaged by a Party or its Affiliates to conduct certain activities of such Party under this Agreement, including (a) contract research organizations, (b) contract manufacturers, and (c) distributors (whether exclusive or non-exclusive), distribution service providers and wholesalers, in each case (a)-(c) whether or not granted a sublicense under the License to perform such activities (including in the case of (c), Commercialization activities).

1.203. "**Sublicensee**" means, on a Product-by-Product and country-by-country basis, a Third Party to whom Sobi or any of its Affiliates or any Sublicensee grants a license or sublicense of Sobi's rights to Exploit Products under the Apellis Technology, excluding all Subcontractors who are engaged on a fee-for-service basis and, solely for purposes of calculating Net Sales, excluding all Functional Sublicensees.

1.204. "**Supply Agreement**" has the meaning set forth in Section 8.6 (Supply Agreement).

1.205. "**Term**" has the meaning set forth in Section 14.1 (Term).

1.206. "**Third Party**" means any Person other than Sobi or Apellis or their respective Affiliates.

1.207. "**Third Party Claim**" has the meaning set forth in Section 12.1 (Indemnification by Apellis).

1.208. "**Third Party Payments**" shall mean the *pro rata* portion reasonably attributable to the Exploitation of Products of all payments (including for royalties, lump sum payments, upfront payments, costs, damages, judgements and awards) which Sobi or its Affiliates or Sublicensees pay to a Third Party (directly or through Apellis under a Collaboration In-License to which Apellis or any of its Affiliates is a Party) for a license under Patent Rights or Know-How owned or controlled by such Third Party that are reasonably necessary or reasonably useful for the Exploitation of the Products in the Field in the Sobi Territory.

1.209. "**TMA**" shall mean thrombotic microangiopathy.

1.210. "**Unilateral Combination Therapy Development Activities**" has the meaning set forth in Section 4.8.1(b) (Unilateral Combination Therapy Development Activities).

1.211. "**Unilateral Additional Development Costs**" has the meaning set forth in Section 4.4.4(b)(iii) (Buy-In).

1.212. "**Unilateral Development Activities**" has the meaning set forth in Section 4.4.4(b)(i) (Unilateral Development Activities).

1.213. "**Unilateral Development Data**" has the meaning set forth in Section 4.4.4(b)(ii) (Unilateral Development Data).

1.214. "**Unilateral Development Notice**" has the meaning set forth in Section 4.4.4(b)(iii) (Buy-In).

1.215. "**Upstream Agreements**" means the Existing Agreements and Collaboration In-Licenses.

1.216. "**U.S.**" or "**United States**" means the United States of America and its possessions and territories.

1.217. "**Valid Claim**" means a claim of (a) an issued, unexpired, and in-force patent, which claim has not been held invalid or unenforceable by a court or other government agency of competent jurisdiction from which holding no appeal can be taken, or for which the applicable time for appeal has expired, and has not been held or admitted to be invalid or unenforceable through re-examination, *inter partes* review, post grant review or disclaimer, opposition procedure, nullity suit, or otherwise, or (b) a pending patent application that has not been finally abandoned, finally rejected, or expired; but, if a claim of a pending patent application has not issued within [**] after the earliest filing date from which such claim takes priority, then such claim will cease to constitute a Valid Claim for the purposes of this Agreement unless and until such claim issues.

1.218. "**VAT**" has the meaning set forth in Section 9.7.2 (VAT).

ARTICLE 2
LICENSES

2.1 Licenses

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2.1.1 **License Grants to Sobi**. Subject to the terms and conditions of this Agreement and the Apellis Retained Rights, Apellis hereby grants to Sobi:

(a) an exclusive, sublicensable (solely as set forth in Section 2.5.2 (Sublicenses)) license under the Apellis Technology (excluding all Unilateral Development Data with respect to which Sobi is the Non-Proposing Party) to:

(i) Develop Products throughout the world in accordance with this Agreement for Commercialization in the Sobi Territory; and

(ii) Commercialize Products in the Sobi Territory in accordance with this Agreement; and

(b) a co-exclusive (with Apellis), sublicensable (solely as set forth in Section 2.5.2 (Sublicenses)) license under the Apellis Technology (excluding all Unilateral Development Data with respect to which Sobi is the Non-Proposing Party) to:

(i) subject to, and solely as set forth in, Section 8.1 (Sobi Right to Manufacture Drug Substance), Section 8.2 (Sobi Right to Manufacture

Drug Product), and the Supply Agreement, Manufacture Compounds and Products throughout the world for Development and Commercialization in the Sobi Territory; and

(ii) conduct Medical Affairs activities with respect to Products in accordance with this Agreement,

(the "**License**").

2.1.2 **License Grants to Apellis**. Subject to the terms and conditions of this Agreement and the Sobi Retained Rights, Sobi hereby grants to Apellis:

(a) an exclusive, sublicensable (solely as set forth in Section 2.5.2 (Sublicenses)), fully-paid, royalty-free license under the Sobi Technology (excluding all Unilateral Development Data with respect to which Apellis is the Non-Proposing Party), to:

(i) Develop Products throughout the world in accordance with this Agreement for (A) Commercialization in the Apellis Territory or (B) sale to Selling Parties for Commercialization in the Sobi Territory in accordance with this Agreement; and

(ii) Commercialize Products in the Apellis Territory in accordance with this Agreement;

(b) a non-exclusive, sublicensable (solely as set forth in Section 2.5.2 (Sublicenses)), fully-paid, royalty-free license under the Sobi Technology (excluding all Unilateral Development Data with respect to which Apellis is the Non-Proposing Party) to:

(i) Manufacture Products throughout the world in accordance with this Agreement, for (A) Commercialization in the Apellis Territory or (B) sale to Selling Parties for Commercialization in the Sobi Territory in accordance with this Agreement; and

(ii) conduct Medical Affairs activities with respect to Products in accordance with this Agreement; and

(c) solely to the extent necessary to Commercialize Non-Systemic Ophthalmology Products, a non-exclusive, sublicensable (solely as set forth in Section 2.5.2 (Sublicenses)), fully-paid, royalty-free license under the Sobi Technology to Develop, Manufacture, Commercialize, and conduct Medical Affairs activities with respect to Non-Systemic Ophthalmology Products anywhere in the world.

2.2 No Implied Licenses; Retained Rights.

2.2.1 Except as explicitly set forth in this Agreement, neither Party grants any rights or license under its Intellectual Property rights to the other Party, express or implied, whether by implication, estoppel, or otherwise.

2.2.2 Notwithstanding anything in this Agreement to the contrary, Apellis shall, as between the Parties, retain for itself (and its Affiliates and sub/licensees) the right under the Apellis Technology, with the right to grant licenses through multiple tiers, to:

(a) Develop Products throughout the world in accordance with the terms and conditions of this Agreement for (i) Commercialization in the Apellis Territory or (ii) sale to Selling Parties for Commercialization in the Sobi Territory in accordance with this Agreement;

(b) Manufacture Products throughout the world in accordance with the terms and conditions of this Agreement for Commercialization in the Apellis Territory;

(c) Manufacture and supply the Products to the Selling Parties pursuant to the terms and conditions of this Agreement and the Supply Agreement for Commercialization by such party inside the Sobi Territory;

(d) conduct Medical Affairs activities with respect to Products in accordance with the terms and conditions of this Agreement;

(e) Exploit Non-Systemic Ophthalmology Products anywhere in the world; and

(f) without limiting the foregoing, exercise its rights and conduct and perform its obligations under this Agreement, including as set out in the Global Development Plan.

(collectively, the foregoing, the "**Apellis Retained Rights**"); but, for the avoidance of doubt, nothing in this Section 2.2.2 (No Implied Licenses; Retained Rights) grants Apellis any rights under any Intellectual Property of Sobi.

2.2.3 Notwithstanding anything in this Agreement to the contrary, Sobi shall, as between the Parties, retain for itself (and its Affiliates and sub/licensees) the right under the Sobi Technology, with the right to grant licenses through multiple tiers, to:

(a) Develop Products throughout the world in accordance with the terms and conditions of this Agreement for Commercialization in the Sobi Territory;

(b) Manufacture Compounds and Products throughout the world for Development and Commercialization in the Sobi Territory;

(c) conduct Medical Affairs activities with respect to Products in accordance with the terms and conditions of this Agreement; and

(d) without limiting the foregoing, exercise its rights and conduct and perform its obligations under this Agreement, including as set out in the Global Development Plan.

(collectively, the foregoing, the "**Sobi Retained Rights**"); but, for the avoidance of doubt, nothing in this Section 2.2.3 (No Implied Licenses; Retained Rights) grants Sobi any rights under any Intellectual Property of Apellis.

2.3 **New In-Licenses.** If a Party becomes aware of any Third Party Intellectual Property that such Party believes is necessary or useful for the Exploitation of any Products developed pursuant to the Global Development Plan ("Additional Third Party IP"), such Party shall notify the JEC, and the JEC shall discuss in good faith whether, and on what terms, either Party should obtain a sublicensable license to such Third Party Intellectual Property, but nothing in this Section 2.3 (New In-Licenses) shall prevent either Party from independently obtaining or negotiating the terms for a license to such Additional Third Party IP. The Party obtaining a license or other rights to any Additional Third Party IP shall use Commercially Reasonable Efforts to ensure that any and all such rights acquired are freely sublicenseable to the other Party to the extent of the licenses and rights granted to such other Party under this Agreement. No more than [**] after executing an agreement pursuant to which it has obtained a license or other rights to any Additional Third Party IP that are sublicensable to the other Party under this Agreement, the in-licensing Party shall provide to the other Party a copy of such agreement and a proposed apportionment of the costs of such license between the Parties, based upon the Parties' proportional interest in the rights under such agreement, and such other Party shall, within [**] of receiving such copy, notify the in-licensing Party in writing whether such other Party agrees (a) to be responsible for the costs of such agreement in accordance with the terms of Section 9.6.2 (Collaboration In-Licenses) and (b) accept all other obligations under such agreement that are applicable to such Party's Exploitation of Products under this Agreement. If such other Party agrees to be responsible for such costs, and accept such other obligations that are applicable to such Party's Exploitation of Products under this Agreement, under such agreement, then such agreement shall be deemed a "Collaboration In-License," and the Additional Third Party IP licensed under such Collaboration In-License shall be Apellis Know-How, Apellis Patent Rights, Sobi Know-How, or Sobi Patent Rights, as applicable. If such other Party does not agree to be responsible for such costs, and accept such other obligations that are applicable to such Party's Exploitation of Products under this Agreement, under such agreement, or if the rights licensed under such agreement are not sublicensable to the other Party under this Agreement, then such agreement shall not be a Collaboration In-License, and the Additional Third Party IP licensed under such agreement shall be deemed not to be Apellis Know-How, Apellis Patent Rights, Sobi Know-How, or Sobi Patent Rights.

2.4 **Technology, Data, and Regulatory Transfer**

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2.4.1 **Initial Transfer**. As soon as reasonably practicable, and in any event within [**] following the Effective Date, the Parties shall discuss in good faith and agree upon, and, following such agreement, shall perform their respective obligations set out in, a technology and data transfer plan governing the contents and mechanics of the transfer of Apellis Know-How (including Manufacturing Know-How, to the extent necessary or useful for Sobi to perform its obligations and exercise its rights under this Agreement or Applicable Law prior to the transfer of Manufacturing Know-How under Section 8.3 (Manufacturing Technical Transfer)), Regulatory Submissions, and Regulatory Data pursuant to this Section 2.4.1 (Initial Transfer). Without limiting the foregoing, for no additional consideration (including no reimbursement for any costs or expenses incurred by or on behalf of Apellis), Apellis shall transfer and deliver to Sobi in the original format (excel, word, powerpoint, etc.) in a method agreed to by the Parties' IT departments (e.g., FTP, physical hard disk):

(a) within [**] following the Effective Date, download access to the complete contents of the diligence data room;

(b) within [**] following the Effective Date, to the extent not included in the diligence data room:

(i) any formal and informal, written or electronic correspondence or communications with or from the relevant Regulatory Authority or other Governmental Authority, as well as minutes of any material meetings, telephone conferences, or discussions with the relevant Regulatory Authority or other Governmental Authority in relation to the PNH and CAD Initial Indications;

(ii) any documents related to the CAD Initial Indication that are required by Sobi to perform the CAD Clinical Trials assigned to Sobi in the Global Development Plan, including those items set forth on Schedule 2.4.1(b) (Initial Transfer - CAD);

(iii) any additional quality assurance related documents (audit reports, CAPAs, Plans) relating to the Initial Indications; and

(c) within [**] following the Effective Date, copies of the following (including all eCTD sequences and source documents (if any) comprising or containing any of the following) to the extent not already provided:

(i) copies of Apellis Know-How in reasonably sufficient detail in order for a reasonably skilled Person to practice such Know-How within the scope of the License; and

(ii) copies of Regulatory Data,

in each case ((a)-(c)) that are: (i) related to the Compound or Products in the Sobi Territory, (ii) necessary for Sobi or its relevant Affiliate(s) to conduct or perform its obligations and exercise its rights under this Agreement (but, with respect to Manufacturing Know-How, solely as necessary for Sobi or its relevant Affiliate(s) to conduct or perform its obligations and exercise its rights under this Agreement prior to the transfer of Manufacturing Know-How under Section 8.3 (Manufacturing Technical Transfer)), and (iii) in Apellis' or any of its Affiliates' possession and Control as of the Effective Date. In addition, Apellis shall provide Sobi with reasonable access to Apellis personnel with relevant expertise to explain any Know-How transferred in accordance with clause (a), (b) or (c).

2.4.2 **Additional Transfers**. Pursuant to one (1) or more technology and data transfer plans established by unanimous agreement of the JDC in accordance with Section 3.3.2(b) (Specific Responsibilities of the JDC), and in any event within a reasonable period of time following any reasonable and specific request from the other Party (but any such request from Sobi regarding Manufacturing Know-How must comply with Section 8.3 (Manufacturing Technical Transfer)) (or, solely with respect to newly generated items created in any [**] that are necessary for the other Party or its relevant Affiliate(s) to conduct or perform its obligations and exercise its rights under this Agreement, within a reasonable period of time following the end of such [**] in which such newly generated items are created), each Party will transfer to the other Party copies (including all eCTD sequences and source documents (if any) comprising or containing any of the following) of all (w) Know-How, (x) Regulatory Submissions and Reimbursement Submissions, (y) Regulatory Data, and (z) other documents or information, in each case ((w)-(z)) that (i) are related to the Products, (ii) are in such Party's (or its Affiliates') possession and Control as of the relevant time, (iii) are (A) necessary or useful for such other Party to Exploit the Compound or Products in its territory in accordance with this Agreement or (B) necessary

to perform its obligations and exercise its rights under this Agreement, and (iv) have not previously been provided to such other Party. To the extent set forth in the applicable transfer plan(s) or otherwise requested or transferred pursuant to this Section 2.4.2 (Additional Transfers), the data transferred pursuant to this Section 2.4.2 (Additional Transfers) shall include Unilateral Development Data and Combination Therapy Data that meets the requirements of clauses (i) through (iv). For clarity, a Party shall have no right to use or reference the foregoing items described in clauses (w)-(z) other than as permitted pursuant to this Agreement.

2.4.3 **Regulatory Transition**. Except with respect to the EMA PNH Regulatory Approval (which shall remain owned by Apellis until assigned to Sobi in accordance with Section 5.2.6 (Assignment of EMA PNH Regulatory Approval)) and the existing Dossier for Clinical Development of a Product in [**], Apellis shall, in a manner and on a date to be mutually agreed by the Parties, but in any event within [**] after the Effective Date, assign to Sobi all of Apellis' and its Affiliates' rights, title, and interests in and to any Regulatory Approvals, INDs, Regulatory Submissions and orphan drug designations (or equivalent), other than CTAs with respect to which Apellis is the sponsor, Controlled by Apellis or any of its Affiliates with respect to Products and countries for which Sobi is the Regulatory/Reimbursement Responsible Party. With respect to any Regulatory Approvals, INDs, Regulatory Submissions and orphan drug designations (or equivalent) that Apellis assigns to Sobi, Apellis shall, at Sobi's reasonable request therefor,promptly execute and deliver, or cause to be executed and delivered, to Sobi or any applicable Regulatory Authority such endorsements, assignments, and other documents as are necessary to assign, convey, transfer, and deliver, as applicable, to Sobi the same.

2.4.4 **Support**. The Parties understand and agree that, in addition to the cooperation and assistance to be expressly provided under this Section 2.4 (Technology, Data, and Regulatory Transfer), from time to time it may be necessary for either Party to seek assistance and cooperation from the other Party in connection with the performance of such Party's obligations and exercise of such Party's rights under this Agreement. Each Party shall, at its own cost and expense, provide any such assistance and cooperation reasonably requested by the other Party.

2.5 Performance by Affiliates, Sublicensees, and Subcontractors

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2.5.1 **Performance by Affiliates**. Each Party may perform some or all of its obligations under this Agreement through its Affiliates; except that each Party will remain responsible for and be the guarantor of any such performance by its Affiliates and will cause its Affiliates to comply with the terms and conditions of this Agreement in connection with such performance. Each Party hereby expressly waives any requirement that the other Party exhaust any right, power, or remedy, or proceed against any of such Party's Affiliates, for any obligation or performance hereunder prior to proceeding directly against such Party.

2.5.2 **Sublicenses**. Subject to the terms and conditions of section 1.5 of the Penn Other Fields License Agreement regarding sublicensing through multiple tiers (which provides that, if Sobi desires to sublicense any Commercialization rights under any rights licensed under the Penn Other Fields License Agreement to a further sublicensee that is not an Affiliate of Sobi, Sobi and Apellis shall notify Penn of the identity of such non-Affiliate further sublicensee within [**] after the grant of such further sublicense, and any such downstream sublicense must require the sub-sublicensee to comply with the terms of the Penn Other Fields License Agreement and prohibit further sublicensing of Commercialization rights):

(a) Subject to Section 2.5.1 (Performance by Affiliates), each Party will have the right to sublicense (including through multiple tiers) any or all of the rights granted to it by the other Party under this Agreement to such Party's Affiliates without the consent of the other Party.

(b) Subject to Sections 2.5.2(c) (Sublicenses), 2.5.2(e) (Sublicenses), and 2.5.2(f) (Sublicenses), each Party will have the right to sublicense any or all of the rights granted to it by the other Party under this Agreement in connection with delegating any of such Party's obligations to Subcontractors in connection with exercising such Party's rights or performing such Party's obligations under this Agreement, except that (i) other than with respect to any contract research organization engaged by Apellis as of the Effective Date, neither Party may engage any contract research organization to perform any Global Development Activities until such Party has consulted with the other Party with respect to the engagement of such contract research organization and (ii) no Subcontractor may grant any further sublicense. For clarity, clause (i) shall not apply to a Party using a contract research organization in respect of such Party's Regional Development Activities.

(c) Subject to Section 2.5.2(f) (Sublicenses), Sobi will have the right to sublicense any or all of the rights granted to it by Apellis under Section 2.1.1 (License Grants to Sobi) to Third Parties for the purpose of Developing, Manufacturing, Commercializing or conducting Medical Affairs with respect to any Product in the Sobi Territory, but:

(i) Sobi may not sublicense any right to Commercialize any Product in any Major European Country without Apellis' prior written approval (which may not be unreasonably withheld, conditioned, or delayed); and

(ii) Sobi may not sublicense any right to Commercialize any Product in any Major Market or Russia without first giving Apellis opportunity to comment on Sobi's proposed sublicensee.

(d) Subject to Section 2.5.2(f) (Sublicenses), Apellis will have the right to sublicense any or all of the rights granted to it by Sobi under Section 2.1.2 (License Grants to Apellis) for the purpose of Commercializing any Product in the Apellis Territory or Developing, Manufacturing, Commercializing, or conducting Medical Affairs with respect to Non-Systemic Ophthalmology Products anywhere in the world.

(e) If Sobi sublicenses to any Third Party any of the Commercialization rights granted to it by Apellis under this Agreement and such sublicense includes any rights licensed under the Penn Other Fields License, Apellis and Sobi shall jointly notify Penn of the identity of such Sublicensee within [**] after the grant of such sublicense.

(f) A Party sublicensing any of the rights granted to it by the other Party under this Agreement shall ensure that each of its sublicensees is bound by a written agreement that is consistent with, and subject to the applicable terms and conditions of, this Agreement, and such sublicensing Party shall provide the other Party with a copy of such sublicense agreement within [**] after the execution of such sublicense agreement. Any such copy may be reasonably redacted to the extent required to remove any confidential, proprietary, or competitive

information, but such copy shall not be redacted to the extent that it impairs the other Party's ability to monitor compliance with this Agreement, unless such redaction is required to prevent breach of the terms of such sublicense or other confidentiality obligation to which the relevant Party or its Affiliates is subject. Such sublicense agreement shall be treated as Confidential Information of the sublicensing Party. Each sublicensing Party will be responsible, and primarily liable, for the performance of each of its sublicensees with all relevant restrictions, limitations, and obligations in this Agreement, and the grant of any sublicense will not relieve either Party of its obligations under this Agreement. Without limiting the foregoing, unless otherwise agreed by the Parties in advance in writing:

(i) the sublicensing Party shall require any Third Party to whom such Party discloses Confidential Information of the other Party to enter into an appropriate written agreement obligating such Third Party to be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are at least as protective of such Confidential Information as are the obligations set forth in Article 13 (Confidentiality), including requiring such Third Party to agree in writing not to issue any publications concerning any Compound or Product except in compliance with the terms of this Agreement; and

(ii) the sublicensing Party shall obligate its sublicensees to agree in writing to assign ownership to the sublicensing Party of, or grant an exclusive, royalty-free, worldwide, perpetual, and irrevocable license (with the right to freely grant sublicenses through multiple tiers) to, all Collaboration Know-How and Collaboration Patent Rights arising under its agreement with such Third Party to the extent related to the Exploitation of any Compound or Product, and such sublicensing Party shall structure each such assignment or exclusive license so as to enable such sublicensing Party to license or sublicense (as applicable) such Collaboration Know-How and Collaboration Patent Rights to the other Party in accordance with this Agreement.

2.6 Exclusivity

. During the Term, with respect to each Initial Indication and each other Indication that the JEC mutually agrees to include in the Global Development Plan, on an Indication-by-Indication basis, Apellis covenants and agrees that neither Apellis nor any of its Affiliates shall, directly or indirectly, alone or with or for any Third Party (including, for clarity, by grant of a license to or entry into any agreement or other arrangement with a Third Party in connection with the same), conduct any clinical Development or Clinical Trial or Commercialize any pharmaceutical product containing, incorporating, or comprising APL-9 (alone or in combination), for the treatment of such Indication unless and until the JEC unanimously agrees that the Parties will no longer Develop or Commercialize Products for such Indication under this Agreement in accordance with Section 3.2.3(i) (Responsibilities). Each of the Parties recognizes that the restrictions contained in, and the terms of, this Section2.6 (Exclusivity) are required for the protection of Sobi's exclusive rights under the License and Apellis' royalties hereunder, and agrees that, if any provision in this Section 2.6 (Exclusivity) is determined by any court to be unenforceable by reason of its extending for too great a period of time or over too great a geographic area, or by reason of its being too extensive in any other respect, such covenant shall be interpreted to extend only for the longest period of time and over the greatest geographic area, and to otherwise have the broadest application as shall be enforceable under Applicable Law.

2.7 Promotional Activities

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2.7.1 **No Promotion**. Except with respect to global congresses, meetings, or roundtables approved by the JMC, Apellis shall not market or promote any Product in the Sobi Territory, and Sobi shall not market or promote any Product in the Apellis Territory.

2.7.2 **Exports and Resale**. Apellis shall use Commercially Reasonable Efforts to monitor and prevent exports or resale of Products from or outside the Apellis Territory for Commercialization in the Sobi Territory, and Sobi shall use Commercially Reasonable Efforts to monitor and prevent exports or resale of Products from or outside the Sobi Territory for Commercialization in the Apellis Territory, in each case to the extent consistent with Applicable Law and using methods commonly used in the industry for such purpose, and the Parties shall keep each other reasonably informed of any such exports or resales of which they become aware.

2.7.3 **Sobi Territory Requests and Orders**. If Apellis or any of its Affiliates or sub/licensees receives a request or order to Commercialize any Product in the Sobi Territory, Apellis shall notify Sobi thereof, shall not accept such request or order, and shall direct the relevant individual or entity to Sobi.

2.7.4 **Apellis Territory Requests and Orders**. If Sobi or any of its Affiliates or Sublicensees receives a request or order to Commercialize any Product in the Apellis Territory, Sobi shall notify Apellis thereof, shall not accept such request or order, and shall direct the relevant individual or entity to Apellis.

2.8 Section 365(n) of the Bankruptcy Code

. All licenses granted by either Party to the other Party under this Agreement are deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined in Section 101 of the U.S. Bankruptcy Code. Each Party, as licensee, may fully exercise all of its rights and elections under any applicable Bankruptcy Code. The Parties further agree that, if a Party elects to retain its rights as a licensee under any applicable Bankruptcy Code, such Party shall be entitled to complete access to any technology licensed to it hereunder and all embodiments of such technology. Such embodiments of the technology shall be delivered to such licensee Party not later than: (a) the commencement of bankruptcy proceedings against the licensor Party, upon written request, unless the licensor Party elects to perform its obligations under this Agreement, or (b) if not delivered under clause (a), upon the rejection of this Agreement by or on behalf of the licensor Party, upon written request. Any agreements supplemental hereto will be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the U.S. Bankruptcy Code. As used herein, "Bankruptcy Code" means the U.S. Bankruptcy Code and any foreign equivalent thereto in any country having jurisdiction over a Party or its assets.

ARTICLE 3
GOVERNANCE

3.1 Alliance Management

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3.1.1 **Alliance Managers**. Within [**] after the Effective Date, each Party will appoint a single individual who possesses sufficient alliance management experience, is otherwise suitably qualified, and has the requisite decision-making authority to act as such Party's alliance manager under this Agreement to support the Development, Manufacturing, Commercialization, and Medical Affairs of the Products worldwide (the "**Alliance**

Manager"). Each Party may change the person designated as such Party's Alliance Manager upon written notice (including via email notification) to the other Party, but any such new Alliance Manager must possess sufficient alliance management experience and otherwise meets the requirements set forth in this Section 3.1.1 (Alliance Managers). Each Party shall ensure that each of such Party's Alliance Managers is bound by obligations of non-use and confidentiality that are at least as protective of the other Party's Confidential Information as are those set forth in Article 13 (Confidentiality).

3.1.2 **Roles and Responsibilities**. The Alliance Managers will be responsible for:

(a) facilitating the flow of information and data and otherwise promoting communication and coordinating the Development, Manufacturing, Commercialization, and Medical Affairs of the Products worldwide, including for the applicable Committees;

(b) providing a single point of communication for seeking consensus, both internally within the respective Party's organization and between the Parties, and for fostering good collaboration, communication, and coordination;

(c) managing Agreement governance and driving timely resolution of issues through informal and formal conflict resolution under this Agreement, including for the applicable Committees;

(d) attending Committee meetings; and

(e) performing such other functions as are requested by the JEC.

3.2 Joint Executive Committee

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3.2.1 **Formation**. As soon as practicable, but no later than [**] after the Effective Date, the Parties shall establish a Joint Executive Committee (the "**JEC**") to review, discuss, and, as applicable, oversee activities under this Agreement. The JEC shall be comprised of an equal number of, and in any event at most [**], representatives from each of Sobi and Apellis, each of whom shall have the appropriate experience, expertise, and decision-making authority to perform his or her responsibilities on the JEC. Each Party shall provide written notice (including via email notification) to the other Party or the other Party's Alliance Manager of its initial representatives to the JEC. Each Party's Chief Executive Officer shall be a representative on the JEC for at least [**] after the Effective Date. Except with respect to each Party's Chief Executive Officer during the first [**] after the Effective Date, either Party may replace its JEC representatives with similarly qualified individuals at any time upon prior written notice (including via email notification) to the other Party or the other Party's Alliance Manager. Either Party may invite up to [**] (or such other number as agreed by the JEC or reasonably required by a Party to fulfill its obligations under this Agreement) of its employees to participate in the discussions and meetings of the JEC by providing written notice (including via email notification) to the other Party or the other Party's Alliance Manager prior to such employee's participation, but such participants will have no voting authority at the JEC. If agreed by the JEC on a case-by-case basis, the JEC may invite other non-employee Third Parties to participate in the discussions and meetings of the JEC, but such participants will have no voting authority at the JEC. Each Party shall ensure that all of its JEC members, and all of its non-member employees and all non-employee Third Parties attending any JEC meeting, are bound by

obligations of non-use and confidentiality that are at least as protective of the other Party's Confidential Information as are those set forth in Article 13 (Confidentiality). The Alliance Managers shall be responsible, on behalf of the JEC, for setting the agenda for meetings of the JEC with input from the JEC members and will disseminate such agendas and presentations to be made at any meeting no later than [**] in advance of each JEC meeting unless otherwise agreed to by the Parties in writing.

3.2.2 **Meetings**. The JEC shall meet in person (alternating between a site designated by each of Apellis and Sobi) or by videoconference or teleconference at least [**] until the earliest of (a) [**], (b) a Change of Control of either Party, or (c) [**], and thereafter shall meet [**] or with such other frequency as the Parties may agree. Specific meeting dates shall be determined by agreement of the Parties. Either Party may also call a special meeting of the JEC (by videoconference or teleconference) upon prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed before the next regularly scheduled JEC meeting, and such Party shall provide the JEC with materials reasonably adequate to enable an informed discussion by its members before such special meeting. Apellis shall host the first meeting of the JEC at a mutually agreeable time and place no later than [**] after the Effective Date. Each Party will be responsible for its own expenses relating to attendance at or participation in JEC meetings. Each Party shall appoint one of its JEC representatives to act as a co-chairperson of the JEC. The responsibility for running each JEC meeting will alternate between the JEC co-chairpersons from meeting-to-meeting, with Apellis' co-chairperson running the first JEC meeting. The JEC co-chairpersons (or, at the election of the JEC co-chairpersons, the Alliance Managers) shall jointly prepare and circulate agendas to JEC representatives at least [**] before each JEC meeting (other than a special meeting as described above) and shall direct the preparation of meeting minutes after each JEC meeting, which shall be approved by the JEC co-chairpersons and circulated to other JEC representatives within [**] after such meeting. Except as expressly set forth in this Section 3.2.2 (Meetings), no JEC co-chairperson shall have any rights or powers greater than those of any other JEC member.

3.2.3 **Responsibilities**. The JEC shall have the duties described below. Within such scope, the JEC shall, subject to Section 3.7 (Decisions of the Committees):

(a) manage the overall strategic alignment between the Parties under this Agreement;

(b) establish and delegate specifically-defined duties to subcommittees, such as the JDC, the JMC, the JCC, and the JMSC, and other operational or ad-hoc subcommittees, on an "as-needed" basis to review, discuss, and, as applicable, oversee particular projects or activities, and receive and discuss reports from such subcommittees and provide guidance to the respective subcommittees regarding the same, as described in Section 3.2.4 (Subcommittees);

(c) review, discuss, and determine whether to amend or approve each Additional Development Proposal submitted by the JDC pursuant to Section 4.4.4(a) (JEC Decision Regarding Additional Development Activities);

(d) attempt to resolve any issues or disputes, including those arising from the Parties, Alliance Managers, JDC, JMC, JCC, JMSC, or any other subcommittee, as described in Section 3.7.2 (Escalation to JEC);

(e) review and discuss the Development, Manufacture, Commercialization, and Medical Affairs of the Products worldwide;

(f) review, discuss, and determine whether to approve any updates to the Global Development Plan (including the associated Global Development Budget) that include Additional Global Development Activities, Combination Therapy Activities or are otherwise material, in each case, as submitted by the JDC, as described in Section 4.4 (Development Plans; Unilateral Development Activities; Amendments) and Section 4.8 (Combination Products, Combination Therapies);

(g) review, discuss, and determine whether to approve the initial Global Branding Strategy, and approve any material updates thereof, in each case, submitted by the JCC as described in Section 6.3 (Global Branding Strategy and Information);

(h) review and monitor the progress of the Parties under the Global Development Plan, including milestones therein;

(i) determine whether to cease Developing or Commercializing any Product for any given Indication under this Agreement;

(j) determine any activities required to be added to the Global Development Plan (and associated Global Development Budget) as a result of a conditional Regulatory Approval in PNH in the European Union and the United Kingdom (and all associated PNH Development Costs to be incurred by either Party in accordance with Section 4.6.2 (PNH Development Costs)), but, if the JEC is unable to determine such matter, such dispute shall be resolved in accordance with Section 16.5.1 (Baseball Arbitration);

(k) determine whether any Shared Development Costs should be borne by the Parties in any ratio other than fifty percent (50%)/fifty percent (50%);

(l) jointly establish and maintain, or establish a subcommittee to establish and maintain, as set forth in the SDEA, all necessary pharmacovigilance requirements for each Product in full compliance with all Applicable Laws and requirements of the Regulatory Authorities in each country in the world, in accordance with Section 5.4.1 (SDEA; Responsibilities);

(m) discuss the licensing of Additional Third Party IP in accordance with Section 2.3 (New In-Licenses);

(n) provide a forum for the Parties to share information on patent prosecution matters and other intellectual property matters, and to facilitate coordination between the Parties in accordance with Article 10 (Intellectual Property Matters); and

(o) perform such other non-decision making functions as appropriate to further the purposes of this Agreement, as agreed upon by the Parties in writing.

3.2.4 **Subcommittees.**

(a) The JEC may, by unanimous agreement, establish and delegate specifically-defined duties to subcommittees and other operational committees or ad-hoc

subcommittees on an "as-needed" basis to review, discuss, and, as applicable, oversee particular projects or activities. The initial subcommittees of the JEC will be the Joint Development Committee ("**JDC**"), the Joint Medical Committee ("**JMC**"), the Joint Commercialization Committee ("**JCC**"), and the Joint Manufacturing and Supply Committee ("**JMSC**"). The JEC may, by unanimous agreement, disband such subcommittees as deemed necessary by the JEC. Each such subcommittee shall consist of the same number of representatives designated by each Party, which number shall be agreed upon by the Parties. Each Party will be free to change its subcommittee representatives upon written notice to the other Party or by sending a substitute representative to any subcommittee meeting, but each Party shall ensure that, at all times during the existence of any subcommittee, such Party has appropriate representatives on such subcommittee in terms of experience, expertise, and seniority for the then-current stage of Development or Commercialization of the Products and the authority to bind such Party with respect to matters within the purview of the relevant subcommittee. Each Party shall ensure that its subcommittee representatives and any substitutes therefor, and any other individual attending any subcommittee meeting on such Party's behalf, shall be bound by obligations of non-use and confidentiality that are at least as protective of the other Party's Confidential Information as are those set forth in Article 13 (Confidentiality). The Alliance Managers of each Party (or their designees) shall attend each meeting of each subcommittee as non-voting participants. Except as expressly provided in this Agreement, no subcommittee will have the authority to bind the Parties hereunder, and each subcommittee shall report to, and have any disputes in such committee resolved by, the JEC. No subcommittee's authority may exceed the authority specified for such subcommittee in this Article 3 (Governance). Any disagreement between the representatives of the Parties on a subcommittee shall be referred to the JEC for resolution in accordance with Section 3.7.2 (Escalation to JEC).

(b) Unless otherwise previously agreed in writing by the Alliance Managers or otherwise set out in this Agreement, the JDC shall meet [**] until the earlier of (A) [**] or (B) [**], and otherwise each subcommittee shall meet at least [**] until the earliest of (i) [**], (ii) a Change of Control of either Party, or (iii) [**], and thereafter shall meet [**] at a time agreed by the Parties, spaced at regular intervals unless the Parties agree in writing to a different frequency, with the location for such meetings to be determined by such subcommittee. Each subcommittee may meet in person, or alternatively, such subcommittee may meet by means of teleconference, videoconference, or other similar communications equipment. Either Party may also call a special meeting of each subcommittee by prior written notice to the other Party in the event such requesting Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, and such requesting Party shall provide such subcommittee, prior to the special meeting, with materials reasonably adequate to enable an informed decision on the relevant matter. No later than [**] prior to any meeting of any subcommittee (other than a special meeting as described above), a designated member of such subcommittee or, if such subcommittee so agrees, one of the Alliance Managers shall prepare and circulate an agenda for such meeting to all members of such subcommittee, but either Party will be free to propose additional topics to be included on such agenda, either prior to or during the course of such meeting. Each Party will bear the expense of its respective subcommittee members' participation in subcommittee meetings. A designated member of each subcommittee or, if such

subcommittee so agrees, one of the Alliance Managers shall be responsible for keeping written minutes of all such subcommittee's meetings that reflect all decisions made at such meetings. Such designated subcommittee member or Alliance Manager shall send meeting minutes to each member of such subcommittee for review and approval within [**] after each meeting of such subcommittee. Such minutes will be deemed approved unless, through communication of the Alliance Managers, one or more members of such subcommittee objects to the accuracy of such minutes within [**] after receipt. Except as expressly set forth in this Section 3.2.4(b) (Subcommittees), no designated member of any subcommittee shall have any rights or powers greater than those of any other member of such subcommittee.

3.2.5 **Disbandment of the JEC**. The JEC will immediately dissolve upon the expiration (or earlier termination) of the Term.

3.3 Joint Development Committee

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3.3.1 **Formation and Purpose of the JDC**. Promptly, but not later than [**] after the Parties establish the JEC, the JEC shall establish a JDC, which will be a subcommittee of the JEC and will have the responsibilities set forth in this Section 3.3 (Joint Development Committee). Each Party shall report to the JDC on all material issues relating to the Development of the Products worldwide at the next JDC meeting after such issues arise. Each Party will bear the expense of its respective JDC members' participation in JDC meetings. The JDC will dissolve upon completion of all Global Development Activities with respect to the Products.

3.3.2 **Specific Responsibilities of the JDC**. In addition to its general responsibilities, subject to the terms and conditions of this Agreement, the JDC shall, in particular:

(a) facilitate the exchange of information between the Parties under this Agreement regarding the strategy for Developing the Products;

(b) establish one (1) or more plans for data and technology transfers and coordinate and ensure successful completion of the Know-How transfers, as described in Section 2.4 (Technology, Data, and Regulatory Transfer);

(c) review and discuss the conduct of all Clinical Trials set forth in the Global Development Plan, as described in Section 4.4 (Development Plans; Unilateral Development Activities; Amendments);

(d) at least [**] during the Term (or more or less frequently as may be agreed upon in writing by the Alliance Managers), review, update, and determine whether to approve the updated Global Development Plan and, if applicable, the corresponding Global Development Budget, and submit to the JEC for review and approval any such update that includes Additional Global Development Activities or is otherwise material, as described in Section 4.4.6 (Updating the Global Development Plan);

(e) review, discuss, and submit to the JEC to review, discuss, and determine whether to approve each Additional Development Proposal and Combination Therapy Development Proposal, and update the Global Development Plan with any such

approved Additional Global Development Activities and Combination Therapy Global Development Activities, as described in Section 4.4.4 (Additional Development) and Section 4.8 (Combination Products, Combination Therapies);

(f) review and discuss each Party's conduct of its respective Global Development Activities set forth in the Global Development Plan and review any [**] update reports thereof as described in Section 4.10.2 (Reports);

(g) review and discuss the Apellis Territory Regional Development Plan and Sobi Territory Regional Development Plan, and the conduct and status of the Apellis Territory Regional Development Activities and Sobi Territory Regional Development Activities;

(h) review, discuss, and approve protocols and statistical analysis plans for Clinical Trials conducted under the Global Development Plan pursuant to Section 4.7 (Clinical Trials);

(i) review, discuss, and coordinate with each Party's regulatory team all strategies, communications, and contents of all meetings, conferences, and discussions with Regulatory Authorities related to each Product, as described in Section 5.2.3 (Meetings with Governmental Authorities);

(j) coordinate, review, and discuss the Parties' Shared Development Costs;

(k) review, discuss, approve, and coordinate the Apellis Readiness Activities and determine any activities additional to those set out in Schedule 4.3.6 (Apellis Readiness Activities) required to ensure inspection readiness for the PEGASUS and PRINCE Clinical Trials in PNH;

(l) review and discuss any material decisions or actions with respect to the EMA PNH Regulatory Approval as described in Section 5.2.5(b) (Regulatory Strategy for EMA PNH Regulatory Approval**)** and Section 5.2.6(b) (Assignment of EMA PNH Regulatory Approval); and

(m) perform such other non-decision making functions as appropriate to further the purposes of this Agreement, as directed by the JEC, or as specified in this Agreement.

3.4 Joint Medical Committee.

3.4.1 **Formation and Purpose of the JMC**. Promptly, but not later than [**] after the Parties establish the JEC, the JEC shall establish a JMC, which will be a subcommittee of the JEC and will have the responsibilities set forth in this Section 3.4 (Joint Medical Committee). Each Party shall report to the JMC on all material issues relating to Medical Affairs with respect to the Products worldwide at the next JMC meeting after such issues arise. Each Party will bear the expense of its respective JMC members' participation in JMC meetings. The JMC will dissolve upon the completion or earlier termination of all Medical Affairs activities with respect to the Products.

3.4.2 **Specific Responsibilities of the JMC**. In addition to its general responsibilities, subject to the terms and conditions of this Agreement, the JMC shall:

(a) develop an initial Medical Affairs Strategy, as described in Section 7.1 (Medical Affairs Strategy);

(b) at least [**] during the Term (or more frequently as may be required), review, update, and determine whether to approve each updated Medical Affairs Strategy and submit to the JEC for review and approval any such update that is material;

(c) review and discuss Medical Education Materials in accordance with Section 7.4 (Medical Education Materials);

(d) review and discuss reports and updates of Medical Affairs activities performed by or on behalf of each Party with respect to any Product and other [**] reports provided by either Party of Medical Affairs activities performed for any Product, as described in Section 7.7 (Reporting);

(e) coordinate each Party's participation at global symposia, congresses, and similar international meetings spanning both Parties' territories concerning Products, and interactions with key opinion leaders concerning Products in the country(ies) in which the other Party has the right to Commercialize Products;

(f) review and discuss Publications and the Publication Plan pursuant to Section 13.7 (Publication);

(g) establish a Publication Plan in accordance with Section 13.7 (Publication); and

(h) perform such other non-decision making functions as appropriate to further the purposes of this Agreement, as directed by the JEC or as specified in this Agreement.

3.5 Joint Commercialization Committee.

3.5.1 **Formation and Purpose of the JCC**. Promptly, but not later than [**] after the Parties establish the JEC, the JEC shall establish a JCC, which will be a subcommittee of the JEC and will have the responsibilities set forth in this Section 3.5 (Joint Commercialization Committee). Each Party shall report to the JCC on all material issues relating to the Commercialization of the Products worldwide at the next JCC meeting after such issues arise. Each Party will bear the expense of its respective JCC members' participation in JCC meetings. The JCC will dissolve upon the completion or earlier termination of all Commercialization activities with respect to the Products.

3.5.2 **Specific Responsibilities of the JCC**. In addition to its general responsibilities, subject to the terms and conditions of this Agreement, the JCC shall:

(a) develop and submit to the JEC to review, discuss, and determine whether to approve the Global Branding Strategy, as described in Section 6.3.1 (Global Branding Strategy);

(b) at least [**] during the Term (or more frequently as may be required), review, update, and determine whether to approve the updated Global Branding Strategy, and submit to the JEC to review, discuss, and determine whether to approve any

update to the Global Branding Strategy, in each case, that is material, as described in Section 6.3.2 (Updating the Global Branding Strategy);

(c) share information about geographical expansion plans and launch sequences for each Product in the Sobi Territory and the Apellis Territory;

(d) share information and cooperate regarding any administration device developed or used or proposed to be developed or used by either Party in relation to the Products;

(e) review and discuss the plans, status, reports, and progress of Commercialization activities, as described in Section 6.10.2 (Reports);

(f) discuss Promotional Materials relating to each Product, as described in Section 6.8 (Promotional Materials);

(g) perform such other non-decision making functions as appropriate to further the purposes of this Agreement, as directed by the JEC or as specified in this Agreement.

3.6 Joint Manufacturing and Supply Committee.

3.6.1 **Formation and Purpose of the JMSC**. Promptly, but not later than [**] after the Parties establish the JEC, the JEC shall establish a JMSC, which will be a subcommittee of the JEC and will have the responsibilities set forth in this Section 3.5 (Joint Manufacturing and Supply Committee). Each Party will bear the expense of its respective JMSC members' participation in JMSC meetings. The JMSC will dissolve upon the completion or earlier termination of all Manufacturing activities with respect to the Products.

3.6.2 **Specific Responsibilities of the JMSC**. In addition to its general responsibilities, subject to the terms and conditions of this Agreement and the Parties' rights and obligations under the Supply Agreement, the JMSC shall:

(a) prepare a Manufacturing and Supply Chain Plan and updates thereto for the review and approval of the Parties in accordance with Section 8.4 (Manufacturing and Supply Chain Plan);

(b) share information regarding capacity planning, supply plans, other supply chain matters, and supply continuity planning for the Products;

(c) share information regarding the Manufacturing process for each Product and review, discuss, and determine any changes thereto (including the costs and timelines therefor);

(d) review and share the results of regulatory, environmental, health, and safety inspections and audits related to the Manufacture of the Products;

(e) determine whether and on what conditions Sobi, itself or through an Affiliate or Third Party reasonably acceptable to Apellis, shall Manufacture, in a particular country or region, the bulk substance form of any Product sold in such country or region as required by Applicable Law, in accordance with Section 8.1 (Sobi Right to Manufacture Drug Substance);

(f) share and review performance of Third Party manufacturers and agree on any necessary actions with respect thereto;

(g) at least [**] on a date agreed to by the Parties in good faith, review and determine the extent to which the Manufacturing Costs are required to be modified or adjusted with respect to any changes in Apellis' actual Manufacturing Cost, subject to reasonable and appropriate limits on such modification or adjustment and any required true-up (the mechanics for which will be mutually agreed upon in the Supply Agreement); and

(h) perform such other non-decision making functions as appropriate to further the purposes of this Agreement, as directed by the JEC or as specified in this Agreement.

3.7 Decisions of the Committees.

3.7.1 **Voting; Consensus**. Each Party's representatives on the JEC and each subcommittee will, collectively, have one vote (the "**Party Vote**") on all matters brought before such Committee for a decision. The JEC and each subcommittee shall make decisions as to matters within its jurisdiction by unanimous Party Vote, which may be reflected in the minutes of the Committee meeting or by an action by written consent signed by a member appointed by each Party or his or her designee identified in writing. Except as otherwise expressly set forth in this Agreement, use of the phrases "determine," "establish," "delegate," "approve," "develop," "update," "submit," "prepare," "resolve," or "determine whether to approve" (including any conjugates thereof) by the JEC, the JDC, the JMC, the JCC the JMSC, or any other subcommittee, will mean that the decision making provisions of this Section 3.7 (Decisions of the Committees) apply to such matter, including the escalation and tie-breaking provisions herein. For the avoidance of doubt, matters that are specified in Section 3.2.3 (Responsibilities), Section 3.3.2 (Specific Responsibilities of the JDC), Section 3.4.2 (Specific Responsibilities of the JMC), 3.5.2 (Specific Responsibilities of the JCC), or 3.6.2 (Specific Responsibilities of the JMSC) to be "managed," "reviewed," "discussed," "monitored," "provided a forum," "performed," "facilitated," "coordinated," "cooperated," or "shared" (including any conjugates thereof) do not require any agreement or decision by either Party and are not subject to the voting and decision-making procedures set forth in this Section 3.7 (Decisions of the Committees).

3.7.2 **Escalation to JEC**. Any disagreement between the representatives of Apellis and Sobi with respect to matters within the scope of authority of the Alliance Managers, the JDC, the JMC, the JCC, the JMSC, or any other subcommittee that cannot be resolved after good faith efforts within [**] after such disagreement is first raised in writing, either via email or Committee meetings, by a Party representative shall, at the election of either Party, be submitted to the JEC for resolution. If the JEC is unable to resolve any such disagreement referred to it by the JDC, JMC, JCC, JMSC, or any other subcommittee, or any disagreement with respect to the matters within the scope of the JEC's authority or any other dispute between the Parties that may be referred to the JEC, in each case, using good faith efforts within a period of [**] from such referral or the start of such disagreement, as applicable, then either Party may immediately refer such matter for resolution to the Chief Executive Officer of Apellis and the Chief Executive Officer of Sobi, or their respective designees from senior management with decision-making authority over such matter (such executives or such designees, each, an "**Executive Officer**").

