2019 ANNUAL REPORT

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, 2019

or

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

For the transition period from to

Commission file number 001-37558

Nabriva Therapeutics plc
(Exact name of registrant as specified in its charter)

Ireland (State or other jurisdiction of incorporation or organization)	**Not applicable** (I.R.S. Employer Identification No.)
25-28 North Wall Quay **IFSC, Dublin 1, Ireland** (Address of principal executive offices)	**Not applicable** (Zip Code)

+353 1 649 2000
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Ordinary Shares, nominal value $0.01 per share	NBRV	The Nasdaq Stock Market LLC

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer ☐	Accelerated filer ☒	Non-accelerated filer ☐	Smaller reporting company ☒
			Emerging growth company ☒

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule12b-2 of the Act). Yes ☐ No ☒

As of June 28, 2019 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's voting securities held by non-affiliates was approximately $176.1 million based on the last reported sale price of the registrant's ordinary shares on June 28, 2019. As of February 28, 2020, the registrant had 94,623,564 ordinary shares outstanding.

NABRIVA THERAPEUTICS plc
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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements contained in this Annual Report, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate, “around” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The forward-looking statements in this report include, among other things, statements about:

- our ability to successfully launch and commercialize XENLETA (lefamulin) for the treatment of community-acquired bacterial pneumonia, or CABP, including the availability of and ease of access to XENLETA through hospital formularies, managed care plans and major U.S. specialty distributors;
- our ability to maintain a sales force for the commercialization of XENLETA and if approved, CONTEPO;
- the timing of receiving marketing approval of CONTEPO and other product candidates, including the completion of any post marketing requirements with respect to XENLETA and any other product candidates we may obtain;
- our expectations regarding how far into the future our cash on hand and anticipated revenues from product sales will fund our ongoing operations and the continued availability and cost of capital to sustain our operations on a longer term basis;
- our ability to comply with the restrictive covenants under our debt facility with Hercules including but not limited to the ability to maintain minimum cash balance requirements;
- our ability to satisfy interest and principal payments under our debt facility with Hercules Capital, Inc., or Hercules;
- our sales, marketing and distribution capabilities and strategy;
- the potential extent of revenues from future sales of XENLETA and/or CONTEPO if approved;
- the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, and whether results of early clinical trials or studies in different disease indications will be indicative of the results of ongoing or future trials;
- our ability to resolve the matters set forth in the Complete Response Letter we received from the U.S. Food and Drug Administration, or FDA, in connection with our New Drug Application, or NDA, for CONTEPO for the treatment of complicated urinary tract infections, or cUTIs, including acute pyelonephritis;
- our plans and the related cost expectations to pursue development of XENLETA for additional indications other than CABP, and of CONTEPO for additional indications other than cUTI;
- our plans to pursue development of other product candidates;
- our plans for making lefamulin available in China;
- our expectations regarding the ability of our customers to satisfy the demand for XENLETA with their existing inventory;
- our expectations with respect to the potential financial impact, synergies, growth prospects and benefits of our acquisition of Zavante Therapeutics, Inc., or Zavante, which was completed on July 24, 2018, or the

Acquisition, pursuant to the Agreement and Plan of Merger dated July 23, 2018, or the Merger Agreement, by and among Nabriva, Zuperbug Merger Sub I, Inc., or Merger Sub I, Zuperbug Merger Sub II, Inc., or Merger Sub II, Zavante and the Zavante stockholder representative, including the potential realization of the expected benefits from the Acquisition;

- our expectations with respect to milestone payments pursuant to the Merger Agreement and expectations with respect to potential advantages of CONTEPO or any other product candidate that we acquired in connection with the Acquisition;
- our ability to establish and maintain arrangements for manufacture of our product candidates;
- the potential advantages of XENLETA, CONTEPO and our other product candidates;
- our estimates regarding the market opportunities for XENLETA, CONTEPO and our other product candidates;
- the rate and degree of market acceptance and clinical benefit of XENLETA for CABP, CONTEPO for cUTI and our other product candidates;
- our ability to establish and maintain collaborations;
- the future development or commercialization of XENLETA in the greater China region and Canada;
- the potential benefits under our license agreements with Sinovant Sciences, Ltd., or the Sinovant License Agreement, and with Sunovion Pharmaceuticals Canada Inc., or the Sunovion License Agreement;
- our ability to acquire or in-license additional products, product candidates and technologies;
- our future intellectual property position;
- our ability to effectively manage our anticipated growth;
- our ability to maintain the level of our expenses consistent with our internal budgets and forecasts;
- the demand for securities of pharmaceutical and biotechnology companies in general and our ordinary shares in particular;
- competitive factors;
- risks of relying on external parties such as contract manufacturing organizations;
- compliance with current or prospective governmental regulation;
- general economic and market conditions;
- our ability to attract and retain qualified employees and key personnel;
- our business and business relationships, including with employees and suppliers, following the Acquisition;
- our ability to satisfy milestone, royalty and transaction revenue payments pursuant to the Stock Purchase Agreement between Zavante and SG Pharmaceuticals, Inc.; and
- other risks and uncertainties, including those described in the ‘‘Risk Factors’’ section of this Form 10-K.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make.

You should refer to the “Risk Factors” section of this Annual Report for a discussion of important factors that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. We do not assume any obligation to update any forward-looking statements, except as required by applicable law.

Throughout this Form 10-K, unless the context requires otherwise, all references to “Nabriva,” “the Company,” we,” “our,” “us” or similar terms refer to Nabriva Therapeutics plc, together with its consolidated subsidiaries.

SPECIAL NOTE REGARDING THE REDOMICILIATION

On June 23, 2017, Nabriva Therapeutics plc, a public limited company organized under the laws of Ireland, or Nabriva Ireland, became the successor issuer to Nabriva Therapeutics AG, a stock corporation (*Aktiengesellschaft*) organized under the laws of Austria, or Nabriva Austria, for certain purposes under both the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, or the Exchange Act. Such succession occurred following the conclusion of a tender offer related to the exchange of American Depositary Shares and common shares of Nabriva Austria for ordinary shares of Nabriva Ireland, which resulted in Nabriva Ireland, a new Irish holding company, becoming the ultimate holding company of Nabriva Austria (the predecessor registrant and former ultimate holding company) and its subsidiaries, which we refer to as the Redomiciliation Transaction. On October 19, 2017, Nabriva Austria was converted into a limited liability company under Austrian law and renamed Nabriva Therapeutics GmbH.

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

PART I

ITEM 1. BUSINESS

Overview

We are a biopharmaceutical company engaged in the research, development and commercialization of novel anti-infective agents to treat serious infections. On August 19, 2019, we received approval from the U.S. Food and Drug Administration, or FDA, of our New Drug Application, or NDA, for XENLETA for the treatment of adults with community-acquired bacterial pneumonia, or CABP. On September 9, 2019, we announced that the oral and intravenous, or IV, formulations of lefamulin (XENLETA) were available in the United States through major specialty distributors. XENLETA is the first oral and IV treatment in the pleuromutilin class of antibiotics available for the systematic administration in humans. We have also submitted an NDA to the FDA for CONTEPO, a potentially first-in-class epoxide antibiotic for IV use in the United States for complicated urinary tract infections, or cUTI. We may potentially develop XENLETA and CONTEPO for additional indications. Both XENLETA formulations and CONTEPO were granted Qualified Infectious Disease Product, or QIDP, and Fast Track designation by the FDA, enabling priority review of the NDAs by the FDA.