3.7.3 **Escalation to Executives**. In the event that the Executive Officers are unable to resolve any dispute referred to them pursuant to Section 3.7.2 (Escalation to JEC) within [**] after such dispute was referred to the Executive Officers, then the provisions of Section 3.7.4 (Final Decision-Making Authority) will apply.

3.7.4 **Final Decision-Making Authority**. If the Executive Officers are unable to reach agreement on any disputed matter so referred to them within [**] after such matter was referred to them (or such longer period as the Executive Officers may agree upon), then, subject to Section 4.4.4 (Additional Development), Section 4.8 (Combination Products, Combination Therapies), and Section 3.7.5 (Limitations on Decision Making Authority):

(a) **No Change; Status Quo**. Neither Party will have final decision-making authority over the following matters, and all such matters must be decided by unanimous agreement in order to take any action or adopt any change from the then-current *status quo*: (i) any change or update to the Global Development Plan or Global Development Budget, (ii) adoption of, or any change or update to, the Global Branding Strategy, (iii) adoption of, or any change or update to, the Medical Affairs Strategy, or (iv) the approval or coordination of or any change or update to the Apellis Readiness Activities.

(b) **Other Decisions**. With respect to any matter not described in Section 3.7.4(a) (No Change; Status Quo), the Party specified below shall, subject to Section 3.7.5 (Limitations on Decision Making Authority), except to the extent otherwise specified in this Agreement, have final decision-making authority with respect to the matters specified below, but any such decision must be (to the extent applicable) (i) consistent with the then-current Global Development Plan and corresponding Global Development Budget (*except* that Apellis (but not Sobi) may spend more than is set forth in the Global Development Budget in conducting any activities set forth in the initial Global Development Plan attached to this Agreement) and the Medical Affairs Strategy, (ii) subject to Section 6.1 (Overview), in accordance with the then-current Global Branding Strategy (if any), and (iii) consistent with such Party's obligations under this Agreement (including such Party's obligation to use Commercially Reasonable Efforts):

(i) Sobi, with respect to decisions which relate:

A. solely to the Development, Commercialization or Medical Affairs of Products to be Commercialized in the Sobi Territory;

B. except with respect to the EMA PNH Regulatory Approval prior to the date on which it is assigned to Sobi in accordance with this Agreement, to regulatory and reimbursement activities and obligations (other than decisions as to whether to seek, continue to seek, maintain, or abandon Regulatory Approval in the Apellis Territory), and applicable regulatory and reimbursement activities for a Product after receipt of Regulatory Approval or Reimbursement Approval for such Product, in any country in the Sobi Territory;

C. to the EMA PNH Regulatory Approval, following the date on which it assigned to Sobi in accordance with this Agreement;

D. with respect to operational matters relating to, and day-to-day conduct of, clinical studies and Clinical Trials sponsored by Sobi or its Affiliates or Sublicensees, in accordance with the approved protocol therefor and the Global Development Plan, in each case as applicable;

E. the Sobi Territory Regional Development Activities; and

(ii) Apellis, with respect to decisions which relate:

A. solely to the Development, Commercialization, or Medical Affairs for Products to be Commercialized in the Apellis Territory;

B. to regulatory and reimbursement activities and obligations (other than decisions as to whether to seek, continue to seek, maintain, or abandon Regulatory Approval in the Sobi Territory), and applicable regulatory and reimbursement activities for a Product after receipt of Regulatory Approval or Reimbursement Approval for such Product, in the Apellis Territory;

C. to the EMA PNH Regulatory Approval, prior to the date on which it assigned to Sobi in accordance with this Agreement;

D. with respect to operational matters relating to, and day-to-day conduct of, clinical studies and Clinical Trials sponsored by Apellis, its Affiliates, or sub/licensees, in accordance with the approved protocol therefor and Global Development Plan, in each case as applicable;; and

E. the Apellis Territory Regional Development Activities.

For clarity, except as set forth in this Section 3.7.4(b) (Other Decisions), neither Party shall have final decision-making authority with respect to any matter in respect of which the Executive Officers are unable to reach agreement within [**] after such matter was referred to them (or such longer period as the Executive Officers may agree upon) and such matters shall be considered for resolution in accordance with Article 16 (Dispute Resolution)).

3.7.5 **Limitations on Decision Making Authority**. Notwithstanding the foregoing provisions of this Section 3.7 (Decisions of the Committees), neither Party may exercise its right to finally resolve a dispute:

(a) in a manner that excuses such Party from any of its obligations specifically enumerated under this Agreement;

(b) in a manner that conflicts with the any of the express terms or conditions of this Agreement (including any obligation to comply with Applicable Law);

(c) in a manner that negates any consent rights or other rights specifically allocated to the other Party under this Agreement;

(d) if the provisions of this Agreement specify that mutual agreement of the Parties is required for such matter;

(e) involving the breach or alleged breach of this Agreement;

(f) in a manner that would require the other Party to perform any act that would breach any obligation to any Third Party (including under any Existing Agreement or Collaboration In-License) or is inconsistent with any Applicable Law;

(g) to determine whether or not a milestone event has been achieved;

(h) to otherwise expand a Party's rights or reduce a Party's obligations under this Agreement; or

(i) except as set forth in Section 3.7.4(b)(i)B (Other Decisions), Section 3.7.4(b)(i)C (Other Decisions), Section 3.7.4(b)(i)D(Other Decisions), Section 3.7.4(b)(i)E (Other Decisions), Section 3.7.4(b)(ii)B (Other Decisions), Section 3.7.4(b)(ii)C (Other Decisions), Section 3.7.4(b)(ii)D (Other Decisions), or Section 3.7.4(b)(ii)E (Other Decisions), in respect of matters specified in Section 3.7.4(b) (Other Decisions) if such matter would materially impact both the Exploitation of Products in or for the Sobi Territory and the Apellis Territory; and

if the applicable matter is set forth in section 5.2.2 of the SFJ Agreement, then Sobi may not exercise its right to finally resolve a dispute with respect to such matter in a manner with which SFJ disagrees.

3.7.6 **No Authority to Amend or Modify**. Notwithstanding any provision of this Agreement to the contrary, (a) neither any Committee nor the Alliance Managers will have any authority to amend, modify, or waive compliance with this Agreement, (b) each Party will retain the rights, powers, and discretion granted to it under this Agreement, and (c) neither any Committee nor the Alliance Managers will be delegated or vested with rights, powers, or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly so agree in writing. It is understood and agreed that issues to be formally decided by a particular Committee or the Alliance Managers are only those specific issues that are expressly provided in this Agreement to be decided by such Committee or the Alliance Managers, as applicable.

ARTICLE 4
DEVELOPMENT

4.1 Overview

. During the Term, other than with respect to Unilateral Development Activities and Unilateral Combination Therapy Development Activities, and subject to the terms and conditions

of this Agreement, the Parties will collaborate through the JDC with respect to the Development of Products as set forth in the Global Development Plan. Each Party shall conduct all Development of any Product in a manner that is consistent with this Agreement and does not conflict with the then-current Global Development Plan; *except* that Apellis (but not Sobi) may spend more than is set forth in the Global Development Budget in conducting any activities set forth in the initial Global Development Plan attached to this Agreement.

4.2 Performance of Development Activities

. Each Party shall, with respect to all Development activities for which such Party is responsible under this Agreement, provide, directly or indirectly through its Affiliates, sub/licensees, Sublicensees, or Subcontractors, all materials, facilities, and resources necessary for it to perform such Development activities with reasonable care and skill, consistent with sound and ethical business and scientific practices, in compliance with all Applicable Laws, including GCP, GVP, GMP and GLP, and otherwise in accordance with the terms of this Agreement. Each Party shall devote the efforts of suitably qualified and trained employees and personnel capable of carrying out the Development activities for which such Party is responsible to a professional workmanlike standard. Without prejudice to any other remedies either Party may have, if a Party notifies the other Party that it has reasonable grounds to suspect that a breach of the other Party's obligations under this Section 4.2 (Performance of Development Activities) has occurred or is reasonably likely to occur, the other Party shall (i) consider in good faith any comments or concerns provided by such Party in such notice with respect to such breach or potential breach and (ii) take commercially reasonable steps to remedy, in all material respects, any actual breach and to avoid any potential breach as soon as reasonably practicable.

4.3 Development Diligence Obligations

. Without limiting either Party's obligations under this Article 4 (Development):

4.3.1 each Party shall use Commercially Reasonable Efforts to perform all Development activities assigned to such Party in the Global Development Plan;

4.3.2 Apellis shall, unless and until the EMA PNH Regulatory Approval is assigned to Sobi in accordance with this Agreement use Commercially Reasonable Efforts to obtain Regulatory Approval from the EMA for a Product in PNH as soon as reasonably practicable following the Effective Date;

4.3.3 Apellis shall use Commercially Reasonable Efforts to obtain Regulatory Approval from the FDA for a Product in each of the Initial Indications;

4.3.4 Sobi shall use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval and, where applicable, Reimbursement Approval for Products in each of the Initial Indications in each Major Market (except that, before the EMA PNH Regulatory Approval is assigned to Sobi in accordance with this Agreement, Apellis, and not Sobi, shall use its Commercially Reasonable Efforts to obtain Regulatory Approval from the EMA for a Product in PNH). Apellis acknowledges that, without prejudice to Section 6.5 (Expansion and Launch in the Sobi Territory), when Sobi determines the timing and order of Development activities and the level of efforts to obtain Regulatory Approval for each Product, Sobi may take into account current status of Development activities, status of Regulatory Approval with EMA, FDA and other Regulatory Authorities, requirements for local Manufacturing in the applicable country(ies), competitiveness of Third Party products, patent and regulatory exclusivity, anticipated or approved labelling, present and future market potential, competitive market conditions and the profitability of the Product

in light of pricing and reimbursement issues, reference Regulatory Approval strategy and reference pricing and reimbursement strategy; and

4.3.5 Apellis shall provide reasonable assistance to Sobi on Sobi's reasonable request to obtain Regulatory Approval and, where applicable, Reimbursement Approval for Products in the Sobi Territory.

4.3.6 Apellis shall perform the Development activities set out in Schedule 4.3.6 (the "**Apellis Readiness Activities**"). Apellis shall provide Sobi with regular and timely updates on the status of such actions and shall consider all reasonable comments from Sobi regarding the performance of the Apellis Readiness Activities in good faith.

4.3.7 Each Party acknowledges that a Party shall not be in breach of its Development diligence obligations under this Agreement to the extent caused by the acts or omissions of the other Party or its Affiliates.

4.4 Development Plans; Unilateral Development Activities; Amendments

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4.4.1 **Global Development Plan**.

(a) Except with respect to any Unilateral Development Activities or Unilateral Combination Therapy Development Activities, the global Development of the Products (including Clinical Trials and, when prepared and approved by unanimous agreement of the JDC or existing as of the date of this Agreement, the protocols and statistical analysis plans for such studies) will be governed by a comprehensive written development plan (as such plan may be updated pursuant to Section 4.4.6 (Updating the Global Development Plan), the "**Global Development Plan**"), which Global Development Plan will include a budget for all activities under such Global Development Plan (the "**Global Development Budget**"). The initial Global Development Plan (including the initial Global Development Budget) is attached hereto as Schedule 4.4.1 (Initial Global Development Plan and Initial Global Development Budget).

(b) Except with respect to any Unilateral Development Activities or Unilateral Combination Therapy Development Activities, any updated Global Development Plan will at all times include:

(i) all activities in furtherance of completing the PNH Phase III Clinical Trials (to the extent not already completed), including all activities to be performed under the current protocols therefor;

(ii) an executive summary of the Development strategies for each then-existing Product for each Initial Indication in the Apellis Territory and each Major Market and each other Indication and country agreed upon by the JDC, including key objectives and expectations;

(iii) dates of expected filing of each Drug Approval Application for each then-existing Product for each Initial Indication in the Apellis Territory and each Major Market and each other Indication and country agreed upon by the JDC;

(iv) all Development activities that, if successful, the Parties reasonably believe are required to, within a reasonable timeframe, obtain, support, and maintain Regulatory Approval and, where required, Reimbursement Approval for each then-existing Product for each Initial Indication in the Apellis Territory, the European Union, and each Major Market and each other Indication and country agreed upon by the JDC;

(v) any other Development activities recommended by the JDC for any Product for each Initial Indication in the Apellis Territory and each Major Market and each other Indication and country agreed upon by the JDC;

(vi) any applicable required or, upon agreement of the Parties, optional post-Regulatory Approval Development activities for Products in the Indications and countries agreed upon by the JDC; and

(vii) a timeline, and an allocation to the applicable Party of responsibility, for each of the activities described in the foregoing clauses.

(c) The Parties shall collaborate in good faith to ensure that the Global Development Plan is at all times consistent with (i) the then-current Development Plan (as defined in the Penn Other Fields License Agreement) provided to Penn under the Penn Other Fields License Agreement and (ii) Apellis' diligence obligations under the Penn Other Fields License Agreement and the SFJ Agreement.

4.4.2 **Apellis Territory Regional Development Plan**. The Development of the Products, outside of the Global Development Activities, to support Regulatory Approval of any Product in the Apellis Territory (including all Unilateral Development Activities and Unilateral Combination Therapy Development Activities conducted by or on behalf of Apellis) will be governed by a comprehensive written development plan (as such plan may be updated by Apellis in accordance with this Section 4.4.2 (Apellis Territory Regional Development Plan), the "**Apellis Territory Regional Development Plan**"). Apellis shall ensure that the Apellis Territory Regional Development Plan does not conflict with the Global Development Plan. Apellis shall ensure that Apellis Territory Regional Development Plan will at all times include all Unilateral Development Activities and Unilateral Combination Therapy Development Activities conducted by or on behalf of Apellis. Apellis shall keep the JDC reasonably informed of the contents of the Apellis Territory Regional Development Plan.

4.4.3 **Sobi Territory Regional Development Plan**. The Development of the Products, outside of the Global Development Activities, to support Regulatory Approval of any Product in the Sobi Territory (including all Unilateral Development Activities and Unilateral Combination Therapy Development Activities conducted by or on behalf of Sobi) will be governed by a comprehensive written development plan (as such plan may be updated by Sobi in accordance with this Section 4.4.3 (Sobi Territory Regional Development Plan), the "**Sobi Territory Regional Development Plan**"). Sobi shall ensure that the Sobi Territory Regional Development Plan does not conflict with the Global Development Plan. Sobi shall ensure that Sobi Territory Regional Development Plan will at all times include all Unilateral Development Activities and Unilateral Combination Therapy Development Activities conducted by or on behalf of Sobi. Sobi shall keep the JDC reasonably informed of the contents of the Sobi Territory Regional Development Plan.

4.4.4 **Additional Development**. If either Party (a "**Proposing Party**" for the purposes of this Section 4.4.4 (Additional Development)) desires to perform, for any Product, any Clinical Trial that is not already set forth in the then-current Global Development Plan ("**Additional Development**"), then such Proposing Party shall present to the JDC to review, discuss, and determine whether to approve a proposal to add such Additional Development to the Global Development Plan (each such proposal, an "**Additional Development Proposal**"). Each Additional Development Proposal shall describe in reasonable detail the proposed additional Development activities (the "**Additional Development Activities**"), including, as applicable, any non-clinical studies, GLP Toxicology Studies, clinical studies, and Clinical Trials, that the Proposing Party desires to conduct or have conducted as part of such Additional Development, including a synopsis of the Clinical Trials or activities, the proposed enrollment criteria, the number of patients to be included, the endpoints to be measured, and the statistical design and powering, as well as a proposed timeline and budget and an analysis of the business opportunity and revenue potential for such Additional Development Activities.

(a) **JEC Decision Regarding Additional Development Activities**. The JDC shall review, discuss, and submit to the JEC to review, discuss, and determine whether to approve each Additional Development Proposal within [**] after receipt thereof from the Proposing Party.

(i) **JEC Approval**. If the JEC unanimously approves an Additional Development Proposal, then, upon such an approval, (A) the Additional Development Activities set forth in such Additional Development Proposal will be "**Additional Global Development Activities**" for purposes of this Agreement, and (B) the JDC will update the Global Development Plan to include such Additional Global Development Activities as set forth in the applicable Additional Development Proposal (as may be amended by the JEC upon such approval) and submit such updated Global Development Plan to the JEC for review, discussion, and approval.

(ii) **No Approval**. If the JEC does not approve an Additional Development Proposal, then the Additional Development Activities proposed in such Additional Development Proposal will not be included in the Global Development Plan, and (A) if the JEC does not approve an Additional Development Proposal because one Party has a reasonable, good faith concern that the proposed Additional Development Activities raise material safety or scientific concerns, then neither Party may conduct the proposed Additional Development Activities unless and until (1) the Parties agree otherwise or (2) a neutral safety committee engaged by the Parties pursuant to Section 16.4 (Neutral Safety Committee) approves such Additional Development Activities, and (B) if the JEC does not approve an Additional Development Proposal for any reason other than those set forth in Section 4.4.4(a)(ii)(A) (No Approval), Section 4.4.4(b) (Performance of Unilateral Development Activities) will apply.

(b) **Performance of Unilateral Development Activities.**

(i) **Unilateral Development Activities**. If, for any reason other than those set forth in Section 4.4.4(a)(ii)(A) (No Approval), the JEC does not approve

an Additional Development Proposal, then the Proposing Party may, upon notice to the other Party (the "**Non-Proposing Party**" for the purposes of this Section 4.4.4 (Additional Development)), subject to Section 4.7 (Clinical Trials), conduct the Additional Development Activities set forth in such Additional Development Proposal at its own cost and expense in a manner and timeline determined by such Party and pursuant to any protocol for such Additional Development Activities determined by such Party; *except* that (A) if Apellis is the Party conducting the Additional Development Activities, then Apellis may not, without Sobi's prior written consent, conduct such Additional Development Activities in the Major Markets (other than [**]) and (B) if Sobi is the Party conducting the Additional Development Activities, then Sobi may not, without Apellis' prior written consent, (I) conduct such Additional Development Activities for any ophthalmology Indication or (II) conduct such Additional Development Activities in the Apellis Territory. If the Proposing Party elects to conduct any Additional Development Activities under any Additional Development Proposal in accordance with the terms of this Section 4.4.4(b)(i) (Unilateral Development Activities), then all such Additional Development Activities will be "**Unilateral Development Activities**" for purposes of this Agreement.

(ii) **Unilateral Development Data**. Notwithstanding any provision to the contrary set forth in this Agreement, except as expressly set forth in this Section 4.4.4(b)(ii) (Unilateral Development Data) or Section 4.4.4(b)(iii) (Buy-In), the Non-Proposing Party shall have no rights with respect to, and may not use or reference, any data (including preclinical, nonclinical, clinical, technical, chemical, safety and scientific data and information) or other results generated by, resulting from, or in connection with the conduct of any Unilateral Development Activities (such data and results, "**Unilateral Development Data**") in any Regulatory Submission in support of a label expansion or to obtain a new Indication for the Product in such Party's territory; *provided however that*, without limiting the foregoing and notwithstanding anything to the contrary in this Agreement (including this Section 4.4.4(b)(ii) (Unilateral Development Data)), each Party shall have the right to use any Unilateral Development Data as reasonably necessary to address issues relating to the safety (including modifications to product labelling as deemed reasonably necessary by a Party) of Products, or (solely with respect to Apellis) Non-Systemic Ophthalmology Products, when and as such data become available. Notwithstanding the foregoing, any Unilateral Development Activities that consist solely of an investigator-sponsored clinical study shall not be considered "Unilateral Development Activities" for the purposes of this Section 4.4.4(b)(ii) (Unilateral Development Data) and Section 4.4.4(b)(iii) (Buy-In), and all data, results, and information generated by, resulting from, or in connection with the conduct of the same may be used by the Non-Proposing Party to the full extent of the license granted to such Non-Proposing Party in Section 2.1.1 (License Grants to Sobi) or Section 2.1.2 (License Grants to Apellis), as applicable, and the right of reference granted to such Non-Proposing Party in Section 5.3 (Right of Reference).

(iii) **Buy-In**. If at any time a Non-Proposing Party desires to obtain rights to, use, or reference any Unilateral Development Data from any Unilateral Development Activities, then such Non-Proposing Party may notify the Proposing Party of such desire in writing. Upon receipt of any such notice, the Proposing Party will promptly provide to the Non-Proposing Party written notice of all reasonable costs and expenses incurred by such Proposing Party in the performance of such Unilateral Development Activities as of the date of such notice, including, as applicable, all Manufacturing Costs incurred or paid under this Agreement or the Supply Agreement to obtain Products for such Unilateral Development Activities (a "**Unilateral Development Notice**" and such costs the "**Unilateral Additional Development Costs**"). Within [**] after receipt of any Unilateral Development Notice, the Non-Proposing Party may reimburse the Proposing Party for [**] percent ([**]%) of the Unilateral Additional Development Costs contained therein that would have been paid by such Non-Proposing Party had such Unilateral Development Activities always been Additional Global Activities. If the Non-Proposing Party so reimburses the Proposing Party, then, from and after the date on which the Proposing Party received the Non-Proposing Party's notice requesting rights to, or the right to use or reference, any Unilateral Development Data from any Unilateral Development Activities, (A) the data and other results generated from such Unilateral Development Activities shall be deemed to no longer be Unilateral Development Data and shall be deemed to be included in the licenses granted under Section 2.1.1 (License Grants to Sobi) or Section 2.1.2 (License Grants to Apellis), as applicable, and the right of reference granted in Section 5.3 (Right of Reference), and (B) if such Unilateral Development Activities are still ongoing, then (I) such activities shall be deemed to no longer be Unilateral Development Activities, (II) such activities shall be deemed to be Additional Global Development Activities, (III) Section 4.4.4(a)(i) (JEC Approval) shall apply to such Additional Global Development Activities, and (IV) the Parties shall share all Shared Development Costs incurred as a result of such Additional Global Development Activities pursuant to Section 4.6 (Development Costs) going forward. This Section 4.4.4(b)(iii) (Buy-In) shall survive any expiration or termination of this Agreement and, for clarity, no Unilateral Development Data shall be included within the Reversion Technology other than in accordance with this Section 4.4.4(b)(iii) (Buy-In).

4.4.5 **Global Development Budget**. The initial Global Development Budget is attached hereto in Schedule 4.4.1 (Initial Global Development Plan and Initial Global Development Budget). Subsequent Global Development Budgets will consist of a detailed written budget, broken down on a [**] basis, for the performance of those activities allocated to each Party under the Global Development Plan for the [**], which budget will include the Development FTE Costs to be incurred by each Party in performing each of the Global Development Activities under the Global Development Plan, as well as any direct Out-of-Pocket Costs expected to be incurred in connection with the performance of the Global Development Activities under the Global Development Plan and all Manufacturing Costs associated with the Manufacture of the Products for purposes of performing the applicable Global Development Activities.

4.4.6 **Updating the Global Development Plan**. In addition to updates made in accordance with Section 4.4.4 (Additional Development), at least [**] during the Term (or more frequently as may be required or as may be reasonably requested by either Party), the JDC shall review and update the Global Development Plan, and the corresponding Global Development Budget, based on currently available information and data. The JDC shall review, discuss, and determine whether to approve any such update to the Global Development Plan, and shall submit to the JEC to review, discuss, and determine whether to approve any such update to the Global Development Plan or Global Development Budget set forth therein, in each case, that is material. Each such update to the Global Development Plan and the corresponding Global Development Budget will become effective and will supersede the previous Global Development Plan and the corresponding Global Development Budget upon approval thereof by the JDC, and, if applicable, the JEC.

4.5 Development Step-In Right

. If (a) either Party materially breaches its obligation under Section 4.3 (Development Diligence Obligations) (excluding Section 4.3.3 (Development Diligence Obligations)) to use Commercially Reasonable Efforts to perform any of the Global Development Activities allocated to such party under the Global Development Plan for any Product within the timelines specified therein or otherwise in accordance with the Global Development Plan or (b) Apellis materially breaches its obligations under Section 2.4 (Technology, Data, and Regulatory Transfer) and, in each case ((a) or (b)) such material breach remains uncured for [**] measured from the date of such Party's receipt of written notice of such material breach from the other Party that identifies the material breach, then (x) with respect to a material breach by a Party of Section 4.3 (Development Diligence Obligations) (excluding Section 4.3.3 (Development Diligence Obligations)), upon written notice to such Party, the other Party may assume responsibility for the applicable Global Development Activities or (y) with respect to a breach of Section 2.4 (Technology, Data, and Regulatory Transfer) by Apellis, Sobi may perform such activities as it reasonably determines are necessary to produce or recreate the items which have not been transferred, including sponsoring Clinical Trials to produce equivalent data for use in Regulatory Submissions; but, if such breach is not susceptible of cure within such [**] cure period even with the use of Commercially Reasonable Efforts, the non-breaching Party's right to assume responsibility for such Global Development Activities shall be suspended by up to an additional [**] period if and for so long as the breaching Party has provided to the non-breaching Party a reasonable written plan, calculated to effect a cure of such breach, and commits to and is diligently performing such plan. If Sobi assumes any of Apellis' Global Development Activity responsibilities pursuant to this Section 4.5 (Development Step-In Right), then, notwithstanding anything to the contrary in this Agreement, Apellis shall reimburse Sobi for [**] percent ([**] %) of all Development FTE Costs, Manufacturing Costs, and Out-of-Pocket Costs incurred by Sobi in conducting such Global Development Activities. If Apellis assumes any of Sobi's Global Development Activity responsibilities pursuant to this Section 4.5 (Development Step-In Right), such assumption shall not affect Sobi's responsibility (if any) for the costs and expenses of such Global Development Activities. The remedies provided in this Section 4.5 (Development Step-In Right) are in addition to, and not in substitution for, any other remedies provided in this Agreement or now or hereafter existing at law or in equity.

4.6 Development Costs

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4.6.1 **Initial Development Costs**. Without limiting Sobi's obligation to pay Apellis the Development Reimbursement Payments pursuant to Section 9.2 (Development Reimbursement Payments), Apellis shall be solely responsible for all Development FTE Costs, Manufacturing Costs, and Out-of-Pocket Costs (including, for clarity any costs of supplying placebo) incurred by a Party or any of its Affiliates in accordance with the initial

Global Development Plan and associated Global Development Budget attached to this Agreement or incurred Apellis or any of its Affiliates in performing the Apellis Readiness Activities (the "**Initial Development Costs**"), and shall reimburse Sobi for any Initial Development Costs that are not disputed in good faith that are incurred by Sobi or any of its Affiliates in conducting activities allocated to Sobi in the then-current Global Development Plan, and conducted in accordance with the then-current Global Development Plan and associated Global Development Budget, within [**] after receipt of any invoice therefor. For the avoidance of doubt, Apellis shall not be responsible for any costs or expenses (including Development FTE Costs and Out-of-Pocket Costs) incurred by Sobi or any of its Affiliates that are not in accordance with the then-current Global Development Budget.

4.6.2 **PNH Development Costs**. Apellis shall be solely responsible for all reasonable Development FTE Costs, Manufacturing Costs, and Out-of-Pocket Costs (including, for clarity any costs of supplying placebo) incurred by a Party or any of its Affiliates in conducting activities required to be added to the Global Development Plan (and associated Global Development Budget) by the JEC (or baseball arbitration), in accordance with Section 3.2.3(j) (Responsibilities), as a result of a conditional Regulatory Approval in PNH in the European Union and the United Kingdom ("**PNH Development Costs**"), and shall reimburse Sobi for any undisputed PNH Development Costs incurred by Sobi or any of its Affiliates in conducting activities allocated to Sobi in the then-current Global Development Plan, and conducted in accordance with the then-current Global Development Plan and associated Global Development Budget, within [**] after receipt of any invoice therefor. For the avoidance of doubt, Apellis shall not be responsible for any costs or expenses (including Development FTE Costs and Out-of-Pocket Costs) incurred by Sobi or any of its Affiliates that are not in accordance with the then-current Global Development Budget.

4.6.3 **Shared Development Costs**. Except for Initial Development Costs or PNH Development Costs, and except as otherwise unanimously agreed by the JEC in accordance with Section 3.2.3(k) (Responsibilities), each Party shall bear fifty percent (50%) of all Development FTE Costs, Manufacturing Costs, and Out-of-Pocket Costs incurred by a Party or any of its Affiliates in accordance with the Global Development Plan and associated Global Development Budget, as well as all costs set forth in Section 5.5.2(a) (Cost Allocation) (collectively, the "**Shared Development Costs**"). Following each [**] in which either Party incurs any Shared Development Costs, such Party will provide to the other Party a written report of the Shared Development Costs incurred by or on behalf of such Party and, no later than [**] after receipt of each such written report, the applicable Party will make a balancing payment to the other Party such that each Party pays its share of all undisputed Shared Development Costs. For the avoidance of doubt, neither Party shall be responsible for any costs or expenses (including Development FTE Costs and Out-of-Pocket Costs) incurred by the other Party or any of its Affiliates that are not in accordance with the then-current Global Development Budget.

4.6.4 **Other Costs**. Subject to the terms of the Supply Agreement, each Party shall solely bear all costs and expenses incurred by such Party or its Affiliates in Developing Products that do not qualify as Initial Development Costs, Shared Development Costs, PNH Development Costs, or Manufacturing Process Costs. Without limiting the foregoing, Apellis shall solely bear all costs and expenses incurred by Apellis in conducting the Apellis Territory Regional Development Activities, and Sobi shall solely bear all costs and expenses incurred by Sobi in conducting the Sobi Territory Regional Development Activities (including all Manufacturing Costs paid by Sobi to Apellis pursuant to the

Supply Agreement for supply of Compounds or Products in order to conduct the Sobi Territory Regional Development Activities).

4.7 Clinical Trials

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4.7.1 **Protocols and Statistical Analysis Plans**. With respect to each Clinical Trial conducted under the Global Development Plan (for the avoidance of doubt, excluding any Clinical Trial that is ongoing as of the Effective Date), the Parties shall, through the JDC, review, discuss, and approve the protocol(s) and statistical analysis plan(s) for such Clinical Trial, in accordance with Section 3.3.2(h) (Specific Responsibilities of the JDC). Such review, discussion, and approval shall not be limited to quarterly JDC meetings, but rather shall occur on the timelines, and at the frequencies, needed to ensure that each Clinical Trial can be started and conducted on a reasonable timeline.

4.7.2 **Restriction on Location of Clinical Trials**. Without limiting any other provision of this Agreement, Apellis may not conduct any Clinical Trial (for the avoidance of doubt, excluding any Clinical Trial that is ongoing in the applicable country(ies) as of the Effective Date) for a Product in a Major Market (other than [**]) without the prior written consent of Sobi (such consent not to be unreasonably withheld, conditioned, or delayed), and Sobi may not conduct any Clinical Trial for a Product in the Apellis Territory without the prior written consent of Apellis (such consent not to be unreasonably withheld, conditioned, or delayed).

4.7.3 **Cooperation and Coordination**. If Apellis or an Affiliate of Apellis conducts a clinical study or Clinical Trial in the Sobi Territory, or Sobi or an Affiliate of Sobi conducts a clinical study or Clinical Trial in the Apellis Territory, as permitted under this Agreement, the Parties shall reasonably cooperate and coordinate with each other with regard to the conduct and enrollment of such clinical study or Clinical Trial and, following completion of such clinical study or Clinical Trial, to the extent permitted by Applicable Law, shall use Commercially Reasonable Efforts to facilitate the transition of patients from such clinical study or Clinical Trial to Commercial supply by the Commercializing Party.

4.8 Combination Products, Combination Therapies

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4.8.1 **Combination Therapy Development**. If either Party (a "**Proposing Party**" for the purposes of this Section 4.8.1 (Combination Therapy Development)) desires to conduct any Development of any Combination Product or any Product as a combination therapy with any other pharmaceutical product other than in the form of a Combination Product (*e.g.*, where a Product is administered sequentially or co-administrated with one (1) or more other pharmaceutical products, but is not co-formulated or co-packaged with any other pharmaceutical product) in order to obtain Regulatory Approval for such Combination Product or combination therapy in any country in which such Party is the Regulatory/Reimbursement Responsible Party (any such Development, "**Combination Therapy Development**"), such Party shall, at least [**] prior to commencing such Combination Therapy Development, notify the other Party (the "**Non-Proposing Party**" for the purposes of this Section 4.8.1 (Combination Therapy Development)) via the JDC of such proposed Development (each a "**Combination Therapy Development Proposal**") including in reasonable detail the proposed Combination Therapy Development activities (the "**Combination Therapy Development Activities**"), including, as applicable, any non-clinical studies, clinical studies, GLP Toxicology Studies, and Clinical Trials that the Proposing Party desires to conduct or have conducted as part of such Combination Therapy

Development, including a synopsis of the Clinical Trials or activities, the proposed enrollment criteria, the number of patients to be included, the endpoints to be measured, and the statistical design and powering, as well as a proposed timeline and budget and an analysis of the business opportunity and revenue potential for such Combination Therapy Development Activities.

(a) **JEC Decision Regarding Combination Therapy Development Activities**. The JDC shall review, discuss, and submit to the JEC to review, discuss, and determine whether to approve each Additional Development Proposal within [**] after receipt thereof from the Proposing Party.

(i) **JEC Approval**. If the JEC unanimously approves a Combination Therapy Development Proposal, then, upon such an approval, (A) the Combination Therapy Development Activities set forth in such Combination Therapy Development Proposal will be "**Combination Therapy Global Development Activities**" for purposes of this Agreement, (B) the JDC will update the Global Development Plan to include such Combination Therapy Global Development Activities as set forth in the applicable Combination Therapy Development Proposal (as may be amended by the JEC upon such approval) and submit such updated Global Development Plan to the JEC for review, discussion, and approval; and (C) the Parties shall share all Shared Development Costs incurred as a result of such Combination Therapy Global Development Activities pursuant to Section 4.6 (Development Costs) going forwards

(ii) **No Approval**. If the JEC does not approve a Combination Therapy Development Proposal, then the Combination Therapy Development Activities proposed in such Combination Therapy Development Proposal will not be included in the Global Development Plan, and (A) if the JEC does not approve an Combination Therapy Development Proposal because one Party has a reasonable, good faith concern that the proposed Combination Therapy Development Activities raise material safety or scientific concerns, then neither Party may conduct the proposed Combination Therapy Development Activities unless and until (1) the Parties agree otherwise or (2) a neutral safety committee engaged by the Parties pursuant to Section 16.4 (Neutral Safety Committee) approves such Additional Development Activities, and (B) if the JEC does not approve an Additional Development Proposal for any reason other than those set forth in Section 4.8.1(a)(ii)(A) (No Approval), Section 4.8.1(b) (Performance of Unilateral Combination Therapy Development Activities) will apply.

(b) **Performance of Unilateral Combination Therapy Development Activities.** If, for any reason other than those set forth in Section 4.8.1(a)(ii)(A) (No Approval), the JDC does not unanimously determine to include, or the JEC does not unanimously confirm inclusion of, any given Combination Therapy Development in the Global Development Plan, then the Proposing Party may, upon notice to the Non-Proposing Party, conduct such Combination Therapy Development at its own cost and expense in accordance with the terms and conditions of this Agreement (each a "**Unilateral Combination Therapy Development Activity**"); *except* that:

(i) Apellis may not, without Sobi's prior written consent (not to be unreasonably withheld, conditioned, or delayed), (A) conduct any Unilateral Combination Therapy Development Activities in any Major Market (other than [**]) or (B) conduct such Unilateral Combination Therapy Development Activities anywhere in the Sobi Territory for [**];

(ii) Sobi may not, without Apellis' prior written consent (not to be unreasonably withheld, conditioned, or delayed), (i) conduct any Unilateral Combination Therapy Development Activities in the Apellis Territory or (ii) conduct any Unilateral Combination Therapy Development Activities for any ophthalmology indication; and

(iii) for [**] after the Proposing Party notifies the Non-Proposing Party that the Proposing Party will be conducting any Unilateral Combination Therapy Development Activities in the other Party's territory, the Parties shall negotiate in good faith a Clinical Trial Collaboration and Supply Agreement with respect to such Combination Therapy Development, but nothing in this Section 4.8.1(b) (No Inclusion in the Global Development) shall require either Party to enter into any such Clinical Trial Collaboration and Supply Agreement.

(iv) If the Parties fail to enter into such a Clinical Trial Collaboration and Supply Agreement within such [**] period the following terms shall apply:

A. all data, results, and information generated by, resulting from, or in connection with the conduct of any applicable Unilateral Combination Therapy Development Activities (the "**Combination Therapy Data**") may be used by the Non-Proposing Party to the full extent of the license granted to such Non-Proposing Party in Section 2.1.1 (License Grants to Sobi) or Section 2.1.2 (License Grants to Apellis), as applicable, and the right of reference granted to such Non-Proposing Party in Section 5.3 (Right of Reference); and

B. the Proposing Party shall provide to the Non-Proposing Party copies of all Combination Therapy Data in accordance with Section 2.4.2 (Additional Transfers).

(c) **Combination Therapy Data and Regulatory Submissions**. Sobi shall be solely responsible for filing or amending any Drug Approval Application, Regulatory Approval, or Reimbursement Approval (as applicable) for any Product in the Sobi Territory as a result of any Combination Therapy Development, and Apellis shall be solely responsible for filing or amending any Drug Approval Application, Regulatory Approval, or Reimbursement Approval (as applicable) for any Product in the Apellis Territory as a result of any Combination Therapy Development. With respect to any Combination Therapy Development other than in the form of a Combination Product, each Party shall consider in good faith any request to amend any Drug Approval Application, Regulatory Approval, or Reimbursement Approval (as applicable) for any Product with respect to which such Party is the

Regulatory/Reimbursement Responsible Party to reflect the results of such Combination Therapy Development.

(d) **No Commercialization Rights**. For the avoidance of doubt, nothing in this Section 4.8 (Combination Therapy Development) grants Apellis any right to Commercialize any Product in the Sobi Territory or grants Sobi any right to Commercialize any Product in the Apellis Territory.

4.9 Compliance

. Each Party shall, and shall ensure that its Affiliates, sub/licensees, Sublicensees, and Subcontractors, comply in all material respects with all Applicable Laws in Developing the Products. Each Party shall promptly inform the JDC of any material investigation or adverse action taken by any Governmental Authority with respect to the Development of any Product of which such Party becomes aware.

4.10 Records, Reports, and Information

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4.10.1 **General**. Each Party shall maintain current, complete, and accurate records of all Development activities conducted by or on behalf of such Party with respect to any Product and all data and other information resulting from such activities. Such records shall properly reflect all such activities done and results achieved in the performance of such activities in sufficient detail and in good scientific manner as appropriate for patent and regulatory purposes and shall include, as applicable, books, records, reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, computer programs, and documentation thereof (*e.g.*, samples of materials and other graphic or written data generated in connection with such Party's Development activities). Each Party shall document all preclinical studies, clinical studies, and Clinical Trials to be conducted for any Product in written study reports in accordance with applicable national and international (*e.g.*, ICH, GCP, GVP, GMP and GLP) guidelines.

4.10.2 **Reports**. Each Party shall keep the other Party reasonably informed, through the JDC, regarding the status and progress of all Global Development Activities allocated to such Party under the Global Development Plan and all other Development activities conducted by or on behalf of such Party with respect to any Product. Without limiting the foregoing, on a [**] basis during the conduct of any Development activities for any Product, within [**] following the end of each [**], each Party shall prepare and provide written reports to the JDC to update the JDC on the status of all such Development activities performed by or on behalf of such Party during the applicable [**]. In addition, the performing Party shall include in such report such other Deliverables, Results, and other information as may be required under the Global Development Plan or otherwise reasonably requested by the other Party, to the extent such Deliverables, Results, and other information have not been previously provided to the other Party. The JDC shall review the [**] update reports and (a) confer regarding the progress towards completing the Global Development Activities allocated to each Party under the Global Development Plan and activities needed to obtain or maintain Regulatory Approval and, where applicable, Reimbursement Approval for the Products in the Initial Indications and any other indications included in the Global Development Plan, and (b) review relevant Deliverables provided and Results generated in the performance of Global Development Activities.

4.11 Inspection of Records

. [**] (or more frequently where there is a reasonable basis for the inspecting Party to suspect that the other Party has failed or is failing to comply with its Development obligations under this Agreement or that the other Party's Development activities are

not in compliance with all Applicable Law, including GCP, GVP, GMP, and GLP), during normal business hours and upon reasonable notice of not less than [**], each Party will have the right to inspect all records of the other Party or its Affiliates that reasonably relate to the performance of any Development of any Product by or on behalf of such other Party or are reasonably necessary for the purposes of verifying such other Party's compliance with this Agreement and all Applicable Law, including GCP, GVP, GMP, and GLP.

4.12 Penn Development Plan and SFJ Reports

. Sobi shall cooperate with Apellis in good faith upon Apellis' reasonable request in Apellis' preparation of all Development-related updates to the Development Plan (as defined in the Penn Other Fields License Agreement) required to be provided to Penn under the Penn Other Fields License Agreement, and all reports required to be provided to the JSC (as defined in the SFJ Agreement) under section 3.5 or 5.3 of the SFJ Agreement.

ARTICLE 5
REGULATORY AND REIMBURSEMENT

5.1 Regulatory and Reimbursement Responsibilities

. Subject to this Article 5 (Regulatory and Reimbursement), (a) the Party sponsoring any clinical study or Clinical Trial (*i.e.*, the Party listed as the sponsor on the clinical study or Clinical Trial protocol) for any Product (including, with respect to Apellis, each of the PNH Phase III Clinical Trials) will be the Regulatory/Reimbursement Responsible Party with respect to such Clinical Trial and (b) except as set forth in clause (a), (i) Apellis will be the Regulatory/Reimbursement Responsible Party with respect to (A) prior to any assignment of such Drug Approval Application in accordance with Section 5.2.6 (Assignment of EMA PNH Regulatory Approval), filing the EMA PNH Regulatory Approval and (B) all Products in the Apellis Territory and (ii) Sobi will be the Regulatory/Reimbursement Responsible Party with respect to all Products in the Sobi Territory (other than with respect to filing the EMA PNH Regulatory Approval prior to assignment of such Drug Approval Application in accordance with Section 5.2.6 (Assignment of EMA PNH Regulatory Approval)). Except as otherwise agreed by the Parties in advance in writing, no Clinical Trial of any Product shall have more than one (1) sponsor, which shall be the same sponsor for such Clinical Trial throughout the world.

5.2 Submissions and Correspondence

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5.2.1 **Regulatory Submissions**. To the extent permitted by Applicable Law, each Party's regulatory team shall reasonably cooperate with the other Party's regulatory team regarding Drug Approval Applications and other material Regulatory Submissions for Products in all markets for which such Party is the Regulatory/Reimbursement Responsible Party. In addition, to the extent permitted by Applicable Law, each Party shall provide the other Party with a reasonable opportunity to review and comment on all material Regulatory Submissions for any Product to be submitted to any Regulatory Authority in the Apellis Territory or any Major Market by or on behalf of such Party (including Drug Approval Applications, material correspondence, meeting requests, briefing materials, and minutes) throughout the process of preparing such Regulatory Submissions and, in particular, shall provide such other Party with drafts of all such Regulatory Submissions on the timeline agreed to by the Parties in good faith in writing prior to the date such Regulatory Submissions are to be finalized to allow for such other Party's review and comment. Each Party shall consider in good faith (and, with respect to the EMA PNH Regulatory Approval, Apellis shall not unreasonably decline to implement) all timely, reasonable comments from the other Party regarding such Party's Regulatory Submissions for Products in the Apellis Territory or any Major Market and, within [**] after submitting any Regulatory Submission for any Product to any Regulatory Authority in the Apellis Territory or any

Major Market provide a copy of such final Regulatory Submission to the other Party. Each Party shall cooperate with the other Party as reasonably requested by such other Party to assist such other Party's efforts to prepare and submit any Regulatory Submissions for Products under this Agreement, including by providing all such supporting documentation for INDs, CTAs, Drug Approval Applications, and other Regulatory Submissions to such other Party as are reasonably requested by such other Party with reasonably sufficient time to allow such other Party to review and incorporate such documentation and timely submit such Regulatory Submissions in accordance with Applicable Law or any other requirements or requests of any applicable Regulatory Authority.

5.2.2 **Correspondence with Authorities**. Without limiting Section 5.2.1 (Regulatory Submissions), to the extent permitted by Applicable Law, each Party shall provide the other Party with (a) access to or copies of all material written or electronic correspondence and communications received by or on behalf of such Party or any of its Affiliates, sub/licensees, or Sublicensees from, or forwarded by or on behalf of such Party or any of its Affiliates, sub/licensees, or Sublicensees, to, any Regulatory Authority in the Apellis Territory or any Major Market, and (b) copies of all material meeting minutes and summaries of all material meetings, conferences, and discussions held by such Party or any of its Affiliates, sub/licensees, or Sublicensees, with any Regulatory Authority in the Apellis Territory or any Major Market, in each case ((a) and (b)), relating to the Exploitation of any Compound or Product, but any information or data not related to any Compound or Product may be redacted. Notwithstanding the foregoing, and without limiting a Party's obligations under Section 5.4 (Adverse Event Reporting), if (i) a Party is unable (having used Commercially Reasonable Efforts to procure the same) to include the obligation on a sub/licensee or Sublicensee to provide the access and copies referred to in the foregoing sentence in the agreement between such Party and such sub/licensees or Sublicensee, or (ii) a sub/licensee or Sublicensee fails to comply with such obligation, despite the relevant Party having used Commercially Reasonable Efforts to enforce the same, the relevant Party shall not be in breach of its obligation to provide such access and copies received, forwarded, or produced by the relevant sub/licensee or Sublicensee. If such written or electronic correspondence received from any such Regulatory Authority relates to any non-approval of an IND or CTA with respect to any Product or the prohibition or suspension of the supply of any Compound or Product, or the initiation of any investigation, review, or inquiry by any Regulatory Authority concerning the safety of any Compound or Product, then the applicable Party shall notify the other Party, and provide the other Party with copies of such written or electronic correspondence, as soon as practicable, but not later than [**] following the applicable Party's receipt, forwarding, or production thereof. Otherwise, each Party shall provide all such correspondence, communications, minutes, summaries, contact reports, and other materials within (a) [**] after the Effective Date (to the extent in the possession or Control of the applicable Party as of the Effective Date) or (b) if received after the Effective Date, [**], with respect to safety events, or otherwise no later than [**] following the applicable Party's receipt, forwarding, or production thereof. Any documents required to be provided pursuant to this Section 5.2.2 (Correspondence with Authorities) may be provided through a share site, data room, or other means of electronically transferring or sharing documents.

5.2.3 **Meetings with Governmental Authorities**.

(a) Except as otherwise set forth in this Agreement, the applicable Regulatory/Reimbursement Responsible Party for a Product in a country will be responsible for all meetings, conferences, and discussions with Regulatory

Authorities and other Governmental Authorities related to Regulatory Approval and, where applicable, Reimbursement Approval of such Product in such country; *except* that the Parties' regulatory teams will work in collaboration with the JDC and JCC to review, discuss, and coordinate all strategies, material communications, and contents of all material meetings, conferences, and discussions with such Regulatory Authorities and other Governmental Authorities in the Apellis Territory, [**], and the Major European Countries related to each Product.

(b) Sobi shall provide Apellis with prompt prior written notice of any material scheduled meeting, conference, or discussion (including any advisory committee meeting, pre-submission meeting, product development meeting, or oral argument) with the EMA or the Regulatory Authority in [**] relating to any Product as soon as practicable after Sobi or any of its Affiliates first receives notice of the scheduling of such meeting, conference, or discussion. Sobi shall provide to Apellis copies of any material correspondence relating to such meetings, conferences, or discussions, including meeting requests, briefing materials, and questions, no later than [**] after Sobi's receipt thereof and in any event prior to the applicable meeting, conference, or discussion. To the extent permitted by Applicable Law, one (1) representative of Apellis selected by Apellis and reasonably acceptable to Sobi will have a right to attend (as an observer) such meetings, conferences, and discussions with the EMA or the Regulatory Authority in [**] related to any Product in any country in the European Union or [**].

(c) Prior to any assignment of the EMA PNH Regulatory Approval in accordance with Section 5.2.6 (Assignment of EMA PNH Regulatory Approval): (i) Apellis shall provide Sobi with prompt prior written notice of any scheduled meeting, conference, or discussion (including any advisory committee meeting, pre-submission meeting, product development meeting, or oral argument) with the EMA relating to the EMA PNH Regulatory Approval as soon as practicable after Apellis or any of its Affiliates first receives notice of the scheduling of such meeting, conference, or discussion; (ii) Apellis shall provide to Sobi copies of any correspondence relating to such meetings, conferences, or discussions, including meeting requests, briefing materials, and questions, no later than [**] after Apellis' receipt thereof and in any event prior to the applicable meeting, conference, or discussion; and (iii) to the extent permitted by Applicable Law, representatives of Sobi selected by Sobi and reasonably acceptable to Apellis will have a right to attend (as an observer) in meetings, conferences, and discussions with the EMA related to the Drug Approval Application for the first Product in PNH.

(d) Apellis shall provide Sobi with prompt prior written notice of any material scheduled meeting, conference, or discussion (including any advisory committee meeting, pre-submission meeting, product development meeting, or oral argument) with the FDA relating to any Product as soon as practicable after Apellis or any of its Affiliates first receives notice of the scheduling of such meeting, conference, or discussion. Apellis shall provide to Sobi copies of any material correspondence relating to such meetings, conferences, or discussions, including meeting requests, briefing materials, and questions, no later than [**] after Apellis' receipt thereof and in any event prior to the applicable meeting, conference, or discussion. To the extent permitted by Applicable Law, one (1) representative of Sobi selected by Sobi and reasonably acceptable to Apellis will have a right to

attend (as an observer) such meetings, conferences, and discussions with the FDA related to any Product.

5.2.4 **Ownership of Regulatory Approvals and Reimbursement Approvals**. The Regulatory/Reimbursement Responsible Party for each Product in a country will have the right to file all Drug Approval Applications and other applications for Regulatory Approvals and Reimbursement Approvals for such Product in such country in such Regulatory/Reimbursement Responsible Party's name, and, subject to the rights granted to the other Party under this Agreement, will own all rights, title, and interest in and to all such Regulatory Approvals and Reimbursement Approvals and all related Regulatory Submissions, Reimbursement Submissions, and orphan drug designations. Each Party shall promptly inform the other Party of (a) the filing of any Drug Approval Application for any Product and (b) the receipt of any Regulatory Approval or Reimbursement Approval for any Product.

5.2.5 **Regulatory Strategy for EMA PNH Regulatory Approval.**

(a) The Parties acknowledge and agree that (i) Apellis shall use Commercially Reasonable Efforts to obtain the right for up to [**] Sobi representatives to attend and participate (as non-voting observers) at each portion of any meeting of the JSC (as defined in the SFJ Agreement) under the SFJ Agreement that relates to the EMA PNH Regulatory Approval and (ii) subject to agreement by SFJ, Sobi may communicate directly with SFJ regarding the EMA PNH Regulatory Approval.

(b) For the avoidance of doubt, prior to assignment of the EMA PNH Regulatory Approval in accordance with Section 5.2.6 (Assignment of EMA PNH Regulatory Approval) the Parties shall, through the JDC pursuant to Section 3.3.2(l) (Specific Responsibilities of the JDC), in good faith seek to agree to a regulatory strategy for the EMA Drug Approval Application in a manner compatible with the obligations imposed on Apellis under section 3.5(b) of the SFJ Agreement. If the Parties are unable to agree such regulatory strategy in good faith, the matter will be subject to the decision-making provisions of Section 3.7 (Decisions of the Committees).

(c) All negotiations pursuant to this Section 5.2.5 (Regulatory Strategy for EMA PNH Regulatory Approval) are confidential and will be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.

5.2.6 **Assignment of EMA PNH Regulatory Approval**. Notwithstanding anything to the contrary in Section 5.2.5 (Regulatory Strategy for EMA PNH Regulatory Approval), promptly, and in no event later than [**], following receipt of Regulatory Approval from the EMA for a Product in PNH or such other reasonable time after [**] as requested by Sobi, Apellis shall, at Apellis' cost, submit to the EMA a request for transfer of the EMA PNH Regulatory Approval to Sobi, which transfer will assign to Sobi all of Apellis' and its Affiliates' rights, title, and interests in and to such EMA PNH Regulatory Approval, as well as the Regulatory Approval from the EMA for such Product in PNH (along with any associated orphan drug designation and pediatric investigation plan). Apellis shall execute and deliver, or will cause to be executed and delivered, to Sobi or any applicable Regulatory Authority such endorsements, assignments, and other documents as are necessary to assign, convey, transfer, and deliver, as applicable, to Sobi such Regulatory Approval and Drug Approval Application. Upon approval of such transfer by the EMA,

Sobi shall be the Regulatory/Reimbursement Responsible Party with respect to such Regulatory Approval. Sobi shall provide Apellis with all necessary documentation required for the request to transfer no later than [**] after receipt of Regulatory Approval from the EMA for the Product in PNH. Any failure by Sobi to provide such documentation on such timeline shall not be a breach of this Agreement by Sobi, but shall relieve Apellis of its obligations under this Section 5.2.6 (Assignment of EMA PNH Regulatory Approval) to the extent and for the duration of such failure. If Apellis assigns the EMA PNH Regulatory Approval to Sobi prior to receipt of Regulatory Approval from the EMA for the applicable Product in PNH:

(a) Sobi shall use Commercially Reasonably Efforts to seek Regulatory Approval from the EMA for such Product in PNH in accordance with Section 4.3.4 (Development Diligence Obligations); *provided that* Sobi shall use no less efforts than those required by Apellis under section 3.5(b) of the SFJ Agreement;

(b) the Parties, acting via the JDC pursuant to Section 3.3.2(l) (Specific Responsibilities of the JDC), shall discuss any material decisions or actions with respect to the EMA Drug Approval Application for such Product in PNH and Sobi shall consider in good faith any reasonable comments of Apellis in relation thereto;

(c) Apellis shall perform or procure the performance of all actions reasonably requested by Sobi and deemed necessary by Sobi in connection with the EMA Drug Approval Application for such Product in PNH and the agreed regulatory strategy, if any;

(d) Sobi shall have the right (and Apellis shall procure the exercise of such right) to request SFJ approval of any proposed changes to the regulatory strategy for such EMA PNH Regulatory Approval following assignment to Sobi;

(e) notwithstanding anything to the contrary in Section 12.2 (Indemnification by Sobi) and subject to Section 5.2.6(h) (Assignment of EMA PNH Regulatory Approval), Section 12.3 (Indemnification Procedures), and Section 12.4 (Limitation of Liability), Sobi hereby agrees to indemnify, defend, and hold Apellis harmless from and against any and all Losses arising in connection with any and all claims by SFJ to the extent resulting from any breach by Sobi of any of Section 5.2.6(a) (Assignment of EMA PNH Regulatory Approval), *provided, however, that*, (i) to the extent Sobi is implementing a regulatory strategy approved by Apellis, Sobi shall only be liable to the extent caused by Sobi's failure to use Commercially Reasonable Efforts (or, if greater, those required by Apellis under section 3.5(b) of the SFJ Agreement) to implement such regulatory strategy and (ii) if Sobi is required to indemnify Apellis in respect of any penalty payments by Apellis to SFJ under the SFJ Agreement, and Apellis subsequently receives or has a right to receive a credit, reduction, refund, or set-off in respect of such penalty payments against any remaining payment obligations of Apellis under that Agreement, Apellis shall, at Sobi's option, either credit against payments due by Sobi under Article 9 (Payments) or refund Sobi the full amount of such credit, reduction, refund, or set-off within [**] of receipt by Apellis of such credit, reduction, refund or set-off;

(f) Apellis shall notify Sobi promptly (but in any case within [**] of the earlier of (i) the date of Apellis' or its Affiliate's receipt of any communication, notice, or other

correspondence from or on behalf SFJ alleging that Apellis or its Affiliate is in breach of its obligations under section 3.5(b) of the SFJ agreement or (ii) the date Apellis forms a belief that it is reasonably likely that Apellis will seek indemnity from Sobi pursuant to Section 5.2.6(e) (Assignment of EMA PNH Regulatory Approval)) of any alleged dispute, claim, or controversy in relation to which Sobi might be expected to indemnify Apellis pursuant to Section 5.2.6(e) (Assignment of EMA PNH Regulatory Approval);

(g) notwithstanding anything to the contrary in Section 12.1 (Indemnification by Apellis) and subject to Section 12.3 (Indemnification Procedures) and Section 12.4 (Limitation of Liability), Apellis hereby agrees to indemnify, defend, and hold Sobi, its Affiliates, and their respective directors, officers, and employees, and all of their respective successors, heirs, and assigns, harmless from and against any and all Losses arising in connection with any and all claims by SFJ to the extent (i) resulting from Apellis' failure to comply with its obligations under the SFJ Agreement prior to assignment of the EMA PNH Regulatory Approval in accordance with Section 5.2.6 (Assignment of EMA PNH Regulatory Approval) (including particularly section 3.5(b) of the SFJ Agreement) prior to transfer of the EMA PNH Regulatory Approval) or (ii) caused by Apellis' act or omission; and

(h) notwithstanding anything to the contrary in this Agreement, the Parties agree that Sobi will have no liability to Apellis in connection with the Drug Approval Application for such Product in PNH, whether under Section 5.2.6(e) (Assignment of EMA PNH Regulatory Approval), Section 12.2 (Indemnification by Sobi) or otherwise to the extent resulting from any act or omission of Apellis or its Affiliates.

5.2.7 **Cost of Regulatory Activities**. Each Party will solely bear all costs and expenses incurred by such Party in connection with the preparation, filing, and maintenance of Regulatory Submissions, Reimbursement Submissions, Regulatory Approvals, and Reimbursement Approvals with respect to any Product, including any filing fees; *except that* Sobi shall reimburse Apellis for all reasonable Out-Of-Pocket costs and expenses mutually agreed in advance in good faith and incurred by Apellis in connection with the preparation, filing, and maintenance of the EMA PNH Regulatory Approval which, for the avoidance of doubt, shall not include any costs and expenses associated with any post-approval Development activities required in connection with such Regulatory Approval.

5.2.8 **SFJ Participation**. Notwithstanding anything to the contrary in this Agreement, Sobi acknowledges and agrees that, pursuant to the terms of the SFJ Agreement, the CEO or the CMO of SFJ shall be entitled to participate on a silent basis in all meetings with the EMA during the Term (as defined in the SFJ Agreement) and, to the extent practicable, Sobi shall give SFJ the opportunity to review pre-meeting briefing materials. Sobi shall ensure that Apellis can provide the JSC (as defined in the SFJ Agreement) and SFJ with copies of the minutes of all such meetings within [**] (as defined in the SFJ Agreement) after Sobi receives the final minutes from the applicable Regulatory Authority (as defined in the SFJ Agreement).

5.3 Right of Reference

. Subject to the rules of the relevant Regulatory Authority and the terms of this Agreement, including Section 4.4.4(b)(ii) (Unilateral Development Data), each Party hereby grants to the other Party a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous Applicable Law recognized outside of the U.S.), to, and a right to copy,

access, and otherwise use, all information and data relating to any Compound or Product in any Regulatory Submission or Regulatory Approval Controlled by such Party, for such other Party's or its Affiliates' use in the Exploitation of (including the filing, issuance, and maintenance of Regulatory Approvals for) the Products in accordance with this Agreement. If requested by either Party, the other Party shall provide a signed statement to this effect in accordance with 21 C.F.R. § 314.50(g)(3) (or any successor rule or analogous Applicable Law outside of the U.S.) to give effect to the intent of this Section 5.3 (Right of Reference). For clarity, nothing in this Section 5.3 (Right of Reference) entitles a Party to use the Unilateral Development Data of the other Party unless such party has exercised its buy-in rights under Section 4.4.4(b)(iii) (Buy-In).

5.4 Adverse Event Reporting

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5.4.1 **SDEA; Responsibilities**. No later than [**] after the Effective Date, the Parties shall discuss and execute a Safety Data Exchange Agreement (the "**SDEA**"), which will set forth the responsibilities of each Party with respect to clinical safety and pharmacovigilance matters relating to each Product and Non-Systemic Ophthalmology Product. The Parties shall update the SDEA from time to time as needed to properly reflect the status of the marketing and sale of each Product and the relevant regulations in each country. In the SDEA, the Parties shall define how clinical safety and pharmacovigilance will be managed by both Parties, how the safety database for the Products will be set up and how safety information will be exchanged, and in particular shall: (a) set forth how cases will be processed in the global safety database; (b) provide for submitting expedited reports in agreed format to health authorities, in accordance with the requirements of Regulatory Authorities; (c) include provisions regarding producing outputs (tables, line listings) for aggregate reports such as periodic safety update reports and development safety update reports; (d) include provisions regarding evaluation of safety and benefit-risk (*e.g.*, results should be discussed in the JEC or a subcommittee, as specified in the SDEA); (e) include provisions regarding performing ongoing safety signal detection and assessment; and (f) include provisions governing safety statements in aggregate reports, in each case ((a)-(f)) in a manner consistent across countries to the extent reasonably practicable. The Parties, through the JEC or any subcommittee established by the JEC for the purpose, shall, as set forth in more detail in the SDEA, jointly establish and maintain all necessary pharmacovigilance activities for each Product in compliance with all Applicable Laws and requirements of all applicable Regulatory Authorities. During the Term, each Party shall notify the other Party regarding all Serious Adverse Events arising in any Clinical Trials of any Product or Non-Systemic Ophthalmology Product, all adverse drug reactions (*i.e.* Adverse Events that are related to a Product or Non-Systemic Ophthalmology Product), and all special case scenarios, as outlined in the EMA's Guideline on Good Pharmacovigilance Practices, Module VI, as individual cases within the timelines specified in the SDEA. Further adverse events may be exchanged as aggregated reports or data sets, as specified in the SDEA. Additionally, any other safety-relevant information (beyond adverse events) shall be exchanged as outlined in the SDEA.

5.4.2 **Regulatory/Reimbursement Responsible Party Responsibilities**. The Regulatory/Reimbursement Responsible Party's responsibilities for each Product in a country will include: (a) receiving and collecting all applicable Adverse Events and adverse drug reactions, as defined in the SDEA, in accordance with the applicable Regulatory/Reimbursement Responsible Party's standard operating procedures, (b) obtaining follow-up information related to any Adverse Events or adverse drug reactions for such Product in such country that is initially made to or received by such Regulatory/Reimbursement Responsible Party and forwarding the same to the non-

Regulatory/Reimbursement Responsible Party as established in the SDEA; (c) making regulatory and safety contacts with the Regulatory Authorities and other Governmental Authorities in such country as the holder of the relevant Regulatory Approvals, INDs, or CTAs (as applicable) for such Product; (d) submitting case reports that qualify for expedited reporting to the Regulatory Authorities in such country as required by Applicable Law; (e) submitting aggregate reports (*e.g.*, post-marketing periodic safety update reports) to the Regulatory Authorities in such country as required by Applicable Law; and (f) promptly communicating to the non-Regulatory/Reimbursement Responsible Party any new safety signal with respect to any Product. The Regulatory/Reimbursement Responsible Party's responsibilities for each Product will also include: (x) establishing and maintaining risk management plans and measures for the applicable countries, except to the extent the Parties agree that the non-Regulatory/Reimbursement Responsible Party will execute such plans; and (y) establishing applicable country-specific named pharmacovigilance contacts as required by Applicable Law. Details regarding the responsibilities outlined above shall be specified in more detail, on a country-by-country level, in the SDEA.

5.4.3 **Audit Rights and Inspection Reports**. Each Party will have the right, upon reasonable (and at least [**]) prior written notice, to periodically audit the other Party's relevant Product-related pharmacovigilance activities to monitor compliance with such other Party's obligations as set forth in this Section 5.4 (Adverse Event Reporting) and the SDEA. Each Party shall, within a reasonable time, reply to the other Party's request for such an audit. Each such audit will be reasonable in scope and take place during normal business hours. Neither Party may request an audit more than [**], except where there is a reasonable basis for such Party to suspect that the other Party has failed or is failing to comply with its obligations under this Section 5.4 (Adverse Event Reporting) or the SDEA. The auditing Party shall share any concerning findings related to the Compound or the Products resulting from any pharmacovigilance audit in a reasonably detailed inspection report, and the Parties shall agree in good faith on the corrective and preventative actions to be taken by the Parties to address such findings, and the Party(ies) responsible for such actions shall take such actions promptly after they are agreed to.

5.4.4 **Allocation of Clinical Safety and Pharmacovigilance Responsibilities.** Each Party shall notify the other Party in writing promptly following the Effective Date regarding the names and contact information of such Party's leaders for clinical safety and pharmacovigilance activities, including such Party's European Union Qualified Person Responsible for Pharmacovigilance. Each Party shall also inform the other Party about outsourcing major components of such Party's clinical safety and pharmacovigilance responsibilities covered by the SDEA.

5.5 Recall, Withdrawal, or Field Alert of the Products

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5.5.1 **Notification and Determination**. If any Governmental Authority (a) threatens in writing, or initiates, any action to remove any Product or Non-Systemic Ophthalmology Product from the market (in whole or in part) or (b) provides written notice regarding a potential safety or quality issue with respect to any Product or Non-Systemic Ophthalmology Product, then, in each case ((a) or (b)), the Party receiving notice thereof will notify the other Party of such communication promptly, but in no event later than [**] after receipt thereof. Notwithstanding the foregoing, in all cases Sobi shall determine whether to initiate any recall, withdrawal, or field alert of any Product in any country in the Sobi Territory and Apellis shall determine whether to initiate any recall, withdrawal, or field alert of any

Product in the Apellis Territory or any Non-Systemic Ophthalmology Product anywhere in the world, including, in each case, the scope of such recall or withdrawal (*e.g.*, a full or partial recall, or a temporary or permanent recall) or field alert. Before either Party initiates a recall, withdrawal, or field alert relating to a Product, the Party initiating such recall, withdrawal, or field alert shall notify the other Party within [**] of such decision and the Parties shall use reasonable efforts to promptly discuss in good faith the reasons therefor, but such discussions will not delay any action that the Party initiating such recall reasonably believes should be taken in relation to any actual or potential recall, withdrawal, or field alert. In the event of any such recall, withdrawal, or field alert relating to a Product, the Party initiating such recall, withdrawal, or field alert shall determine the necessary actions to be taken and will implement such actions.

5.5.2 **Cost Allocation**. Except as set forth in the Supply Agreement, (a) the Parties shall share as Shared Development Costs, all reasonable costs and expenses incurred by a Party in connection with implementing a recall, withdrawal, or field alert with respect to any Product then being Developed under the Global Development Plan, and (b) each Party will solely bear all costs and expenses incurred by such Party in connection with implementing a recall, withdrawal or field alert in each case with respect to any Product being Commercialized by such Party, *provided that* to the extent such recall, withdrawal, or field alert is required as a result of a failure by or on behalf of Apellis to Manufacture in accordance with applicable Specifications and the Supply Agreement, but not to the extent any such recall is attributable to the breach or negligence of Sobi, its Affiliates, or Sublicensees, Apellis will reimburse Sobi for all costs and expenses incurred by Sobi in connection with implementing such recall, withdrawal, or field alert.

ARTICLE 6
COMMERCIALIZATION

6.1 Overview

. Subject to the terms and conditions of this Agreement, (a) Apellis shall Commercialize Products in the Apellis Territory and (b) Sobi shall Commercialize Products in the Sobi Territory. Neither Party may Commercialize any Product in a manner inconsistent with this Agreement. Each Party shall, where commercially reasonable in the relevant country, Commercialize the Products in each country in such Party's territory in a manner that is consistent with the then-current Global Branding Strategy (including as to Product Trademarks), if any. If a Party determines that it is not commercially reasonable in a given country to Commercialize a Product in a manner that is consistent with the then-current Global Branding Strategy (if any), such Party shall so notify the JCC and give the other Party opportunity to comment on the positioning, messaging, branding, packaging, and labeling (including Product Trademarks) intended to be used in such country and shall, notwithstanding the foregoing, use Commercially Reasonable Efforts to comply with the Global Branding Strategy and reasonable comments from the other Party.

6.2 Commercialization Diligence Obligations

. Sobi shall use Commercially Reasonable Efforts to Commercialize a Product in each of the Initial Indications in (a) at least [**] of the Major European Countries and (b) each of Canada, Japan, Brazil, and China. Apellis acknowledges that, without prejudice to Section 6.5 (Expansion and Launch in the Sobi Territory), when determining the timing and order of Commercial launch of a given Product and Initial Indication in each Major Market, Sobi may reasonably take into account reference pricing strategy. Apellis acknowledges that Sobi shall not be in breach of its Commercialization diligence obligations under this Agreement to the extent caused by the acts or omissions of Apellis or its Affiliates.

6.3 Global Branding Strategy and Information

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6.3.1 **Global Branding Strategy**. At least [**] prior to the anticipated First Commercial Sale of the first Product in the later of the Sobi Territory or the Apellis Territory, the JCC shall discuss in good faith and use reasonable efforts to agree and submit to the JEC to review, discuss, and determine whether to approve, an initial Global Branding Strategy. If the Parties cannot agree upon a Global Branding Strategy, the Parties shall instead reasonably coordinate on Product branding matters.

6.3.2 **Updating the Global Branding Strategy**. At least [**] during the Term (or more frequently as may be required or as may be reasonably requested by either Party), the JCC shall review and, if unanimously agreed by the JCC, update any prior approved Global Branding Strategy based on currently available information and data. The JCC shall review, discuss, and determine whether to approve any such update to the Global Branding Strategy, and shall submit to the JEC to review, discuss, and determine whether to approve each such update to the Global Branding Strategy that is material. Each such update to the Global Branding Strategy will become effective and will supersede the previous Global Branding Strategy upon approval thereof by the JCC, and, if applicable, JEC. If such update is not unanimously approved by the JCC and the JEC, then the prior approved Global Branding Strategy (if any) shall remain in place.

6.4 Pricing

. Each Party will be free, in its sole discretion, to determine the price, if any, that it charges Third Parties for each Product in each country in which such Party is Commercializing such Product, but, to the extent permitted by Applicable Law in the relevant country, each Party shall endeavor to consider each Product's value in setting the price of such Product.

6.5 Expansion and Launch in the Sobi Territory

. Without limiting its obligations under Section 6.2 (Commercialization Diligence Obligations), Sobi will be free, in its sole discretion determine geographical expansion and launch sequences for each Product in the Sobi Territory. Sobi shall give the JCC a reasonable opportunity to comment on Sobi's proposed expansion and launch sequences for each Product in the Sobi Territory in advance of Sobi's final determination of the same.

6.6 Commercialization Costs

. Each Party shall solely bear all costs and expenses incurred by such Party in Commercializing Products.

6.7 Compliance

. Each Party shall, and shall ensure that its Affiliates, sub/licensees, Sublicensees, and Subcontractors, comply in all material respects with all Applicable Laws in Commercializing the Products. Each Party shall promptly inform the JCC of any material investigation or adverse action taken by any Governmental Authority with respect to the Commercialization of any Product of which such Party becomes aware.

6.8 Promotional Materials

. Each Party shall submit copies of initial versions of, and (in respect of the Major Markets and Apellis Territory only) any material updates to, the Promotional Materials that it uses to Commercialize Products in its territory to the JCC for discussion purposes only. Each Party shall ensure that all Promotional Materials used by or on behalf of such Party for any Product are compliant with Applicable Laws and materially consistent with the Global Branding Strategy, if any.

6.9 Product Trademarks

. Subject to Section 6.1 (Overview), each Party shall determine the trademarks used in connection with the Exploitation of the Products in its respective territory following reasonable consultation with the other Party (excluding any house marks or composite marks that include a house mark, the "**Product Trademarks**").

6.9.1 **Ownership; Use**. Apellis will own all Product Trademarks in the Apellis Territory, and Sobi will own all Product Trademarks in the Sobi Territory. Each Party agrees that it and its Affiliates shall not use, register, or attempt to register any Product Trademark so resembling any existing trademark of the other Party in the applicable jurisdiction(s) as to be likely to cause confusion or deception, and each Party agrees that such Party and its Affiliates shall not use, register, or attempt to register in the other Party's territory any trademark so resembling the Product Trademarks in such other Party's territory as to be likely to cause confusion or deception.

6.9.2 **Responsibility for Product Trademarks**.

(a) Apellis shall be responsible for (i) registering, prosecuting, and enforcing the Product Trademarks in the Apellis Territory, (ii) preparing any guidelines applicable to the use of the Product Trademarks in the Apellis Territory, and (iii) investigating and defending any infringement or threatened infringement relating to any Product Trademark in the Apellis Territory. Apellis will own and be responsible for securing any domain names associated with the Product Trademarks targeted at the Apellis Territory. Subject to Section 6.9.2(c) (Responsibility for Product Trademarks), neither Sobi nor any of its Affiliates shall obtain or hold any domain name associated with the Product Trademarks targeted at the Apellis Territory in its own name. Apellis shall not use nor permit the use by its Affiliates or licensees of the Product Trademarks in connection with any Non-Systemic Ophthalmology Product anywhere in the world. Apellis shall not use any Product Trademark as part of any Drug Approval Application filed with the EMA for PNH without Sobi's prior written consent.

(b) Sobi shall be responsible for (i) registering, prosecuting, and enforcing the Product Trademarks in the Sobi Territory, (ii) preparing any guidelines applicable to the use of the Product Trademarks in the Sobi Territory, and (iii) investigating and defending any infringement or threatened infringement relating to any Product Trademark in the Sobi Territory. Sobi will own and be responsible for securing any domain names associated with the Product Trademarks targeted at the Sobi Territory. Subject to Section 6.9.2(c) (Responsibility for Product Trademarks), neither Apellis nor any of its Affiliates shall obtain or hold any domain names associated with the Product Trademarks targeted at the Sobi Territory in its own name.

(c) The Parties shall, through the JEC, discuss and determine ownership and content of the landing pages for any domain names associated with any Product that are targeted at both the Sobi Territory and the Apellis Territory (including ".com" and ".net" domains). Each such landing page shall utilize then-current technology as necessary to direct those Persons located in a particular country to the appropriate website specified by Sobi for Persons located in the Sobi Territory and by Apellis for Persons located in the Apellis Territory. For clarity, Apellis shall be responsible for the web presence for Products in the Apellis Territory and Sobi shall be responsible for the web presence for Products in the Sobi Territory; and the responsible Party shall ensure that such web presence (including all associated content) shall comply with all Applicable Law and regulatory requirements.

6.9.3 **Respect of Product Trademarks**. Neither Party shall, and each Party shall ensure that its Affiliates do not: (a) attack, challenge, oppose, petition to cancel, or initiate legal action or

proceedings in connection with any Product Trademark in any country in the other Party's territory during the Term, or challenge the registration of any Product Trademark in any country in the other Party's territory during the Term; (b) file, register, or maintain any registrations for any trademarks or trade names (including with respect to any Non-Systemic Ophthalmology Product) in any country in the other Party's territory that are confusingly similar to any Product Trademark in such country, without the express prior written consent of the other Party; or (c) authorize or assist any Third Party to do the foregoing.

6.9.4 **Apellis Name**. To the extent permitted by Applicable Law and the relevant Regulatory Authority(ies), and provided such inclusion is not reasonably likely to cause confusion regarding the holder of the relevant Regulatory Approval or the source of the Product, the packaging for each Product sold in the Sobi Territory Manufactured by Apellis shall identify Apellis as the manufacturer of the Product and shall include the Apellis company trademark, *provided* that, to the extent permitted by Applicable Law, the Apellis company name and trademark will appear on the outside of the packaging, but will not be located on the front side of the packaging and will appear smaller and less prominent than the Sobi name and company trademark. If Apellis ceases to Manufacture the relevant Product, other than as a result of Apellis' breach of this Agreement, the Parties will discuss in good faith whether and how Apellis' name and company trademark may continue to appear on Product packaging in the Sobi Territory to the extent permitted by Applicable Law and the relevant Regulatory Authority(ies). Apellis hereby grants to Sobi a non-exclusive, royalty-free license to use the Apellis name and company trademark for such purpose. Sobi shall provide Apellis with a mock-up of its proposed packaging in advance of the use of such packaging, following which Apellis will have [**] to provide its reasonable comments on such proposed packaging which Sobi shall consider in good faith. Sobi will use Commercially Reasonable Efforts to maintain the quality of the Product on which the Apellis trademarks are presented in a manner consistent with (i) Applicable Law, (ii) the quality standards set out in Schedule 6.9.4 (Apellis Trademark Standards), and (iii) any other reasonable quality standards as may be mutually agreed from time to time by the Parties, acting reasonably and in good faith, *provided that* failure to do so will not be a breach of this Agreement and Apellis' sole and exclusive remedy will be the right to require Sobi to cease to Manufacture or have Manufactured Products bearing the Apellis trademark and Sobi shall use Commercially Reasonable Efforts to cease such activities as soon as reasonably practicable (taking into account Sobi and its Affiliates' and Sublicensee's ability to continue to supply the markets in the Sobi Territory with sufficient Product to meet demand and avoid supply interruption, the requirements of Applicable Law and any Regulatory Authority), *provided that* Sobi shall continue to have the right to Manufacture and Commercialize Product bearing the Apellis name and company trademark provided it complies with the foregoing obligation during the aforementioned ramp-down period. From and after any Change of Control of Apellis, Sobi's obligations to display the Apellis name and trademark on the packaging of Products in the Sobi Territory under this Section 6.9.4 (Apellis Name) shall cease and Sobi's remaining obligations under this Section 6.9.4 (Apellis Name) shall cease if and when, at Sobi's sole discretion, Sobi ceases including the Apellis name and trademark on the packaging of Products in the Sobi Territory.

6.10 Records, Reports, and Information

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6.10.1 **General**. Each Party shall (and shall ensure that its Affiliates, licensees, and sublicensees) maintain current and accurate records of all Commercialization activities conducted by or

on behalf of such Party or any of its Affiliates, sub/licensees, or Sublicensees with respect to any Product.

6.10.2 **Reports**.

(a) On a [**] basis (or, during any period in which the JCC is only meeting [**], on a [**] basis), each Party shall provide an update, through the JCC, on the plan, status, and progress of all material Commercialization activities to be conducted in the Apellis Territory, each Major Market, and all other countries in the Sobi Territories as a combined territory, or that have been conducted, by or on behalf of such Party or any of its Affiliates, sub/licensees, or Sublicensees with respect to any Product.

(b) Without limiting the foregoing, beginning in the [**], on [**] basis during the Term, (i) at the [**] meeting of the JCC in [**], each Party shall present to the JCC a high level plan which reasonably details material Commercialization activities planned to be performed by such Party or its applicable Affiliate(s), sub/licensees, or Sublicensee(s) with respect to any Product during the following [**] in the Apellis Territory, each Major Market, and all other countries in the Sobi Territories as a combined territory and (ii) at the [**] meeting of the JCC in each [**], each Party shall present to the JCC a reasonably detailed high level report on the status of material Commercialization activities in the Apellis Territory, each Major Market, and all other countries in the Sobi Territory as a combined territory performed by such Party or its applicable Affiliate(s), sub/licensees, or Sublicensee(s) with respect to any Product during the prior [**]. Either Party may reasonably request further details regarding topics in a report presented by the other Party in accordance with this Section 6.10.2(b) (Reports), and such other Party shall use Commercially Reasonable Efforts to provide a reasonably detailed high level follow-up report on such topics at the next meeting of the JCC.

6.11 Penn Development Plan

. Sobi shall cooperate with Apellis in good faith in Apellis' preparation of all Commercialization-related updates to the Development Plan (as defined in the Penn Other Fields License Agreement) to be provided to Penn under the Penn Other Fields License Agreement to the extent related to the Commercialization of the Products in the Sobi Territory.

ARTICLE 7
MEDICAL AFFAIRS

7.1 Medical Affairs Strategy

. The JMC shall develop a global Medical Affairs strategy for all Products throughout the world, including with respect to Medical Education Materials (the "**Medical Affairs Strategy**"). At least [**] during the Term (or more frequently as may be required or as may be reasonably requested by either Party), the JMC shall review and update the Medical Affairs Strategy based on currently available information and data. The JMC shall review, discuss, and determine whether to approve any such update to the Medical Affairs Strategy, and shall submit to the JEC to review, discuss, and determine whether to approve each such update to the Medical Affairs Strategy that is material. Each such update to the Medical Affairs Strategy will become effective and will supersede the previous Medical Affairs Strategy upon approval thereof by the JMC, and, if applicable, JEC. Sobi shall be responsible for Medical Affairs in connection with Products in the Sobi Territory, and Apellis shall be responsible for Medical Affairs in connection with Products in the Apellis Territory. Each Party shall conduct all Medical Affairs activities for the Products based on and materially consistent with the Medical Affairs Strategy. The Medical Affairs Strategy shall be compliant with all Applicable Laws and each Party's written compliance

policies and procedures and will address, without limitation, all matters identified in the definition of "Medical Affairs."

7.2 Compassionate Use, Early Access Programs, and Named Patient Programs

. Sobi shall be responsible for and control all compassionate use, early access programs, and named patient programs for Products in the Sobi Territory, and Apellis shall be responsible for and control all compassionate use, early access programs and named patient programs for Products in the Apellis Territory. Except with respect to any compassionate use program existing or committed as of the Effective Date, following the Effective Date neither Party may conduct any compassionate use (for clarity, not including any early access program or named patient program) program with respect to any Product without the prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed). Promptly after the Effective Date, Apellis shall summarize to Sobi and, on Sobi's reasonable request, shall, to the extent permitted by Applicable Law and consistent with patient safety, transfer responsibility in the Sobi Territory for, any committed compassionate use, early access, or named patient programs for Products resulting from Development activities prior to the Effective Date.

7.3 Medical Affairs Costs

. Except as otherwise set forth in the Medical Affairs Strategy or unanimously agreed by the JMC, each Party shall solely bear all costs and expenses incurred by such Party in conducting Medical Affairs for Products.

7.4 Medical Education Materials

. Apellis shall be responsible for preparing, producing, and disseminating all Medical Education Materials for use in the Apellis Territory. Sobi shall be responsible for preparing and producing all Medical Education Materials for use in the Sobi Territory. Each Party shall submit copies of initial versions of, and any material updates to, the material Medical Education Materials for which it is responsible (excluding translations of Medical Education Materials that have been previously provided to the JMC) to the JMC. Each Party shall ensure that all Medical Education Materials used by or on behalf of such Party for any Product are compliant with Applicable Laws and materially consistent with the Medical Affairs Strategy.

7.5 Congresses; Key Opinion Leaders

. The JMC shall, in accordance with Section 3.4.2(e) (Specific Responsibilities of the JMC), coordinate each Party's participation at global symposia, congresses, and similar meetings concerning Products, and interactions with key opinion leaders concerning Products in the country(ies) in which the other Party has the right to Commercialize Products.

7.6 Medical Information

. Each Party shall establish and maintain a separate medical information function to address scientific and medical information requests from healthcare providers relating to the Products. Each Party shall ensure that such Party's medical information functions respond to scientific and medical information requests related to the Products in a manner materially consistent with the Medical Affairs Strategy.

7.7 Reporting

. Each Party shall provide the JMC with proposed updates to the Medical Affairs Strategy for the JMC's review. Each Party shall keep the other Party reasonably informed, through the JMC, about the status of such Party's Medical Affairs activities for the Products in the Apellis Territory, each Major Market, and all other countries in the Sobi Territory in combination by providing, on a [**] basis (or, during any period in which the JMC is only meeting [**], on a [**] basis), a reasonably detailed summary report of such Medical Affairs activities conducted during the prior [**] (or [**] as applicable).

7.8 Compliance

. Each Party shall, and shall ensure that its Affiliates, sub/licensees, Sublicensees, and Subcontractors, comply in all material respects with all Applicable Laws in conducting Medical

Affairs with respect to the Products. Each Party shall promptly inform the JMC of any investigation or adverse action taken by any Governmental Authority with respect to the conduct of Medical Affairs with respect to any Product of which such Party becomes aware.

ARTICLE 8
MANUFACTURING

8.1 Sobi Right to Manufacture

Drug Substance.

8.1.1 **Drug Substance**. Notwithstanding Sections 8.5 (Supply of Compound and Product for Development Activities) and 8.6 (Supply Agreement), Apellis acknowledges and agrees that Sobi shall have the right to Manufacture, through any of Apellis' contract manufacturing organizations (or any Third Party supplier to Apellis' contract manufacturing organizations of materials or intermediates) or any contract manufacturing organization or supplier identified by Sobi and reasonably acceptable to Apellis, the Compound in formulated bulk drug substance form ("**Drug Substance**") (a) upon a Change of Control of Apellis or (b) upon a Failure to Supply under the Supply Agreement.

8.1.2 **Local Manufacturing**. If Sobi notifies the JMSC that, under Applicable Law or the requirements of any Regulatory Authority or any other Governmental Authority, local Manufacturing by or on behalf of Sobi is required in a particular country or region in the Sobi Territory of the Drug Substance of any Product sold in such country or region, the JMSC shall determine whether and on what conditions Sobi shall, itself or through an Affiliate or Third Party reasonably acceptable to Apellis, Manufacture such Drug Substance in such country or region, pursuant to Section 3.6.2(e) (Specific Responsibilities of the JMSC).

(a) If the JMSC cannot agree on a process for Manufacturing Drug Substance in a given country or region in the Sobi Territory where local Manufacturing of such Drug Substance is required in order for Sobi to Develop or Commercialize any Product in such country or region, then (i) such disagreement shall be referred to the JEC for resolution in accordance with Section 3.7.2 (Escalation to JEC) and (ii) Sobi may not Manufacture Drug Substance in such country or region, but Sobi's diligence obligations with respect to such Product in such country or region shall cease unless and until the JEC unanimously agrees to a process for such local Manufacturing.

(b) For purposes of this Section 8.1.2 (Local Manufacturing), (i) Apellis shall not unreasonably refuse to agree to any contract manufacturing organization or any plan to address any requirement under Applicable Law or the requirements of any Regulatory Authority or any other Governmental Authority for local Manufacturing, (ii) Apellis acknowledges that China is an important market for Products for Sobi, and (iii) Sobi acknowledges (A) the importance of Apellis' contractual obligations under the Apellis Supply Agreements and (B) the sensitivity of confidential Manufacturing Know-How and other Know-How of Apellis and its Third Party manufacturing partners.

8.2 Sobi Right to Manufacture Drug Product

. The Parties shall collaborate in good faith to qualify and validate a contract manufacturing organization reasonably acceptable to both Parties to serve as a second source of supply for final dosage form (but not in Finished Form) of the Products ("**Drug Product**") for Apellis and a primary source of supply for Drug Product for Sobi, provided

however that, if the Parties cannot agree on such contract manufacturing organization Sobi may identify a contract manufacturing organization reasonably acceptable to Apellis (and Apellis may not unreasonably withhold its consent to such contract manufacturing organization) and with whom Sobi shall be the contracting party, to be qualified and validated as a primary source of supply for Drug Product for Sobi (in either case, such contract manufacturing organization the "**Second Source**"). Subject to the terms of the Supply Agreement, Sobi may obtain [**] percent ([**]%) of its requirements of Drug Product from such Second Source at any time during the Term, but Sobi will coordinate with Apellis via the JMSC to minimize adverse effects upon Apellis.

8.3 Manufacturing Technical Transfer

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8.3.1 **Manufacturing Know-How**. Without limiting either Party's obligations under Section 2.4 (Technology, Data, and Regulatory Transfer) or Section 8.1.2 (Local Manufacturing), within a reasonable time period following the engagement by Sobi of an applicable contract manufacturing organization or supplier reasonably acceptable to Apellis pursuant to Section 8.1 (Sobi Right to Manufacture Drug Substance) (with respect to Drug Substance) or Sobi's engagement of the Second Source (with respect to Drug Products), as applicable, Apellis shall provide (or cause its relevant Affiliates or subcontractors of Drug Substance or Drug Product, as applicable, to provide) such contract manufacturing organization, supplier, or Second Source (as applicable) with all Apellis Know-How necessary to Manufacture the Drug Substance or the Drug Product, as applicable, (the "**Manufacturing Know-How**") that has not previously been transferred in accordance with Section 2.4 (Technology, Data, and Regulatory Transfer) or Section 8.1.2 (Local Manufacturing), to be held in confidence by such contract manufacturing organization, supplier, or Second Source (as applicable) until such time (if any) that Sobi obtains the right to Manufacture Drug Substance or Drug Product (as applicable) pursuant to Section 8.1 (Sobi Right to Manufacture Drug Substance) or Section 8.2 (Sobi Right to Manufacture Drug Product) (as applicable).

8.3.2 **Manufacturer Know-How**.

(a) To the extent necessary to obtain and maintain Regulatory Approvals for Products in each country in the Sobi Territory and to Manufacture Drug Substance or Drug Product (as applicable) pursuant to Section 8.1 (Sobi Right to Manufacture Drug Substance) or Section 8.2 (Sobi Right to Manufacture Drug Product) (as applicable), Apellis will exercise Commercially Reasonable Efforts to either (i) obtain for Sobi from [**] the right to use and disclose or reference (itself or through [**]) any Know-How, Intellectual Property, Regulatory Data, or drug master file controlled by [**] that is not Assigned Manufacturer IP or Licensed Manufacturer IP or (ii) subject to Section 8.3.2(b) (Manufacturer Know-How), promptly establish an alternate supplier to provide any such Know-How (an "**Alternate Supplier**"). If (A) in order to enable Sobi to obtain and maintain Regulatory Approval for a Product in a country in the Sobi Territory, Apellis is required to establish an Alternate Supplier and (B) such establishment of an Alternate Supplier delays Sobi's receipt of Regulatory Approval for such Product in such country, then (if it has not already been paid) Sobi shall no longer be required to pay Apellis the [**] Dollar ($[**]) Development Milestone Payment for the [**].

(b) If Apellis is required to establish an Alternate Supplier pursuant to Section 8.3.2(a)(ii) (Manufacturer Know-How), Apellis shall:

(i) use Commercially Reasonable Efforts to establish an Alternate Supplier that is fully and properly qualified and validated and in a position to Manufacture Drug Substance or Drug Product (as applicable) in accordance with Sobi's then-current Development timeline and the Global Development Plan;

(ii) reasonably consult with Sobi in any negotiations with such Alternate Supplier and consider in good faith any reasonable comments of Sobi on the proposed agreement(s) with such Alternate Supplier; and

(iii) use Commercially Reasonable Efforts to arrange with such Alternate Supplier that any Know-How developed by such Alternate Supplier that is necessary to obtain and maintain Regulatory Approvals for Products in each country in the Sobi Territory and to Manufacture Drug Substance or Drug Product will be Controlled by Apellis.

(c) In the event that, despite the use of Commercially Reasonable Efforts, Apellis is both unable to obtain for Sobi the rights set forth in Section 8.3.2(a)(i) (Manufacturer Know-How) and unable to obtain a Alternate Supplier as set forth in Section 8.3.2(a)(ii) (Manufacturer Know-How), then:

(i) the Parties will cooperate in good faith to resolve the issue, using Commercially Reasonable Efforts, as soon as reasonably practicable; and

(ii) to the extent and for so long as Sobi is unable to obtain and maintain Regulatory Approval for a given Product in a given country due to Sobi's inability to use or disclose applicable Know-How controlled by the Manufacturers of such Product, Sobi's diligence obligations to obtain Regulatory Approval for, and Commercialize, such Product in such country under Section 4.3 (Development Diligence Obligations) and Section 6.2 (Commercialization Diligence Obligations) shall cease, Apellis shall have no right to terminate this Agreement with respect to such country pursuant to Section 14.2.2(b) (Breach by Sobi), and nothing in this Agreement (other than Article 13 (Confidentiality)) shall restrict Sobi from performing such activities as it reasonably determines are necessary to produce or recreate the Know-How that Sobi needs to obtain and maintain Regulatory Approval for such Product in such country. The remedies provided in this Section 8.3.2(c)(ii) (Manufacturer Know-How) are in addition to, and not in substitution for, any other remedies provided in this Agreement or now or hereafter existing at law or in equity.

8.4 Manufacturing and Supply Chain Plan

. No later than [**] after the Parties establish the JMSC, the JMSC shall prepare and provide to the Parties for review and approval a reasonably detailed plan for the Manufacture and supply of the Compounds and Products (including any Manufacturing improvements) by or on behalf of Apellis for Development and Commercialization purposes for the following [**] period (the "**Manufacturing and Supply Chain Plan**"). The initial draft of such plan and all updates thereto shall provide an overview of the following for at least the following [**] period: (a) reserved capacity (to the extent reasonable and applicable) and minimum purchase commitments for supply of the Compounds and Products, (b) each Third Party engaged to perform each step in the Manufacturing activities and supply chain of Apellis, including an end-to-end mapping of all such Third Parties engaged, (c) Apellis' plans to establish alternate suppliers (to the

extent reasonable and applicable), (d) Apellis' capabilities for undertaking Manufacturing lifecycle management changes with respect to any Compound or Product, and (e) a go-to-market supply plan for Product to be supplied under the Supply Agreement. The JMSC shall review and update, and provide to the Parties for review and approval, the updated Manufacturing and Supply Chain Plan at least [**] (unless the Parties agree in writing to a different frequency).

8.5 Supply of Compound and Product for Development Activities.

8.5.1 **Development Supply**. Pursuant to the terms of the Supply Agreement once executed and, prior to execution, pursuant to this Section 8.5.1 (Development Supply), Apellis shall Manufacture and supply (or ensure the Manufacture and supply of) quantities of Compound, Product, and placebo as necessary for the completion of: (x) the Global Development Activities assigned to Apellis or Sobi in the Global Development Plan and (y) the Unilateral Development Activities and Unilateral Combination Therapy Development Activities conducted by or on behalf of Apellis or Sobi.

8.5.2 **Shelf Life and Compliance**. Apellis shall ensure that, at the time of delivery of Compound or Product for Development purposes in accordance with Section 8.5.1 (Development Supply) or the Supply Agreement:

(a) the Compound, Product, and placebo, as applicable, shall have a remaining shelf life as is required to conduct the Clinical Trial for which it is being supplied; and

(b) the Compound, Product, and placebo, as applicable, shall have been Manufactured, released, stored, supplied, packaged, and labelled in compliance with: (i) the applicable specifications; (ii) the Quality Agreement; and (iii) all Applicable Law, applicable GMP, and GCP.

8.5.3 **Inspection.** If Apellis becomes aware or determines that Compound, Product, or placebo, as applicable, supplied by Apellis to Sobi pursuant to this Section 8.5 (Supply of Compound and Product for Development Activities) is not, or has not been Manufactured, released, stored, supplied, packaged, and labelled, in compliance with the requirements set forth in Section 8.5.2 (Shelf Life and Compliance), then Apellis shall promptly provide written notice thereof to Sobi and shall remedy such non-compliance and, without limiting the foregoing, shall promptly enforce any rights or obligations under Apellis' written agreement with any contract manufacturing organization or Third Party supplier to ensure such violations are rectified as expeditiously as possible. In the event of such notice, or if Sobi has reasonable concerns about compliance with such requirements, Apellis shall, to the extent permitted under its applicable agreements, permit (and shall cause its contract manufacturing organization or Third Party supplier to permit) Sobi or an independent Third Party to enter the manufacturing site of such contract manufacturing organization or supplier to inspect and verify compliance with such requirements.

8.5.4 **Responsibility**. Apellis shall be solely responsible for obtaining and maintaining (or for ensuring that its relevant contract manufacturers obtain and maintain) all approvals of Regulatory Authorities that are required to Manufacture, release, store, and supply the Compound, Product, or placebo, as applicable, in compliance with Applicable Law and GMP.

Sobi shall be excused from any non-performance under this Agreement to the extent resulting from Apellis' Failure to Supply Product under this Agreement in a timely manner.

8.6 Supply Agreement

. Without limiting Section 8.5 (Supply of Compound and Product for Development Activities), within [**] after the Effective Date, the Parties shall negotiate in good faith and enter into a supply agreement that will govern the terms and conditions of the Manufacture and supply of Drug Substance and Drug Product by Apellis to Sobi and its Affiliates for use in Development and Commercialization, along with a related quality agreement (the "**Supply Agreement**"). The Supply Agreement shall be consistent with this Agreement and shall contain the terms set forth in Schedule 8.6 (Supply Agreement Material Terms), and otherwise contain terms customary for supply agreements between licensees and licensors. Apellis shall supply, and Sobi shall purchase, Drug Substance and Drug Product in the quantities, on the timelines, at the prices, and otherwise subject to the terms and conditions, set forth in the Supply Agreement. For the avoidance of doubt, none of the JMSC, the JDC, the JMC, JCC nor the JEC shall have any power or authority to amend or require any amendment to the Supply Agreement. For clarity, Sobi shall be excused from any non-performance under this Agreement resulting from Apellis' Failure to Supply Product under the Supply Agreement in a timely manner.

8.7 Packaging and Delivery

. Sobi shall be responsible for all Finished Form packaging for Products for clinical studies and Clinical Trials conducted by or on behalf of Sobi and for Commercialization in each country in the Sobi Territory, except for clinical studies and Clinical Trials as to which the Global Development Plan provides that Sobi and Apellis shall mutually agree upon the responsibility for such Finished Form packaging. Without limiting the foregoing, Sobi shall have the right, in its sole discretion, to co-pack the Product with an administration device in any country in the Sobi Territory.

8.8 Supply Shortages

. In the event that any shortage in the quantities of materials or Compound or constraint of Apellis' or its Affiliates' or any Third Party's Manufacturing capacity will or is reasonably likely to affect quantities of Supplied Product (as defined in Schedule 8.6 (Supply Agreement Material Terms)) available to Sobi, Apellis shall not prioritize supply to Apellis (either for the Product or the Non-Systemic Ophthalmology Product) or Third Party(ies), and, as may be more specifically provided for in the Supply Agreement, Apellis shall allocate or cause to be allocated available quantities of materials, Compound or capacity, to ensure that Sobi receives at least its *pro rata* share, taking into account the needs of patients (including patient safety and the needs of patients relying on supply of Products for life saving purposes).

8.9 Manufacturing Process Costs

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8.9.1 **Cost Sharing**. Each Party shall bear its *pro rata* share (based upon, prior to execution of the Supply Agreement, each Party's anticipated future respective demand for the Product and any Non-Systemic Ophthalmology Product for its territory and, following execution of the Supply Agreement, as provided for therein) of all reasonable Out-of-Pocket Costs incurred by Apellis or any of its Affiliates in conducting process development, capital investments in facilities or equipment, or other similar activities, including such activities intended to improve the Manufacturing process for, or reduce the costs of Manufacturing, any Compound or Product as reasonably substantiated in writing in advance of incurring such Out-of-Pocket Costs and taking into account the Parties' relative Manufacturing volumes and requirements ("**Manufacturing Process Costs**"), as long as:

(a) Sobi's share of such Manufacturing Process Costs and related activities:

(i) are (A) for Calendar Year 2021 no more than the lesser of (1) [**] percent ([**]%) of such Manufacturing Process Costs actually incurred by Apellis or (2) [**] dollars ($[**])) (such amount and a reasonable description of

such corresponding activities are set forth on Schedule 8.9 (Estimated Manufacturing Process Costs)), or (B) less than [**] dollars ($[**]) in any other given Calendar Year (such amounts set forth in this clause (i) being deemed approved by Sobi); or

(ii) except as set forth in clause (i), (A) with respect to any other estimated costs set forth on Schedule 8.9 (Estimated Manufacturing Process Costs), have been approved in writing by Sobi within [**] after the Effective Date (or such later date by which Apellis has provided reasonable documentation to Sobi, as is customary for a public company to review in connection with such investment, substantiating the business case and basis(es) for such Manufacturing Process Costs, including the related risks and benefits thereof, and the Parties have had a reasonable opportunity to discuss the extent of such development, investment, or activities and the costs related thereto) or (B) are otherwise approved in advance in writing by Sobi; and

(b) any quantifiable reduction in costs of the Manufacturing process is reflected in any Manufacturing Costs paid by Sobi from and after the date of such reduction.

Sobi shall reimburse, subject to this Section 8.9 (Manufacturing Process Costs), Apellis for its share of such Manufacturing Process Costs within [**] after receipt of any invoice therefor.

8.9.2 **No Cost Sharing**. If (x) Apellis proposes undertaking any process development, capital investments in facilities or equipment, or other activities to improve the Manufacturing process for, or reduce the costs of Manufacturing, any Compound or Product in accordance with Section 8.9.1 (Cost Sharing) and (y) Sobi declines to bear (and is not deemed to approve pursuant to Section 8.9.1(a)(i) (Cost Sharing)) its *pro rata* share of the Manufacturing Process Costs that will be incurred in conducting such activities, then Apellis may refuse to permit Sobi to benefit from any improvements or cost reductions resulting from such activities unless and until Sobi, at its sole election (after having been provided with a reasonably detailed summary of such Manufacturing Process Costs incurred to date and reasonably expected to be incurred thereafter), provides written notice to Apellis that it elects to bear Sobi's *pro rata* share of the Manufacturing Process Costs and pays Apellis [**] percent ([**]%) of Sobi's *pro rata* share of such Manufacturing Process Costs that Apellis has incurred as of the date that such notice is provided by Sobi to Apellis; *provided, however*, that, after Sobi provides such notice, and provided that Sobi pays such [**] percent ([**]%) of the *pro rata* share of such Manufacturing Process Costs, Sobi shall bear only [**] percent ([**]%) of its *pro rata* share of such Manufacturing Process Costs incurred by Apellis after such notice is provided.

8.10 **Regulatory Disclosure Fees**. If, pursuant to the terms of any Apellis Supply Agreement, any party to such Apellis Supply Agreement charges Apellis a fee in connection with the disclosure of any Know-How relating to the Manufacture of any Compound or Product to any Regulatory Authority in the Sobi Territory, Sobi shall be solely responsible for such fee and shall reimburse Apellis for any such fee within [**] after receipt of any invoice therefor.

8.11 **Apellis Supply Agreement**. With respect to each Apellis Supply Agreement negotiated by Apellis after the Effective Date, Apellis shall use good faith efforts to permit Sobi to review and comment

on drafts of such Apellis Supply Agreement and shall consider all reasonable comments from Sobi regarding such Apellis Supply Agreement in good faith.

ARTICLE 9
PAYMENTS

9.1 Upfront Fee

. In partial consideration of the rights and licenses granted by Apellis to Sobi under this Agreement, within [**] after the Effective Date, Sobi shall pay to Apellis a one-time upfront amount equal to two hundred fifty million dollars ($250,000,000.00).

9.2 Development Reimbursement Payments

. Subject to (a) Apellis' exercise of Commercially Reasonable Efforts toward the completion of the Global Development Activities assigned to Apellis in the Global Development Plan in accordance with the timelines set forth therein and (b) Apellis incurring at least Eighty Million Dollars ($80,000,000.00) in internal and external costs and expenses in Developing Compounds and Products, within [**] after the corresponding date set forth in table 9.2 below, Sobi shall make the following payments ("**Development Reimbursement Payments**") to Apellis to reimburse Apellis for a portion of the costs and expenses incurred by Apellis in conducting such Global Development Activities:

Table 9.2: Development Reimbursement Payments	
Date	***Payment***
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

9.3 Development Milestones

. Subject to the terms and conditions of this Agreement, including Section 8.3.2(a) (Manufacturer Know-How), Sobi shall pay to Apellis the following one (1) time milestone payments (each, a "**Development Milestone Payment**") upon the first achievement of each corresponding milestone event (each, a "**Development Milestone Event**").

Table 9.3: Development Milestones	
Development Milestone Event	***Development Milestone Payment***
First Regulatory Approval and Reimbursement Approval of a Product [**]	[**]
First Regulatory Approval and Reimbursement Approval of a Product [**]	[**]
First Regulatory Approval and Reimbursement Approval of a Product [**]	[**]
First Regulatory Approval and Reimbursement Approval of a Product [**]	[**]

Table 9.3: Development Milestones	
Development Milestone Event	***Development Milestone Payment***
First Regulatory Approval and Reimbursement Approval of a Product [**]	[**]
First Regulatory Approval and Reimbursement Approval of a Product [**]	[**]
First Regulatory Approval and Reimbursement Approval of a Product [**]	[**]
First Regulatory Approval and Reimbursement Approval of a Product [**]	[**]
First Regulatory Approval and Reimbursement Approval of a Product [**]	[**]
First Regulatory Approval and Reimbursement Approval of a Product [**]	[**]
First Regulatory Approval and Reimbursement Approval of a Product [**]	[**]
First Regulatory Approval and Reimbursement Approval of a Product [**]	[**]

9.3.1 Sobi shall notify Apellis of the achievement of each Development Milestone Event within [**] after such achievement and Apellis may issue an invoice to Sobi in respect of the same. Within [**] after receipt of each Development Milestone Event invoice, Sobi shall pay the applicable Development Milestone Payment amount to Apellis.

9.3.2 Each Development Milestone Payments shall be paid only once on the first occurrence of such Development Milestone Event by Sobi or any of its Affiliates or Sublicensees, notwithstanding the potential Development of multiple Products hereunder which may involve separate Clinical Trials or Regulatory Approvals and regardless of how many times such Development Milestone Event is achieved or the number of Products that achieve such Development Milestone Event.

9.4 Commercial Milestones

. Subject to the terms and conditions of this Agreement, Sobi shall pay to Apellis the following one (1) time milestone payments (each, a "**Commercial Milestone Payment**") upon the first achievement of the corresponding milestone event (each, a "**Commercial Milestone Event**").

Table 9.4: Commercial Milestones	
Commercial Milestone Event	***Commercial Milestone Payment***
Aggregate Net Sales in a Calendar Year of all Products in the Sobi Territory greater than $[**]	[**]
Aggregate Net Sales in a Calendar Year of all Products in the Sobi Territory greater than $[**]	[**]
Aggregate Net Sales in a Calendar Year of all Products in the Sobi Territory greater than $[**]	[**]

Table 9.4: Commercial Milestones	
Commercial Milestone Event	***Commercial Milestone Payment***
Aggregate Net Sales in a Calendar Year of all Products in the Sobi Territory greater than $[**]	[**]
Aggregate Net Sales in a Calendar Year of all Products in the Sobi Territory greater than $[**]	[**]

9.4.1 Sobi shall notify Apellis of the achievement of any Commercial Milestone Event within [**] after becoming aware of such achievement, and Apellis may issue an invoice to Sobi in respect of the same. Sobi shall pay Apellis the applicable Commercial Milestone Payment within [**] after receipt of each Commercial Milestone Event invoice.

9.4.2 Each Commercial Milestone Payments shall be paid only once, regardless of how many times such Commercial Milestone Event is achieved or the number of Products that achieve such Commercial Milestone Event.

9.4.3 For the avoidance of doubt, the potential aggregate total of all Commercial Milestone Payments payable for Products under this Agreement if all Commercial Milestone Events for the Products are achieved will be $675,000,000.00.

9.4.4 Net Sales in a given country shall not be considered for the purposes of the calculation of the Commercial Milestone Events in this Section9.4 (Commercial Milestones) following expiration of the Royalty Term in a such country.

9.5 Royalty Payments

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9.5.1 **Royalty Rate**. Subject to Section 9.5.2 (Royalty Term) and Section 9.5.3 (Royalty Reduction), Sobi shall pay to Apellis royalties on aggregate Net Sales of Products in the Sobi Territory in each Calendar Year as set forth below:

Table 9.5.1: Royalty Rates	
Aggregate Net Sales of all Products in the Sobi Territory in a Calendar Year	***Royalty Rate***
Portion of aggregate Net Sales of Products in the Sobi Territory up to and including [**] Dollars ($[**])	[**]%
Portion of aggregate Net Sales of Products in the Sobi Territory greater than [**] Dollars ($[**]) and up to and including [**] Dollars ($[**])	[**]%
Portion of aggregate Net Sales of Products in the Sobi Territory greater than [**] Dollars ($[**]) and up to and including [**] Dollars ($[**])	[**]%
Portion of aggregate Net Sales of Products in the Sobi Territory greater than [**] Dollars ($[**]) and up to and including [**] Dollars ($[**])	[**]%
Portion of aggregate Net Sales of Products in the Sobi Territory greater than [**] Dollars ($[**])	[**]%

Each royalty rate set forth in the table above will apply only to that portion of the aggregate Net Sales of Products in the Sobi Territory during a given Calendar Year that falls within

the indicated portion. For example, if aggregate Net Sales of Products in the Sobi Territory in a given Calendar Year were [**] Dollars ($[**]), then the royalties payable with respect to such Net Sales would be:

[**].

No multiple royalties will be payable under this Section 9.5 (Royalty Payments) regardless of the number of Valid Claims in any Apellis Patent Rights covering a Product.

9.5.2 **Royalty Term**. Royalties payable under this Section 9.5 (Royalty Payments) shall be paid by Sobi on a Product-by-Product and country-by-country basis from the Effective Date until the latest of:

(a) expiration of the last-to-expire Valid Claim in the Apellis Patent Rights (for the avoidance of doubt, including Joint Patent Rights) Covering such Product in such country;

(b) ten (10) years following the First Commercial Sale of such Product in such country; and

(c) the expiration of all Regulatory Exclusivity for such Product in such country;

(each such term with respect to a Product in a country, a "**Royalty Term**"); except that, notwithstanding anything to the contrary in this Agreement, if at any time (i) the Royalty Term for a Product and country in the Sobi Territory has expired (and, for the avoidance of doubt, all Valid Claims as defined under this Agreement Covering such Product in such country have expired) but (ii) because there is a pending Valid Claim (as defined in the Penn Other Fields License) that has been pending for more than [**], Apellis owes Penn a royalty for Sales (as defined in the Penn Other Fields License) of such Product in such country under the Penn Other Fields License, then Sobi shall report and pay to Apellis royalties on such Sales of Products in the Sobi Territory equal to the royalties owed by Apellis to Penn for such Sales under the Penn Other Fields License.

9.5.3 **Royalty Reduction.**

(a) On a Product-by-Product and country-by-country basis, subject to Section 9.5.3(d) (Royalty Reduction), during any period in which (i) such Product in such country is not Covered by a Valid Claim in the Apellis Patent Rights (for the avoidance of doubt, including Joint Patent Rights) in the applicable country and (ii) there is no Regulatory Exclusivity with respect to such Product in such country, the royalty rate with respect to such Product in such country will be reduced to [**] percent ([**]%) of the applicable rate set forth in Section 9.5.1 (Royalty Rate).

(b) On a Product-by-Product and country-by-country basis, subject to Section 9.5.3(d) (Royalty Reduction), Sobi may deduct from the royalties otherwise owed to Apellis pursuant to Section 9.5.1 (Royalty Rate) with respect to such Product in such country, [**] percent ([**]%) of any Third Party Payments paid by Sobi with respect to such Product in such country.

(c) On a Product-by-Product and country-by-country basis, if, during any Calendar Quarter during the Royalty Term for such Product in such country:

(i) there are one (1) or more Generic Products or Biosimilar Products being sold in such country with respect to such Product; and

(ii) either:

A. such Generic Product(s) or Biosimilar Product(s), by unit equivalent volume in such country, exceed a [**] percent ([**]%) share of the aggregate market in such country of such Product and all such Generic Product(s) or Biosimilar Product(s) (based on the number of units of such Product and such Generic Product(s) or Biosimilar Product(s) in the aggregate sold in such country, as reported by a well-known reporting service agreed between the Parties acting reasonably (*e.g.*, [**])); or

B. as a result of competition from Generic Products or Biosimilar Products in such country, the Net Sales of such Product are reduced by [**] percent ([**]%) in a Calendar Quarter when compared to the Calendar Quarter before the entry of the relevant Generic Product or Biosimilar Product in such country,

then, subject to Section 9.5.3(d) (Royalty Reduction), the royalty rates payable under this Agreement with respect to such Product in such country for such Calendar Quarter shall be reduced to [**] percent ([**]%) of the applicable rate set forth in Section 9.5.1 (Royalty Rate) and Sobi shall not be in breach of its obligations under Section 6.2 (Commercialization Diligence Obligations) if Sobi ceases or reduces its efforts to actively market or promote such Product in such country following the entry of such Generic Product or Biosimilar Product, as long as such cessation or reduction satisfies the definition of Commercially Reasonable Efforts under the circumstances. For purposes of this Section 9.5.3(c) (Royalty Reduction), (X) "**Generic Product**" means, in a particular country with respect to a Product regulated as a drug product, any drug product that: (1) contains the same active ingredient as the Product; (2) has received all necessary approvals by the applicable Regulatory Authorities authorizing the marketing and sale of such product as a drug product; (3) is marketed or sold by a Third Party that has not obtained the rights to market or sell such product as a licensee, sublicensee or distributor of Sobi or any of its Affiliates or Sublicensees with respect to such product, other than as a result of settlement of any litigation; and (4) is approved for use in such country pursuant to an abbreviated regulatory approval process governing approval of follow-on drug products based on the then-current standards for regulatory approval in such country (e.g., a non-U.S. equivalent to an abbreviated new drug application submitted pursuant to Section 505(j) of the FD&C Act (21 U.S.C. 355(j)), a new drug application submitted pursuant to Section 505(b)(2) of the FD&C Act (21 U.S.C. 355(b)(2)), or a relevant equivalent under foreign law) and where such regulatory approval was based in whole or in part upon the findings by the Regulatory Authority of clinical safety and efficacy based on data generated by Sobi (or its Affiliate or Sublicensee) or Apellis (or its Affiliate or sublicensee) included in a Regulatory Submission for Regulatory Approval in a particular country with respect to the Product, and (Y) "**Biosimilar Product**" means, in a particular country with respect to a Product regulated as a

biological product, any biological product that: (I) has received all necessary approvals and licensures by the applicable Regulatory Authorities in such country to market and sell such product as a biosimilar product; (II) is marketed or sold by a Third Party that is not a Sublicensee, other than a Sublicensee who is a Sublicensee as a result of settlement of any litigation; and (III) is approved as a (1) (1) "similar biological medicinal product" with respect to which such Product is the "reference medicinal product," or (2) if not in the European Union, as the foreign equivalent of a "biosimilar" or "similar biological medicinal product" of such Product; in each case ((1)-(2)), for use in such country pursuant to an abbreviated regulatory approval process governing approval of biosimilars based on the then-current standards for regulatory approval in such country (and where such regulatory approval was based in part upon findings by the Regulatory Authority of clinical safety and efficacy based on clinical data generated by Sobi (or its Affiliate or Sublicensee) or Apellis (or its Affiliate or sublicensee) with respect to such Product.

(d) In no event shall the royalty reductions described in this Section 9.5.3 (Royalty Reduction), alone or together, reduce the royalties payable by Sobi for a Product in a country in any given Calendar Quarter to less than [**] percent ([**]%) of the amounts otherwise payable by Sobi for such Product in such country in such Calendar Quarter pursuant to Section 9.5.1 (Royalty Rate). Sobi may carry over and apply any such royalty reductions that are incurred or accrued in a Calendar Quarter and are not deducted in such Calendar Quarter due to the limitation set forth in the first sentence of this Section 9.5.3(d) (Royalty Reduction), to any subsequent Calendar Quarter(s) and shall begin applying such reductions to such royalties as soon as practicable and continue applying such reductions on a Calendar Quarter basis thereafter until fully deducted, in all cases subject to the limitation set forth in the first sentence of this Section 9.5.3(d) (Royalty Reduction).

9.5.4 **Expiration of Royalty Term**. Upon the expiration of the Royalty Term with respect to a Product in a country, the license granted by Apellis to Sobi pursuant to Section 2.1.1(a)(ii) (License Grants to Sobi) with respect to such Product in such country shall be deemed to be fully paid-up, royalty-free, non-terminable, irrevocable, and perpetual, but, solely following the expiration of the applicable Royalty Term, Sobi shall (in accordance with a plan agreed by the Parties at such time in good faith) assume and be solely responsible for any outstanding amounts payable to Apellis' Third Party licensors (including Penn, as set forth in Section 9.5.2 (Royalty Term)) to the extent related to the Sobi Territory (and for clarity, Apellis shall continue to be responsible for any outstanding amounts related to the Apellis Territory).

9.5.5 **Royalty Reports; Payments**. Sobi shall, within [**] following the end of each Calendar Quarter, provide Apellis with a good faith estimate of royalties that will be paid to Apellis under this Agreement for such Calendar Quarter. Sobi shall, within [**] following the end of each Calendar Quarter in which a royalty payment accrues, (a) provide to Apellis a report specifying for such Calendar Quarter: the number units of each Product sold by Sobi, its Affiliates or its Sublicensees on which royalty payments are owed to Apellis; subject to Sobi using Commercially Reasonably Efforts to procure the same, the number of units of Each Product sold by any Functional Sublicensee on which royalty payments are owed to Apellis; the gross amount received for such sales (with gross amount received for sales by Functional Sublicensees broken out separately, where such information is available); the

Net Sales during such Calendar Quarter, including any deductions taken as permitted under such definition, listed by category of cost, with Net Sales received for sales by Functional Sublicensees broken out separately, where such information is available; the amount of any credits or reductions, if any, taken or made pursuant to Section 9.5.3 (Royalty Reductions); the calculation of the royalty payable to Apellis for such Net Sales pursuant to Section 9.5 (Royalty Payments); the applicable exchange rate to convert from each country's currency to U.S. Dollars under Section 9.9 (Currency Conversion); and the royalty calculation and royalties payable in U.S. Dollars, and (b) make the royalty payments owed to Apellis hereunder in accordance with such royalty report in arrears. If Sobi is not able to obtain any information set forth in this Section 9.5.5 (Royalty Reports; Payments) regarding Functional Sublicensee sales despite Sobi having used Commercially Reasonable Efforts to obtain it, and the Parties are unable to agree upon such information, the Parties shall submit such dispute for resolution to a mutually agreed independent accounting expert, whose decision will be final and binding on the Parties and shall be deemed included in the applicable royalty report(s). In addition, at Apellis' reasonable request, Sobi shall cooperate with Apellis in good faith to provide Penn any additional royalty-related information reasonably requested or required by Penn under the Penn Other Fields License Agreement. Without prejudice to Article 13 (Confidentiality), Apellis undertakes to maintain as Sobi's Confidential Information all information regarding royalties and royalty estimates furnished by Sobi hereunder, except that Apellis shall be entitled to disclose such information in its quarterly reports (i) aggregated with other information in such manner that the information regarding royalties and royalty estimates cannot be identified as relating to Sobi or (ii) following Sobi's disclosure of its full royalty report within [**] following the end of each Calendar Quarter. Apellis acknowledges that information regarding royalties and royalty estimates may constitute inside information in relation to Sobi.

9.6 Payments under Upstream Agreements

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9.6.1 **Penn Other Fields License Agreement**. As between the Parties, Apellis is solely responsible for all amounts payable under the Penn Other Fields License Agreement with respect to the Development, Manufacture, or Commercialization of any Compound or Product worldwide.

9.6.2 **Collaboration In-Licenses**. The costs of each Collaboration In-License, to the extent the costs directly relate to the Development, Manufacture, or Commercialization of Products in the Apellis Territory, or to the Development, Manufacture, or Commercialization of any Non-Systemic Ophthalmology Product anywhere in the world, shall be paid by Apellis. The costs of each Collaboration In-License, to the extent the costs directly relate to the Development, Manufacture, or Commercialization of Products in the Sobi Territory shall be paid by Sobi, subject to deduction from royalties to the extent set forth in Section 9.5.3(b) (Royalty Reduction). To the extent the costs of any Collaboration In-License relate to both (a) the Development, Manufacture, or Commercialization of Products in the Apellis Territory or Non-Systemic Ophthalmology Products anywhere in the world, on the one hand, and (b) the Development, Manufacture, or Commercialization of Products in the Sobi Territory, on the other hand, such costs shall be fairly apportioned between the Parties, and each Party shall reimburse the other Party for its share of such costs within [**] after receipt of any invoice therefor (in the case of Sobi, subject to deduction from royalties to the extent set forth in Section 9.5.3(b) (Royalty Reduction)).

9.7 Taxes and Withholding

; VAT.

9.7.1 **Taxes and Withholding**. Except as expressly set forth in this Section 9.7 (Taxes and Withholding; VAT), each Party shall pay any and all taxes levied on account of all payments it receives under this Agreement. Each Party shall provide such information and documentation to the other Party as are reasonably requested by such other Party to determine if any withholding taxes apply to any payments to be made by such other Party under this Agreement and to establish qualification for a reduced withholding rate or an exemption from such withholding tax under the applicable bilateral income tax treaty or relevant statutory provision. If a Party believes that it is required to withhold taxes on a payment to the other Party, the paying Party shall notify the other Party of such determination no less than [**] prior to making such payment. To the extent that Applicable Laws require that taxes be withheld with respect to any payments to be made by a Party to the other Party under this Agreement, the paying Party shall: (a) deduct those taxes from the remittable payment, (b) pay the taxes to the proper taxing authority, and (c) send evidence of the obligation together with proof of tax payment to the other Party on a reasonable and timely basis following such tax payment. Each Party agrees to cooperate with the other Party in claiming refunds, reductions, or exemptions from such deductions or withholdings under any relevant agreement or treaty that is in effect. Notwithstanding anything to the contrary in this Agreement, in the event a Party redomiciles, assigns its rights or obligations under Section 17.1 (Assignment) of this Agreement, (each, a "**Tax Action**" and such Party, the "**Acting Party**"), and, as a result of such Tax Action, the amount of tax required to be withheld under this Section 9.7.1 (Taxes and Withholding) in respect of a payment to the other Party (the "**Non-Acting Party**") is greater than the amount of such tax that would have been required to have been withheld absent such Tax Action (for the sake of clarification, based on current law (including the double tax treaties between (i) Sweden and the United States and (ii) Sweden and Switzerland), the Parties anticipate a zero percent (0%) rate of withholding for payments made under this Agreement (i.e., before taking into account any Tax Action taken by any Party))), then any such amount payable to the Non-Acting Party shall be adjusted to take into account such withholding taxes as may be necessary so that, after making all required withholdings or credits, the Non-Acting Party receives an amount equal to the sum it would have received had no such Tax Action occurred. The obligation to adjust payments pursuant to the preceding sentence shall not apply, however, to the extent such increased withholding tax (i) would not have been imposed but for a Tax Action taken by the Party receiving the payment subject to withholding under this Section 9.7.1 (Taxes and Withholding) or (ii) is attributable to the failure by the Non-Acting Party to comply with the requirements of this Section 9.7.1 (Taxes and Withholding). For purposes of this Section 9.7.1 (Taxes and Withholding), a "redomiciliation" shall include a reincorporation or other action resulting in a change in tax residence of the applicable Party or its assignee.

9.7.2 **VAT**. Notwithstanding anything to the contrary in this Agreement (including anything to the contrary in Section 9.7.1 (Taxes and Withholding)), this Section 9.7.2 (VAT) shall apply with respect to value added tax or any similar tax ("**VAT**"). All amounts agreed by the Parties under this Agreement are exclusive of VAT. If, under Applicable Law, any VAT is required to be paid in respect of any supply of goods or services under this Agreement, the Party receiving such supply of goods or services shall pay VAT at the applicable rate either (i) to the other Party or, if provided under Applicable Law, (ii) directly to the relevant tax authorities. In each case, the Party providing such supply of goods or services shall issue valid VAT invoice to the other Party in respect of the supply of goods or services.

9.8 Late Payments

, Disputed Payments.

9.8.1 **Late Payments.** Subject to Section 9.8.2 (Disputed Payments), any amount owed by a Party to the other Party under this Agreement that is not paid on or before the date such payment is due shall bear interest at a rate per annum equal to the lesser of (a) the Prime Rate in effect during the period in which such payment is overdue, as published by the *Wall Street Journal*, plus [**], and (b) the highest rate allowed by Applicable Law, in each case ((a) or (b)), such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest; except that, subject to Section 9.8.2 (Disputed Payments), if Sobi has not paid Apellis any amount owed under this Agreement within [**] of the date of Sobi's receipt of a relevant breach notice, the applicable interest rate per annum will be equal to the lesser of (x) [**] the Prime Rate in effect during the period in which such payment is overdue, as published by the *Wall Street Journal*, plus [**], and (y) the highest rate allowed by Applicable Law, for the period commencing on the [**] following Sobi's receipt of such breach notice until the earlier of (i) payment in full of the applicable undisputed amounts by Sobi and (ii) the effective date of any termination of this Agreement.

9.8.2 **Disputed Payments.** If a dispute arises between the Parties, each acting in good faith, in respect of any part of an invoice, the disputing Party shall notify the other Party promptly in writing with particulars of such dispute and shall be entitled to withhold payment of the so disputed part of the invoice. Each Party shall use reasonable efforts to promptly and in good faith resolve the dispute in accordance with Article 16 (Dispute Resolution). Payment of any disputed amounts (together with any interest calculated in accordance with Section 9.8.1 (Late Payments)) shall be made within [**] following the resolution of such dispute, and, unless the arbitrators determine upon a preponderance of the evidence that the paying Party withheld the disputed payment in bad faith (where such burden of proof shall rest solely with the payee Party), the payee Party may not use such withholding as a basis for terminating this Agreement pursuant to Section 14.2 (Termination for Breach).

9.9 Currency Conversion

. Each Party shall use its then-current standard exchange rate methodology, as applied in its external reporting, for the translation of foreign currency transactions into Dollars under this Agreement. Each Party shall give the other Party prompt written notice of any changes to such Party's customary and usual procedures for currency conversion, which shall only apply (a) after such notice has been delivered and (b) if the changes continue to maintain a set methodology for currency conversion.

9.10 Blocked Payments

. If, by reason of Applicable Law in any country, it becomes impossible or illegal for a Party or any of its applicable Affiliates or Sublicensees to transfer, or have transferred on its behalf, any payments to the other Party, the payor Party shall promptly notify the payee Party of the conditions preventing such transfer and such royalties or other payments shall be deposited in local currency in the relevant country to the credit of the payee Party in a recognized banking institution designated by the payee Party or, if none is designated by the payee Party within a period of [**], in a recognized banking institution selected by the payor Party and identified in a notice given to the payee Party pursuant to Section 17.8 (Notices).

9.11 Payment Method

. All payments to be made by a Party to the other Party under this Agreement shall be made in Dollars by wire transfer in immediately available funds to a bank account designated in writing by such other Party.

9.12 Financial Audits

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9.12.1 **Records Retention.** Each Party shall keep (and shall cause its Affiliates, sub/licensees, and Sublicensees to keep), complete and accurate books, records, and related background information pertaining to Shared Development Costs, and Sobi shall keep (and shall cause its Affiliates, sub/licensees, and Sublicensees to keep) complete and accurate books, records, and related background information pertaining to Initial Development Costs, PNH Development Costs, Net Sales and their calculation hereunder, in each case in reasonable detail to permit the other Party to confirm the accuracy of all payments made or required to be paid hereunder for at least the preceding [**].

9.12.2 **Party Audits**.

(a) Upon reasonable (but in any case no less than [**]) advance notice by a Party (the "**Auditing Party**") to the other Party (the "**Audited Party**"), and not more than [**] and [**] (in each case, except for cause), the Audited Party and its Affiliates will permit, and Sobi will cause its sub/licensees and Sublicensees (as applicable) to permit, an independent certified public accounting firm of internationally recognized standing, selected by the Auditing Party and reasonably acceptable to the Audited Party, to have access during normal business hours to such of the records of the Audited Party and its Affiliates and, if applicable, sub/licensees and Sublicensees, as may be reasonably necessary to verify the accuracy of any payments made or required to be made under this Agreement (including with respect to any costs and expenses incurred by a Proposing Party under Section 4.4.4(b)(iii) (Buy-In)), for any year ending not more than [**] prior to the date of such request. The accounting firm will enter into a confidentiality agreement reasonably acceptable to the Audited Party governing the use and disclosure of the Audited Party's and its Affiliates', sub/licensees, and Sublicensees' information disclosed to such firm, and such firm will disclose to the Auditing Party only whether the payments made under this Agreement were accurate and the specific details concerning any discrepancies.

(b) Any disputes with respect to the findings of such accounting firm may be referred by either Party to the dispute resolution procedure set forth in Article 16 (Dispute Resolution). If Sobi is found to have been underpaid any amounts payable to Apellis hereunder, then Apellis shall be entitled to recover any undisputed discrepancy no later than [**] after delivery to the Parties of the final report from such accounting firm. If either Party is found to have overcharged the other Party for any Shared Development Costs hereunder, then the other Party shall be entitled to recover any undisputed overpayment no later than [**] after delivery to the Parties of the final report from such accounting firm. The fees charged by such accounting firm shall be paid by the Auditing Party, except that, if the audit discloses a net underpayment or overcharging of amounts owed of more than [**] percent ([**]%) of total amounts owed or supposed to be charged by the Audited Party for any Calendar Year period covered by the audit, then the Audited Party shall pay the reasonable fees and expenses charged by such accounting firm. The Auditing Party shall treat all financial information disclosed by its accounting firm pursuant to this Section 9.12 (Financial Audits) as Confidential Information of the Audited Party for purposes of Article 13 (Confidentiality), and shall cause its accounting firm to do the same.

9.12.3 **Penn Audits**

. Upon reasonable prior written notice to Sobi, Sobi and its Affiliates and Sublicensees shall provide independent certified public accountants selected by Penn and

reasonably acceptable to Sobi with access to all of the books, records, and related background information required by Section 9.12.1 (Records Retention) to conduct a review or audit of Sales (as defined in the Penn Other Fields License Agreement), Net Sales (as defined in the Penn Other Fields License Agreement), and all of the royalties, fees, and other payments payable under the Penn Other Fields License Agreement. Access shall be made available: (a) during normal business hours; (b) in a manner reasonably designed to facilitate Penn's review or audit without unreasonable disruption to the audited Person's business; and (c) no more than [**] during the Term (as defined in the Penn Other Fields License Agreement) and for a period of [**] thereafter. Sobi shall promptly pay to Apellis the amount of any underpayment determined by the review or audit, plus accrued interest as calculated under the Penn Other Fields License Agreement. If the review or audit determines that, as a result of an under-reporting or underpayment by Sobi or any of its Affiliates or Sublicensees to Apellis, Apellis has underpaid to Penn any payment under the Penn Other Fields License Agreement by [**] percent ([**]%) or more, then Sobi shall also reimburse Apellis an amount equivalent to the amount Apellis is obliged to pay to Penn under the Penn Other Fields License Agreement in respect of the costs and expenses of Penn and its accountants in connection with such review or audit. Apellis shall use reasonable efforts to coordinate any Apellis audit with any Penn audit pursuant to this Section 9.12.3 (Penn Audits) to minimize disruption to the Sobi business.

ARTICLE 10
INTELLECTUAL PROPERTY MATTERS

10.1 Ownership

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10.1.1 **Collaboration Know-How**. Subject to the terms and conditions set forth in this Agreement, including the licenses granted in Section 2.1.1 (License Grants to Sobi) and Section 2.1.2 (License Grants to Apellis):

(a) each Party will own all rights, title, and interests in and to any and all Collaboration Know-How made, invented, conceived, discovered, developed, or otherwise generated solely by or on behalf of such Party or its Affiliates, Subcontractors or (with respect to Sobi) Sublicensees or (with respect to Apellis) sub/licensees and any and all Patent Rights Covering or claiming any such Collaboration Know-How;

(b) the Parties will jointly own any and all Joint Technology, and, subject to the licenses granted hereunder, each Party is entitled to practice the Joint Technology for all purposes on a worldwide basis and to license such Joint Technology through multiple tiers without the consent of the other Party (and, where consent is required by Applicable Law, such consent is deemed hereby granted) and without a duty of accounting to the other Party. Each Party will grant and hereby does grant to the other Party all further permissions, consents, and waivers with respect to, and all licenses under, the Joint Technology throughout the world necessary to provide the other Party with full rights of Exploitation of the Joint Technology; and

(c) for purposes of the foregoing allocation of ownership, determinations of inventorship will be made in accordance with U.S. patent law, regardless of where the invention was made.

10.1.2 **Disclosure**. Each Party shall promptly disclose to the other Party all Collaboration Know-How made, invented, conceived, discovered, developed, or otherwise generated by or on behalf of such Party or any of its Affiliates, Subcontractors, (with respect to Sobi) Sublicensees, or (with respect to Apellis) sub/licensees, or Persons acting on its or their behalf, whether solely or jointly with others, including all invention disclosures or other similar documents generated by such Party or submitted to such Party by its or its Affiliates', Subcontractors', (with respect to Sobi) Sublicensees', or (with respect to Apellis) sub/licensees' employees, agents, or independent contractors relating thereto. Each Party shall also promptly respond to reasonable requests from the other Party for additional information relating to any Collaboration Know-How disclosed by such other Party pursuant to this Section 10.1.2 (Disclosure). Neither Party may file any patent application claiming or disclosing any Collaboration Know-How prior to disclosing such Collaboration Know-How to the other Party pursuant to this Section 10.1.2 (Disclosure).

10.1.3 **Employees and Independent Contractors**. Each Party shall require all of its and its Affiliates' and (with respect to Sobi) Sublicensees' and (with respect to Apellis) sub/licensees' employees to assign to such Party all Collaboration Know-How and Collaboration Patent Rights that are made, invented, conceived, discovered, developed, or otherwise generated by such employees. Each Party shall (and shall require its Affiliates and (with regard to Sobi) Sublicensees and (with regard to Apellis) sub/licensees) to require (or, in the case of any contracts existing as of the Effective Date, use Commercially Reasonable Efforts to require) any Subcontractors, agents, or independent contractors performing an activity on such Party's, its Affiliates', Sublicensees', or sub/licensees' behalf pursuant to this Agreement to assign, or grant an exclusive, royalty-free, worldwide, perpetual, and irrevocable license (with the right to grant sublicenses through multiple tiers) to, all Collaboration Know-How and Collaboration Patent Rights that are made, invented, conceived, discovered, developed, or otherwise generated by such Subcontractors, agents, or independent contractors to such Party, to the extent such Collaboration Know-How and Collaboration Patent Rights are related to the Exploitation of Products, and such Party shall structure (or, in the case of any contracts existing as of the Effective Date, use Commercially Reasonable Efforts to structure) such assignment or exclusive license so as to enable such Party to sublicense such Collaboration Know-How and Collaboration Patent Rights to the other Party in accordance with this Agreement (including permitting such other Party to grant further sublicenses in accordance with this Agreement).

10.2 Prosecution and Defense

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10.2.1 **Prosecution Rights.**

(a) As of the Effective Date, pursuant to section 7.1 of the Penn Other Fields License Agreement, Penn controls the preparation, prosecution and maintenance of the Penn Patent Rights (as defined in the Penn Other Fields License Agreement) and the selection of patent counsel, with input from Apellis.

(b) As between the Parties, Apellis will have the first right (but not the obligation) to prepare, file, prosecute, and maintain (collectively, "**Prosecute**") (i) all Apellis Patent Rights, other than Joint Patent Rights, in Apellis' name and (ii) all Joint Patent Rights in both Parties' names. Subject to Section 11.5.3(f) (Additional Covenants of Apellis), in the event that Apellis declines to Prosecute any Apellis Patent Rights, other than Joint Patent Rights, in the Sobi Territory or any Joint

Patent Rights, it shall give Sobi reasonable notice to this effect, sufficiently in advance to permit Sobi to undertake such Prosecution in any applicable country without a loss of rights, and thereafter Sobi may, upon written notice to Apellis, Prosecute such Patent Rights in the owning Party(ies)' name(s).

(c) As between the Parties, Sobi will have the sole right (but not the obligation) to Prosecute the Sobi Patent Rights, other than Joint Patent Rights, in Sobi's name.

(d) The Party Prosecuting any given Apellis Patent Rights or Sobi Patent Rights (for the avoidance of doubt, including Joint Patent Rights) (the "**Prosecuting Party**") shall keep the other Party reasonably informed as to material developments with respect to the Prosecution of such Patent Rights that encompass any Product specifically or generically. The Prosecuting Party shall (i) provide the other Party the timely opportunity to have reasonable input into the strategic aspects of such Prosecution and shall consider such other Party's input with respect to such strategic aspects in good faith, (ii) promptly provide to the other Party drafts of all material patent-related filings and communications related to such Patent Rights, including copies of office actions or other correspondence that the Prosecuting Party receives from any patent office, drafts of office action responses, and other material correspondence that the Prosecuting Party provides to any patent office, and copies and drafts of all interferences, reissues, re-examinations, oppositions, and requests for Patent Term Extensions, in each case, for such other Party's review and comment, and (iii) consider in good faith any reasonable comments timely provided by the other Party with respect to such draft filings and communications.

10.2.2 **Defense of Patent Rights.**

(a) As between the Parties, Apellis will have the first right (but not the obligation) to defend against any declaratory judgment action, *inter partes* review, opposition proceeding, interference, or other action challenging any Apellis Patent Right (for the avoidance of doubt, including any Joint Patent Right), other than with respect to (i) any counter-claims or defenses in any enforcement action brought by Sobi pursuant to Section10.3 (Intellectual Property Enforcement), or (ii) any action by a Third Party in response to an enforcement action brought by Sobi to Section 10.3 (Intellectual Property Enforcement), which, in both cases ((i) and (ii)), will be controlled by Sobi. In the event that Apellis declines to defend any Apellis Patent Rights in the Sobi Territory or any Joint Patent Rights anywhere in the world, it shall give Sobi reasonable notice to this effect, sufficiently in advance to permit Sobi to undertake such defense in any applicable country without a loss of rights, and thereafter Sobi may, upon written notice to Apellis, defend such Patent Rights.

(b) As between the Parties, Sobi will have the sole right (but not the obligation) to defend against any declaratory judgment action, *inter partes* review, opposition proceeding, interference, or other action challenging any Sobi Patent Right other than any Joint Patent Right.

(c) The Party defending any given Apellis Patent Rights or Sobi Patent Rights (for the avoidance of doubt, including Joint Patent Rights) (the "**Defending Party**") shall keep the other Party reasonably informed as to material developments with respect to the defense of such Patent Rights that encompass any Product specifically or

generically. The Defending Party shall (i) provide the other Party the timely opportunity to have reasonable input into the strategic aspects of such defense and shall consider the other Party's input with respect to such strategic aspects in good faith, (ii) promptly provide to the other Party drafts of all defense-related notices and documents related to such Patent Rights, including copies of notices or documents that the Defending Party receives from any Governmental Authority or counterparty, drafts of filings or responses, or other documents that the Defending Party provides to any Governmental Authority or counterparty, in each case, for the other Party's review and comment, and (iii) consider in good faith any reasonable comments timely provided by the other Party with respect to such notices and documents.

10.2.3 **Cooperation**. The non-Prosecuting Party or non-Defending Party shall (a) obtain and deliver to the Prosecuting Party or Defending Party (as applicable) any necessary documents for the Prosecuting Party or Defending Party (as applicable) to exercise its rights to Prosecute or defend (as applicable) all Patent Rights pursuant to Section 10.2.1 (Prosecution Rights) or Section 10.2.2 (Defense of Patent Rights) (as applicable), (b) render all signatures that will be necessary in connection with any filings and documents in connection with such Prosecution and defense, and (c) cooperate with and assist the Prosecuting Party or Defending Party (as applicable) in all other reasonable ways that are necessary for the Prosecution or defense of such Patent Rights (including with respect to assignments, declarations, filing divisionals or continuations, or otherwise).

10.2.4 **Other Prosecution and Defense**. Except as expressly set forth in this Section 10.2 (Prosecution and Defense), as between the Parties, each Party will have the sole right, in its sole discretion, to Prosecute and defend against a declaratory judgment action, *inter partes* review, opposition proceeding, interference, or other action challenging, any Patent Rights owned or Controlled by such Party, at such Party's sole cost and expense.

10.2.5 **Costs**. Each Party will solely bear all costs and expenses incurred by such Party with respect to Prosecution or defense of any Apellis Patent Rights or Sobi Patent Rights (for the avoidance of doubt, including Joint Patent Rights).

10.3 Intellectual Property Enforcement

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10.3.1 **Notice**. If Apellis receives notice of, or otherwise becomes aware of, any alleged or threatened infringement or misappropriation of any Apellis Technology (for the avoidance of doubt, including any Joint Technology) by a Third Party that is competitive with a Product ("**Competitive Infringement**") anywhere in the world, it shall promptly notify Sobi thereof. If Sobi receives notice of, or otherwise becomes aware of, any alleged or threatened Competitive Infringement anywhere in the world, it shall promptly notify Apellis thereof.

10.3.2 **Enforcement of Technology.**

(a) Apellis shall use reasonable efforts to obtain for Sobi the right to exercise (or, to the extent that it cannot obtain such right despite the use of reasonable efforts, shall exercise at Sobi's expense and direction) Apellis' right to enforce the Penn Patent Rights (as defined in the Penn Other Fields License Agreement) against any Competitive Infringement in the Sobi Territory in accordance with the provisions of Article 8 of the Penn Other Fields License Agreement. To the extent that Apellis

is able to obtain for Sobi the right to exercise Apellis' right to enforce the Penn Patent Rights (as defined in the Penn Other Fields License Agreement) against any Competitive Infringement in the Sobi Territory in accordance with the provisions of Article 8 of the Penn Other Fields License Agreement, Sobi will have the initial right, but not the obligation, to initiate a suit or take other appropriate action that Sobi believes is reasonably required to enforce the Apellis Technology (for the avoidance of doubt, including any Joint Technology) against any Competitive Infringement in the Sobi Territory. Sobi shall give Apellis advance notice of Sobi's intent to file any such suit or take any such action and the reasons therefor, and shall provide Apellis with a reasonable opportunity to make suggestions and comments regarding such suit or action, which Sobi shall consider in good faith. Thereafter, Sobi shall, acting reasonably, determine whether to diligently pursue such suit or take some other action and shall keep Apellis promptly informed, and shall from time to time consult with Apellis regarding the status of such suit or action and, to the extent permitted by any protective order and permitted by Applicable Law, shall provide Apellis with copies of all material documents (*e.g.*, complaints, answers, counterclaims, material motions, orders of the court, memoranda of law and legal briefs, interrogatory responses, depositions, material pre-trial filings, expert reports, affidavits filed in court, transcripts of hearings and trial testimony, trial exhibits and notices of appeal) filed in, or otherwise relating to, such suit or action. Apellis shall have the right to participate and be represented in any such suit by its own counsel at its own expense (and such expenses shall not be reimbursed pursuant to Section 10.3.2(e) (Enforcement of Technology)).

(b) If Sobi fails to initiate a suit or take such other appropriate action under Section 10.3.2(a) (Enforcement of Technology) at least [**] prior to any deadline on which initiation of a suit or other appropriate action is required to avoid limiting or compromising the remedies (including monetary relief and stay of regulatory approval) available against the applicable alleged Third Party infringer, then Apellis may, in its discretion, provide Sobi with written notice of Apellis' intent to initiate a suit or take other appropriate action to combat such infringement or unauthorized use or misappropriation (as applicable). If Apellis provides such notice, then Apellis shall have the right, but not the obligation, to initiate a suit or initiate or take such other appropriate action that it believes is reasonably required to protect the applicable Apellis Technology from such infringement or unauthorized use or misappropriation. Apellis shall give Sobi advance notice of Apellis' intent to file any such suit or take any such action and the reasons therefor and shall provide Sobi with an opportunity to make suggestions and comments regarding such suit or action, which Apellis shall consider in good faith. Thereafter, Apellis shall keep Sobi promptly informed and shall from time to time consult with Sobi regarding the status of any such suit or action and shall provide Sobi with copies of all material documents (*e.g.*, complaints, answers, counterclaims, material motions, orders of the court, memoranda of law and legal briefs, interrogatory responses, depositions, material pre-trial filings, expert reports, affidavits filed in court, transcripts of hearings and trial testimony, trial exhibits and notices of appeal) filed in, or otherwise relating to, such suit or action. Sobi shall have the right to participate and be represented in any such suit by its own counsel at its own expense (and such expenses shall not be reimbursed pursuant to Section 10.3.2(e) (Enforcement of Technology)).

(c) Other than with respect to Competitive Infringement in the Sobi Territory, Apellis will have the sole right, but not the obligation, to initiate a suit or take other appropriate action that Apellis believes is reasonably required to enforce the Apellis Technology (for the avoidance of doubt, including any Joint Technology) against any infringement or unauthorized use or misappropriation by a Third Party. For clarity, Sobi will have the sole right, but not the obligation, to initiate a suit or take other appropriate action that Sobi believes is reasonably required to enforce the Sobi Technology that is not Joint Technology against any infringement anywhere in the world.

(d) If required under Applicable Law in order for a Party to initiate or maintain any suit in accordance with this Section 10.3.2 (Enforcement of Technology), the other Party shall join as a party to the suit. If requested by the Party initiating suit, the other Party shall provide reasonable assistance to the Party initiating suit in connection therewith, and the requesting Party shall reimburse the other Party for all reasonable costs and expenses incurred by the other Party in providing such assistance within [**] after receipt of any invoice therefor. The Party initiating suit shall assume and pay all of its own Out-of-Pocket Costs incurred in connection with any litigation or proceedings described in this Section 10.3.2 (Enforcement of Technology), including the fees and expenses of the counsel selected by it.

(e) Any damages or other monetary awards recovered in any action, suit, or proceeding brought in accordance with this Section 10.3.2 (Enforcement of Technology) shall first, to the extent the action, suit, or proceeding involved any Patent Rights licensed under the Penn Other Fields License Agreement, be applied as set forth in section 8.2 of the Penn Other Fields License Agreement (*i.e.*, first, applied to reimburse Apellis and its Affiliates, Sobi and its Sublicensees, and Penn for their Litigation Expenses (as defined in the Penn Other Fields License Agreement), and, second, as to any remainder, if such litigation is brought by Apellis or any of its Affiliates, [**] percent ([**]%) shall be paid to Apellis and its Affiliates and [**] percent ([**]%) shall be paid to Penn) and, second, be applied to reimburse each Party for all of the reasonable attorneys' fees or expenses, whether incurred directly or indirectly, in reference to a pertinent litigation or investigation, including court costs, local counsel fees, deposition costs, subpoena costs, court reporter costs, expert fees, and other reasonable expenses directly incurred for investigation or litigation of claims, incurred by such Party in connection with such action that have not previously been reimbursed, and, if such recovery is insufficient to cover all such costs and expenses of both Parties, it shall be shared in proportion to the total of such costs and expenses incurred by each Party. Any remaining proceeds in the Apellis Territory shall be retained by Apellis, and any remaining proceeds in the Sobi Territory shall be retained by Sobi and, excluding any special, punitive, aggravated, consequential or non-compensatory damages or (without limiting the first sentence of this Section 10.3.2(e) (Enforcement of Technology)) any attorneys' fees or expenses, court costs, local counsel fees, deposition costs, subpoena costs, court reporter costs, expert fees, and other reasonable expenses directly incurred for investigation or litigation or non-compensatory damages, treated as Net Sales for purposes of royalty and Commercial Milestone Event calculations hereunder unless otherwise agreed by the Parties.

(f) Except as expressly set forth in this Section 10.3.2 (Enforcement of Technology), as between the Parties, each Party will have the sole right, in its sole discretion, to take any action to enforce any Intellectual Property owned or Controlled by such Party against infringement or misappropriation by a Third Party, at such Party's sole cost and expense.

(g) The Parties acknowledge that Penn reserves the right to voluntarily intervene and join in any litigation under this Section 10.3.2 (Enforcement of Technology) relating to any Intellectual Property licensed under the Penn Other Fields License Agreement. If Penn is required to participate in any litigation brought by Sobi under this Section 10.3.2 (Enforcement of Technology), (such as, for example, but not limited to, being joined or named as a defendant, necessary party, involuntary plaintiff, or indispensable party), then (i) Sobi may seek to join Penn involuntarily and (ii) if Penn cannot be joined involuntarily, Apellis shall (at Sobi's request) enforce its right under section 8.3(b) of the Penn Other Fields License Agreement to join Penn in any litigation referred to in this Section 10.3.2 (Enforcement of Technology) if Penn's participation is required for standing to bring or maintain the lawsuit in which Sobi seeks to join Penn, and Sobi shall reimburse Penn's Litigation Expenditures (as defined in the Penn Other Fields License Agreement) on an ongoing basis, within [**] of submission of actual invoices. In any litigation brought by Penn under section 8.4 of the Penn Other Fields License Agreement, at the request and expense of Penn, Sobi shall cooperate with Penn to the extent reasonable and reasonably possible unless Sobi reasonably deems that doing so would present unacceptable business or legal risks. Sobi shall not settle or compromise any litigation enforcing any Penn Patent Rights (as defined in the Penn Other Fields License Agreement) in a manner that imposes any obligations or restrictions on Penn without Penn's prior written permission.

(h) If Penn brings any litigation to enforce any Penn Patent Rights pursuant to section 8.4 of the Penn Other Fields License Agreement, then, at the request and expense of Penn or Apellis, Sobi shall cooperate to the extent reasonable and reasonably possible, subject to any applicable limitation set forth in section 8.5 of the Penn Other Fields License Agreement.

10.4 Defense of Claims

. Each Party shall promptly inform the other Party in writing if it receives written notice, or otherwise becomes aware, of a claim of alleged infringement, misappropriation, or other violation of a Third Party's Intellectual Property based upon either Party's Exploitation of any Product. Except as expressly set forth in Article 12 (Indemnification), the Party that is subject to such claim will have the right, but not the obligation, to defend against such claim. The defending Party shall keep the other Party advised of all material developments in the conduct of any proceedings in defending any claim of alleged infringement, misappropriation, or other violation related to any Products, and, at the defending Party's request, the other Party shall reasonably cooperate with the defending Party in the conduct of such defense, and the defending Party shall reimburse the other Party for all reasonable costs and expenses incurred by the other Party in providing such cooperation within [**] after receipt of any invoice therefor. In no event may the defending Party settle any such claim of infringement, misappropriation, or other violation in a manner that would limit the rights of the other Party or impose any obligation on the other Party, in each case, without such other Party's prior written consent, which shall not be unreasonably withheld, delayed, or conditioned.

10.5 Patent Term Extensions

. Apellis will have the sole right to determine and control all filings of requests for Patent Term Extensions to Products in the Apellis Territory. Sobi will have the sole right to determine and control all filings of requests for Patent Term Extensions to Products in the Sobi Territory, but, other than with respect to the Patent families listed in Schedule 10.5 (Patent Term Extensions) for which Sobi shall be free to request Patent Term Extensions without Apellis' consent, Sobi may not request any Patent Term Extension with respect to any Apellis Patent Right (other than the Apellis Patent Rights listed in Schedule 10.5 (Patent Term Extensions)) without Apellis' prior written consent, which consent Apellis may withhold in its sole discretion. Upon the reasonable request of either Party, the other Party shall provide support, assistance, and all necessary documents, in fully executed form if needed, to such requesting Party for the purpose of supporting, filing, obtaining, and maintaining such Patent Term Extensions in any country in the world in accordance with this Section 10.5 (Patent Term Extensions), and the requesting Party shall reimburse the other Party for all reasonable costs and expenses incurred by the other Party in providing such support, assistance, and documents within [**] after receipt of any invoice therefor.

10.6 35 U.S.C. § 102(c)

. Notwithstanding anything to the contrary in this Article 10 (Intellectual Property Matters), no Party will have the right to make an election under 35 U.S.C. § 102(b)(2)(C) or 35 U.S.C. § 102(c) when exercising its rights under this Article 10 (Intellectual Property Matters) without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned, or delayed. With respect to any such permitted election, the Parties shall use reasonable efforts to cooperate and coordinate their activities with respect to any submissions, filings, or other activities in support thereof. The Parties acknowledge and agree that this Agreement is deemed a "joint research agreement" as defined in 35 U.S.C. § 100(h).

10.7 Recording

. If either Party deems it necessary or desirable to register or record this Agreement or provide evidence of this Agreement with any patent office or other appropriate Governmental Authority in one (1) or more jurisdictions in the world, then the other Party shall reasonably cooperate to execute and deliver to such Party any documents accurately reflecting or evidencing this Agreement that are necessary or desirable, in such Party's reasonable judgment, to complete such registration or recordation.

10.8 Costs

. Except as expressly set forth in this Article 10 (Intellectual Property Matters), each Party will solely bear all costs and expenses incurred by such Party in performing any obligations or exercising any rights under this Article 10 (Intellectual Property Matters).

ARTICLE 11
REPRESENTATIONS, WARRANTIES, AND COVENANTS

11.1 Mutual Representations and Warranties of the Parties

. Each Party represents and warrants to the other Party as of the Effective Date that:

11.1.1 such Party is a company or corporation duly organized, validly existing, and in good standing under the Applicable Laws of the jurisdiction of such Party's incorporation or organization and has full corporate or other organizational power and authority to execute and deliver this Agreement and to perform such Party's obligations under this Agreement and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement;

11.1.2 this Agreement has been duly executed and delivered on behalf of such Party, and is valid, legally binding, and enforceable against such Party in accordance with its terms, subject to

applicable bankruptcy, insolvency, moratorium and other similar Applicable Laws affecting creditors' rights generally and by general principles of equity;

11.1.3 except with respect to SFJ under the SFJ Agreement (with respect to which Apellis represents and warrants it has received the required consents), the execution, delivery, and performance of this Agreement by such Party does not require any authorization, consent, approval, license, exemption of or filing or registration with any Third Party (including any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign) or under any Applicable Law currently in effect, and none of the foregoing is or will be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement and such other agreements except as may be required to obtain clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (15 U.S.C. Sec. 18a), and the rules and regulations promulgated thereunder, or equivalent rules and regulations under Applicable Law in other countries, to conduct clinical studies or Clinical Trials or to seek or obtain Regulatory Approvals;

11.1.4 the execution and delivery of this Agreement and the performance by such Party of such Party's obligations hereunder have been duly authorized by all necessary corporate action and do not violate such Party's charter documents, bylaws or other organizational documents or any requirement of any Applicable Law or, except with respect to the required consent from SFJ under the SFJ Agreement (which Apellis represents and warrants it has received), any agreement to which such Party is a party in any material respect;

11.1.5 such Party has the full right, power, and authority to grant all of the license and rights granted by such Party under this Agreement;

11.1.6 neither such Party nor its Affiliates is debarred or is subject to debarment pursuant to Section 306 of the FD&C Act (or similar Applicable Law outside of the U.S.) or is the subject of a conviction described in such Section ("**Debarred**"), and neither such Party nor any of its Affiliates has used or will use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been Debarred; and

11.1.7 such Party or one (1) of its applicable Affiliates is entitled to claim the benefits of the income tax treaty between Switzerland and Sweden generally as a "resident" of such jurisdiction (within the meaning of Article 4 thereof).

11.2 Additional Representations and Warranties of Sobi.

Sobi represents and warrants to Apellis as of the Effective Date that it has not filed or taken steps to file any prophetic patent application which claims the composition of matter, formulation, or method of using any Compound (excluding any already existing patent application that claims any Manufacturing or delivery technologies).

11.3 Additional Representations and Warranties of Apellis

. Apellis represents and warrants to Sobi as of the Effective Date that:

11.3.1 Apellis has not previously assigned, transferred, conveyed, or granted any license or other rights under the Apellis Technology that would conflict with or limit the scope of any of the rights or licenses granted to Sobi hereunder;

11.3.2 Apellis' rights, title, and interests in and to all of the Apellis Technology are free of any lien, charge, encumbrance, or security interest that could reasonably be expected to conflict with or limit the scope of or have a material adverse impact on any of the rights or licenses granted to Sobi hereunder;

11.3.3 Schedule1.19 (Apellis Patent Rights) sets forth a complete and accurate list of all Patent Rights existing as of the Effective Date, including the ownership thereof, that are Controlled by Apellis or any of its Affiliates and are necessary or useful to Exploit in the Sobi Territory any Compound or Product existing as of the Effective Date;

11.3.4 Apellis exclusively owns all rights, title, and interests in and to the Patent Rights set forth on Schedule1.19 (Apellis Patent Rights), or, where Apellis does not exclusively own all rights, title, and interests in and to such Patent Rights, Apellis holds a valid and enforceable exclusive license to such Patent Rights, and Schedule 1.19 (Apellis Patent Rights) identifies the Third Party owner of such Patent Rights and any agreement pursuant to which Apellis Controls such Patent Rights;

11.3.5 neither Apellis nor any of its Affiliates has received written notice of any claim, demand, proceedings, investigation, or other legal action of any nature pending or threatened by any Regulatory Authority or other Third Party with respect to the Compound, any Product, the Apellis Technology, any facility where the Products are Manufactured, or the transactions contemplated by this Agreement, and there is no judgment or settlement against or owed by Apellis or its Affiliate related to any of the foregoing;

11.3.6 neither Apellis nor any of its Affiliates has received written notice of any claim, judgment, or settlement against or owed by Apellis with respect to the Apellis Technology, nor any pending reissue, reexamination, *inter partes* review, interference, opposition, litigation, or other proceeding seeking to invalidate or otherwise challenge the ownership, scope, duration, validity, enforceability, priority, or right to use any Apellis Patent Right, and neither Apellis nor any of its Affiliates has received written notice of any threatened claim or litigation or any reissue, reexamination, *inter partes* review, interference, opposition, litigation, or other proceeding seeking to invalidate or otherwise challenge the ownership, scope, duration, validity, enforceability, priority, or right to use any Apellis Patent Right;

11.3.7 all Apellis Patent Rights in the Sobi Territory set forth on Schedule1.19 (Apellis Patent Rights) that are owned by Apellis or being prosecuted or maintained by or on behalf of Apellis or its Affiliates under any Existing Agreement and, to Apellis' knowledge, all other Apellis Patent Rights in the Sobi Territory set forth on Schedule 1.19 (Apellis Patent Rights) that are in-licensed by Apellis (a) are being diligently prosecuted or maintained in the respective patent offices in accordance, in all material respects, with Applicable Law and (b) have been filed and maintained in accordance, in all material respects, with all Applicable Laws and all applicable fees required to be paid by Apellis in order to prosecute or maintain the Apellis Patent Rights have been timely paid, and (c) to Apellis' knowledge, if issued, are valid and enforceable;

11.3.8 Apellis has taken commercially reasonable measures to protect the secrecy, confidentiality and value of the confidential Apellis Know-How and, to Apellis' knowledge, no event has occurred which has resulted in the unauthorized use or disclosure of any confidential Apellis Know-How or which otherwise resulted in any confidential Apellis Know-How unintentionally falling into the public domain;

11.3.9 there is no pending claim, proceeding, or litigation, or claim, proceeding, or litigation that has been threatened in writing, that challenges, or any written communication challenging, the rights of Apellis to use or license any of the Apellis Technology or any Compound or Product;

11.3.10 to Apellis' Knowledge, the Product as it currently exists, if and when made, used, sold, or imported will not infringe any Third Party's Intellectual Property Right existing as at the Effective Date;

11.3.11 to Apellis' Knowledge, no Third Party is infringing upon, misappropriating or otherwise violating the Apellis Technology;

11.3.12 Apellis has provided to Sobi complete and correct copies of each Existing Agreement and each of the Existing Manufacturing Agreements, as it exists as of the Effective Date, the Existing Agreements (and, if any Know-How or Patent Rights licensed by Apellis or any of its Affiliates from [**] become Apellis Technology pursuant to Section 1.17 (Apellis Know-How) or Section 1.19 (Apellis Patent Rights), the [**] Agreement) and the Existing Manufacturing Agreements, are the only agreements to which Apellis or its Affiliates is a party under which any of the Apellis Technology is in-licensed, and, to Apellis' knowledge, each Existing Agreement and each Existing Manufacturing Agreement is valid, binding, enforceable, and in full force and effect;

11.3.13 the Existing Manufacturing Agreements are the only agreements which Apellis has entered into as of the Effective Date under which any material Manufacturing Know-How (including, for clarity, Manufacturing Know-How that would be required to be provided to the FDA or EMA in connection with the grant or maintenance of a Regulatory Approval for a Product) has been developed;

11.3.14 Apellis has obtained any consents and provided any notices required to be provided under the Existing Agreements in connection with the execution and delivery of this Agreement and the performance by Apellis of Apellis' obligations hereunder, and the execution, delivery, and performance of this Agreement by Apellis does not constitute a breach or default under any of the Existing Agreements;

11.3.15 subject to any rights retained by Penn under the Penn Other Fields License Agreement, none of the Existing Agreements (or any agreement to which Apellis or an Affiliate of Apellis is a party) contains provisions that conflict with the exclusive rights and licenses granted to Sobi hereunder or cause Apellis to not Control any Patent Rights or Know-How that would otherwise constitute Apellis Technology;

11.3.16 (a) neither Apellis nor its Affiliates, nor, to Apellis' knowledge, any counterparty to any Existing Agreement, is in breach or default under any Existing Agreement; (b) there is no, and there has not been any, act or omission by Apellis or its Affiliates that would be reasonably likely to give rise to a termination right of any other party to any Existing Agreement; (c) neither Apellis nor its Affiliates has received or provided any written notice of breach or default with respect to any Existing Agreement or any written request to amend any provision of any Existing Agreement (except with respect to amendments already existing and disclosed to Sobi as of the Effective Date); (d) to Apellis' knowledge, no circumstances or grounds exist that would reasonably be expected to give rise to a claim of material breach or a right of rescission, termination, revision, or amendment of any of the Existing Agreements, including the execution, delivery and performance of this

Agreement; and (e) neither Apellis nor its Affiliates has waived any of their respective rights under any Existing Agreement, and, to Apellis' and its Affiliates' knowledge, no such rights have lapsed or otherwise expired or been terminated;

11.3.17 except with respect to the Apellis Technology licensed under the Penn Other Fields License Agreement, the Apellis Technology has not been created pursuant to, and is not subject to, any funding agreement with any Governmental Authority or any other Third Party, other than SFJ under the SFJ Agreement, and is not subject to the requirements of the Bayh-Dole Act or any similar provision of any Applicable Law;

11.3.18 except for any information disclosed in documents 2.10.1 (Apellis PEGASUS Mock Inspection Report FINAL), 2.10.2 (Mock Inspection Executive Summary and Action Plan), and 2.10.3 (PAI gap assessment_21Aug2020) of the diligence data room, Apellis has (a) conducted all activities relating to the Development and Manufacture of the Compound and Products in material compliance with Applicable Law, including all GLP, GMP, GVP, GDP and GCP (as applicable), and (b) complied in all material respects with all Applicable Laws, including all GLP, GMP, GVP, GDP and GCP (as applicable) in its interactions with and submissions to all Regulatory Authorities with respect to the Products;

11.3.19 Apellis has complied with all, and has provided Sobi with complete and accurate copies of all Regulatory Approvals, INDs, and other material permits, licenses, franchises, authorizations, and clearances issued by the FDA or any other applicable Regulatory Authority as are required in connection with the Development and Manufacture conducted to date by Apellis or its Affiliates of the Compound and Product, and such Regulatory Approvals, INDs, and other permits, licenses, franchises, authorizations and clearances are in full force and effect and Apellis or its relevant Affiliate has taken all actions required to maintain their validity and effectiveness. To Apellis' knowledge, no event has occurred which would reasonably be expected to result in the revocation or termination of any such Regulatory Approvals, INDs, and other permits, licenses, franchises, authorizations and clearances. Neither Apellis nor any of its Affiliates has received any written communication threatening to withdraw or suspend any Regulatory Approvals, INDs, and other permits, licenses, franchises, authorizations and clearances;

11.3.20 neither Apellis nor any of its Affiliates has received any warning letters or written correspondence from the FDA or any other Regulatory Authority requiring the termination, suspension, or material modification of any clinical or pre-clinical studies or tests with respect to the Compound or Product or commencing or threatening withdrawal of any Regulatory Approval or IND for the Compound or Product held by Apellis;

11.3.21 (a) to Apellis' knowledge, Apellis has disclosed all facts required to be disclosed with respect to the Compound and Product to each applicable Regulatory Authority, and (b) Apellis has filed with the applicable Regulatory Authority all required notices, reports, and other Regulatory Data with respect to each IND held by Apellis for the Compound and Product;

11.3.22 (a) Apellis has filed all Regulatory Submissions related to the Compound or Products in good faith with, to Apellis' Knowledge, the reasonable belief that any Drug Approval Application for a Product included in such Regulatory Submissions will result in a Regulatory Approval being granted by the applicable Regulatory Authority, (b) to Apellis' Knowledge, except for any information fairly disclosed in the diligence data room on or

by [**], there are no material facts or circumstances which would be reasonably likely to result in the application for Regulatory Approval for a Product filed before the Effective Date not resulting in the grant of a Regulatory Approval, and (c) all Regulatory Submissions related to the Compound or Products were, when filed, materially complete and accurate, and not misleading in any material respect;

11.3.23 Apellis is not as of the Effective Date in material dispute with any Third Party supplier responsible for the supply of the Compound or Product;

11.3.24 Apellis has not initiated a voluntary proceeding under any applicable bankruptcy code;

11.3.25 there is no involuntary proceeding under any applicable bankruptcy code pending against Apellis as of the Effective Date;

11.3.26 Apellis Controls all Assigned Manufacturer IP and Licensed Manufacturer IP;

11.3.27 Apellis has obtained agreements or appropriate assurances of cooperation from [**] necessary for the filing of Regulatory Submissions for Regulatory Approval of the Products in [**];

11.3.28 Apellis has obtained agreements or appropriate assurances of cooperation from [**] necessary for the filing of Regulatory Submissions for Regulatory Approval of the Products in [**]; and

11.3.29 other than the Assigned Manufacturer IP and Licensed Manufacturer IP, there is no other manufacturing Know-How controlled by a Third Party that (a) has been provided by or on behalf of Apellis to the FDA or EMA in connection with the Drug Approval Application (and associated orphan drug designation and pediatric investigation plan) filed with the FDA and EMA for the first Product in PNH; or (b) to Apellis' knowledge, is required to be provided to the FDA or EMA in connection with the grant or maintenance of a Regulatory Approval for a Product.

11.4 Mutual Covenants

. Each Party hereby covenants to the other Party, during the Term, as follows:

11.4.1 Such Party shall, and shall cause its Affiliates, (with respect to Sobi) Sublicensees, and (with respect to Apellis) sub/licensees, and Subcontractors to, perform such Party's activities under this Agreement, including with respect to the Development, Manufacture, and Commercialization activities contemplated hereunder, in compliance in all material respects with all Applicable Laws, including GLP, GMP, GVP, GDP and GCP (as applicable). Without limiting the foregoing, such Party shall not, and shall cause its Affiliates, (with respect to Sobi) Sublicensees, and (with respect to Apellis) sub/licensees, and Subcontractors not to, directly or indirectly offer or pay, or authorize such offer or payment, of any money or anything of value to improperly or corruptly seek to influence any Government Official or any other Person in order to gain an improper business advantage. Throughout the Term, each Party shall, and shall cause its Affiliates, (with respect to Sobi) Sublicensees, (with respect to Apellis) sub/licensees, and Subcontractors to, comply with Schedule 11.4.1 (Compliance with Applicable Law).

11.5 Additional Covenants of Apellis

. Apellis covenants to Sobi, during the Term, that:

11.5.1 Apellis and its Affiliates shall (a) maintain (i) ownership and Control of all Apellis Technology owned by Apellis or its Affiliates at any time during the Term and (ii) Control of all Apellis Technology in-licensed by Apellis or its Affiliates at any time during the Term, and (b) not assign, transfer, encumber, or otherwise grant any Third Party any rights with respect thereto that would conflict with or adversely affect the rights granted to Sobi under this Agreement;

11.5.2 neither Apellis nor any of its Affiliates shall effect any corporate restructuring or enter into any new agreement or otherwise obligate itself to any Third Party, or amend an Existing Agreement, in each case, in a manner that conflicts with the rights and licenses (or sublicenses, as the case may be) granted to Sobi hereunder;

11.5.3 Apellis and its Affiliates shall:

(a) in respect of each Collaboration In-License to which Apellis or any of its Affiliates is a party, promptly following execution thereof notify Sobi in writing of any terms of such Collaboration In-License which are applicable to Sobi as a sublicensee of rights thereunder;

(b) not materially breach or be in material default under any of Apellis' obligations under any Upstream Agreement to which Apellis or any of its Affiliates is a party and shall promptly take all reasonable steps to remedy any such breach of which it becomes aware;

(c) not do any act or make any omission that would be reasonably likely to give rise to a termination right of any other party to any Upstream Agreement to which Apellis or any of its Affiliates is a party;

(d) not terminate any Upstream Agreement to which Apellis or any of its Affiliates is a party, or agree, consent, or acquiesce to amend, supplement, modify, or waive any provision thereof;

(e) use Commercially Reasonable Efforts to enforce the terms of any Upstream Agreement to which it is a party in the case of a breach by any counterparty to such agreements, and shall keep Sobi reasonably informed in connection therewith, including providing prompt notice of any breach by the counterparty thereto;

(f) diligently exercise, or obtain for Sobi the right to exercise, in each case in accordance with Section 10.2 (Prosecution and Defense), Apellis' right to Prosecute any relevant Patent Rights under the Penn Other Fields License Agreement, including to the extent necessary, entering into a patent management agreement with Penn as envisaged under the Penn Other Fields License Agreement, in the event that Apellis becomes aware that Penn ceases to Prosecute such Patent Rights.

(g) provide Sobi with reasonable notice, information, and opportunity to comment regarding any decisions to be taken by the joint steering committee constituted pursuant to any Upstream Agreement to which Apellis or any of its Affiliates is a party which could have an adverse effect on the rights of Sobi hereunder and shall consider Sobi's timely, reasonable comments in good faith prior to exercising such voting and other decision making rights; and

(h) not assign, novate or otherwise transfer any Upstream Agreement to which it is a party to a Third Party, except in connection with a permitted assignment of this Agreement in accordance with Section17.1 (Assignment),

in each case of (b)-(d) and (h) in any manner that adversely affects the rights or licenses granted to Sobi hereunder, and, in each case of (a), (e), (f), and (g), as necessary to ensure that the rights and licenses granted to Sobi hereunder are not adversely affected, without Sobi's prior written consent;

11.5.4 Apellis and its Affiliates shall furnish Sobi with copies of all notices that Apellis or its Affiliates receive in connection with an Upstream Agreement within [**] following Apellis' or its Affiliates' receipt of the same; and

11.5.5 Apellis and its Affiliates shall, in respect of each Collaboration In-License to which Sobi or any of its Affiliates is a party, not materially breach or be in material default under any obligations under such Collaboration In-License which are applicable to it as a sublicensee of rights thereunder and of which Sobi has provided notice to Apellis in accordance with this Agreement.

11.6 Additional Covenants of Sobi

. Sobi covenants to Apellis, during the Term, that:

11.6.1 neither Sobi nor any of its Affiliates shall effect any corporate restructuring or enter into any new agreement or otherwise obligate itself to any Third Party, or amend an existing agreement with a Third Party, in each case, in a manner that conflicts with the rights and licenses (or sublicenses, as the case may be) granted to Apellis hereunder;

11.6.2 Sobi and its Affiliates shall:

(a) in respect of each Collaboration In-License to which Sobi or any of its Affiliates is a party, promptly following execution thereof notify Apellis in writing of any terms of such Collaboration In-License which are applicable to Apellis as a sublicensee of rights thereunder;

(b) not materially breach or be in material default under any of its obligations under any Collaboration In-License to which Sobi or any of its Affiliates is a party and shall promptly take all reasonable steps to remedy any such breach of which it becomes aware;

(c) not do any act or make any omission that would be reasonably likely to give rise to a termination right of any other party to any Collaboration In-License to which Sobi or any of its Affiliates is a party; and

(d) not terminate any Collaboration In-License to which Sobi or any of its Affiliates is a party, or agree, consent, or acquiesce to amend, supplement, modify, or waive any provision thereof;

(e) use Commercially Reasonable Efforts to enforce the terms of any Collaboration In-License to which it is a party in the case of a breach by any counterparty to such agreements, and shall keep the other Party reasonably informed in connection therewith, including providing prompt notice of any breach by the counterparty thereto;

(f) provide Apellis with reasonable notice, information, and opportunity to comment regarding any decisions to be taken by the joint steering committee constituted pursuant to any Collaboration In-License to which Sobi or any of its Affiliates is a party which could have an adverse effect on the rights of Apellis hereunder and shall consider the Apellis' timely, reasonable comments in good faith prior to exercising such voting and other decision making rights; and

(g) not assign, novate or otherwise transfer any Collaboration In-License to which it is a party to a Third Party, except in connection with a permitted assignment of this Agreement in accordance with Section17.1 (Assignment),

in each case of (b)-(d) and (g) in any manner that adversely affects the rights or licenses granted to Apellis hereunder, and, in each case of (a), (e), and (f), as necessary to ensure that the rights and licenses granted to Apellis hereunder are not adversely affected, without Apellis' prior written consent;

11.6.3 Sobi and its Affiliates shall furnish Apellis with copies of all notices that Sobi or its Affiliates receive in connection with any Collaboration In-License within [**] following Sobi's or its Affiliates' receipt of the same; and

11.6.4 Sobi and its Affiliates shall, in respect of each Collaboration In-License to which Apellis or any of its Affiliates is a party, not materially breach or be in material default under any obligations under such Collaboration In-License which are applicable to it as a sublicensee of rights thereunder and of which Apellis has provided notice to Sobi in accordance with this Agreement.

11.7 No Other Representations or Warranties

. THE REPRESENTATIONS AND WARRANTIES OF EACH PARTY SET FORTH IN THIS Article 11 (REPRESENTATIONS, WARRANTIES, AND COVENANTS) ARE IN LIEU OF ANY OTHER REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, AND ANY IMPLIED WARRANTIES OF NON-INFRINGEMENT, ALL OF WHICH ARE HEREBY SPECIFICALLY EXCLUDED AND DISCLAIMED.

ARTICLE 12
INDEMNIFICATION

12.1 Indemnification by Apellis

. Apellis hereby agrees to indemnify, defend, and hold Sobi, its Affiliates, and their respective directors, officers, and employees, and all of their respective successors, heirs, and assigns, harmless from and against any and all losses, damages, liabilities, costs, and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") arising in connection with any Third Party charges, complaints, actions, suits, proceedings, hearings, investigations, claims, demands, judgments, orders, decrees, stipulations, or injunctions (each, a "**Third Party Claim**") to the extent resulting or otherwise arising from (a) any breach by Apellis of any of its representations, warranties, or covenants in this Agreement, (b) any violation of Applicable Law, negligence, or willful misconduct by or on behalf of Apellis or its Affiliates in performing any obligations or exercising any rights under this Agreement, (c) any Exploitation of any Compound, Product or Non-Systemic Ophthalmology Product by or on behalf of Apellis or its Affiliates (other than by or on behalf of Sobi or its Affiliates); (d) the Exploitation of any Compound or Product following the Term and the use of the Reversion Technology in connection with the same, (e) any Exploitation of the inventory acquired by Apellis under Section 15.2.8(b)

(Inventory) or (f) any use by Sobi of the Apellis name and company trademark in accordance with Section 6.9.4 (Apellis Name) in each case ((a)-(f)) except to the extent that such Losses are subject to indemnification by Sobi pursuant to Section 12.2 (Indemnification by Sobi) or Section 5.2.6(e) (Assignment of EMA PNH Regulatory Approval) or to the extent that such Losses are in respect of matters within the scope of the indemnity under Section 5.2.6(g) (Assignment of EMA PNH Regulatory Approval).

12.2 Indemnification by Sobi

. Sobi hereby agrees to indemnify, defend, and hold Apellis, its Affiliates, and their respective directors, officers, and employees, and all of their respective successors, heirs, and assigns (the "**Apellis Indemnitees**"), harmless from and against any and all Losses arising in connection with any and all Third Party Claims to the extent resulting or otherwise arising from (a) any breach by Sobi of any of its representations, warranties, or covenants in this Agreement, (b) any violation of Applicable Law, negligence, or willful misconduct by or on behalf of Sobi or its Affiliates in performing any obligations or exercising any rights under this Agreement, or (c) any Exploitation of any Compound or Product by or on behalf of Sobi or its Affiliates, in each case ((a)-(c)), except to the extent that such Losses are subject to indemnification by Apellis pursuant to Section 12.1 (Indemnification by Apellis) or Section 5.2.6(g) (Assignment of EMA PNH Regulatory Approval) or to the extent that such Losses are in respect of matters within the scope of the indemnity under Section 5.2.6(e) (Assignment of EMA PNH Regulatory Approval).

12.3 Indemnification Procedures

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12.3.1 **Notice of Claim**. All indemnification claims in respect of any indemnitee seeking indemnification under Section 12.1 (Indemnification by Apellis), Section 12.2 (Indemnification by Sobi), Section 5.2.6(e) (Assignment of EMA PNH Regulatory Approval), or Section 5.2.6(g) (Assignment of EMA PNH Regulatory Approval), as applicable (collectively, the "**Indemnitees**" and each, an "**Indemnitee**"), shall be made solely by the corresponding Party (the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party (the "**Indemnifying Party**") prompt written notice (an "**Indemnification Claim Notice**") of any Third Party Claim or Losses as to which the Indemnified Party intends to make a request for indemnification under Section 12.1 (Indemnification by Apellis), Section 12.2 (Indemnification by Sobi), Section 5.2.6(e) (Assignment of EMA PNH Regulatory Approval), or Section 5.2.6(g) (Assignment of EMA PNH Regulatory Approval), as applicable. In no event will the Indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice shall contain a description of the applicable Third Party Claim and the nature and amount of the applicable Losses (to the extent that the nature and amount of such Losses are known at such time). Together with the Indemnification Claim Notice, the Indemnified Party shall furnish promptly to the Indemnifying Party copies of all notices and documents (including court papers) received by any Indemnitee in connection with the applicable Third Party Claim.

12.3.2 **Control of Defense**. At its option, the Indemnifying Party may assume the defense of any Third Party Claim subject to indemnification under Section 12.1 (Indemnification by Apellis), Section 12.2 (Indemnification by Sobi), Section 5.2.6(e) (Assignment of EMA PNH Regulatory Approval), or Section 5.2.6(g) (Assignment of EMA PNH Regulatory Approval), as applicable, by giving written notice to the Indemnified Party within [**] after the Indemnifying Party's receipt of an Indemnification Claim Notice. Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel it selects, and such Indemnifying Party shall thereafter continue to defend such Third Party Claim in good faith. Should the

Indemnifying Party assume the defense of a Third Party Claim and continue to defend such Third Party Claim in good faith, the Indemnifying Party will not be liable to the Indemnified Party or any other Indemnitee for any legal expenses subsequently incurred by such Indemnified Party or other Indemnitee in connection with the analysis, defense, or settlement of the Third Party Claim.

12.3.3 **Right to Participate in Defense**. Without limiting Section 12.3.2 (Control of Defense), any Indemnitee will be entitled to participate in the defense of a Third Party Claim for which it has sought indemnification hereunder and to employ counsel of its choice for such purpose, but such employment will be at the Indemnitee's own expense unless (a) the employment thereof has been specifically authorized by the Indemnifying Party in writing, or (b) the Indemnifying Party has failed to assume the defense of, or failed to continue to defend in good faith, such Third Party Claim in accordance with this Section 12.3 (Indemnification Procedures), in which case the Indemnified Party will be allowed to control the defense at the Indemnifying Party's cost and expense.

12.3.4 **Settlement**. The Indemnifying Party shall not agree to any settlement of, or the entry of any judgment arising from, any indemnification claim without the prior written consent of the Indemnified Party (such consent not to be unreasonably withheld, delayed or conditioned); provided, however, that the consent of the Indemnified Party shall not be required with respect to any such settlement or judgment if the Indemnifying Party or its insurer agrees in writing to pay or cause to be paid any amounts payable pursuant to such settlement or judgment and includes a full release of the Indemnified Party from further liability and if such settlement or judgment imposes no admission of liability by or other obligation on the Indemnified Party that will not be assumed and performed in full by the Indemnifying Party. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnitee will admit any liability with respect to, or settle, compromise, or discharge, any Third Party Claim without first offering to the Indemnifying Party the opportunity to assume the defense of the Third Party Claim in accordance with Section 12.3.2 (Control of Defense).

12.3.5 **Cooperation**. If the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each Indemnitee to, cooperate in the defense or prosecution thereof and furnish such records, information, and testimony, provide such witnesses, and attend such conferences, discovery proceedings, hearings, trials, and appeals as may be reasonably requested in connection with such Third Party Claim. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any such materials. The Indemnifying Party shall reimburse the Indemnified Party for all its reasonable Out-of-Pocket Costs incurred in connection with such cooperation within [**] after receipt of any invoice therefor.

12.4 Limitation of Liability

. EXCEPT IN THE CASE OF FRAUD, GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES (INCLUDING LOST PROFITS OR LOSS REVENUES) ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 12.4

(LIMITATION OF LIABILITY) IS INTENDED TO OR WILL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 12.1 (INDEMNIFICATION OF APELLIS), SECTION 12.2 (INDEMNIFICATION OF SOBI) SECTION 5.2.6(e) (ASSIGNMENT OF EMA PNH REGULATORY APPROVAL), OR SECTION 5.2.6(g) (ASSIGNMENT OF EMA PNH REGULATORY APPROVAL), OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF EXCLUSIVITY OBLIGATIONS UNDER SECTION 2.6 (EXCLUSIVITY) OR CONFIDENTIALITY OBLIGATIONS UNDER Article 13 (CONFIDENTIALITY).

12.5 Insurance

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12.5.1 **Party Insurance**. Each Party shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations hereunder and consistent with normal business practices of prudent companies similarly situated at all times during which the Products are being clinically tested in human subjects or commercially distributed or sold by such Party pursuant to this Agreement, and the insurance coverage shall in no event be less than (a) prior to the First Commercial Sale of a Product in any country, $[**] per loss occurrence and $[**] in the aggregate, and (b) after the First Commercial Sale in any country, $[**] per loss occurrence and $[**] in the aggregate. It is understood that such insurance will not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 12 (Indemnification). Each Party shall provide the other Party with written evidence of such insurance upon request. Notwithstanding anything to the contrary herein, Apellis expressly reserves the right to self-insure.

ARTICLE 13
CONFIDENTIALITY

13.1 Confidential Information

. As used in this Agreement, the term "**Confidential Information**" means all confidential or proprietary information or materials, whether tangible or intangible, and whether written or oral, provided by or on behalf of one Party (the "**Disclosing Party**") to the other Party (the "**Receiving Party**") in connection with this Agreement (including information exchanged prior to the date hereof in connection with the transactions set forth in this Agreement, and including any "Confidential Information" disclosed by either Party pursuant to the Existing CDA), but Confidential Information will not include any information or materials that:

13.1.1 were already known to the Receiving Party (other than under an obligation of confidentiality to the Disclosing Party) at the time of disclosure by or on behalf of the Disclosing Party to the Receiving Party, to the extent such Receiving Party has documentary evidence to that effect;

13.1.2 were generally available to the public or otherwise part of the public domain at the time of disclosure thereof by or on behalf of the Disclosing Party to the Receiving Party;

13.1.3 became generally available to the public or otherwise part of the public domain after disclosure thereof by or on behalf of the Disclosing Party to the Receiving Party, other than as a result of any fault of the Receiving Party or any of its Affiliates or any Third Party to whom the Receiving Party or any of its Affiliates provided such information or materials;

13.1.4 were lawfully disclosed to the Receiving Party by a Third Party who lawfully possessed such information or materials and had no obligation to the Disclosing Party not to disclose such information or materials to others; or

13.1.5 were independently discovered or developed by or on behalf of the Receiving Party without the use of or reference to any Confidential Information belonging to the Disclosing Party, to the extent such Receiving Party has documentary evidence to that effect.

Notwithstanding anything to the contrary in the foregoing sentence, but subject to Sections 13.1.2, 13.1.3, and 13.1.4, the Collaboration Know-How shall be deemed the Confidential Information of both Parties, with each Party deemed both the Disclosing Party and the Receiving Party with respect thereto, and neither Party may rely on any exception set forth in Section 13.1.1 or 13.1.5 with respect thereto.

13.2 Use of Confidential Information

. The Receiving Party shall not use the Disclosing Party's Confidential Information for any purpose other than in the exercise of its rights or performance of its obligations under this Agreement.

13.3 Know-How.

13.3.1 Apellis and its Affiliates shall continue to protect the confidential Apellis Know-How using the same degree of care and in accordance with the same internal processes and safeguards that it applied to the confidential Apellis Know-How immediately prior to the Effective Date, but in all cases no less than a reasonable degree of care.

13.3.2 Each Party and its Affiliates shall protect the confidential Collaboration Know-How using the same degree of care and in accordance with the same internal processes and safeguards with which it maintains the confidentiality of its own Confidential Information, but in all cases no less than a reasonable degree of care.

13.4 Confidentiality Obligations

. The Receiving Party shall keep confidential all of the Disclosing Party's Confidential Information using the same degree of care and in accordance with the same internal processes and safeguards with which it maintains the confidentiality of its own Confidential Information, but in all cases no less than a reasonable degree of care. The Receiving Party may disclose the Disclosing Party's Confidential Information:

13.4.1 to such of its and its Affiliates', (with respect to Apellis) sub/licensees, and (with respect to Sobi) Sublicensees' respective directors, managers, employees, independent contractors, agents, or consultants who have a need to know such Confidential Information to exercise the Receiving Party's rights or perform the Receiving Party's obligations under this Agreement, but the Receiving Party shall, and shall require its Affiliates, (with respect to Apellis) sub/licensees, and (with respect to Sobi) Sublicensees to, advise its and its Affiliates' and Sublicensees' directors, managers, employees, independent contractors, agents, or consultants who receive such Confidential Information of the confidential nature thereof and of the obligations contained in this Agreement relating thereto, and the Receiving Party shall ensure (including, in the case of a Third Party, by means of a written agreement with such Third Party having terms at least as protective as those contained in this Article 13 (Confidentiality)) that all such directors, managers, employees, independent contractors, agents, and consultants comply with such obligations;

13.4.2 to patent offices in order to seek or obtain Patent Rights in accordance with this Agreement or to Regulatory Authorities in order to seek or obtain approval to conduct Clinical Trials or other clinical studies or to gain Regulatory Approval or Reimbursement Approval with respect to Products in accordance with this Agreement, but any such disclosure may be made only following reasonable notice to the Disclosing Party and to the extent reasonably necessary to seek or obtain such Patent Rights, Regulatory Approvals, or Reimbursement Approvals (and, to the extent permitted by Applicable Law, the Receiving Party shall use reasonable efforts to obtain confidential treatment of such Confidential Information);

13.4.3 to the extent such disclosure is reasonably necessary to comply with Applicable Law, but, to the extent permitted by Applicable Law, the Receiving Party shall give reasonable advance written notice of such disclosure to the Disclosing Party to permit the Disclosing Party sufficient opportunity to, and, at the Disclosing Party's reasonable request and sole expense, shall assist the Disclosing Party to, object to such disclosure or to take measures to ensure confidential treatment of such information, including seeking a protective order or other appropriate remedy;

13.4.4 without limiting Section 13.4.3 (Confidentiality Obligations), as required by the NASDAQ regulations or any listing agreement with or rules of a national securities exchange, in which case the Receiving Party shall provide the Disclosing Party with at least [**] notice unless otherwise not practicable or permissible under Applicable Law or under applicable regulations of, agreement with, or rules of a national securities exchange, but in any event no later than the time that the disclosure required by such NASDAQ regulations or listing agreement is made, but, to the extent permitted by Applicable Law and applicable regulations of, agreement with, or rules of a national securities exchange, the Receiving Party shall use reasonable efforts to ensure confidential treatment of such information; or

13.4.5 to counterparties to the Existing Agreements or Collaboration In-Licenses to the extent required under the terms of such Existing Agreements or Collaboration In-Licenses, to *bona fide* actual or potential (with respect to Sobi) Sublicensees or (with respect to Apellis) sub/licensees or Subcontractors, or to *bona fide* actual or potential investors or acquirors, in each case pursuant to customary confidentiality agreements containing terms no less protective of the Confidential Information than are those set forth in this Article 13 (Confidentiality); or

13.4.6 as reasonably necessary to issue press releases alerting the public to the status of Development or Commercialization of any Product, as long as such press releases are made in accordance with the Receiving Party's standard practices with respect to such press releases and, unless such Party reasonably determines that such inclusion is required by Applicable Law or applicable regulations of, agreement with, or rules of a national securities exchange or such information has previously been made public by or on behalf of Apellis or its Affiliates, do not include any Confidential Information of the Disclosing Party, any confidential Apellis Know-How, or any confidential Collaboration Know-How which has not previously been made public in accordance with this Agreement or otherwise by agreement of the Parties, but such Party shall, to the extent such Party reasonably determines that it is in compliance with Applicable Law and applicable regulations of, agreement with, and rules of a national securities exchange, provide a copy of such press release to the other Party for such other Party's review at least [**] prior to the issuance of such press release and consider in good faith any timely and reasonable comments provided by such other Party.

13.5 Notification

. The Receiving Party shall notify the Disclosing Party promptly upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information, and shall cooperate with the Disclosing Party in any reasonably requested fashion to assist the Disclosing Party to regain possession of such Confidential Information and to prevent its further unauthorized use or disclosure.

13.6 Publicity; Filing of this Agreement

.

13.6.1 The press release to be issued in connection with the transactions hereunder is set forth on Schedule 13.6 (Press Release). Except as otherwise provided in this Section 13.6 (Publicity; Filing of this Agreement), each Party shall maintain the confidentiality of all provisions of this Agreement, and, without the prior written consent of the other Party, neither Party nor any of either Party's respective Affiliates shall make any press release or other public announcement regarding this Agreement, or otherwise disclose the provisions of this Agreement to any Third Party.

13.6.2 Notwithstanding Section 13.6.1 (Publicity; Filing of this Agreement), each Party may summarize or disclose the provisions of this Agreement, as reasonably necessary:

(a) to those of its directors, officers, employees, accountants, attorneys, underwriters, lenders and other financing sources, advisors, and agents whose duties reasonably require them to have access to such provisions, as long as such directors, officers, employees, accountants, attorneys, underwriters, lenders and other financing sources, advisors, and agents are required to maintain the confidentiality of such provisions;

(b) as required by the NASDAQ regulations or any listing agreement with or rules of a national securities exchange, in which case the disclosing Party shall provide the non-disclosing Party with at least [**] notice unless otherwise not practicable or permissible under Applicable Law or under applicable regulations of, agreement with, or rules of a national securities exchange, but in any event no later than the time that the disclosure required by such NASDAQ regulations or listing agreement is made, but to the extent permitted by Applicable Law and applicable regulations of, agreement with, or rules of a national securities exchange, the disclosing Party shall use reasonable efforts to ensure confidential treatment of such information;

(c) as may be required by Applicable Law (including any rule or regulation promulgated by the U.S. Securities and Exchange Commission), in which case the disclosing Party shall, to the extent permitted by Applicable Law and applicable regulations of, agreement with, or rules of a national securities exchange, provide the non-disclosing Party with prompt advance notice of such disclosure and cooperate with the non-disclosing Party to seek a protective order or other appropriate remedy, including a request for confidential treatment in the case of a filing with the Securities and Exchange Commission;

(d) by filing the press release set forth on Schedule 13.6 (Press Release), or by filing a report on Form 8-K along with a copy of this Agreement in redacted form;

(e) as required under the terms of the Existing Agreements or Collaboration In-Licenses, in each case pursuant to customary confidentiality agreements

containing terms no less protective of the Confidential Information than are those set forth in this Article 13 (Confidentiality); or

(f) as has been previously permitted by the other Party.

A Party may publicly disclose, without regard to the preceding requirements of this Section 13.6 (Publicity; Filing of this Agreement), any information that was previously publicly disclosed pursuant to this Section 13.6 (Publicity; Filing of this Agreement).

13.7 Publication

. Within [**] after the formation of the JMC, the JMC shall agree on a plan (a "**Publication Plan**") setting forth the strategy, procedures, and rules governing academic, scientific, medical, and other publications and presentations that contain or refer to the Apellis Technology or Sobi Technology (for the avoidance of doubt, including any Joint Technology), or otherwise relate to any Compound or Product, or any Exploitation thereof (other than any publication or presentation that relates to any Non-Systemic Ophthalmology Product, but does not specifically relate any Product) (each, a "**Publication**"). Neither Party may publish any Publication except in accordance with the Publication Plan. For the avoidance of doubt, nothing in this Section 13.7 (Publication) limits Apellis' right to publish any publication or presentation that relates to any Non-Systemic Ophthalmology Product and does not specifically relate to any Product.

13.8 Use of Names

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13.8.1 **Party Names**. Except as otherwise set forth in this Agreement or as required under Applicable Law or applicable regulations of, agreement with, or rules of a national securities exchange, neither Party shall use the name of the other Party in relation to this transaction in any public announcement, press release, or other public document without the written consent of such other Party, which consent will not be unreasonably withheld; *except that*, subject to Section 13.6 (Publicity; Filing of this Agreement), either Party may use the name of the other Party in any document required to be filed with any Governmental Authority, including the Securities and Exchange Commission.

13.8.2 **Use of Penn's Name**. Except as otherwise set forth in this Agreement or as required under Applicable Law or applicable regulations of, agreement with, or rules of a national securities exchange, Sobi and its Affiliates, Sublicensees, Subcontractors, employees, and agents may not use the name, logo, seal, trademark, or service mark (including any adaptation of them) of Penn or any Penn school, organization, employee, student or representative, without the prior written consent of Penn. For clarity, notwithstanding the foregoing, Sobi and its Affiliates, Sublicensees, Subcontractors, vendors, and manufacturers shall have the right to mark the Products and packaging thereof with relevant patent numbers

13.9 Survival

. The obligations and prohibitions contained in this Article 13 (Confidentiality) as they apply to Confidential Information will survive any expiration or termination of this Agreement for a period of [**].

ARTICLE 14
TERM AND TERMINATION

14.1 Term

. This Agreement will become effective on the Effective Date and, unless earlier terminated pursuant to this Article 14 (Term and Termination), will remain in effect until it expires (a) on a

Product-by-Product and country-by-country basis, upon the expiration of the Royalty Term for such Product in such country and (b) in its entirety, upon the expiration of all Royalty Terms for all Products in all countries in the Sobi Territory (the "**Term**").

14.2 Termination for Breach

.

14.2.1 **Breach by Apellis**. In the event of a material breach of this Agreement by Apellis, which material breach remains uncured for [**] measured from the date of Apellis' receipt of written notice of such material breach from Sobi that identifies the material breach in reasonable detail, without prejudice to Section 17.6 (Remedies), Sobi may either (a) terminate this Agreement in its entirety by written notice of termination to Apellis or (b) elect to continue this Agreement, initiate arbitration against Apellis for damages and offset from Sobi's payment obligations hereunder one hundred percent (100%) of all damages assessed in accordance with Section 16.5 (Arbitration).

14.2.2 **Breach by Sobi**.

(a) In the event of a material breach of this Agreement by Sobi, which material breach remains uncured for [**] (or, subject to Section 9.8 (Late Payments), [**] in the case of Sobi's payment obligations under this Agreement) measured from the date of Sobi's receipt of written notice of such material breach from Apellis that identifies the material breach in reasonable detail, without prejudice to Section 17.6 (Remedies), Apellis may terminate this Agreement in its entirety by written notice of termination to Sobi, but, if such breach is not susceptible of cure within such [**] cure period even with the use of Commercially Reasonable Efforts, Apellis' right to terminate shall be suspended if and for so long as Sobi has provided to Apellis a reasonable written plan, calculated to effect a cure of such breach, and commits to and is diligently performing such plan.

(b) In the event of a material breach by Sobi of Section 4.3 (Development Diligence Obligations) or Section 6.2 (Commercialization Diligence Obligations) with respect to Sobi's obligation to use Commercially Reasonable Efforts to Develop, obtain Regulatory Approval for, and Commercialize a Product for PNH and ALS in any of China, Japan, Brazil, or Canada, which remains uncured for [**] measured from the date of Sobi's receipt of written notice of such material breach from Apellis that identifies the material breach in reasonable detail, without prejudice to Section 17.6 (Remedies), Apellis may terminate this Agreement with respect to such country by written notice of termination to Sobi, but, if such breach is not susceptible of cure within such [**] cure period even with the use of Commercially Reasonable Efforts, Apellis' right to terminate shall be suspended if and for so long as Sobi has provided to Apellis a reasonable written plan, calculated to effect a cure of such breach, and commits to and is diligently performing such plan. When determining the timing and order of Commercial launch of a given Product and Indication in each Major Market, Sobi may reasonably take into account reference pricing strategy, and, when Sobi determines the timing and order of Development activities and the level of efforts to obtain Regulatory Approval for such Product, Sobi may take into account current status of Development activities in other countries, status of Regulatory Approval with EMA, FDA, and other Regulatory Authorities, requirements for local Manufacturing in the applicable country(ies), competitiveness of Third Party products, patent and regulatory exclusivity, anticipated or approved labelling,

present and future market potential, competitive market conditions and the profitability of the Product in light of pricing and reimbursement issues, reference Regulatory Approval strategy and reference pricing and reimbursement strategy.

14.3 Termination for Patent Challenge

. If (a) Sobi or any of its Affiliates challenges the validity, scope, or enforceability of, or otherwise opposes, any Apellis Patent Right in any action or proceeding, other than as may be necessary or reasonably required to assert a defense, cross-claim, or counter-claim in an action or proceeding asserted by Apellis or any of its Affiliates or other sub/licensees or the counterparty to an Upstream Agreement or their licensees or assignees against Sobi or any of its Affiliates or Sublicensees, or to respond to a court request or order or administrative agency request or order, (each such challenge, a "**Challenge**") or (b) any of Sobi's Sublicensees participates in a Challenge and Sobi does not terminate its sublicense with such Sublicensee upon written notice from Apellis, Apellis shall have the right to terminate this Agreement upon [**] written notice unless Sobi or its applicable Affiliate or Sublicensee has filed a motion to dismiss with prejudice such action or caused such action to be dismissed with prejudice within [**] following receipt of such notice. Notwithstanding the foregoing, none of the following activities shall be a Challenge and Apellis shall not have a right to terminate this Agreement under this Section 14.3 (Termination for Patent Challenge) with respect to: (a) any actions undertaken by an Affiliate of Sobi that first becomes such an Affiliate as a result of an acquisition of all or any part of Sobi or any of its Affiliates, where such new Affiliate was participating in the Challenge prior to such acquisition; (b) situations where Sobi or its Affiliate or Sublicensee is to participate in a challenge to the validity, scope, or enforceability of, or otherwise oppose, any Apellis Patent Right pursuant to a subpoena or court order or participates in a proceeding that is initiated by a patent office and not at the instigation of Sobi or any of its Affiliates or Sublicensees. For clarity, this Section 14.3 (Termination for Patent Challenge) shall not apply to arguments made by Sobi or its Affiliates or Sublicensees that distinguish the inventions claimed in an Apellis Patent Right from those claimed in the patent applications owned or controlled by Sobi or any of its Affiliates or Sublicensees in the ordinary course of ex parte prosecution of such patent applications.

14.4 Termination for Insolvency

. To the extent permitted by Applicable Law, either Party may terminate this Agreement upon the filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings, upon the appointment of a receiver or trustee over all or substantially all property, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; *except* that, in the case of any involuntary bankruptcy proceeding, such right to terminate will only become effective if such other Party consents to the involuntary bankruptcy or such proceeding is not dismissed within [**] after the filing thereof.

14.5 Termination by Sobi for Convenience

. At any time after the earlier of (a) the second anniversary of the Effective Date or (b) receipt of the first Regulatory Approval for the first Product in any Major European Country, Sobi may terminate this Agreement in its entirety, at its sole discretion and for any or no reason, upon ninety (90) days' prior written notice to Apellis.

ARTICLE 15
EFFECTS OF EXPIRY AND TERMINATION

15.1 Effects of Expiration

. Upon any expiration (but not earlier termination) of this Agreement, each Receiving Party shall return or destroy all documents, tapes, and other media containing Confidential Information of the Disclosing Party that remain in the possession of the Receiving Party or any of its directors, managers, employees, independent contractors, agents, or consultants; *except that* (a) nothing herein will require the destruction or deletion of back-up media made in the ordinary course of business and not accessible in the ordinary course of business, as long as the

Receiving Party does not access, and ensures that no other Person may access, any of the Disclosing Party's Confidential Information on any such back-up media; (b) the Receiving Party may keep one (1) copy of the Disclosing Party's Confidential Information in the legal department files of the Receiving Party, solely for archival purposes, but such archival copy will be deemed to be the property of the Disclosing Party, and will continue to be subject to the provisions of Article 13 (Confidentiality) indefinitely and (c) Sobi shall not be obliged to return or destroy any documents, tapes, and other media containing Apellis Know-How or Collaboration Know-How and Apellis shall not be obligated to return or destroy any documents, tapes and other media containing Collaboration Know-How.

15.2 Effects of Termination.

Upon any termination of this Agreement, in its entirety or with respect to any given country(ies), in addition to, and without affecting, any other rights or remedies that the terminating Party may have, whether under statute, common law, or otherwise, the following provisions shall take effect, either with respect to all countries in the world (in the event of a termination of this Agreement in its entirety) or with respect to the terminated country(ies) (in the event of a termination of this Agreement with respect to one (1) or more country(ies)) (the "**Terminated Territory**"):

15.2.1 **Licenses**. All licenses granted by Apellis to Sobi under this Agreement in the Terminated Territory shall terminate in their entirety.

15.2.2 **Reversion License**.

(a) Sobi (i) hereby grants to Apellis, effective upon the termination of this Agreement in the Terminated Territory, an exclusive, freely sublicensable (through multiple tiers), royalty-bearing (solely as set forth in as set forth below in this Section 15.2.2(a) (Reversion License)), perpetual, irrevocable license under the Sobi Technology and (ii) shall, at Apellis' written request, negotiate with Apellis in good faith a non-exclusive, freely sublicensable (through multiple tiers), royalty-bearing license under any Sobi Intellectual Property (other than the Sobi Technology) that is necessary or useful to Exploit Products (as such Products exist as of the effective date of termination) in the Terminated Territory (all Sobi Technology and other Intellectual Property licensed under clauses (i) and (if applicable) (ii), collectively, the "**Reversion Technology**") to Exploit the Products in the Terminated Territory. If Apellis elects in writing to obtain a royalty-bearing license as described in clause (ii) above, the Parties will discuss in good faith via their respective Executive Officers to agree on the extent of such license and an equitable royalty payable by Apellis to Sobi to reflect the value of the applicable Sobi Intellectual Property upon the effective date of such termination. Solely in the event that, following a Change of Control of Apellis, this Agreement is terminated by Sobi for Apellis' or its successor's material breach of this Agreement pursuant to Section 14.2.1 (Breach by Apellis), then Apellis' license to the Sobi Technology under Section 15.2.2(a)(i) (Reversion License) shall bear a royalty of [**] percent ([**]%) of "Net Sales," as defined in this Agreement, *mutatis mutandis*, in the Terminated Territory in a manner analogous to that set forth in Section 9.5 (Royalty Payments) (except that Section 9.5.3(b) (Royalty Reduction) and Section 9.5.4 (Expiration of Royalty Term) shall not apply) and Sections 9.7 (Taxes and Withholding) through 9.12 (Financial Audits), *mutatis mutandis*, with the term of such royalty for the Products in each country being ten (10) years from the later of (a) the effective date of termination and (b) the date of First Commercial Sale of the first Product in such country. For clarity, any Sobi

Technology or other Intellectual Property resulting from Sobi's Unilateral Development Activities shall only be included in the Reversion Technology if Apellis opts to obtain rights therefore in accordance with Section 4.4.4(b)(iii) (Buy-In).

(b) APELLIS AGREES AND ACKNOWLEDGES THAT THE LICENSE OF THE REVERSION TECHNOLOGY UNDER THIS SECTION 15.2.2 (REVERSION LICENSE) AND APELLIS' AND ITS AFFILIATES' AND ITS AND THEIR SUBLICENSEES' USE OF THE REVERSION TECHNOLOGY IS PROVIDED ON AN "AS-IS" BASIS AND THAT ALL WARRANTIES, REPRESENTATIONS AND CONDITIONS WHETHER ORAL, WRITTEN, EXPRESS OR IMPLIED BY STATUTE, COMMON LAW OR OTHERWISE (INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF QUALITY, FITNESS FOR PURPOSE, VALIDITY OF ANY PATENTS OR NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS) ARE EXPRESSLY EXCLUDED AND SPECIFICALLY DISCLAIMED, TO THE EXTENT PERMITTED BY APPLICABLE LAW.

(c) Apellis shall pay Sobi for Apellis' pro rata share of any in-licensor payments associated with Apellis' Exploitation of any Product or Non-Systemic Ophthalmology Product pursuant to any sublicense under Sobi's upstream licenses included in the Reversion Technology.

15.2.3 **Development Costs**. Sobi shall pay its pro rata share of Development Costs it committed to prior to notice of termination until the earlier of (a) [**] following the effective date of termination and (b) wind-down or transfer to Apellis of the relevant activity for which the Development Costs were incurred.

15.2.4 **Report**. Within [**] after such termination, Sobi shall provide to Apellis a fair and accurate summary report of the status of the Development, Commercialization, Medical Affairs, and Manufacturing activities conducted by Sobi with respect to the Products in the Terminated Territory.

15.2.5 **Trademarks**. Sobi shall transfer and assign to Apellis all rights, title, and interests in and to the Product Trademarks in the Terminated Territory.

15.2.6 **Regulatory Affairs**. Sobi shall, as soon as reasonably practicable, transfer and assign to Apellis all Regulatory Data, Regulatory Submissions, Reimbursement Submissions, Regulatory Approvals, and Reimbursement Approvals with respect to the Products in the Terminated Territory. Sobi may retain a copy of such Regulatory Data, Regulatory Submissions, Reimbursement Submissions, Regulatory Approvals, and Reimbursement Approvals for its records.

15.2.7 **Ongoing Clinical Trials**. Solely in the event of a termination of this Agreement in its entirety, with respect to each Clinical Trial for any Product that is ongoing on the effective date of termination, the Parties shall (to the extent applicable) use Commercially Reasonable Efforts to transition full responsibility for, and control of, such Clinical Trial to Apellis, and Sobi shall remain responsible for its applicable share of all cost and expenses (including any Shared Development Costs) with respect to such Clinical Trial until full responsibility for, and control of, such Clinical Trial has been transitioned to Apellis.

15.2.8 **Inventory**.

(a) Without limiting Sobi's obligations under Section 15.2.6 (Regulatory Affairs), in the event of a termination of this Agreement in its entirety, or with respect to any given country(ies), Sobi will have the right, but not the obligation, for [**] following the effective date of such termination to sell any remaining inventory of Product for the Terminated Territory then owned by and in the possession of Sobi or its Affiliates, as long as Sobi continues to make milestone and royalty payments under Article 9 (Payments) in respect of the Net Sales resulting from sales of such inventory.

(b) Following the [**] period specified in Section 15.2.8(a) (Inventory), or at Sobi's request, solely in the event of a termination of this Agreement in its entirety, Apellis shall have the option, exercisable within [**] following the effective date of termination, to obtain inventory of the Products then owned by and in the possession of Sobi or its Affiliates at a price equal to, as applicable, the amount Sobi paid Apellis for such inventory or Sobi's Manufacturing Costs for such inventory. If Apellis exercises the option set forth in the preceding sentence, then Sobi shall grant, and hereby does grant, effective on the exercise of such option, a royalty-free right and license to use any trademarks, names, and logos of Sobi appearing on such inventory of the applicable Products for a period of [**] solely to permit the orderly sale of such inventory, subject to Apellis meeting reasonable quality control standards imposed by Sobi on the use of such trademarks, names, and logos, which will be consistent with the standards used by Sobi prior to such termination.

(c) APELLIS AGREES AND ACKNOWLEDGES THAT ANY INVENTORY ACQUIRED UNDER SECTION 15.2.8(b) (INVENTORY) IS PROVIDED ON AN "AS-IS" BASIS AND THAT ALL WARRANTIES, REPRESENTATIONS, AND CONDITIONS, WHETHER ORAL, WRITTEN, EXPRESS, OR IMPLIED BY STATUTE, COMMON LAW, OR OTHERWISE (INCLUDING ANY IMPLIED WARRANTIES OF QUALITY OR FITNESS FOR PURPOSE OR NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS) ARE EXPRESSLY EXCLUDED AND SPECIFICALLY DISCLAIMED, TO THE EXTENT PERMITTED BY APPLICABLE LAW.

15.2.9 **Manufacturing**. Solely in the event of a termination of this Agreement in its entirety, to the extent that Sobi was using a Third Party manufacturer to Manufacture any Compounds or Products immediately prior to such termination, at Apellis' written request, to the extent permitted by the terms of any applicable contract with such Third Party manufacturer and to the extent such contract exclusively relates to the Compounds or Products, Sobi shall use Commercially Reasonable Efforts to assign to Apellis the manufacturing agreements with such Third Party with respect to the Compounds and Products.

15.2.10 **Prosecution**. Sobi shall, if applicable, provide reasonable assistance to Apellis and reasonable cooperation in connection with the transition of Prosecution, defense, and enforcement responsibilities to Apellis with respect to the Apellis Technology (for the avoidance of doubt, including any Joint Technology) then being Prosecuted, defended, or enforced by Sobi in the Terminated Territory, including execution of such documents as may be reasonable necessary to effect such transition.

15.2.11 **Post-Termination Confidentiality Obligations**. Solely in the event of a termination of this Agreement in its entirety, Sobi shall return or destroy all documents, tapes, or other media containing Confidential Information of Apellis that remain in the possession of Sobi or its directors, managers, employees, independent contractors, agents, or consultants; *except that* (a) nothing herein will require the destruction or deletion of back-up media made in the ordinary course of business and not accessible in the ordinary course of business, as long as Sobi does not access, and ensures that no other Person may access, any of Apellis' Confidential Information on any such back-up media and (b) Sobi may keep one (1) copy of Apellis' Confidential Information in Sobi's legal department files, solely for archival purposes, but such archival copy will be deemed to be the property of Apellis, and will continue to be subject to the provisions of Article 13 (Confidentiality) indefinitely.

15.2.12 **Upstream Payments**. Notwithstanding anything to the contrary in this Agreement, Apellis shall be solely responsible for any payments that become owed under any Upstream Agreement with respect to the Exploitation of any Product in the Terminated Territory following the applicable termination and shall be responsible for complying with all terms of the Upstream Agreements related to such Exploitation of Products in the Terminated Territory following such termination.

15.3 Committees

. Upon termination or expiration of this Agreement for any reason, all Committees shall be immediately dissolved.

15.4 Transition.

Upon termination or expiration of this Agreement for any reason, the Parties will cooperate in good faith to effect a smooth transition of any Development or Commercialization activities as soon as reasonably practicable.

15.5 Accrued Rights

. Termination or expiration of this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of a Party prior to the effective date of such termination or expiration. Termination or expiration of this Agreement for any reason will not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.

15.6 Sublicenses

. Upon the termination of this Agreement pursuant to Section 14.2 (Termination for Breach), Section 14.3 (Termination for Patent Challenge), or Section 14.4 (Termination for Insolvency), at each Sublicensee's request, Apellis shall grant to such Sublicensee a direct license on the terms set forth in this Agreement, provided that (a) such Sublicensee is not then in default of its sublicense agreement and not the cause of Licensee's material breach hereunder, (b) such terms shall include an obligation to pay royalties at a rate which is the greater of the royalty rate set forth in this Agreement and that set forth in the relevant sublicense, and any country-specific regulatory milestones applicable to such sublicense calculated in the same manner as set forth in Section 9.3 (Development Milestones) of this Agreement, and (c) unless otherwise agreed by Apellis, the terms of such direct license shall not require Apellis to undertake any obligations to the Sublicensee beyond the grant of the direct license. For clarity, nothing in this Section 15.6 (Sublicenses) shall be interpreted as requiring the survival of any of Sobi's obligations under this Agreement following termination, which shall be governed solely by Section 15.7 (Survival).

15.7 Survival

. Notwithstanding any provision to the contrary set forth in this Agreement, the following provisions will survive any expiration or termination of this Agreement: Article 1 (Definitions), Article 15 (Effects of Termination), Article 16 (Dispute Resolution), and Article 17 (Miscellaneous), and Sections 2.1.2(c) (License Grants to Apellis), 2.2.1 (No Implied Licenses; Retained Rights), 2.2.2 (No Implied Licenses; Retained Rights), 2.8 (Section 365(n) of the

Bankruptcy Code), 4.10.1 (General) (only until the expiry of the period required by Applicable Law), 5.2.6(e) (Assignment of EMA PNH Regulatory Approval), 5.2.6(g) (Assignment of EMA PNH Regulatory Approval), 5.4 (Adverse Event Reporting) (until the longer of the expiry of the period required by Applicable Law and the expiry or earlier termination of the SDEA), 6.10.1 (General) (only until the expiry of the period required by Applicable Law), 9.12.1 (Records Retention) (only for the period stated therein), 10.1 (Ownership), 10.6 (35 U.S.C. § 102(c)), 11.7 (No Other Representations or Warranties), 12.1 (Indemnification by Apellis), 12.2 (Indemnification by Sobi), 12.3 (Indemnification Procedures), 12.4 (Limitation of Liability), 13.9 (Survival) (including the provisions referenced therein for the time period specified therein). Except as set forth in this Section 15.7 (Survival) or otherwise expressly set forth herein, upon termination or expiration of this Agreement, all other rights and obligations of the Parties will cease.

ARTICLE 16
DISPUTE RESOLUTION

16.1 Governing Law

. This Agreement, and all claims arising under or in connection therewith, will be governed by and interpreted in accordance with the substantive laws of the State of New York, without regard to conflict of law principles thereof.

16.2 Disputes

. Except as otherwise expressly set forth in this Agreement, disputes of any nature arising under, relating to, or in connection with this Agreement (except for disputes arising at or referred to the JEC pursuant to Article 3 (Governance), which will be resolved in accordance with Section 3.7 (Decisions of the Committees)) will be resolved pursuant to this Article 16 (Dispute Resolution).

16.3 Resolution by Executive Officers

. With respect to all disputes, claims, or controversies arising out of or in connection with this Agreement that do not involve a failure to reach agreement on a matter reserved for decision by a Committee while the Committees remain in existence, including any alleged failure to perform under, or breach of, this Agreement, or any issue relating to the formation, existence, validity, enforceability, performance, interpretation, breach, termination, or application of this Agreement ("**Disputes**"), if the Parties are unable to resolve such Dispute within [**] after such Dispute is first identified by either Party in writing to the other, then the Parties will refer such Dispute to the Executive Officers of each Party. The Executive Officers of both Parties will meet to attempt to resolve such Dispute. Such resolution, if any, of a referred issue will be final and binding on the Parties. All negotiations pursuant to this Article 16 (Dispute Resolution) are confidential and will be treated as compromise and settlement negotiations for purposes of applicable rules of evidence. If the Executive Officers cannot resolve such Dispute within [**] after either Party requests such a resolution in writing, then such Dispute shall be resolved as set forth in Section 16.5 (Arbitration).

16.4 Neutral Safety Committee

. If the JEC does not approve an Additional Development Proposal because one Party has a reasonable, good faith concern that the proposed Additional Global Development Activities raise material safety or scientific concerns, then, at the Proposing Party's request, the Parties agree to submit such matter to a committee of three (3) Qualified Safety Experts (each and every such committee of three Qualified Safety Experts, a "**Neutral Safety Committee**") appointed as provided in this Section 16.4 (Neutral Safety Committee) to determine whether the proposed Additional Development Activities raise material safety or scientific concerns for the Development or Commercialization of any Product. Within [**] following any such request for a Neutral Safety Committee, each of Sobi and Apellis shall nominate a Qualified Safety Expert to participate on the applicable Neutral Safety Committee and, if the Parties are unable to agree upon a third Qualified Safety Expert for such Neutral Safety Committee within [**] following such

request for a Neutral Safety Committee, then the initial two (2) Qualified Safety Experts shall select such third Qualified Safety Expert. Each Neutral Safety Committee shall act as follows: (a) each Qualified Safety Expert (and the Neutral Safety Committee as a whole) shall act as an expert and not as an arbitrator; (b) each decision of the Neutral Safety Committee shall be by majority vote of the three (3) Qualified Safety Experts; and (c) the decision of the Neutral Safety Committee is, in the absence of fraud or manifest error, final and binding on the Parties. The costs and expenses of any Neutral Safety Committee shall be shared fifty percent (50%)/fifty percent (50%) by the Parties, and each Party shall pay its share of such costs and expenses within [**] after receipt of any invoice therefor.

16.5 Arbitration

. Subject to Section 16.5.1 (Baseball Arbitration) and Section 16.5.2 (Intellectual Property Disputes), all Disputes arising out of or in connection with this Agreement that are not resolved in accordance with Article 3 (Governance), Section 16.3 (Resolution by Executive Officers), or Section 16.4 (Neutral Safety Committee) and are not subject to a Party's final decision-making authority in accordance with Article 3 (Governance) shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce (the "**Rules**") by three arbitrators appointed in accordance with said Rules. The language of the arbitration shall be English. The place of arbitration shall be New York, New York. The arbitrators shall award to the prevailing party, if any, as determined by the arbitrator(s) its reasonable attorneys' fees and costs. Judgment on an award may be entered in any court having jurisdiction thereof. The parties shall maintain the confidential nature of the arbitration proceeding and the Award, including the hearing, except as may be necessary to prepare for or conduct the arbitration hearing on the merits, or except as may be necessary in connection with a court application for a preliminary remedy, a judicial challenge to an award or its enforcement, or unless otherwise required by law or judicial decision.

16.5.1 **Baseball Arbitration**.

In respect of a matter that requires resolution via baseball arbitration the following additional procedure shall apply:

(a) Within [**] after the appointment of the arbitrators, each Party will provide the arbitrators with a proposal and written memorandum in support of its position regarding the Dispute, as well as any documentary evidence it wishes to provide in support thereof (not to exceed [**]) (each a "**Proposal**") and the arbitrators will provide each Party's Proposal to the other Party after it receives it from both Parties.

(b) Within [**] after a Party submits its Proposal, the other Party will have the right to submit a rebuttal memorandum (not to exceed [**]), if any, to the arbitrators and the other Party. If requested by the arbitrators, the Parties will make oral submissions to the arbitrators based on such Party's Proposal.

(c) Within [**] after the receipt by the arbitrators of both Parties' written submissions (or expiration of the [**] period if any Party fails to submit a response), the arbitrators will issue a final award in writing, stating their reasoning, provided that the arbitrators will select one of the Parties' Proposals. The decision of the arbitrators will be the sole, exclusive, binding and non-appealable remedy between them regarding the dispute referred to baseball arbitration.

16.5.2 **Intellectual Property Disputes**.

Unless otherwise agreed by the Parties, a dispute between the Parties relating to the validity or enforceability of any Patent Right shall not be subject to arbitration, but shall instead be submitted to a court or patent office of competent jurisdiction in the relevant country or jurisdiction in which such Patent Right was issued

or, if not issued, in which the underlying patent application was filed, and any dispute between the Parties relating to the ownership or inventorship of any Patent Right shall not be subject to arbitration, but shall instead be submitted to a federal district court of competent jurisdiction located in New York, New York.

16.6 Equitable Remedies

. Notwithstanding any provision to the contrary set forth in this Agreement, the Parties each stipulate and agree that (a) any breach of this Agreement will cause irrevocable harm for which monetary damages would not provide a sufficient remedy; and (b) in such case of such breach of this Agreement, the non-breaching Party will be entitled to equitable relief, including, as applicable, specific performance, temporary or permanent restraining orders, preliminary injunction, permanent injunction, or other equitable relief, without the posting of any bond or other security, from the arbitrators or any court of competent jurisdiction.

ARTICLE 17
MISCELLANEOUS

17.1 Assignment

. Neither this Agreement nor any interest hereunder will be assignable or delegable by either Party without the prior written consent of the other Party, except as follows: (a) a Party may, subject to the terms of this Agreement, assign its rights and delegate its obligations under this Agreement in whole to its successor-in-interest in connection with the sale of all or substantially all of its assets to which this Agreement specifically relates, whether in a merger, acquisition, or similar transaction or series of related transactions, as long as (i) such sale is not primarily for the benefit of its creditors and (ii) such successor-in-interest agrees in writing to be bound by the terms and conditions of this Agreement; and (b) a Party may assign its rights and delegate its obligations under this Agreement to any of its Affiliates, as long as, in each case ((a) and (b)), such assigning Party remains liable for all of its rights and obligations under this Agreement. This Agreement will be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein will be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 17.1 (Assignment) will be null, void, and of no legal effect.

17.2 Entire Agreement; Amendment

. This Agreement and the DTPA do, and, when negotiated and entered into, the SDEA, Supply Agreement, and Quality Agreement will, collectively, set forth the entire agreement between the Parties, and supersede all previous and contemporaneous negotiations, representations, or agreements, written or oral, regarding the subject matter hereof and thereof. Any other express or implied agreements, understandings, negotiations, writings, or commitments, either oral or written, with respect to the subjects and licenses hereunder and thereunder are superseded by the terms of this Agreement and the DTPA, and, when negotiated and entered into, the SDEA, Supply Agreement, and Quality Agreement, including the Existing CDA, which is hereby terminated effective as of the Effective Date. This Agreement may be amended only by an instrument in writing duly executed on behalf of all of the Parties. In case of inconsistencies between this Agreement and any Schedule hereof, the terms of this Agreement will prevail unless the Parties agree explicitly that the Schedule should prevail.

17.3 Force Majeure

. If the performance of any part of this Agreement by a Party is prevented, restricted, interfered with, or delayed by an occurrence beyond the control of such Party (and which did not occur as a result of such Party's financial condition, negligence, or fault), including fire, earthquake, flood, embargo, power shortage or failure, acts of war or terrorism, insurrection, riot, lockout or other labor disturbance, governmental acts or orders or restrictions (even if foreseeable as a result of the COVID-19 pandemic), pandemic (including COVID-19, even though foreseeable), or other acts of God, such Party shall, upon giving written notice to the other Party,

be excused from such performance to the extent of such prevention, restriction, interference, or delay, but the affected Party shall use its Commercially Reasonable Efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed. Without limiting the foregoing, when such circumstances arise, the Parties shall negotiate in good faith any modifications of the terms of this Agreement that may be necessary or appropriate in order to arrive at an equitable solution.

17.4 Costs and Expenses.

Except as otherwise expressly set forth in this Agreement, each Party shall bear its own costs and expenses in performing its obligations under this Agreement.

17.5 Waiver

. The failure of either Party to require performance by the other Party of any of such other Party's obligations under this Agreement will in no manner affect the right of such Party to enforce the same at a later time. No waiver by any Party of any condition, or of the breach of any provision, term, representation, or warranty contained in this Agreement, will be deemed to be, or construed as, a further or continuing waiver of any such condition or breach, or of any other condition or of the breach of any other provision, term, representation, or warranty hereof.

17.6 Remedies

. The remedies provided in this Agreement are not exclusive and a Party suffering from a breach or default of this Agreement may pursue all other available remedies, both legal and equitable, alternatively, or cumulatively.

17.7 Severance

. If any provision or portion thereof in this Agreement is for any reason invalid, illegal, or unenforceable, then the same will not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement will be construed in such fashion as to maintain its existence, validity, and enforceability to the greatest extent possible. In any such event, this Agreement will be construed as if such provision or portion thereof had never been contained in this Agreement, and there will be deemed substituted therefor such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by Applicable Law unless doing so would have the effect of materially altering the rights and obligations of the Parties, in which event, this Agreement may be terminated by mutual written agreement of the Parties.

17.8 Notices

. All notices that are required or permitted hereunder will be in writing and sufficient if delivered by internationally-recognized overnight courier, addressed as follows (with a courtesy copy sent by email, which will not constitute notice):

If to Apellis:	Apellis Pharmaceuticals, Inc. APL Del Holdings, LLC 100 5th Avenue Waltham, MA 02451 USA Attn: David Watson, General Counsel
With a copy to:	Apellis Switzerland GmbH Zählerweg 10, 6300 Zug Switzerland Attn: Managing Director

With a copy to: WilmerHale
60 State Street
Boston, MA 02109
USA
Attn: Steven D. Barrett

If to Sobi: Swedish Orphan Biovitrum AB (publ)
SE-112 76 Stockholm, Sweden
Attn: General Counsel

With a copy to: Latham & Watkins LLP
12670 High Bluff Drive
San Diego, CA 92130
Attn: Steve Chinowsky, Frances Stocks Allen
Email: steve.chinowsky@lw.com, frances.stocks.allen@lw.com

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given on the third Business Day after dispatch.

17.9 Relationship of the Parties, No Rights of Third Parties

. Nothing in this Agreement is intended or will be deemed to constitute a partnership, agency, employer-employee, or joint venture relationship between the Parties. No Party will incur any debts or make any commitments for the other. Neither Apellis, on the one hand, nor Sobi, on the other hand, shall have the authority to make any statements, representations or commitments of any kind or to take any action that will be binding on the other Party without the prior written consent of the other Party to do so. All individuals employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party. There are no express or implied third party beneficiaries hereunder.

17.10 Relationship of the Apellis Entities.

17.10.1 Each undersigned Apellis entity acknowledges that Apellis GmbH shall act as Apellis' designated representative and to represent each Apellis entity, as may be relevant or necessary, for the purposes contemplated by this Agreement. Each Apellis entity hereby irrevocably agrees that it shall be bound by any steps or actions taken or any agreement entered into by Apellis GmbH acting in accordance with this Agreement.

17.10.2 Sobi shall (a) be entitled to deal exclusively with Apellis GmbH on all matters relating to this Agreement (with respect to matters regarding Apellis) and (b) have the right to rely, without independent investigation or verification, upon all decisions, communications or writings made, given or executed by Apellis GmbH (with respect to matters regarding Apellis) and actions taken or omitted to be taken by Apellis GmbH pursuant to this Agreement, all of which actions or omissions shall be legally binding upon each Apellis entity as if such entity had taken such action or omitted to take action. Each Apellis entity agrees not to institute any action, proceeding or claim against Sobi or its Affiliates alleging that Apellis GmbH did not have the authority to act on behalf of each Apellis entity in connection with any such action, omission or execution. No modification or revocation of this authorization (that is granted by the Apellis entities to Apellis GmbH to serve as Apellis' representative in this Agreement) shall be effective as against Sobi or its Affiliates.

17.10.3 Each Apellis entity hereby agrees and acknowledges that each of Apellis GmbH, Apellis Inc. and APL DEL Holdings LLC (or any successor to APL DEL Holdings LLC) shall be jointly and severally liable hereunder for any obligation, liability, act or omission of any Apellis entity, including those set forth in Section 5.2.6(g) (Assignment of the EMA PNH Regulatory Approval) and Section 12.1 (Indemnification by Apellis).

17.11 Interpretation

. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include", "includes," "including," and "e.g." will be deemed to be followed by the phrase "without limitation," (c) the word "will" will be construed to have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument, or other document herein will be construed as referring to such agreement, instrument, or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements, or modifications set forth herein or therein), (e) any reference herein to any Person will be construed to include such Person's successors and assigns, (f) the words "herein," "hereof," and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Schedules will be construed to refer to Sections or Schedules of this Agreement, and references to this Agreement include all Schedules hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals, and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties, or any Committee hereunder "agree," "consent," or "approve" or the like will require that such agreement, consent, or approval be specific and in writing, whether by written agreement, letter, approved minutes, or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule, or regulation, or article, section, or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule, or regulation, (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or," (l) references to any Sections include Sections and subsections that are part of the related Section (e.g., a section numbered "Section 2.2" would be part of "Section 2", and references to "Section 2.2" would also refer to material contained in the subsection described as "Section 2.2(a)"); and (m) the captions to the Sections hereof are not a part of this Agreement and shall not be used to inform interpretation of this Agreement, but are merely guides or labels to assist in locating and reading the several Sections hereof.

17.12 Further Assurance

. Each of Apellis and Sobi agrees to duly execute and deliver, or cause to be duly executed or delivered, such further instruments and do and cause to be done such further acts, including the filing of additional assignments, agreements, documents, and instruments, as the other Party may at any time and from time to time reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes of, or to better assure and confirm unto such other Party its rights and remedies under, this Agreement.

17.13 Counterparts

. This Agreement may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[Signature Page Follows]

In Witness Whereof, the Parties have caused this Agreement to be executed by their representatives thereunto duly authorized as of the Effective Date.

Swedish Orphan Biovitrum AB (publ)

By: /s/ Guido Oelkers
Name: Guido Oelkers
Title: CEO & President

By: /s/ Torbjorn Hallberg
Name: Torbjorn Hallberg
Title: General Counsel

In Witness Whereof, the Parties have caused this Agreement to be executed by their representatives thereunto duly authorized as of the Effective Date.

Apellis Pharmaceuticals, Inc.

By: __/s/ Cedric Francois_____
Name: Cedric Francois
Title: CEO

Apellis Switzerland GmbH

By: ____/s/ Thomas Lackner_____
Name: Thomas Lackner
Title: SVP, Head of Europe

APL Del Holdings, LLC

By: __/s/ David Watson_____
Name: David Watson
Title: Manager

Exhibit 10.26

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed.
Double asterisks denote omissions.

COMMERCIAL SUPPLY AGREEMENT

This Commercial Supply Agreement (this "**Agreement**") is made effective as of January 1, 2021(the "**Effective Date**") by and between Apellis Pharmaceuticals, Inc. a Delaware corporation ("**Apellis US**"), Apellis Switzerland GmbH, a Swiss limited liability company ("**Apellis CH**") (collectively, Apellis US and Apellis CH are "**Apellis**"), Bachem Americas, Inc., a California corporation ("**Bachem US**"), and Bachem AG, a Swiss corporation ("**Bachem CH**") (collectively, Bachem US and Bachem CH are "**Bachem**"). Apellis and Bachem are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Apellis US and Bachem US entered into a Manufacturing Services Agreement effective May 11, 2018 concerning the production by Bachem for Apellis of Drug Substance (defined below) for certain clinical trials, as amended by the certain Addendum to the Master Services Agreement effective August 30 , 2019 (collectively, the "**Clinical Supply Agreement**").

WHEREAS, Apellis has developed a pharmaceutical product candidate containing the Drug Substance, and is pursuing the clinical development and commercialization of such pharmaceutical product candidate for a broad range of diseases that are driven by uncontrolled or excessive activation of the complement cascade, including but not limited to those within hematology, ophthalmology and nephrology.

WHEREAS, the Parties wish to also enter into this Agreement to provide for Apellis to purchase from Bachem and for Bachem to supply Apellis with a portion of Apellis' requirements for the commercial supply of Drug Substance for the Product.

NOW, THEREFORE, in consideration of the foregoing and the premises and conditions set forth herein, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

1.1 "**Affiliate**" means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one (1) or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, by contract or otherwise.

1.2 "**Agency**" means any applicable local, national or supranational government regulatory authority involved in granting approvals and/or exercising authority with respect to the Manufacturing of a Product, including in the U.S., the FDA; in the European Union, the European Medicines Agency or any competent Governmental Authority in the European Union; in Switzerland, the Swiss Agency for Therapeutic Products (Swissmedic); in Japan, the Pharmaceuticals and Medical Devices Agency; and any other applicable Governmental Authority having jurisdiction over a pharmaceutical Product and in any other portion of the Territory; and any successor Governmental Authority having substantially the same function as those enumerated above.

1.3 "**Agreement**" has the meaning set forth in the introductory paragraph.

1.4 "**Apellis**" has the meaning set forth in the introductory paragraph.

1.5 "**Apellis CH**" has the meaning set forth in the introductory paragraph.

1.6 "**Apellis Indemnitee**" has the meaning set forth in Section 12.2.

1.7 "**Apellis IP**" means (i) all technology, Apellis Supplied Materials, know-how, inventions, discoveries, ideas, concepts, trade-secrets, improvements, processes, process improvements, information, Specifications, analytical test methods, CMC documentation, DMFs or data, whether patentable or not, [**]. and (ii) any Apellis intellectual property rights therein.

1.8 "**Apellis Property**" has the meaning set forth in Section 9.1.

1.9 "**Apellis Supplied Materials**" has the meaning set forth in Section 2.13.

1.10 "**Apellis US**" has the meaning set forth in the introductory paragraph.

1.11 "**Applicable Law**" means all applicable statutes, ordinances, regulations, rules, or orders of any kind whatsoever of any Governmental Authority in the Territory, including the FDCA, Prescription Drug Marketing Act, the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335a et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), Federal Civil False Claims Act (31 U.S.C. §3729 et seq.), and Anti-Kickback Statute (42 U.S.C. §1320a-7b et seq.), all as amended from time to time, together with any rules, regulations, and compliance guidance promulgated thereunder.

1.12 "**Approved Manufacturer**" has the meaning set forth in Section 2.9.

1.13 "**Bachem**" has the meaning set forth in the introductory paragraph.

1.14 "**Bachem CH**" has the meaning set forth in the introductory paragraph.

1.15 "**Bachem Indemnitee**" has the meaning set forth in Section 12.1.

1.16 "**Bachem IP**" means all intellectual property (including trademarks), data, information, reports, manufacturing know-how and any and all related documentation, which are (i) developed, generated or derived, directly or indirectly by or on behalf of Bachem prior to the Effective Date [**] or (ii) any manufacturing know-how developed or generated by Bachem during the Term [**].

1.17 "**Bachem US**" has the meaning set forth in the introductory paragraph.

1.18 "**Batch**" means the Drug Substance that results from a single Manufacturing process, inclusive of Materials and testing.

1.19 "**Batch Record**" means the complete written record, as described more fully in the Quality Agreement, of the history of a Drug Substance Batch and its production and processing, the Certificate of Analysis and any other related controls required by cGMPs.

1.20 "**Breaching Party**" has the meaning set forth in Section 10.2.

1.21 "**Business Day**" means a day other than Saturday, Sunday or any other day on which commercial banks located in the State of New York or the State of Washington, U.S., are authorized or obligated by Applicable Law to close.

1.22 "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, however, that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first complete Calendar Quarter thereafter; and (b) the last Calendar Quarter of the Term shall end upon the expiration or termination of this Agreement.

1.23 "**Calendar Year**" means the twelve-month period ending on December 31; provided, however, that (a) the first Calendar Year of the Term shall begin on the Effective Date and end on December 31, 2021; and (b) the last Calendar Year of the Term shall end on the effective date of expiration or termination of this Agreement.

1.24 "**Certificate of Analysis**" means a certificate in writing for each batch of Drug Substance, that provides full analytical results of the batch of Drug Substance and certifies (a) the conformity of the batch of Drug Substance to the Specifications and (b) that manufacturing and release records of the respective batch of Drug Substance were reviewed by Bachem and manufacturing and release of the respective batch of Drug Substance is in accordance with all applicable cGMP requirements.

1.25 "**Claim**" has the meaning set forth in Section 12.1.

1.26 "**Clinical Supply Agreement**" has the meaning set forth in the Recitals.

1.27 "**Commercially Reasonable Efforts**" means with respect to the efforts to be expended, or considerations to be undertaken, by a Party or its Affiliate with respect to any objective, activity or decision to be undertaken hereunder, reasonable, good faith efforts to accomplish such objective, activity or decision as such Party would normally use to accomplish a similar objective, activity or decision under similar circumstances.

1.28 "**Confidential Information**" means all non-public or proprietary information disclosed by either Party (the disclosing Party) to the other Party (the receiving Party) in connection with the activities contemplated by this Agreement, which may include ideas, inventions, discoveries, concepts, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, inventories, machines, techniques, development, designs, drawings, computer programs, skill, experience, documents, apparatus, results, clinical and regulatory strategies, Regulatory Documentation, and submissions pertaining to, or made in association with, filings with any Governmental Authority, data, including pharmacological, toxicological and clinical data, analytical and quality control data, manufacturing data and descriptions, patent and legal data, market data, financial data or descriptions, devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials and compounds, and the like, without regard as to whether any of the foregoing is marked "confidential" or "proprietary," or disclosed in oral, written, graphic, or electronic form. Confidential Information shall exclude information that: (i) at the time of disclosure, is generally available to the public, other than by a breach of the receiving Party or any of its Affiliates of any confidentiality obligation owed to the disclosing Party or any of its Affiliates; (ii) after disclosure hereunder, becomes generally available to the public, except through breach by the receiving Party or any of its Affiliates of this Agreement or any other confidentiality obligation owed by the receiving Party or any of its Affiliates to the disclosing Party or any of its Affiliates; (iii) the receiving Party can demonstrate by contemporaneous written records was in its or its Affiliate's possession prior to the time of such disclosure by the disclosing Party or any of its Affiliates hereunder, and was not acquired directly or indirectly from the disclosing Party or any of its Affiliates; (iv) becomes available to the receiving Party from a Third Party that is not legally prohibited from disclosing such Confidential Information, provided such Confidential Information was not acquired directly or indirectly from the disclosing Party or any of its Affiliates; (v) the receiving Party can demonstrate by contemporaneous written records was developed by or for the receiving

Party or any of its Affiliates independently of the disclosure of Confidential Information by the disclosing Party or any of its Affiliates. All Apellis Property, whether disclosed by Apellis or its Affiliates to Bachem or its Affiliates or developed under this Agreement, is considered Confidential Information of Apellis and not of Bachem, with Apellis considered the disclosing Party and Bachem considered the receiving Party. Confidential Information shall include the terms and conditions of this Agreement, which shall be deemed the Confidential Information of both Parties. All Bachem IP, whether disclosed by Bachem or its Affiliates to Apellis or its Affiliates, owned by Bachem prior to the Effective Date, or developed under this Agreement is considered Confidential Information of Bachem, and not of Apellis, with Bachem considered the disclosing Party and Apellis considered the receiving Party.

1.29 "**COVID-19 Pandemic**" means the pandemic of coronavirus disease 2019 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) including any mutations of this virus and subsequent epidemics or pandemics in connection with it.

1.30 "**Continuous Improvement Program**" has the meaning set forth in Section 4.6.

1.31 "**Cure Period**" has the meaning set forth in Section 10.2.

1.32 "**Delivery**" or "**Deliver**" or "**Delivered**" means Bachem's delivery of Drug Substance pursuant to a given Firm Order in accordance with the Delivery Terms and the provisions of this Agreement, as further referenced in Sections 1.34 and 3.4.

1.33 "**Delivery Address**" means, with respect to a given order of Drug Substance, the address where the quantities of Drug Substance under such order are to be shipped, as set forth in the applicable order.

1.34 "**Delivery Date**" means the date by which Apellis shall take delivery of Drug Substance as set forth in a Firm Order.

1.35 "**Delivery Terms**" means FCA (Incoterms 2020) Bachem's designated manufacturing Facility for the finished, packaged and labelled Drug Substance.

1.36 "**Disqualified Person**" means any person or entity that: (a) manufactures, distributes, sells or markets any product(s) that compete with any Product; (b) has compliance issues with the European Medicines Agency or the FDA or any other Agency; or (c) is identified as a proscribed party on the Entity List or the Denied Persons list administered by the US Department of Commerce or the US Department of Treasury.

1.37 "**DMF**" means a Drug Master File (or similar file) on file (or to be filed) with an Agency with respect to the Drug Substance (including any active substances master files, certificate of suitability or other suitable chemical pharmaceutical documentation containing factual information on the Drub Substance registered with an Agency).

1.38 "**Dispute**" has the meaning set forth in Section 11.1.

1.39 "**Drug Substance**" means APL-2 (pegcetacoplan) drug substance, quantities to be supplied under this Agreement.

1.40 "**DSCSA**" means the United States Drug Supply Chain Security Act (21 U.S.C. §581 et seq.) and applicable regulations promulgated thereunder, as amended from time to time.

1.41 "**Effective Date**" has the meaning set forth in the introductory paragraph.

1.42 "**Equipment**" means all equipment and machinery used to (or otherwise necessary for), directly or indirectly, Manufacture Drug Substance.

1.43 "**Facility**" means (a) the Bachem facility located at [**] ("**Bachem [**] Facility**"), and (b) upon mutual agreement of the Parties in accordance with Section 2.7, the Bachem facility located at [**] (if and only if such facility is approved by applicable Regulatory Authority(es) for the Manufacture of Drug Substance).

1.44 "**FDA**" means the U.S. Food and Drug Administration and any successor agency(ies) or authority having substantially the same function.

1.45 "**FDCA**" means the United States Federal Food, Drug and Cosmetic Act of 1938 (21 U.S.C. §301 et seq.) and applicable regulations promulgated thereunder, as amended from time to time.

1.46 "**Firm Order**" means a purchase order for Drug Substance issued by Apellis under this Agreement and confirmed by Bachem. Each Firm Order shall specify the quantity of Drug Substance ordered, the required Delivery Date, and the Delivery Address (as well as any specific shipping instructions, if applicable), in each instance in accordance with this Agreement.

1.47 "**Force Majeure Event**" has the meaning set forth in Section 13.5.

1.48 "**Good Distribution Practices**", "**GDP**" or "**cGDP**" means the then-current good distribution practices required by Swissmedic, as set forth in the TPA, as amended, and the regulations and ordinances promulgated thereunder, for the distribution (including acquisition, stockage, storage, and offering) of pharmaceutical materials, and comparable Applicable Law related to the distribution of pharmaceutical materials in jurisdictions outside of Switzerland, including (i) the European Commission Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01) and, regarding active pharmaceutical ingredients, (ii) EudraLex Volume 4 Part II on Basic Requirements for Active Substances used as Starting Materials.

1.49 "**Good Manufacturing Practices**", "**GMP**" or "**cGMP**" means the regulation for Good Manufacturing Practice as outlined in the ICH Q7 guideline for the production and release of active substances, in EC Directives 1252/2014/EU and 2003/94/EC, and EudraLex Volume 4 Part II on Basic Requirements for Active Substances used as Starting Material as applicable and as amended from time to time and transposed into the respective national laws of Switzerland, the member states of the European Union or the equivalent US (FDA) laws and regulations.

1.50 "**Governmental Authority**" means any multi-national, national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, instrumentality, agency, bureau, branch, office, commission, council, court or other tribunal).

1.51 "**Indemnifying Party**" has the meaning set forth in Section 12.3(a).

1.52 "**Indemnitee**" has the meaning set forth in Section 12.3(a).

1.53 "**Invoice**" means Bachem's invoice (in U.S. Dollars) for a given quantity of Drug Substance Delivered pursuant to this Agreement. A complete Invoice shall contain the following (and any other relevant information specifically requested by Apellis, acting reasonably): (a) name of Bachem and "Remit to" address; (b) Apellis's Firm Order number; (c) invoice number; (d) invoice date; (e) description and quantity of Drug Substance; (f) country of origin / country of manufacture; (g) total invoice amount with any miscellaneous charges (in accordance with this Agreement) each listed separately; (g) payment terms

(which payment terms shall be consistent with the payment terms set forth in this Agreement); (h) a valid tax invoice meeting applicable invoicing requirements from a tax perspective and; (i) any other information required under the Applicable Law. The Invoice shall be in English.

1.54 "**Latent Defect**" means any Deficiency (including any Drug Substance that fails to meet the representations, warranties or other quality requirements set forth in this Agreement) that is not readily determinable upon a reasonable inspection of the Drug Substance (based on physical inspection, identity test and review of the Certificate of Analysis) or the applicable Batch Records.

1.55 "**Liability**" or "**Liabilities**" means losses, damages, fees, costs and other liabilities incurred by a Party related to such Party's performance or conduct, or by virtue of being a "Party", under this Agreement.

1.56 "**Losses**" has the meaning set forth in Section 12.1.

1.57 "**Manufacture**" or "**Manufacturing**" or "**Manufactured**" means, with respect to Drug Substance, all operations performed by or on behalf of Bachem for the manufacture and supply of Drug Substance pursuant to this Agreement, including, as applicable, receipt (including testing) and storage of Materials, production, visual inspection, packaging, labeling, handling, warehousing, quality control testing (including in-process, release and stability testing), release, as applicable, and shipping of Drug Substance, and also including such activities as may be specified in the master batch records.

1.58 "**Materials**" means all raw materials, components, and other potential substance-contacting items necessary for, or otherwise used in, the Manufacture of Drug Substance pursuant to this Agreement.

1.59 "**Minimum Remaining Shelf-Life**" means the minimum remaining of the maximum shelf-life (i.e., for purposes of this Agreement, the maximum shelf-life for Drug Substance shall be the stated shelf-life for the Drug Substance) for Drug Substance that is required to be remaining at the time of Delivery pursuant to this Agreement. The Minimum Remaining Shelf-Life for the Drug Substance shall be [**]. Once stability data confirms that an extension of shelf life is possible, Apellis agrees to extend the Minimum Remaining Shelf Life, accordingly.

1.60 "**NDA**" means a New Drug Application (as defined in the FDCA), including all supplements, amendments, variations, extensions and renewals thereof and any comparable application in another country within the Territory.

1.61 "**Non-Breaching Party**" has the meaning set forth in Section 10.2.

1.62 "**Party(ies)**" has the meaning set forth in the introductory paragraph.

1.63 Intentionally Omitted.

1.64 Intentionally Omitted.

1.65 "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

1.66 "**Product**" means the finished dosage form of APL-2 (pegcetacoplan) pharmaceutical product in final finished form that was manufactured and/or processed from Drug Substance supplied by Bachem under this Agreement.

1.67 "**Quality Agreement**" means that certain quality agreement to be executed by the Parties setting out the roles and responsibilities related to the Manufacturing of Drug Substance, a copy of which will be attached as **Attachment A** hereto.

1.68 "**Records**" means Bachem's (or its Affiliate's or Subcontractor's, as applicable) records related to the performance of this Agreement, which shall include Manufacturing documents, batch records, test results, reports, and any other GMP relevant documentation related to the performance of this Agreement.

1.69 "**Regulatory Approval**" means any and all approvals (including supplements, amendments, pre- and post-approvals), licenses, registrations or authorizations of any national, regional, state or local Agency, department, bureau, commission, council or other governmental entity, that are necessary for the commercialization of a Product under this Agreement in the Territory.

1.70 Intentionally Omitted.

1.71 "**Regulatory Documentation**" means, with respect to Product, all: (a) Regulatory Materials, including all data contained therein and all supporting documents created for, submitted to or received from an applicable Agency relating to such Regulatory Materials; and (b) other documentation Controlled by a Party which is reasonably necessary in order to Commercialize Product in the Field in the Territory, including any registrations and licenses, regulatory drug lists, advertising and promotion documents shared with Agencies, adverse event files, complaint files and Manufacturing records.

1.72 "**Regulatory Materials**" means, with respect to the Product, all documentation, correspondence, submissions and notifications submitted to or received from an Agency that are necessary or reasonably useful in order to Commercialize such Product in the Field in the Territory. For the avoidance of doubt, Regulatory Materials shall include, with respect to each Product, all Investigational New Drug applications (INDs), NDAs, Regulatory Approvals, and amendments and supplements for any of the foregoing, as well as the contents of any minutes from meetings (whether in person or by audio conference or videoconference) with an Agency.

1.73 "**Replenishment Period**" has the meaning set forth in Section 2.6(b).

1.74 "**Retention Period**" has the meaning set forth in Section 6.1.

1.75 **"Safety Stock"** has the meaning set forth in Section 2.6(a). The Safety Stock Materials are defined in Schedule 2.6.

1.76 "**Shortage**" means an actual or anticipated shortage of Drug Substance (based upon the amount ordered in the corresponding Firm Order and based upon the Delivery Date set forth in the corresponding Firm Order) or other failure to Deliver such Drug Substance in accordance with this Agreement (based upon the amount ordered in the corresponding Firm Order and based upon the Delivery Date set forth in the corresponding Firm Order), including as a result of a shortage of Materials required for Manufacturing such Drug Substance or a shortage of capacity to Manufacture such Drug Substance, or as a result of the Delivery of Drug Substance that does not comply with the terms of this Agreement (including any non-compliance with the representations, warranties or quality requirements set forth in this Agreement), or as a result of Delivery of Drug Substance that is delayed beyond the required Delivery Date set forth in the corresponding Firm Order, provided that such delay beyond the Delivery Date was determined to be within Bachem's control.

1.77 "**Specifications**" means the specifications for the Drug Substance set forth in the NDA approved by the FDA, as such specifications may be modified from time to time in response to actions by the FDA

or another Agency without the need to amend this Agreement. The current proposed Drug Substance specifications shall be contained in the Quality Agreement(s) which shall be modified promptly upon receipt of NDA approval from FDA to reflect the specifications set forth in the NDA approval without the need to amend this Agreement.

1.78 "**Subcontractor**" means any person that, as a subcontractor or agent of Bachem, performs any of the services or functions required to be performed by Bachem under this Agreement.

1.79 "**Supply Committee**" has the meaning set forth in Section 4.1.

1.80 "**Supply Interruption**" has the meaning set forth in Section 2.5(c).

1.81 "**Supply Price**" means the price set forth in Schedule 7.1.

1.82 "**Term**" has the meaning set forth in Section 10.1.

1.83 "**Territory**" means worldwide, with the agreed understanding between the Parties that certain countries, currently unknown to Bachem, may have laws and regulations, in which regulatory support and compliance by Bachem will require from Apellis additional expense and/or extended timelines. The Parties further agree that any regulatory filings outside [**] shall be discussed in good faith and subject to mutual agreement.

1.84 "**Third Party**" means any Person other than (a) Apellis, (b) Bachem or (c) an Affiliate of either of Apellis or Bachem.

1.85 "**U.S.**" means the United States of America, including its territories and possessions, including the District of Columbia and Puerto Rico.

1.86 "**Validation**" or **"Validating**" or "**Validated**" means documented evidence that provides a high degree of assurance that the Manufacturing process controls are adequate to consistently produce Drug Substance, in accordance with cGMPs, and that meets the Specifications.

1.87 "**Violation**" means that either Bachem, or any of its officers, directors, employees or Subcontractors has been: (a) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General website, including 42 U.S.C. 1320a-7(a) (https://oig.hhs.gov/exclusions/authorities.asp); (b) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (https://oig.hhs.gov/exclusions/index.asp) on said website or the U.S. General Services Administration's list of Parties Excluded from Federal Programs (http://www.sam.gov); or (c) listed by any U.S. Federal agency as being suspended, debarred, excluded, or otherwise ineligible to participate in Federal procurement or non-procurement programs, including under 21 U.S.C. 335a (http://www.fda.gov/ora/compliance_ref/debar/) (each of (a), (b) and (c) collectively the "**Exclusions Lists**").

ARTICLE 2
SUPPLY OF PRODUCT

2.1 **Manufacture and Supply of Drug Substance**. Apellis hereby appoints Bachem to Manufacture Drug Substance at the Facility subject to the terms and conditions set forth herein. Bachem accepts such appointment to Manufacture Drug Substance. Bachem shall Manufacture and supply to Apellis (and/or its designee, as applicable), and Apellis shall purchase from Bachem, Drug Substance in accordance with Article 3.

2.2 **Apellis Requirements Obligation**. Apellis shall obtain from Bachem pursuant to this Agreement [**]% of its requirements for the Drug Substance during the Term. During the period prior to [**], Apellis shall not purchase Drug Substance from any Third Party for commercial sale except as otherwise provided in Section 2.5. For clarity, Apellis may obtain Drug Substance for clinical trial use from one or more Third Parties at any time and Apellis may qualify one or more Third Parties for the manufacture and supply of Drug Substance for commercial sale (including allowing such Third Parties to generate validation batches of Drug Substance) in accordance with Section 2.8. [**].

2.3 **Bachem Supply Obligation**. Bachem shall Manufacture all agreed quantities of Drug Substance per full Calendar Year and supply such Drug Substance to Apellis and its designees Drug Substance pursuant to Firm Orders submitted from time to time by Apellis in accordance with Section 3.2. Bachem shall be solely responsible, at its sole cost and expense, for performance of all Manufacturing and agrees to provide all labor and expertise necessary for the performance of the Manufacturing of Drug Substance as well as all facilities, Equipment, machinery and Materials (other than Apellis Supplied Materials) necessary to Manufacture the Drug Substance for the Territory, including maintaining sufficient stocks of Materials necessary to supply Apellis' requirements of Drug Substance under this Agreement. The Parties shall on [**] basis review and agree upon the acceptable ratio of starting [**] for each Batch of Drug Substance, it being understood that the current Batch yield is approximately [**] and that the current nominal Batch size is between [**] and [**].

2.4 **Exclusivity**. During the Term, and subject to Apellis' annual compliance with its purchase obligations, as expressly set forth in Section 2.2, and for a period of [**] following termination or expiration of this Agreement, Bachem shall Manufacture and supply the Drug Substance exclusively for Apellis and shall not Manufacture or supply the Drug Substance or any process intermediate thereof for any Third Party.

2.5 **Supply Interruption**.

(a) If a Shortage arises or Bachem becomes aware of an anticipated Shortage, Bachem shall notify Apellis in writing within [**], setting forth the underlying reasons for such Shortage (e.g., available quantities of Materials, Manufacturing capacity or other resources needed in the Manufacture of Drug Substance), proposed remedial measures, and the date such Shortage is expected to end. Bachem shall use Commercially Reasonable Efforts to end the Shortage at its sole cost, provided that such Shortage was determined to be solely within Bachem's control.

(b) If Bachem is unable to supply any Drug Substance subject to a Firm Order submitted by Apellis within [**] after its initial failure to supply measured from the relevant Delivery Date (and in the amount specified in Section 3.4) or the expiration of the Replenishment Period (as defined in Section 2.6(b)), as applicable), then Bachem shall consult with Apellis and the Parties shall work together to remedy the Shortage at Bachem's expense.

(c) If Bachem is unable to remedy the Shortage after an aggregate period of [**] (or longer as agreed in writing by the Parties), commencing with the date upon which such failure to supply began (as specified in Section 2.5(b)) (a "**Supply Interruption**"), then Apellis shall have the right to: **(i)** cancel any outstanding Firm Order until the Supply Interruption has been rectified, and Apellis shall have no obligation to Bachem for any Firm Order of the Drug Substance to the extent the Drug Substance has not been supplied as of the date of delivery of such cancelation notice; and/or **(ii)** have the Drug Substance manufactured by an Approved Manufacturer rather than by Bachem. Apellis may continue to use the Approved Manufacturer to supply the Drug Substance until Bachem notifies Apellis that it is again able to supply at least [**]% of Apellis' requirements for the Drug Substance and substantiates such claim to Apellis' reasonable satisfaction. Upon such a showing, Apellis shall commence purchasing

from Bachem at least [**]% of Apellis's requirements for such Drug Substance, provided that: (1) Apellis shall not be required to cancel any then outstanding purchase orders with the Approved Manufacturer to the extent such orders have been accepted by such Approved Manufacturer and are binding obligations of Apellis and (2) Bachem shall pay all cancellation costs incurred by Apellis in switching its purchases from such Approved Manufacturer to Bachem. Apellis shall use Commercially Reasonable Efforts to avoid significant cancellation fees in any contracts it enters with an Approved Manufacturer. Apellis shall not order Drug Substances from an Approved Manufacturer for delivery more than [**] following the date of such order.

2.6 Safety Stock.

(a) Subject to Section 2.5(b), Bachem shall within [**] of the Effective Date have a safety stock of each of the raw materials set forth on Schedule 2.6 ("Safety Stock Materials") in a quantity that is equal to the [**] and thereafter throughout the Term Bachem shall maintain a safety stock of such Safety Stock Materials in a quantity that is equal to the quantity of Safety Stock Materials required to Manufacture the quantity of Product ordered by Apellis in the previous [**] (the "**Safety Stock**"). Bachem will use Safety Stock to supply Product ordered by Apellis, and will maintain the appropriate level of Safety Stock by promptly replenishing that quantity of Safety Stock Materials used in such supply in accordance with Section 2.6(b). If Apellis has failed, for a period of [**] to purchase a quantity of Product equal to or greater than the [**] previous Purchase Orders, then Bachem may reduce the Safety Stock to a level reflecting the reduction in actual purchases by Apellis for such [**] period. Unless mutually agreed to otherwise, Bachem will manage Safety Stock on a "First In, First Out" basis to fulfil Apellis purchase orders for Product on a routine basis.

(b) Bachem shall replenish its Safety Stock of each of the raw materials set forth on Schedule 2.6 within [**] of use pursuant to Section 2.6(a) (the "**Replenishment Period**"). Bachem shall within [**] of the end of the Replenishment Period notify Apellis in writing of its inability to replenish the Safety Stock.

2.7 Qualification and Validation of Bachem [**] Facility. Bachem, at its cost, shall be responsible for qualifying and Validating the Equipment as appropriate (including conducting installation, operational and performance qualification), production, cleaning, packaging, process and any other appropriate steps performed at the Bachem [**] Facility in accordance with the Applicable Laws (including cGMPs) and Bachem's SOPs. If any Agency finds Bachem's Validation procedures to be unacceptable, then all Validation must be repeated to meet the criteria given in the regulatory requirements and guidelines and to receive all Agency approvals. All costs for such Agency requests resulting solely from an Apellis submission and specific to the Drug Substance and not applicable generally to products Manufactured at the Facility shall be borne by Apellis. The allocation of costs for Agency requests that are applicable generally to products Manufactured at the Facility shall be mutually agreed by the Parties.

2.8 Qualification and Validation of Second Bachem [**] Facility. Within [**] following the Effective Date, the Parties shall confer regarding (i) the timeline for regulatory approval of the Bachem [**] Facility, (ii) a schedule for qualifying and Validating the Equipment (including conducting installation, operational and performance qualification), production, cleaning, packaging, process and any other appropriate steps performed at Bachem's [**] Facility in accordance with Applicable Laws (including cGMPs); and (ii) the allocation of costs required qualify and Validate the Bachem [**] Facility. Qualification and Validation procedures used by Bachem immediately prior to the Effective Date may be used; provided that such procedures (i) are found to be acceptable to Apellis, (ii) meet applicable regulatory requirements and (iii) are found acceptable by Agency inspectors, if applicable. If Apellis or any Agency

finds Bachem's qualification or Validation procedures to be unacceptable, then all qualification and Validation must be repeated to meet the criteria of all applicable regulatory requirements and guidelines and to receive all Agency and Apellis approvals. Notwithstanding the foregoing, if Apellis reasonably finds, or any Agency finds, Bachem's Validation or qualification procedures to be unacceptable, then all Validation or qualification must be repeated to meet the criteria given in the cGMPs. All costs for such Agency requests resulting solely from an Apellis submission and specific to the Drug Substance and not applicable generally to products Manufactured at the Facility shall be borne by Apellis. The allocation of costs for Agency requests that are applicable generally to products Manufactured at the Facility shall be mutually agreed by the Parties.

2.9 **Approved Manufacturer**. Bachem shall, within [**] of Apellis' request at any time after a Product has received Regulatory Approval, assist Apellis in the [**] of one or more Apellis' designated alternative supplier(s) of Drug Substance (each, an "**Approved Manufacturer**"). [**]. Apellis shall require any Approved Manufacturer to agree in writing to observe the terms of this Agreement relating to confidentiality and the manufacture of Drug Substance. [**].

2.10 **Person in Facility**. Apellis may have a mutually agreed to number of employees present during mutually agreed stages of the Manufacturing of Drug Substance for the purposes of observing and documenting Manufacturing of the Drug Substance. During such time, such employees shall have access to those portions of the Facility where Drug Substance is Manufactured and full visibility and transparency to the activities being undertaken with respect to the Manufacture of Drug Substance. Any Apellis employees who are present at the Facility shall comply with Bachem's site regulations and rules and shall conduct themselves in a manner that minimizes disruptions of operations at the Facility or distractions to personnel performing such operations. Apellis shall not be obligated to pay for such visits. For purposes of clarity, the Person(s) so appointed by Apellis shall remain an employee(s) of Apellis and there shall not be created any form of employer/employee relationship with Bachem.

2.11 **Samples**. Upon Apellis's request, Bachem will provide to Apellis, [**], samples of Drug Substance from an Apellis-specified Batch in quantities and sizes reasonably requested by Apellis, as set forth in Schedule 2.11, for inspection, testing and analysis. Bachem will ship such samples, at Apellis' cost, as requested by Apellis to a Apellis designated address.

2.12 **Materials**. With the exception of the Apellis Supplied Materials referred to in Section 2.13, if any, Bachem shall be responsible for procuring all Materials, in adequate quantities to Manufacture Drug Substance. Bachem shall purchase adequate quantities of such Materials and shall be responsible for negotiating the price for such Materials. For clarity, the Supply Price takes into account the costs of such Materials.

2.13 **Apellis Supplied Materials**.

(a) Apellis shall supply (or have supplied) to Bachem those quantities of the Material set forth on Schedule 2.13 (the "Apellis Supplied Materials") that Apellis determines are reasonably necessary for Bachem to Manufacture the quantities of Drug Substance that are ordered. Such Apellis Supplied Materials shall be delivered by or on behalf of Apellis to the applicable Facility accompanied by a Certificate of Analysis. Notwithstanding the delivery of the Apellis Supplied Materials to Bachem, as between the Parties, such Apellis Supplied Materials shall at all times remain the property of Apellis. Upon receipt of the Apellis Supplied Materials, Bachem shall perform testing as agreed in the Quality Agreement to confirm that such Apellis Supplied Materials are not defective, and Bachem shall immediately notify Apellis in writing of any obvious defects in the Apellis Supplied Materials. All Apellis Supplied Materials supplied to Bachem shall be handled, stored and maintained by Bachem in accordance with

Applicable Law (including cGMPs and, if and to the extent applicable, cGDPs) and in a separate, secured storage area and clearly marked and identified by Bachem as the property of Apellis. Bachem will have the risk of loss or damage to the Apellis Supplied Materials while in the possession of Bachem, should they not be stored under the correct conditions as indicated on the manufacturer's Certificate of Analysis for such Apellis Supplied Materials. Bachem acknowledges that certain Apellis Supplied Materials may have biological or chemical properties that are unknown or unexpected at the time of transfer and that such Apellis Supplied Materials are transferred to Bachem with no warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose and must be used only as described in this Agreement. Apellis shall notify Bachem of any biological or chemical hazards that do become known to Apellis. Bachem shall not allow any pledge, lien, restriction, claim, charge, security interest and/or other encumbrance to be placed on the Apellis Supplied Materials. Unless otherwise consented to by Apellis in writing, Bachem shall not obtain any Apellis Supplied Materials from any other source.

(b) Unless otherwise consented to by Apellis in writing, Bachem shall use the Apellis Supplied Materials solely and exclusively to Manufacture Drug Substance for Apellis in accordance with this Agreement and for no other purpose. Bachem shall withdraw the Apellis Supplied Materials from storage for the performance of the Manufacturing activities under this Agreement and generally respecting the procedure of first expiry/first out. At the request and direction of Apellis from time to time, Bachem shall return to Apellis all or any portion (as requested by Apellis) of unused inventory of Apellis Supplied Materials.

(c) Bachem shall without undue delay notify Apellis in writing whenever the inventories of Apellis Supplied Materials supplied by or on behalf of Apellis become insufficient to Manufacture the applicable Product to meet the Delivery Dates specified in the applicable Firm Orders placed by Apellis under this Agreement. In addition, Bachem shall provide Apellis with detailed usage reports of the Apellis Supplied Material for each production lot which shall be provided in writing immediately after the applicable Batch is produced.

(d) Apellis shall without undue delay notify Bachem in writing whenever it is unable to supply sufficient quantities of Apellis Supplied Materials. In the event that Apellis fails to supply sufficient quantities of Apellis Supplied Materials, then Apellis shall not be deemed to be in breach of this Agreement, and the sole and exclusive remedy of Bachem shall be that Bachem be relieved of its obligations to Manufacture and timely deliver those quantities of the Drug Substance ordered by Apellis under this Agreement that Bachem is unable to Manufacture as a direct result of the failure of Apellis to supply such quantities of Apellis Supplied Materials, until such time as sufficient quantities of Apellis Supplied Materials are supplied by or on behalf of Apellis (provided, that, for clarity, Bachem shall still be obligated to Manufacture and supply any and all quantities of the Drug Substance ordered by Apellis hereunder which can be Manufactured based on the quantities of Apellis Supplied Materials which have been provided). Apellis agrees that it shall also pay for any reasonable direct costs (direct labor and overhead costs) incurred related to manufacturing capacity that, as a direct result of Apellis' failure to supply necessary Apellis Supplied Materials, could have been utilized for other purposes, provided Bachem utilizes Commercially Reasonable Efforts to utilize the manufacturing capacity that is not utilized by Apellis for other purposes.

(e) Bachem shall be responsible for the risk of loss of Apellis Supplied Materials upon delivery of such Apellis Supplied Materials to Bachem. Bachem will be financially responsible for any loss of such Apellis Supplied Materials to the extent such loss results from (i) breach of this Agreement by Bachem or (ii) the negligence or wilfull misconduct of Bachem (or Bachem's

Affiliates, agents or contractors), in which case, Bachem shall be responsible for, and shall reimburse Apellis for, the costs of such Apellis Supplied Materials, plus any shipping costs and other out-of-pocket costs (e.g., duties, taxes (including, VAT, if applicable), testing and other similar costs) incurred by or on behalf of Apellis with respect to such Apellis Supplied Materials. Bachem shall not be liable for losses during the manufacturing process resulting directly from Supplied Materials that do not conform to the agreed quality parameters (e.g., specifications, qualified or validated manufacturing process, GMP, GDP). The Parties shall on [**] basis agree upon the acceptable yield loss thresholds with respect to the quantities of Apellis Supplied Materials that may be lost in conducting the Manufacturing process for the Drug Substance as part of their [**] review of Drug Substance Batch yield pursuant to Section 2.3. In the event that, with respect to a given Batch of Drug Substance Manufactured under this Agreement, the actual yield loss for the applicable Apellis Supplied Material is greater than the specified acceptable yield loss threshold due to Bachem's (i) failure to follow the Manufacturing Process (as defined in the Quality Agreement) or the Quality Agreement, (ii) negligence or (iii) wilfull misconduct, then Bachem shall be responsible for, and shall reimburse Apellis for, the costs of such lost Apellis Supplied Materials that were in excess of the acceptable yield loss threshold, plus any shipping costs and other out-of-pocket costs (e.g., duties, taxes (including, VAT, if applicable), testing and other similar costs) incurred by or on behalf of Apellis (or any of its Affiliates) with respect to such lost Apellis Supplied Materials.

(f) Apellis shall provide to Bachem material safety data sheets relating to the Apellis Supplied Materials, and other similar information known to Apellis relating to handling, safety and environmental precautions with respect to the Apellis Supplied Materials, in each case, to the extent in Apellis' possession. It is the sole responsibility of the Bachem to communicate such information to its employees, agents, and representatives engaged in Manufacturing of Product and furthermore Bachem shall ensure that all safety and other procedures outlined in the Apellis IP are followed by Bachem and its employees, agents and representatives.

2.14 **Storage**. Bachem shall, in accordance with the Applicable Laws (including cGMPs), and Drug Substance Specifications, maintain adequate storage accommodations for all of the Materials, Drug Substance and any other materials or products reasonably requested by Apellis. Bachem shall notify Apellis immediately whenever the inventories of Materials become insufficient to Manufacture the Drug Substance to meet the Delivery Date(s).

2.15 **Waste**. Bachem shall be solely responsible for maintaining safety procedures in connection with the Manufacture of Drug Substance and for the generation, treatment, storage and/or disposal of waste relating thereto, all of which shall comply with all Applicable Laws, including all applicable environmental and occupational safety and health requirements in the jurisdiction of the Facility. At the request of Apellis, Bachem shall provide a Certificate of Destruction to Apellis upon completion of disposal of any Drug Substance, key-intermediate or Apellis Supplied Material.

2.16 **Subcontracting**. Bachem shall not subcontract any of its obligations under this Agreement to a Third Party without the prior written consent of Apellis, with the exception of certain post manufacturing analytical testing, which may be subcontracted to various qualified testing facilities audited and approved by Bachem and listed in the Quality Agreement, subject to compliance with Section 9.2 of the Quality Agreement including its provisions regarding resolution of Apellis objections to the use of a proposed subcontractor. With respect to any subcontracting, Bachem shall remain fully responsible and liable for all obligations under this Agreement, and fully guarantees and warrants the performance (in accordance with this Agreement) of any responsibilities so subcontracted, and assumes full vicarious liability for such activities performed by any Subcontractor. Any subcontracting of any Manufacturing or other activities under this Agreement shall be subject to the terms and conditions of this Agreement. Any and all costs associated with engaging a Third Party Subcontractor (including any technology transfer to such Third

Party Subcontractor) shall be borne solely by Bachem and shall not be included in the Supply Price, and the use of a Third Party Subcontractor shall not result in any increase in the Supply Price, unless Apellis expressly agrees in writing to an increase in the Supply Price as a result thereof. For clarity, the consent of Apellis pursuant to this Section 2.16 shall not be required for Subcontractors performing any Manufacturing activities for Apellis at the Facility with respect to the Manufacture of Drug Substance immediately prior to the Effective Date; such Subcontractors are deemed being authorized by Apellis.

ARTICLE 3
PRODUCT ORDERS; DELIVERY

3.1 Forecasts.

(a) Apellis's initial forecast setting forth its anticipated need for Drug Substance will be provided to Bachem within [**] following the Effective Date. Such initial forecast will cover the first [**] following the Effective Date. Within [**] following the commencement of the first full Calendar Quarter in 2020 following the Effective Date, Apellis shall provide Bachem on a Calendar Quarterly basis, with a [**] rolling forecast, the first [**] of each such forecast will be binding on Apellis and the remaining [**] of each such forecast shall be non-binding.

(b) Bachem shall communicate regularly with Apellis during the Term regarding Bachem's ability to meet Apellis' Drug Substance forecast requirements and Safety Stock requirements and will promptly advise Apellis in writing of any anticipated inability to meet such forecasts, explaining the nature, impact and estimated duration of such inability.

3.2 Firm Orders. Apellis CH shall place Firm Orders for its requirements of Drug Substance in accordance with the binding portion of its forecast for the relevant period at least [**] before the requested Delivery Date. The Firm Orders will contain the requested Delivery Date (month) for each production batch of the Drug Substance. Firm Orders will be made on such form of purchase order or document as Apellis may specify from time to time in writing; provided that the terms and conditions of this Agreement shall be controlling over any terms and conditions included in any Firm Order. Any term or condition of such Firm Order that is different from or contrary to the terms and conditions of this Agreement shall be void, unless otherwise agreed between the Parties in writing.

3.3 Additional Quantities of Drug Substance. If Apellis requires additional Drug Substance at any time (in addition to the quantities ordered in accordance with Section 3.2), Apellis shall notify Bachem in writing (and shall deliver a Firm Order to Bachem for such additional quantities) and Bachem shall use Commercially Reasonable Efforts to supply such additional quantities of Drug Substance for Apellis, subject to its existing commitments.

3.4 Delivery Against Firm Orders. Bachem will acknowledge acceptance of all Firm Orders within [**] following receipt. Bachem has the right to refuse a Firm Order in the event and to the extent such Firm Order is for a quantity of Drug Substance that exceeds the quantity set forth in the forecast most recently submitted for such month; provided that Bachem may accept such Firm Order with the understanding that while it will use Commercially Reasonable Efforts to supply such excess quantity, but shall not be liable for its failure to supply such excess quantity. Bachem shall Deliver Drug Substance only against specific Firm Orders Bachem shall submit mutually agreed [**] documentation to Apellis for its review and approval. [**]. Notwithstanding the above, Bachem shall Deliver Drug Substance under each Firm Order no later than the Delivery Date specified in the applicable Firm Order; provided, however, that no Delivery of Drug Substance shall be made more than [**] in advance of the date specified for Delivery in a Firm Order without Apellis' prior written approval. Should Apellis be unable to accept shipment on the agreed Delivery Date in the applicable Firm Order, Bachem may transfer the agreed quantity of Drug Substance

in the Firm Order to the Customer warehouse on the agreed Delivery Date. The Facility shall be indicated on documents accompanying each Delivery of Drug Substance. In the event Bachem will fail to meet a Delivery Date set forth in a Firm Order, Bachem shall bear the incremental costs required for expedited transport above and beyond the cost incurred by the method outlined in the Delivery Terms. In the event that Apellis fails to take delivery of the Drug Substance on the Delivery Date, Bachem may transfer the Drug Substance to the customer warehouse, and Bachem shall invoice the Firm Order transferred to storage within [**] of Apellis' receipt of the [**] documentation. At this time Bachem may invoice Apellis, and ownership of said Drug Substance will transfer to Apellis. Apellis will be responsible for any costs incurred by Bachem in connection with a delay in delivery.

3.5 **Delivery**. Bachem shall effect Delivery of each Firm Order in accordance with Applicable Laws (including cGMPs and, if and to the extent applicable, cGDPs) and the Drug Substance Specifications (and for clarity, Bachem shall only effect Delivery of Drug Substance pursuant to a Firm Order). Bachem shall Deliver or arrange for Delivery of Drug Substance in accordance with the Delivery Terms, in order to fill such Firm Order. Each container shall be marked as to the identity of the Drug Substance, the quantity of Drug Substance, the related Firm Order number, and any other information required by the Firm Order. Except as otherwise provided in Section 3.10(b), Bachem shall bear all risk of loss or damage with respect to Drug Substance(s) until such Drug Substance(s) ownership is transferred to Apellis in accordance with Section 3.8. Each Delivery of Drug Substance shall be accompanied by a packing slip and a Material Safety Data Sheet, and Bachem's Certificate of Analysis for such Drug Substance. Bachem shall not Deliver Drug Substance unless and until such Drug Substance has been quality released by Bachem. It is also Bachem's responsibility at its own cost to collect all necessary information for the Annual Reports for FDA. The copy of each Annual Report is to be provided to Apellis upon request.

3.6 **Acceptance; Rejection**. In the event that any Drug Substance delivered to Apellis or any Apellis designated location fails to conform to the Drug Substance warranties set forth in Section 8.2, Apellis may reject such shipment by providing Bachem written notice within [**] of the shipment of the Drug Substance. Apellis will have the right to test any quantity of the Drug Substance delivered by Bachem in order to verify that such quantity satisfies the Specifications but will not have any obligation to do so unless required by Applicable Law. Any notice of rejection by Apellis shall specify the nonconformity. If there is no dispute between the Parties relating to the existence of the nonconformity, any quantity of the Drug Substance supplied by Bachem does not conform to the Drug Substance warranties set forth in Section 8.2, Bachem may, at Apellis's election and Bachem's agreement, reprocess or rework the rejected Drug Substance. If reprocessing or reworking is not otherwise feasible, Bachem shall promptly (i) replace such nonconforming Drug Substance in a timely manner at no additional cost, or (ii) credit Apellis' account for or refund the price invoiced for such nonconforming Drug Substance. Any dispute between the Parties regarding whether Drug Substance fails to conform to the Drug Substance warranties set forth in Section 8.2 shall be resolved in accordance with the procedure set forth in Section 3.7. Apellis retains the right to determine the disposition of any and all Drug Substance Manufactured under this Agreement; provided, however, that Bachem shall have the right to offer for sale to Apellis any excess or nonconforming Drug Substance Manufactured hereunder; provided, further, however, that any such excess or nonconforming Drug Substance not offered to Apellis or not purchased by Apellis shall be promptly and properly destroyed by Bachem. Nothing in this Section 3.6 shall limit the rights of Apellis to seek damages or otherwise exercise its rights to remedies after acceptance of Drug Substance that fails to conform to the Drug Substance warranties set forth in Section 8.2 if the nonconformity is a Latent Defect, provided that Apellis provides Bachem with prompt notice of such Latent Defect after discovery thereof and prior to the stated expiration date of such Drug Substance.

3.7 **Conflict Resolution regarding Deficiencies**. In the event that a dispute arises between the Parties regarding whether or not any Drug Substance fails to conform to the Drug Substance warranties set forth in Section 8.2, they shall resolve such dispute in accordance with this Section 3.7. The Parties, acting

through their appropriate scientific and technical personnel shall promptly communicate in person or by audio conference or videoconference to determine whether the scientific methods being performed by or on behalf of each party to evaluate the alleged conformity are being performed in the same manner and if they are not whether such difference is the basis for the dispute. The Parties shall next exchange samples of the Drug Substance from the Batch that is the subject of the dispute using a mutually agreed and carefully controlled process, for testing by each Party to determine whether the alleged nonconformity is due to the treatment of the Drug Substance samples being tested is the basis for the dispute. If the dispute remains unresolved, the Parties, acting through their appropriate scientific and technical personnel shall meet to work through the analysis of one or more mutually agreed sample(s) taken from the Drug Substance Batch that is the subject of the dispute. If the Parties fail to resolve the dispute using these methods within [**] after the dispute arises, then the Parties shall submit a sample of the Drug Substance Batch that is the subject of the dispute to an independent test facility to be agreed upon by both Parties, such agreement not to be unreasonably withheld, and to accept the results of the testing performed by that independent testing facility as binding with regard to whether the Drug Substance from the Batch that is the subject of such dispute conforms to the Drug Substance warranties set forth in Section 8.2. Apellis will engage the independent test facility and pay the charges for such testing unless the results show that the applicable Drug Substance was nonconforming, in which case Bachem shall pay the charges for such testing (or reimburse Apellis if it has already paid such charges).

3.8 Transfer of Title. Title to Drug Substance supplied hereunder shall pass to Apellis contemporaneously with the transfer of risk of loss, as established by the Delivery Terms or when Drug Substance is transferred to customer warehouse.

3.9 Packaging. All Drug Substance supplied hereunder shall be packaged in accordance with the Drug Substance Specifications and the Quality Agreement, and Bachem shall ensure that such packaging is otherwise in accordance with Applicable Law (including cGMPs and DSCSA) and, if and to the extent applicable, cGDPs). Without limiting the foregoing, all Drug Substance supplied hereunder shall also be labeled with a traceable batch number and the date of Manufacture.

3.10 Handling and Storage; Storage following Acceptance. Prior to Delivery of Drug Substance to Apellis, Bachem shall handle and store all Drug Substance (including all Materials used in the Manufacture of such Drug Substance) in accordance with Bachem's SOPs and Applicable Laws (including cGMPs and, if and to the extent applicable, cGDPs), as well as the Drug Substance Specifications. Any storage of Drug Substance beyond three months will be covered by a separate Storage Agreement

ARTICLE 4
GOVERNANCE AND PAYMENT; CHANGE MANAGEMENT

4.1 Supply Committee.

(a) Within [**] after the Effective Date, a Supply Committee ("**Supply Committee**") shall be established with the responsibilities and authority set forth in this Section 4.1. The Supply Committee shall consist of [**] members, [**] members to be appointed by each of Apellis and Bachem; provided, that the Parties shall use reasonable efforts to appoint members who are familiar with manufacturing strategy, medicines and process delivery, quality and procurement. Each Party may, with notice to the other, substitute any of its members serving on the Supply Committee. The Parties may also, by mutual agreement, increase or (subject to Section 4.1(d)) decrease the number of members serving on the Supply Committee; provided that the number of members representing each Party remains equal. Apellis shall have the right to appoint one of its members to be the chairperson of the Supply Committee.

(b) The Supply Committee shall have the following responsibilities: (i) functioning as a forum under which Bachem and Apellis would exchange information to enable the Parties to review and approve proposed changes to the Manufacturing process described in Sections 4.2, 4.3, 4.4 and 4.5; (ii) monitoring the qualification and Validation of the Bachem [**] Facility pursuant to Section 2.6 and the Bachem [**] Facility pursuant to Section 2.7; (iii) monitoring the provision of assistance and technical information to any Approved Manufacturer in accordance with Section 2.8; (iv) monitoring Continuous Improvement Program efforts; and (v) functioning as a forum under which Bachem and Apellis would exchange information to enable the applicable Party to manage the day-to-day aspects of the manufacturing and supply chain for the Drug Substance and establishing production capability at either Bachem Facilities or Approved Manufacturer sites to facilitate a comprehensive business continuity plan with respect to supply of Drug Substance for the Product.

(c) The Supply Committee shall hold meetings as mutually agreed by the Parties. The first meeting of the Supply Committee shall be held within [**] of the Effective Date. Meetings may be held by telephone or video conference. Minutes of all meetings setting forth decisions of the Supply Committee shall be prepared by the chairperson and circulated to both Parties within [**] after each meeting, and shall not become official until approved by both Parties in writing; minutes shall be presented for approval as the first order of business at the subsequent Supply Committee meeting, or if it is necessary to approve the minutes prior to such subsequent meeting, then the Parties shall approve the minutes within [**] of receipt thereof.

(d) The quorum for Supply Committee meetings shall be [**] members, provided there are at least [**] members from each of Bachem and Apellis present. The Supply Committee will render decisions by unanimous vote. The members of the Supply Committee shall act in good faith to cooperate with one another and to reach agreement with respect to issues to be decided by the Supply Committee.

(e) Disagreements among the Supply Committee shall be resolved via good-faith discussions; provided, that in the event of a disagreement that cannot be resolved within [**] after the date on which the disagreement arose, the matter shall be referred to the Parties for resolution in accordance with Section 11.1.

(f) Unless otherwise agreed by the Parties, the term for the Supply Committee shall commence on the date it is established by the Parties and continue until all Products have been launched in all countries of the Territory, unless an earlier termination date is mutually agreed by the Parties.

4.2 Changes and Change Control.

(a) All changes requiring Apellis prior written consent shall be handled in accordance with the obligations set forth in the Quality Agreement.

(b) Any change shall, in each instance, comply with the Applicable Laws (including cGMPs) and shall be made in accordance with the Quality Agreement. In the event that Bachem is required to implement a Major Change (as defined in Section 11.1 of the Quality Agreement) in order to comply with the Applicable Laws (including cGMPs) or such Major Change is otherwise agreed to by Apellis in writing, Bachem shall: (x) immediately notify Apellis of such Major change and use Commercially Reasonable Efforts to implement such Major Change as soon as reasonably practicable or mutually agreed; (y) mutually agree with Apellis on a course of action to ensure that all Drug Substance Manufactured following such Major change meets the Drug Substance Specifications and the Drug Substance quality and yields achieved prior to such

change; and (z) provide Apellis with all information with respect to the Manufacture of the Drug Substance in connection with such change reasonably needed to amend any regulatory filings. To the extent permitted by Applicable Laws, Bachem shall continue to supply Apellis with unchanged Drug Substance until such time Apellis informs Bachem that the Drug Substance Manufactured following such change is permitted under the amended regulatory filings therefor. In the event that Bachem intends to implement Major Change, Apellis shall work in a timely fashion to provide any required response to Bachem without undue delay and approval of such changes by Apellis shall not unreasonably be withheld or delayed. It shall be solely the responsibility of Apellis US to evaluate if such a change is in conformance with their regulatory filing and to use at least Commercially Reasonable Efforts to adapt such filing for mutually agreed changes and changes required by Applicable Laws (including cGMPs) or Agencies.

(c) Prior to implementing any such Major Change, the Parties shall agree on the reasonable costs thereof; provided that Bachem shall use Commercially Reasonable Efforts to mitigate the costs thereof. Notwithstanding the foregoing, (i) if the change is required by Applicable Laws and such required change solely benefits the Manufacture of the Drug Substance, then Apellis shall be responsible for reimbursing Bachem for the costs of such required change and (ii) in all other cases, Bachem shall bear all costs of such change.

4.3 Discretionary Changes. In the event that either Party desires to propose discretionary changes (i.e., changes which are not required by cGMPs or other Applicable Laws) during the Term to the Drug Substance Specifications or to the Manufacturing process (in each case, which discretionary changes would otherwise require consent as set forth in Section 4.2(a)), the Parties shall discuss such discretionary changes and any Manufacturing issues identified by either Party in connection with implementing such change. In all cases, such discretionary changes shall be made in accordance with any change control procedures in the Quality Agreement to the extent applicable. The provisions of Sections 4.2(b) and 4.2(c) shall apply with respect to implementing any such discretionary change. Notwithstanding the foregoing, in all cases, the Drug Substance Specifications may be amended or supplemented from time to time by Apellis upon written notice to Bachem in accordance with any change control procedures in the Quality Agreement.

4.4 Manufacturing at Facility. Bachem shall Manufacture all Drug Substance supplied hereunder at the Facility. Manufacturing of Drug Substance may not be relocated from the Facility without Apellis' prior written consent (in its sole discretion). Any such relocation of the Manufacturing of Drug Substance shall comply with the Applicable Laws (including cGMPs) and shall be made in accordance with Sections 4.2(b) and 4.2(c), and the Quality Agreement, to the extent applicable. Without limiting the foregoing, in the event that Bachem desires to relocate the Manufacturing of Drug Substance, in connection with such relocation, the Parties shall discuss any amendments to this Agreement as reasonably requested by Apellis or the Bachem (as the case may be), including with respect to (i) the Delivery Terms, (ii) provisions related to transfer of title, in each case, to take into account the relocation of such activities, and (iii) the procedures to be followed to secure any Regulatory Approvals required by in connection with such relocation. Bachem shall be responsible for the costs of any relocation and any Drug Substance cost increase in connection with such relocation.

4.5 Process Yield. The Parties will meet on [**] basis during the Term to review the Batch yields for the Drug Substance Manufactured during the prior [**]. If the Drug Substance Batch production yield is repeatedly above or below the agreed upon average yield described in Section 2.3, as such average yield may be adjusted during the Term pursuant to the Continuous Improvement Program, the Parties will evaluate such trends and agree to negotiate in good faith a fair and equitable adjustment to the pricing for the Drug Substance.

4.6 Continuous Improvement. Bachem shall use Commercially Reasonable Efforts to identify and implement continuous cost, quality and Apellis service improvement programs by seeking productivity

improvements, by minimizing waste and improving Drug Substance yields, and by (i) purchasing quality Materials at lower cost, (ii) improving Manufacturing processes within the validated parameters for the Drug Substance, (iii) streamlining organizational processes, and (iv) reducing cycle times and lead times. The Parties shall meet at least once per Calendar Year during the Term to discuss and agree on (a) objectives for a continuous improvement program, including cost improvements that may be obtained in respect of the matters described above ("**Continuous Improvement Program**") and (b) the means of measuring and implementing the results of the Continuous Improvement Program. Progress against objectives shall be measured quarterly. Bachem shall use all reasonable endeavors to achieve the agreed objectives and targets identified for the relevant period. The up front costs for any such agreed upon development improvements shall be apportioned between the Parties by mutual agreement. The net benefits of cost reductions and improved efficiencies shall be shared equally by the Parties, including as reductions to the Supply Price under this Agreement. In such case, the Parties shall reasonably discuss and agree on the amount of such reductions to the Supply Price.

ARTICLE 5
QUALITY

5.1 **Notification of Agency Action**. Each Party shall immediately notify the other Party of any information such Party receives regarding any threatened or pending action by any Agency that has the potential to impact Drug Substance supplied to Apellis hereunder, including and not limited to any Agency non-approval, regulatory action or Out of Specification or Out of Trend (upon stability testing) in accordance with the Quality Agreement. Upon receipt of any such information, the Parties shall consult in an effort to arrive at a mutually acceptable procedure for taking appropriate action; provided, however, that nothing contained herein shall be construed as restricting the right of either Party to make a timely report of such matter to any Agency or take other action that it deems to be appropriate or required by Applicable Law.

5.2 **Safety or Efficacy Claims**. Each Party shall immediately (and in any event within the period specified in the Quality Agreement) notify the other Party of any information of which it is aware concerning Drug Substance supplied to Apellis which may affect the safety or efficacy claims or the continued marketing of a Product. Any such notification will include all related information in detail. Upon receipt of any such information, the Parties shall consult in an effort to arrive at a mutually acceptable procedure for taking appropriate action; provided, however, that nothing contained herein shall be construed as restricting the right of either Party to make a timely report of such matter to any Agency or take other action that it deems to be appropriate or required by Applicable Law. Each Party will notify the other immediately of any health hazards with respect to Drug Substance which may impact employees involved in the Manufacturing of Drug Substance.

5.3 **Complaints**. Each Party shall immediately notify the other Party of any complaints received by such Party concerning the Drug Substance or the Product. Each Party shall investigate complaints and shall take corrective action to avoid future occurrences.

5.4 **Agency Inspection**. Bachem shall immediately notify Apellis in writing in the event that Bachem is notified of any proposed visit or inspection by any governmental authority, including, any Agency (such as the FDA or Swissmedic) or any environmental regulatory authority if such visit or inspection is related to Drug Substance. Apellis shall have the right to be onsite during the visit or inspection, but shall not be allowed participate in the inspection unless it is a pre-approval inspection.. Bachem shall promptly (and in no event later than [**]) furnish Apellis with copies of all reports, documents or correspondence with respect to any Agency requests or inspections of the Facility related to the Manufacture of the Drug Substance, including but not limited to any Form 483 or Establishment Inspection Report (EIR) relating to the Manufacture of the Drug Substance. Bachem shall also provide Apellis any proposed corrective actions,

responses and other changes arising out of such review or inspection by such Agency that is related to the Drug Substance.

5.5 Labelling. Bachem will comply with all specified labelling as to the Drug Substance and each component and container as required by Applicable Law.

5.6 Batch Records. Bachem shall provide Apellis with [**] Batch records and [**] related to Drug Substance for each Batch in accordance with the Quality Agreement. [**] must be approved by Apellis in accordance with the Quality Agreement.

5.7 Quality Agreement. The Parties shall enter into a Quality Agreement with respect to the Manufacture of Drug Substance within [**] of the Effective Date, but in any event prior to the Manufacture of Drug Substance for commercial purposes. Upon execution, such Quality Agreement shall be appended to this Agreement as **Appendix B**.

ARTICLE 6
RECORDS; AUDITS; RECALLS; REGULATORY MATTERS

6.1 Records. Bachem shall retain all records related to the (a) Manufacture of Drug Substance(s) for a period of not less than [**] from the date of Manufacture of each Batch of Drug Substance(s) to which said records pertain (or such longer period as required by Applicable Law) and (b) Manufacture of Validation batches for [**] past the effective date of termination of this Agreement (or such longer period as required by Applicable Law) (each such period shall be referred to as the "**Retention Period**").

6.2 Audit Rights. The Records shall be open to inspection and subject to audit, during normal working hours (but not more than [**] except in the case of emergency or for-cause (and for clarity, cause may include a Supply Interruption) in which case such [**] limit shall not apply) by Apellis or its authorized representative (a) as required by governmental authorities or (b) as may desirable by Apellis for any other valid business purpose related to verification of Bachem's compliance with its obligations under this Agreement. Bachem shall preserve such Records for a period of [**] after batch release or for such longer period as may be required by Applicable Law. For the purpose of such audits, inspections, examinations and evaluations, Apellis or its authorized representative shall have access to such Records beginning on the Effective Date. In addition, Bachem shall provide adequate and appropriate workspace for Apellis or its authorized representatives to conduct such audit. Apellis and/or its authorized representative will be required to follow all rules, regulations and standard operating procedures of Bachem when on site. Apellis or its authorized representative shall give Bachem at least [**] advanced written notice of an intent to audit (except in the case of emergency or for-cause). Bachem may require that any Person performing an audit on Apellis's behalf, including, but not limited to, an employee of Apellis, execute a confidentiality agreement in a form acceptable to Bachem.

6.3 Decisions on Recalls. As between the Parties, Apellis shall have the ultimate responsibility as to whether to institute a recall or withdrawal of Product or Drug Substance (whether instituted at the request of an Agency or voluntarily instituted by Apellis); provided that, to the extent practical, Apellis shall notify Bachem thereof prior to implementation.

6.4 Recalls. In the event that a Product or Drug Substance is recalled or withdrawn, Apellis shall be responsible for such recall or withdrawal. Bachem shall fully cooperate with Apellis in connection with such recall or withdrawal. Apellis shall bear the cost of such recall or withdrawal and Apellis shall reimburse Bachem for reasonable out of pocket expenses incurred by Bachem in connection with such recall or withdrawal; provided, that in the event a Product or Drug Substance is recalled or withdrawn as the result of a Manufacturing issue as to which Bachem is obligated to provide indemnification hereunder, Bachem shall reimburse Apellis for (a) all reasonable costs associated with the recalled or withdrawn

Product or Drug Substance, including the Supply Price for Product and (b) all reasonable and documented expenses incurred in connection with such recall or withdrawal, in each case subject to the limitation of liability provisions set forth in Sections 12.4 and 12.5 of this Agreement.

6.5 Disclosure of Audits. Apellis acknowledges that governmental authorities (including Agencies) may, in conducting an inspection of Bachem, request copies of reports of Bachem audits of its suppliers. For clarity, in response to such a request, Bachem may provide to the governmental authority (including any Agency) the report of any compliance audit conducted in accordance with this Agreement or the Quality Agreement.

6.6 Regulatory Matters. Bachem shall cooperate with Apellis as reasonably requested and mutually agreed with respect to Regulatory Submissions regarding the Drug Substance. Without limiting the foregoing, Bachem shall use reasonable efforts to address any questions or requests of Apellis regarding the Batch Records, reports, analysis, and documentation generated in connection with the activities conducted by Bachem hereunder, which may be subject to an additional cost to Apellis, depending on the extent of work required. Upon Apellis' request and at Apellis' cost, Bachem shall compile Records and other relevant documents reasonably requested by Apellis regarding Drug Substance that may be necessary for preparing Regulatory Submissions or communicating with Regulatory Authorities relating to the Drug Substance.

ARTICLE 7
PAYMENT AND TAXES

7.1 Supply Price. For each unit of Drug Substance ordered by Apellis under Firm Orders and supplied by Bachem to Apellis in accordance with the terms and conditions of this Agreement, Apellis shall pay Bachem the Supply Price set forth on **Schedule 7.1** ("**Supply Price**"). The Supply Price shall be determined in accordance with **Schedule 7.1** based upon the aggregate quantity of Drug Substance subject to a Purchase Order submitted by Apellis in each Calendar Year. Subject to adjustment pursuant to Section 7.4, the maximum Supply Price will be fixed for the initial Term of this Agreement and subject to adjustment in accordance with Section 10.1 in any renewal Term.

7.2 Invoicing; Payment. Bachem shall provide Apellis with an Invoice for each Batch of Drug Substance Delivered against a Firm Order placed by Apellis in accordance with this Agreement, which will be based on the then current Supply Price. Such Invoices shall be delivered electronically to [**] upon release of a batch. Apellis shall pay each Invoice within [**] from the date the Invoice is delivered. All payments under this Agreement shall be made in U.S. Dollars by wire transfer into an account designated by the receiving Party.

7.3 Annual True Up. Within [**] prior the end of each Calendar Year, the Parties shall calculate the actual amount of Drug Substance ordered for delivery in such Calendar Year under this Agreement. If the actual amount of Drug Substance ordered for delivery in such Calendar Year is different than the amount of Drug Substance forecasted for such Calendar Year, and as a result of such difference, a different price per gram should have been used to calculate the supply price based on the sum total of such actual volume ordered under this Agreement, the Parties shall recalculate the Supply Price, and Apellis or Bachem, as applicable, shall issue an invoice or credit memo in the amount necessary to reconcile the difference between the Supply Price paid by Apellis based on the forecasted volume to be ordered and the actual volume ordered by Apellis for such period.

7.4 Process Improvements and Sharing of Cost Efficiencies. If Bachem is able to realize any productivity improvements or cost improvements through the Continuous Improvement Program, or otherwise, Bachem shall pass onto Apellis the benefit of such quantifiable cost savings and efficiencies as

can be verified by documentary evidence and in the manner as mutually agreed to in Section 4.6.

7.5 Taxes. In the event any payments made pursuant to this Agreement are or become subject to withholding taxes under the laws or regulations of any jurisdiction, the Party making such payment shall be entitled to deduct and withhold the amount of such taxes for the account of the payee to the extent required by Applicable Law; and such amounts payable to the payee shall be reduced by the amount of taxes deducted and withheld (subject to the last sentence of this Section). Any such withholding taxes required under Applicable Law to be paid or withheld shall be an expense of, and borne solely by, the payee. If the Party making payment pursuant to this Agreement fails to deduct and withhold all or a portion of the amount of tax required by Applicable Law to be deducted and withheld and such Party is required by Applicable Law to pay all or a portion of such tax to a governmental authority for the account of the payee, payee shall, upon request from the other Party, immediately pay to the other Party an amount equal to the amount paid to the governmental authority for the account of the payee. However, in the event that there are withholding taxes on payments made pursuant to this Agreement that are in excess of what the payee Party may recover, then the Parties shall discuss responsibility for such withholding taxes in good faith.

7.6 Late Payment. If a Party does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to such Party until the date of payment at the per annum rate of [**] percent ([**]%) over the then-current prime rate quoted by Citibank in New York City or the maximum rate allowable by Applicable Law, whichever is lower. In the event Apellis desires to dispute in good faith any Invoice, or item(s) under any Invoice, Apellis will provide Bachem with a written notice setting forth the details of the disputed Invoice or item(s) and the amount in question. Apellis will timely pay to Bachem any other undisputed amounts on any such Invoice. The Parties will work together, in good faith, to resolve such dispute within [**] after such notice of dispute is sent. Apellis' failure to pay an Invoice or item of an invoice that it disputes in good faith shall not constitute a material breach under this Agreement. If, notwithstanding such efforts, the Parties are unable to resolve a dispute within such [**] period, the Parties shall resolve such dispute pursuant to the provisions of Article 11. In the event the Parties have not resolved such a dispute within the [**] period set forth above and escalate such dispute for resolution pursuant to the provisions of Article 11, Bachem shall have the option to suspend work under this Agreement until the dispute is resolved.

ARTICLE 8
REPRESENTATIONS, WARRANTIES AND COVENANTS

8.1 Mutual Representations, Warranties and Covenants. Each of the Parties hereby represents and warrants to the other Party as of the Effective Date and hereinafter, as set forth below, covenants that:

(a) Organization. It is duly organized, validly existing, and in good standing under Applicable Law of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

(b) Binding Agreement. This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other Applicable Law of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

(c) Authorization. The execution, delivery, and performance of this Agreement by such Party have been duly authorized by all necessary corporate action and do not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it is bound, nor violate any Applicable Law or any order, writ, judgment, injunction, decree,

determination, or award of any court or governmental body, or administrative or other agency presently in effect applicable to such Party.

(d) **No Further Approval**. It is not aware of any government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Law, currently in effect, necessary for, or in connection with, the transactions contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement and such other agreements (save for Regulatory Approvals and similar authorizations from Governmental Authorities necessary for the Commercialization of the Products as contemplated hereunder).

(e) **No Inconsistent Obligations**. It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfilment of its obligations hereunder.

(f) **Grant of Rights**. To its knowledge, it has the right to grant the license granted to the other Party hereunder and to provide the Confidential Information provided to the other Party hereunder.

8.2 **Representations and Warranties for Drug Substance**. Bachem represents and warrants as of the Effective Date, and hereinafter, as set forth below, covenants to Apellis that all Drug Substance shall, at the time of Delivery:

(a) be Manufactured in accordance with, and shall meet, the Drug Substance Specifications;

(b) be Manufactured in accordance with all Applicable Laws (including cGMPs and DSCSA) in effect on the day of Delivery;

(c) not be adulterated or misbranded within the meaning of FDCA;

(d) not be an article that may not, under the provisions of the FDCA or any similar Applicable Law of any other jurisdiction, be introduced into stream of commerce; and

(e) have at least the Minimum Remaining Shelf-Life, as set forth in Section 1.59.

8.3 **No Third Party Infringement**. Bachem represents and warrants as of the Effective Date, and hereinafter, as set forth below, covenants to Apellis that Bachem's Manufacture of the Drug Substance in accordance with this Agreement has not and shall not knowingly infringe the intellectual property rights of any Third Party.

8.4 **Apellis Supplied Material**. Apellis represents and warrants as of the Effective Date, and hereinafter, as set forth below, covenants to Bachem that Apellis has the rights to transfer the Apellis Supplied Materials to Bachem for the purposes contemplated by this Agreement and to grant Bachem the rights granted to Bachem by Apellis under this Agreement with respect to Apellis IP.

8.5 **Excluded Entities**. Bachem represents and warrants that, as of the date of this Agreement, neither it, nor any of its officers, directors, employees, or, to Bachem's knowledge, Subcontractors has been in Violation. Bachem shall notify Apellis in writing immediately if any Violation occurs or comes to its attention at any time during the Term. If a Violation exists with respect to any of Bachem's officers,

directors, employees, or Subcontractors, Bachem shall promptly remove such individual(s) or entities from performing any service, function or capacity related to the Manufacturing of Drug Substance. Apellis shall have the right, in its sole discretion, to terminate this Agreement in the event of any such Violation.

8.6 Compliance with Laws. Bachem shall comply with and give all notices required by Applicable Law bearing on the performance of this Agreement as existing on the Effective Date and as enacted or amended during the Term. Bachem shall notify Apellis if it becomes aware of any non-compliance in connection with this Agreement and shall take all appropriate action necessary to comply with such Applicable Laws.

8.7 Encumbrances. Bachem represents, warrants and covenants that it will have good and marketable title, free and clear of any pledge, lien, restriction, claim, charge, security interest and/or other encumbrance, to all Drug Substance to be Delivered under this Agreement, and all Drug Substance supplied to Apellis shall be free and clear of all pledges, liens, restrictions, claims, charges, security interests and/or other encumbrances at the time of Delivery.

8.8 No Other Representations or Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE 9, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, EITHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, INCLUDING ANY EXPRESS OR IMPLIED WARRANTY OF QUALITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR USE, OR WARRANTY OF NON-INFRINGEMENT OR AS TO THE VALIDITY OF ANY PATENTS.

ARTICLE 9
IP MATTERS; TECHNOLOGY TRANSFER; CONFIDENTIALITY; PUBLICITY

9.1 Intellectual Property Rights. As between the Parties, Apellis owns all right, title, and interest in and to the Drug Substance and the Product, as applicable, and all Apellis IP (collectively "**Apellis Property**"), and to the extent Bachem or any of its Affiliates has or may acquire or be deemed to have acquired any rights in any Apellis Property, Bachem hereby agrees, on behalf of itself and its Affiliates, to transfer and assign, and hereby transfers and assigns, all of its and its Affiliates' right, title, and interest in such Apellis Property to Apellis. As between the Parties, Bachem owns all right, title and interest in and to the Bachem IP. Upon Apellis' request at any time, Bachem shall, and shall require its Affiliates to, deliver to Apellis any and all documents and information reasonably necessary to protect Apellis's interest in the Apellis Property. Bachem shall promptly notify Apellis in writing of any Apellis Property that arises from the performance of the Manufacturing activities pursuant to this Agreement and shall, at Apellis' written request, reasonably assist Apellis in protecting Apellis' rights to such Apellis Property.

9.2 Apellis License. Apellis hereby grants to Bachem a nonexclusive, royalty-free, limited, non-transferable, non-sublicensable license, during the Term, to use the applicable Apellis Property, solely to the extent necessary to Manufacture and supply Drug Substance in accordance with this Agreement and to otherwise comply with its obligations hereunder. No other rights or licenses, either express or implied, to any patents, patent applications, trademarks, know-how, or other intellectual property owned or licensed by Apellis, are granted. Apellis also grants Bachem a non-exclusive, transferable, perpetual, paid-up and royalty free license to the Apellis IP that is developed by or on behalf of Bachem in the course of the activities performed pursuant to this Agreement and that is capable of being used independently of the Apellis Property and generally applicable to peptide manufacturing.

9.3 **Bachem License**. Bachem hereby grants to Apellis a [**] license, with the right to [**] in the course of the activities performed pursuant to this Agreement, [**].

9.4 **Technology Transfer**. Upon written request of Apellis, Bachem shall promptly (within no more than [**] following receipt of such request) initiate transfer to Apellis in writing of all technical information related to the Manufacture of Drug Substance pursuant to this Agreement, including, but not limited to, information concerning [**] under this Agreement. Apellis shall be entitled to use and [**] the Drug Substance or Product. Apellis agrees to [**] transfer including, but not limited to, [**]. Upon written request by Apellis, Bachem shall [**] pursuant to this Agreement, including information concerning [**]. To the extent that [**] pursuant to this Section 9.4 to be [**], Apellis shall [**] and the Parties shall [**].

9.5 **Confidentiality Obligations**. During the Term of this Agreement and for [**] thereafter without regard to the means of termination, each Party (i) shall maintain in confidence all Confidential Information of the other Party; (ii) shall not use such Confidential Information for any purpose except as permitted by this Agreement; and (iii) shall not disclose such Confidential Information to anyone other than those of its Affiliates, sublicensees, prospective sublicensees, employees, consultants or agents who are bound by written obligations of nondisclosure and non-use no less stringent than those set forth in this Section 9.5 and to whom such disclosure is necessary in connection with such Party's activities as contemplated in this Agreement. Each Party shall ensure that such Party's Affiliates, sublicensees, prospective sublicensees, employees, consultants and agents comply with these obligations. Each Party shall notify the other Party promptly on discovery of any unauthorized use or disclosure of the other Party's Confidential Information.

9.6 **Permitted Disclosure**. Notwithstanding the provisions of Section 9.5, a receiving Party may disclose Confidential Information of the disclosing Party to the extent such disclosure is (a) made in response to a valid order or subpoena of a court of competent jurisdiction or other governmental body of a country or any political subdivision thereof of competent jurisdiction; provided, that receiving Party provides the other Party with prior written notice of such disclosure (if practicable) in order to permit the other Party to seek a protective order or other confidential treatment of such Confidential Information; and provided further that any Confidential Information so disclosed will be limited to that information that is legally required to be disclosed in such response to such court or governmental order or subpoena; (b) otherwise required by Applicable Law; provided, that receiving Party provides the disclosing Party with prior written notice of such disclosure (if practicable) in order to permit the disclosing Party to seek a protective order or confidential treatment of such Confidential Information; and provided further that any Confidential Information so disclosed will be limited to that information that is legally required by Applicable Law to be disclosed; (c) made by the receiving Party to an Agency, as required to obtain or maintain Regulatory Approvals; provided that reasonable efforts shall be used to ensure confidential treatment of such Confidential Information; (d) made by the receiving Party to a Third Party as may be necessary or useful in connection with the commercialization of a Product (including the manufacture of a Product); provided the Third Party is bound by written confidentiality obligations no less protective that those set forth in this Agreement; (e) made by receiving Party to a U.S. or foreign tax authority to the extent legally required by Applicable Law to be disclosed; (f) made by receiving Party to its representatives or to Third Parties in connection with sublicensing or financing activities of the receiving Party; provided that the Third Party is bound by written confidentiality obligations no less protective that those set forth in this Agreement; (g) made by receiving Party to comply with Applicable Laws related to securities laws disclosure requirements or any disclosure requirements of any applicable stock market or securities exchange; or (h) made in accordance with Section 9.7.

9.7 **Public Announcements**. No public announcement or disclosure may be made by either Party with respect to the subject matter of this Agreement without the prior written consent of the other Party; provided, that the provisions of this Section 9.7 will not prohibit (a) any disclosure required by any applicable legal requirement, including any legal requirement or listing standard of any exchange or quotation system on

which the disclosing Party's securities are listed or traded or to be listed or traded (in which case the disclosing Party will provide the other Party with the opportunity to review in advance the disclosure and to contest the same, including reasonable opportunity to seek a protective order or to seek confidential treatment of such disclosures under Rule 24b-2 of the Securities Exchange Act of 1934, as amended), (b) any disclosure made in connection with the enforcement of any right or remedy relating to this Agreement, (c) any disclosure made by Apellis or Bachem to their respective employees, collaborators, licensors, licensees, contract research organizations, business partners, investors, potential investors, lenders and potential lenders provided the person receiving the disclosure has undertaken a confidentiality obligation to Apellis or Bachem, as applicable, substantially similar to the confidentiality obligations the Parties have undertaken to each other under this Agreement, or (d) any disclosure made pursuant to a press release in a form mutually agreed to by the Parties (or any other subsequent disclosure containing substantially similar information).

ARTICLE 10
TERM AND TERMINATION

10.1 **Term**. The initial term of this Agreement shall commence upon the Effective Date and, unless earlier terminated pursuant to this Article 9, shall remain in effect until the five (5) year anniversary of the Effective Date. Thereafter, this Agreement shall automatically renew for an additional 2-year term (the initial term and such renewal term (if applicable) the "**Term**"). At least twenty four (24) months prior to the end of the initial Term, Bachem shall notify Apellis in writing if it is willing to continue to Manufacture and supply Drug Substance following the end of the initial Term. If Bachem so notifies Apellis in writing, then Apellis shall have the right (but not the obligation), for a period of twelve (12) months thereafter, to discuss with Bachem the pricing terms that would apply during such renewal Term, and in the event that Apellis and Bachem agree on such pricing terms in writing, then they shall enter into an amendment to this Agreement for the pricing terms applicable for the renewal Term. If Bachem does not so notify Apellis in writing that it is willing to supply beyond the end of the initial Term, then Bachem acknowledges that Apellis shall have the right, but not the obligation, to increase orders of Drug Supply under this Agreement during the remainder of the initial Term in order to build inventory and Bachem shall fill such orders in accordance with this Agreement subject to its available capacity in the context of its existing organization. For clarity, (i) neither Party shall have any obligation to renew this Agreement unless and until agreed to by such Party, and (ii) unless otherwise expressly agreed to by the Parties in writing, any new or different terms which are negotiated as part of the renewal, if any, shall only apply during the renewal Term and shall not in any way alter the terms of this Agreement during the initial Term.

10.2 **Termination for Material Breach**. Either Party (the "**Non-Breaching Party**") may terminate this Agreement in the event the other Party (the "**Breaching Party**") commits a material breach of this Agreement or the Quality Agreement, and such material breach has not been cured within [**] after receipt of written notice of such breach by the Breaching Party from the Non-Breaching Party (the "**Cure Period**"). The written notice describing the alleged material breach shall provide sufficient detail to put the Breaching Party on notice of such material breach. Any termination of this Agreement pursuant to this Section 10.2 shall become effective at the end of the Cure Period, unless the Breaching Party has cured any such material breach and notified the Non-Breaching Party thereof prior to the expiration of such Cure Period, or, if such material breach is not reasonably susceptible to cure within the Cure Period, then, the Non-Breaching Party's right of termination shall be suspended only if, and for so long as, the Breaching Party has provided to the Non-Breaching Party a written plan that is reasonably calculated to effect a cure of such material breach, such plan is accepted by the Non-Breaching Party (such acceptance not to be unreasonably withheld, delayed or conditioned), and the Breaching Party commits to and carries out such plan as provided to the Non-Breaching Party. The right of either Party to terminate this Agreement as provided in this Section 10.2 shall not be affected in any way by such Party's waiver of or failure to take action with respect to any previous breach under this Agreement.

10.3 **Termination for Force Majeure Event**. A Party may terminate this Agreement upon written notice if a Force Majeure Event has delayed performance by the other Party for more than [**] or an aggregate [**] in any [**] period.

10.4 **Termination by Apellis**. Apellis shall have the right to terminate this Agreement in its entirety at any time after the Effective Date (a) if (i) any required NDA, DMF or other permit or license relating to a Product is not approved or not issued, or is deactivated, by any Agency or other governmental authority, or (ii) Bachem fails to satisfy Validation or other cGMP requirements; or (b) if any required license, permit or certificate of Bachem related to the Facility or the Manufacture of Drug Substance is not approved or not issued, or is deactivated or withdrawn, by any Agency or other governmental authority.

10.5 **Termination for Bankruptcy**. Either Party may terminate this Agreement in its entirety upon providing written notice to the other Party on or after the time that such other Party (a) makes a general assignment for the benefit of creditors, (b) files an insolvency petition in bankruptcy, (c) petitions for or acquiesces in the appointment of any receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, (d) commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation or any other similar proceeding for the release of financially distressed debtors, or (e) becomes a party to any proceeding or action of the type described above, and such proceeding or action remains un-dismissed or un-stayed for a period of more than [**].

10.6 **Termination by Mutual Agreement.** The Parties may terminate this Agreement at any time by mutual written agreement.

10.7 **Effects of Termination**. All of the following effects of termination are in addition to the other rights and remedies that may be available to either of the Parties under this Agreement and shall not be construed to limit any such rights or remedies.

(a) In the event that this Agreement is terminated by Apellis in accordance with Section 10.2 (Material Breach), Section 10.4 (Termination by Apellis) or Section 10.5 (Bankruptcy), Apellis shall (in its discretion) either: (i) keep any or all outstanding Firm Orders in place (on a Firm Order-by-Firm Order basis as determined by Apellis), in which case Bachem shall Manufacture and Deliver, in accordance with this Agreement, all quantities of Drug Substance ordered pursuant to such Firm Orders (regardless of whether the Delivery Date for such Drug Substance is before or after such termination) and Apellis shall pay the Supply Price with respect to such Drug Substance which meet the representations, warranties and covenants set forth in this Agreement; or (ii) cancel any or all outstanding Firm Orders (on a Firm Order-by-Firm Order basis as determined by Apellis), and with respect to any such cancelled Firm Orders, Apellis shall have no further liability with respect thereto; provided that Apellis shall only have the right to cancel Firm Orders pursuant to this clause (ii) if this Agreement is terminated by Apellis pursuant to Section 10.2 or Section 10.4.

(b) In the event that this Agreement is terminated by Bachem pursuant to Section 10.2 or by Apellis pursuant to Section 10.4(a) or Section 10.3, Apellis shall purchase the quantity of Safety Stock of Drug Substance existing as of the time of such termination (if any) that is in finished, packaged and labelled form (provided that all such Drug Substance meets the representations, warranties and covenants set forth in this Agreement), and in connection therewith, Bachem shall Deliver all such quantities of Safety Stock in accordance with this Agreement, and Apellis shall pay the applicable Supply Price with respect to such Drug Substance. Notwithstanding the foregoing or anything to the contrary contained herein, from and after the delivery of any

notice of termination pursuant to this Agreement, Bachem shall not replenish (or otherwise add any additional quantities of Drug Substance to) any Safety Stock then being held for Apellis.

(c) Upon expiration or termination of this Agreement, Apellis and Bachem shall immediately settle all outstanding invoices and other monies owed to the other pursuant to this Agreement. The termination or expiration of this Agreement shall not affect the rights and obligations of the Parties accruing prior to such termination or expiration, including, but not limited to, Apellis' reimbursement to Bachem for any work in progress and all non-cancelable commitments to purchase Materials entered into by Bachem specifically to conduct the Services hereunder that Bachem cannot reasonably utilize in other projects and that meet the relevant specifications therefor that had been agreed upon by the Parties in writing. Subject to the foregoing, expiration or termination of this Agreement shall relieve and release the Parties from any liabilities and obligations under this Agreement, other than those specifically set forth in this Article 9 and those that survive termination in accordance with Section 10.8.

10.8 **Remedies**. Notwithstanding anything to the contrary in this Agreement, except as otherwise explicitly set forth in this Agreement, termination or expiration of this Agreement shall not relieve the Parties of any Liability or obligation which accrued hereunder prior to the effective date of such termination or expiration, nor prejudice either Party's right to obtain performance of any obligation. Each Party shall be free, pursuant to Article 10, to seek, without restriction as to the number of times it may seek, damages, costs and remedies that may be available to it under Applicable Law or in equity.

10.9 **Survival**. In the event of termination of this Agreement, in addition to the provisions of this Agreement that continue in effect in accordance with their terms, the following provisions of this Agreement shall survive: Articles 1, 8, 9, 11 and 12, and Sections 6.1-6.5, 7.3, 7.5, 10.7, 10.8, 13.1-13.2, 13.4-13.5, and 13.7-13.13.

ARTICLE 11
DISPUTE RESOLUTION

11.1 **Disputes**. The Parties shall initially attempt in good faith to resolve any significant controversy, claim, allegation of breach or dispute arising out of or relating to this Agreement (hereinafter collectively referred to as a "**Dispute**") through negotiations between senior executives of Apellis and Bachem. Only if the Dispute is not resolved through negotiations, may a Party resort to litigation. During the pendency of any dispute resolution proceeding between the Parties under this Section 11.1, the obligation to make any payment under this Agreement from one Party to the other Party, which payment is the subject, in whole or in part, of a proceeding under this Section 11.1, shall be tolled until the final outcome of such dispute has been established. Any undisputed payment obligations (including undisputed portions of a payment obligation that is subject to a proceeding under this Section 11.1) shall not be tolled during such dispute.

ARTICLE 12
INDEMNIFICATION

12.1 **Indemnification by Apellis**. Apellis hereby agrees to defend, indemnify and hold harmless Bachem and its Affiliates, and each of their respective directors, officers, employees, agents and representatives (each, a "**Bachem Indemnitee**") from and against any and all claims, suits, actions, demands, liabilities, expenses and/or losses, including reasonable legal expenses and attorneys' fees (collectively, the "**Losses**"), to which any Bachem Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (each, a "**Claim**") to the extent such Losses arise directly or indirectly out of: (a) the breach by Apellis of any warranty, representation, covenant or

agreement made by Apellis in this Agreement; (b) the storage, use, transfer or sale, labeling, packaging, distribution, promotion, marketing, sale, or other disposition of Drug Substance (in each case after Delivery to Apellis) or the manufacture, use, transfer or sale, labelling, packaging distribution, promotion, marketing, sale or other disposition of any Product; (c) the failure by Apellis to comply with Applicable Law relating to the Product; (d) the negligence, gross negligence, illegal conduct or willful misconduct of Apellis or an Affiliate or sublicensee, or any officer, director, employee, agent or representative thereof; or (e) any Claim that the manufacture, use or sale of a Product infringes any patents, copyrights or trademarks or misappropriates any know-how owned by a Third Party; except, with respect to each of subsections (a), (b), (c), (d) and (e) above, to the extent such Losses arise directly or indirectly from the negligence, gross negligence, illegal conduct or willful misconduct of any Bachem Indemnitee or the breach by Bachem of any warranty, representation, covenant or agreement made by Bachem in this Agreement or are subject to indemnification by Bachem under Section 12.2.

12.2 Indemnification by Bachem. Bachem hereby agrees to defend, indemnify and hold harmless Apellis and its Affiliates and each of their respective directors, officers, employees, agents and representatives (each, a "**Apellis Indemnitee**") from and against any and all Losses to which any Apellis Indemnitee may become subject as a result of any Claim to the extent such Losses arise directly or indirectly out of: (a) the breach by Bachem of any warranty, representation, covenant or agreement made by Bachem in this Agreement; (b) the failure of Drug Substance to meet the Drug Substance warranties set forth in Section 8.2; (c) the failure by Bachem to comply with Applicable Laws with respect to the Manufacture of the Drug Substance; (d) the negligence, gross negligence, illegal conduct, or willful misconduct of Bachem or its Affiliates or Subcontractors, or any officer, director, employee, agent or representative thereof; or (e) any Claim that the Manufacture of Drug Substance infringes any patents, copyrights or trademarks or misappropriates any know-how owned by a Third Party (except to the extent such Claim is based upon any Apellis IP provided to Bachem); except, with respect to each of subsections (a), (b), (c) (d) or (e) above, to the extent such Losses arise directly or indirectly from the negligence, gross negligence, illegal conduct or willful misconduct of any Apellis Indemnitee or the breach by Apellis of any warranty, representation, covenant or agreement made by Apellis in this Agreement or are subject to indemnification by Apellis under Section 12.1.

12.3 Indemnification Procedures.

(a) Notice. Promptly after a Bachem Indemnitee or a Apellis Indemnitee (each, an "**Indemnitee**") receives notice of a pending or threatened Claim, such Indemnitee shall give written notice of the Claim to the Party from whom the Indemnitee is entitled to receive indemnification pursuant to Sections 12.1 or 12.2, as applicable (the "**Indemnifying Party**"). However, an Indemnitee's delay in providing or failure to provide such notice shall not relieve the Indemnifying Party of its indemnification obligations, except to the extent it can demonstrate actual prejudice due to the delay or lack of notice.

(b) Defense. Upon receipt of notice under this Section 12.3 from the Indemnitee, the Indemnifying Party will have the duty to either compromise or defend, at its own expense and by counsel (reasonably satisfactory to Indemnitee) such Claim. The Indemnifying Party will promptly (and in any event not more than [**] after receipt of the Indemnitee's original notice) notify the Indemnitee in writing that it acknowledges its obligation to indemnify the Indemnitee with respect to the Claim pursuant to this Article 11 and of its intention either to compromise or defend such Claim. Once the Indemnifying Party gives such notice to the Indemnitee, the Indemnifying Party is not liable to the Indemnitee for the fees of other counsel or any other expenses subsequently incurred by the Indemnitee in connection with such defense, other than the Indemnitee's reasonable out of pocket Third Party expenses related to its investigation and cooperation, except as otherwise provided in the next sentence. As to all Claims as to which

the Indemnifying Party has assumed control under this Section 12.3(b), the Indemnitee shall have the right to employ separate counsel and to participate in the defense of a Claim (as reasonably directed by the Indemnifying Party) at its own expense; provided, however, that if the Indemnitee shall have reasonably concluded, based upon a written opinion from outside legal counsel, that there is a conflict of interest between the Indemnifying Party and the Indemnitee in the defense of such Claim, the Indemnifying Party shall pay the fees and expenses of one law firm serving as counsel for the Indemnitee in relation to such Third Party Claim.

(c) **Cooperation**. The Indemnitee shall reasonably cooperate with the Indemnifying Party and its legal representatives in the investigation and defense of any Claim. The Indemnifying Party shall keep the Indemnitee informed on a reasonable and timely basis as to the status of such Claim (to the extent the Indemnitee is not participating in the defense of such Claim) and conduct the defense of such Claim in a prudent manner.

(d) **Settlement**. If an Indemnifying Party assumes the defense of a Claim, no compromise or settlement of such Claim may be effected by the Indemnifying Party without the Indemnitee's written consent (such consent not to be unreasonably withheld, delayed or conditioned). Notwithstanding the foregoing, the Indemnitee's consent shall not be required of a settlement where: (i) there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnitee; (ii) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party; (iii) the Indemnitee's rights under this Agreement are not adversely affected; and (iv) there is a full release of the Indemnitee from such Claim. If the Indemnifying Party fails to assume defense of a Claim within a reasonable time, the Indemnitee may settle such Claim on such terms as it deems appropriate with the consent of the Indemnifying Party (such consent not to be unreasonably withheld, delayed or conditioned), and the Indemnifying Party shall be obligated to indemnify the Indemnitee for such settlement as provided in this Article 12. It is understood that only Apellis and Bachem may claim indemnification under this Agreement (on its own behalf or on behalf of its Indemnitees), and other Indemnitees may not directly claim indemnity under this Agreement.

12.4 **Insurance.** Each Party shall procure and maintain insurance policies for the following coverages with respect to product liability, personal injury, bodily injury, and property damage arising out of such Party's (and its Affiliates') performance under this Agreement: (a) during the Term of this Agreement, comprehensive general liability, including broad form and contractual liability, in a minimum amount of $[**] combined single limit per occurrence (or claim) and $[**] in the aggregate annually; and (b) prior to the first commercial sale of Drug Substance or a Product, as applicable, until [**] after the last sale of Drug Substance or a Product, as applicable, product liability coverage, in a minimum limit of $[**] combined single limit per occurrence (or claim) and $[**] in the aggregate annually. The policies of insurance required by this Section 12.4 will be issued by an insurance carrier with an A.M. best rating of "A" or better. Each Party will provide the other Party with insurance certificates evidencing the required coverage within [**] after the Effective Date and the commencement of each policy period and any renewal periods. Each certificate will provide that the insurance carrier will notify the other Party in writing at least [**] prior to the cancellation or material change in coverage. For clarity, the foregoing insurance requirements shall not in any way limit a Party's liability with respect to its indemnification or other obligations under this Agreement.

12.5 **Limitation of Liability**. EXCEPT FOR A PARTY'S OBLIGATIONS SET FORTH IN THIS ARTICLE 12 AND ANY BREACH OF ARTICLE 8, IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY (OR THE OTHER PARTY'S AFFILIATES OR SUBLICENSEES)

IN CONNECTION WITH THIS AGREEMENT FOR LOST REVENUE, LOST PROFITS, LOST SAVINGS, LOSS OF USE, DAMAGE TO GOODWILL, OR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR INDIRECT DAMAGES IN CONNECTION WITH THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY, INCLUDING CONTRACT, NEGLIGENCE, OR STRICT LIABILITY, EVEN IF THAT PARTY HAS BEEN PLACED ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THIS LIMITATION ALSO APPLIES TO THE EXTENT A PARTY'S LIABILITY IS BASED ON ACTS OR OMISSIONS OF ITS AGENTS, EMPLOYEES, SUB-CONTRACTORS, SUB-SUPPLIERS, JOINT VENTURE PARTNERS OR OTHER THIRD PARTIES ENGAGED IN THE PERFORMANCE OF THIS AGREEMENT. IT DOES NOT APPLY IN CASE OF WILLFUL MISCONDUCT OR GROSS NEGLIGENCE OF THE RESPECTIVE PARTY, IN CASE OF CLAIMS BASED BY FRAUDULENT CONCEALMENT OF A DEFECT ("ARGLIST"), BODILY INJURY OR DEATH CULPABLY CAUSED BY THE RESPECTIVE PARTY OR ITS AGENTS, AS WELL TO THE EXTENT THE RESPECTIVE PARTY'S LIABILITY IS BASED ON MANDATORY LAW, SUCH AS APPLICABLE PRODUCT LIABILITY ACTS.

12.6 **Damages Cap**. IN ADDITION TO THE LIMITATION OF LIABILITY IN SECTION 12.5 EXCEPT FOR (a) EACH PARTY'S INDEMNIFICATION OBLIGATIONS SET FORTH IN THIS ARTICLE 12; (b) ANY BREACH OF ARTICLE 8 BY SUCH PARTY; AND (c) DAMAGES ARISING OUT OF SUCH PARTY'S GROSS NEGLIGENCE OR WILFUL MISCONDUCT, EACH PARTY'S MAXIMUM AGGREGATE LIABILITY TO COMPENSATE THE OTHER PARTY FOR ALL DAMAGES UNDER THIS AGREEMENT WILL BE SET ON A PER CALENDAR YEAR BASIS AND FOR THE CALENDAR YEAR IN WHICH THE CAUSE OF SUCH LIABILITY LIES OR EXISTS (WHETHER IN CONTRACT, TORT, STRICT LIABILITY, STATUTE, OR OTHERWISE) AND SHALL BE LIMITED TO A MAXIMUM OF $[**] USD.

ARTICLE 13
MISCELLANEOUS

13.1 **Notices**. All notices and other communications given or made pursuant hereto shall be in writing and shall be deemed to take effect as follows: (i) upon receipt if delivered either in person on any Business Day in the delivery location prior to 6 pm local time; or (ii) on the next succeeding Business Day if delivered in person on a non-Business Day or after 6 pm local time; or (iii) one (1) Business Day after having been delivered to a recognized air courier for overnight delivery (with delivery tracking provided, signature required and delivery prepaid); or (iv) if delivered by email, when the primary recipient, by an email sent to the email address for the sender stated in this Section 13.1 or by a notice delivered by another method in accordance with this Section 13.1, acknowledges having received that email, with an automatic "read receipt" not constituting acknowledgment of an email for purposes of this Section 13.1, in each case, to the Parties at the following addresses, each as may be specified below (or at such other address for a party as shall be specified by notice given in accordance with this Section 13.1).

If to Apellis:

Apellis Pharmaceuticals, Inc.
100 5th Avenue
Waltham, MA 02451 USA
Attention: VP, Head of Global Supply Chain

with a copy to:

Apellis Pharmaceuticals, Inc.
100 5th Avenue
Waltham, MA 02451
Attention: General Counsel

If to Bachem:

Bachem Americas, Inc.
3132 Kashiwa Street
Torrance, CA 90505 USA
Attention: [**]
Telephone: [**]
Email: [**]
(primary recipient)

with a copy to:

Bachem AG
Haupstrasse 144
4416 Bubendorf
Switzerland
Attention: [**]
Telephone: [**]
Email: [**]

13.2 Governing Law. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed in accordance with the laws of [**], without giving effect to any choice of law principles that would result in the application of the laws of any other jurisdiction. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to the transactions contemplated by this Agreement.

13.3 Designation of Affiliates. Each Party may discharge any obligation and exercise any right hereunder through delegation of its obligations or rights to any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

13.4 Relationship of the Parties. It is expressly agreed that Bachem, on the one hand, and Apellis, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency, including for tax purposes. Neither Bachem nor Apellis shall have the authority to make any statements, representations or commitments of any kind, or to take any action which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of that Party and not of the other Party and all costs and obligations incurred by reason of such employment shall be at the expense of such Party.

13.5 Force Majeure. A Party shall not be liable for non-performance or delay in performance, except for defaulted obligations of payment, to the extent that such nonperformance or delay in performance is not due to its negligence and is caused by any event reasonably beyond the control of such Party, including wars, hostilities, revolutions, riots, civil commotion, national emergency, strikes, lockouts, unavailability of supplies, epidemics, pandemics, fire, flood, earthquake, force of nature, explosion, terrorist act, embargo, or any other Act of God, (each a "**Force Majeure Event**"). Notwithstanding the foregoing, the COVID-19 Pandemic shall not be considered a Force Majeure Event, unless a Party's non-performance or delay in performance is (i) the direct result of orders and regulations of a Governmental Authority to combat the COVID-19 Pandemic which the addressees are legally obliged to comply with (e.g. closure of the Facility, quarantine regulations, requisition of production capacities) and/or (ii) such Party has taken Commercially

Reasonable measures to avoid harmful effects of the COVID-19 Pandemic(i.e., as set forth by the regulations issued by the Swiss Bundesamt für Gesundheit for Bachem AG, and the applicable California health authority for Bachem Americas, Inc.). In the event of any such delay, the delayed Party may defer its performance for a period equal to the time of such delay, provided that the delayed Party gives the other Party prompt written notice oif the occurrence of any Force Majeure Event, the nature thereof, and the extent to which the delayed Party will be unable fully to perform its obligations under this Agreement, and uses its good faith efforts to cure the excused breach. In the event of a Force Majeure that lasts for more than [**] or [**] in any [**] period, the other Party shall have the right upon written notice to the delayed Party to terminate this Agreement in accordance with Section 10.3.

13.6 Assignment. Neither Party shall assign this Agreement or an of the rights or obligations hereunder, without the prior written consent of the other Party, except that either party may, without the other party's consent, assign the Agreement to an Affiliate or to a successor to substantially all of the business or assets of the assigning company or the assigning company's business unit responsible for performance of the Agreement.

13.7 Binding Effect; No Third Party Beneficiaries. This Agreement shall be binding upon and inure to the benefit of, and shall be enforceable only by, the Parties and their respective successors and permitted assigns. It is the explicit intention of the Parties that no Person, other than the named Parties or their successors or permitted assigns, is or shall be entitled to bring any action to enforce any provision of this Agreement, as a third party beneficiary or otherwise.

13.8 Severability. If any one (1) or more of the provisions of this Agreement (a) is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken or (b) a Governmental Authority of competent jurisdiction advises the Parties that such provision violates Applicable Law over which such Governmental Authority has jurisdiction, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable provision such that the objectives contemplated by the Parties when entering this Agreement may be realized.

13.9 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

13.10 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof.

13.11 Headings. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

13.12 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural shall include the singular, and the use of any gender shall be applicable to all genders. Whenever this Agreement refers to a number of days without using a term otherwise defined herein, such number refers to calendar days. The terms "including," "include," "includes" or "for example" shall not limit the generality of any description preceding such term and, as used herein, shall have the same meaning as "including, but not limited to," and/or "including, without limitation." The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provision.

13.13 Entire Agreement. This Agreement, including the Attachments hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. In the event of any inconsistency between the body of this Agreement and either any Attachments to this Agreement or any subsequent agreements ancillary to this Agreement, unless otherwise express stated to the contrary in such Attachment or ancillary agreement, the terms contained in this Agreement shall control.

13.14 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by .pdf or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were the original signatures.

13.15 Interpretation. Each Party acknowledges and agrees that: In construing this Agreement, except where the context requires otherwise, (a) use of the singular includes the plural and vice versa; (b) the words "include" "including", "includes" and "e.g." means "including without limitation"; (c) the word "or" is used in the inclusive sense that is typically associated with the phrase "and/or"; (d) the words "herein," "hereof" and "hereunder," and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof; (e) the verb "will" shall be construed to have the same meaning and effect as the word "shall"; (f) use of any gender includes any other gender; (g) whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified; (h) references to a particular Applicable Law means an Applicable Law in effect as of the relevant time, including all rules and regulations thereunder and any successor Applicable Law in effect as of the relevant time, and including the then-current amendments thereto; (i) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement; (j) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein shall be interpreted in a correlative manner; (k) the words "Dollar" and "dollar" and the symbol "$" mean U.S. Dollars; (l) the word "notify" or "notice" means a notice in writing; and (m) all references herein to Articles, Sections or Attachments shall be construed to refer to Articles, Sections and Attachments of this Agreement.

[Remainder of this page intentionally left blank --signature page follows]

IN WITNESS WHEREOF, the Parties have entered into this Agreement as of the Effective Date.

APELLIS PHARMACEUTICALS, INC.

By: ____/s/ Nur Nicholson_____
Name: Nur Nicholson
Title: Chief Technical Operations Officer

APELLIS SWITZERLAND GMBH

By: ____/s/ Thomas Lackner_____
Name: Thomas Lackner
Title: SVP, Head of Europe

BACHEM AMERICAS, INC.

By: __/s/ Peter Hutchings_____
Name: Peter Hutchings
Title: VP, Business Development

By: __/s/ Michael Brenk_____
Name: Michael Brenk
Title: VP, Finance/HR

BACHEM AG

By: _/s/ Boris Corpataux_____
Name: Boris Corpataux
Title: VP, BD & Sales

By: __/s/ Roland Schürmann_____
Name: Roland Schüurmann
Title: COO

Exhibit 21.1

SUBSIDIARIES OF APELLIS PHARMACEUTICALS, INC.

Subsidiary	Jurisdiction of Incorporation or Organization
Apellis Australia Pty Ltd.	Australia
Apellis Bermuda Ltd	Bermuda
APL DEL Holdings LLC	United States
Apellis Germany GmbH	Germany
Apellis Ireland Ltd.	Ireland
Apellis Netherlands, B.V.	Netherlands
Apellis Switzerland GmbH	Switzerland
Apellis U.K. Limited	United Kingdom
Apellis MA Securities Inc.	United States
APL Sales I, LLC	United States
APL PRG I, Corp.	United States

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in Registration Statement No. 333-235830 and 333-229091 on Form S-3 and Registration Statement No. 333-229876, 333-221528, 333-236708 and 333-236710 on Form S-8 of our reports dated February 25, 2021, relating to the financial statements of Apellis Pharmaceuticals, Inc. and its subsidiaries and the effectiveness of Apellis Pharmaceuticals, Inc. and its subsidiaries' internal control over financial reporting appearing in this Annual Report on Form 10-K for the year ended December 31, 2020.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

February 25, 2021

Exhibit 23.2

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 Nos. 333-235830 and 333-229091) of Apellis Pharmaceuticals, Inc., and
(2) Registration Statement (Form S-8 No. 333-236710) pertaining to the 2020 Inducement Stock Incentive Plan of Apellis Pharmaceuticals, Inc., and
(3) Registration Statement (Form S-8 No. 333-236708) pertaining to the 2017 Stock Incentive Plan and Stock Option Inducement Awards (March 2019-February 2020) of Apellis Pharmaceuticals, Inc., and
(4) Registration Statement (Form S-8 No. 333-229876) pertaining to the 2017 Stock Incentive Plan, Inducement Stock Option Award, and 2017 Employee Stock Purchase Plan of Apellis Pharmaceuticals, Inc., and
(5) Registration Statement (Form S-8 No. 333-221528) pertaining to the 2010 Equity Incentive Plan, 2017 Stock Incentive Plan, and 2017 Employee Stock Purchase Plan of Apellis Pharmaceuticals, Inc.;

of our report dated February 26, 2019, with respect to the consolidated financial statements of Apellis Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Apellis Pharmaceuticals, Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 25, 2021

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Cedric Francois, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2020 of Apellis Pharmaceuticals, Inc.;

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.

Date: February 25, 2021

By: /s/ Cedric Francois

Cedric Francois
Chief Executive Officer and President

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Timothy E. Sullivan, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2020 of Apellis Pharmaceuticals, Inc.;

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.

Date: February 25, 2021

By: /s/ Timothy E. Sullivan

Timothy E. Sullivan
Chief Financial Officer and Treasurer

Exhibit 32.1

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 of Apellis Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ending December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Cedric Francois, the Chief Executive Officer and President of the Company, hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 25, 2021

By: /s/ Cedric Francois

Cedric Francois
Chief Executive Officer and President

Exhibit 32.2

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 of Apellis Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ending December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Timothy Sullivan, Chief Financial Officer and Treasurer of the Company, hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 25, 2021

By: /s/ Timothy E. Sullivan

Timothy E. Sullivan
Chief Financial Officer and Treasurer