The recent coronavirus outbreak is the most recent reminder of the impact infectious diseases have on humanity. Similar to influenza virus infection, patients infected with the coronavirus are at increased risk for secondary bacterial pneumonia. Based on the information available from China, up to 15% of COVID-19 infected patients have also developed secondary bacterial pneumonia. Given high mortality in the setting of concomitant viral and bacterial infection, timely and appropriate empiric antibacterial therapy should be considered and promptly administered to patients with suspected or documented bacterial superinfection in the setting of COVID-19, particularly in patients with risk factors for increased mortality such as older age, diabetes, and immunosuppressive conditions. Nabriva is working closely with the Biotechnology Innovation Organization (BIO), a biotechnology trade association, in organizing an industry response. Nabriva is also monitoring efforts by the U.S. Biomedical Advanced Research and Development Authority (BARDA) in its preparation for the potential need for widespread CABP treatment and has proactively submitted a brief via https://www.medicalcountermeasures.gov/ to make XENLETA available as a potential treatment option in patients infected with the coronavirus with suspected or documented secondary bacterial pneumonia. In addition, Nabriva is supporting Sinovant – its development and commercialization partner in greater China for lefamulin – who is working closely with the National Medical Products Administration in China to be prepared to offer lefamulin, should it be needed for the treatment of suspected or documented secondary bacterial pneumonia.

XENLETA

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

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

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

As a result of increasing resistance to antibiotics and the wide array of potential pathogens that cause CABP, the current standard of care for hospitalized patients with CABP whose treatment is initiated in the hospital usually involves first-line empiric treatment with a combination of antibiotics (cephalosporins and macrolides) or monotherapy with a respiratory fluoroquinolone. In patients where MRSA is suspected, fluoroquinolones are also typically administered in combination with other antibiotics. Combination therapy presents the logistical challenge of administering multiple drugs with different dosing regimens, with some drugs available only as IV, and may increase the risk of drug-drug interactions and the potential for serious side effects. Fluoroquinolones are associated with safety and tolerability concerns, including a relatively high risk for developing *Clostridium difficile* infection and because of their generally broad spectrum of activity, increasing rates of resistance for uropathogens.

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

Many currently available antibiotic therapies are only available for IV administration and are prescribed for seven to fourteen days, meaning continued treatment requires prolonged hospitalization or a switch to a different antibiotic administered orally, with the attendant risk that the patient might respond differently.

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

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

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

concentrations in lung fluids and lung immune cells, the flexibility to step down from IV to oral administration as both oral and IV formulations are available and a favorable safety and tolerability profile.

On June 24, 2019, we announced that the European Medicines Agency, or EMA, determined that our Marketing Authorization Application, or MAA, for the IV and oral formulations of XENLETA was valid. Validation of the MAA confirms that the submission is sufficiently complete to begin the formal review process and an opinion of the EMA Committee for Medicinal Products for Human Use, or CHMP, is anticipated in the second half of 2020.

The EMA's review of the application will follow the centralized marketing authorization procedure. If approved by the EMA, XENLETA will receive marketing authorization in all of the member states of the European Union, or EU, as well as in Norway, Liechtenstein, Iceland and the United Kingdom. If approved, we intend to work with a commercial partner to make XENLETA available to patients in the EU.

CONTEPO

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

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

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

We submitted an NDA for marketing approval of CONTEPO for the treatment of cUTI including acute pyelonephritis, or AP, in adults in the United States, to the FDA in October 2018. The NDA submission is utilizing the 505(b)(2) regulatory pathway and is supported by a robust data package, including a pivotal Phase 2/3 clinical trial (known as ZEUS™), which met its primary endpoint of statistical non-inferiority to high dose piperacillin/tazobactam in patients with cUTI, including AP. In April 2019, the FDA issued a Complete Response Letter, or CRL, in response to our NDA for CONTEPO for the treatment of cUTIs, including acute pyelonephritis, stating that it was unable to approve the application in its current form. The CRL requests that issues related to facility inspections and manufacturing deficiencies at our active pharmaceutical ingredient contract manufacturer be addressed prior to the FDA approving the NDA. We requested a "Type A" meeting with the FDA to discuss its findings. This meeting occurred in July 2019 and we resubmitted our NDA to the FDA in December 2019. The FDA has granted us a PDUFA target action date of June 19, 2020 for CONTEPO. We cannot predict the final outcome of any interactions with the FDA or when CONTEPO will receive marketing approval, if at all.

Our Strategy

We are a biopharmaceutical company focused on the commercialization of novel anti-infective products. The key elements of our strategy to achieve our objectives are:

- ***Maximize the commercial potential of XENLETA for CABP and CONTEPO for cUTI's.*** We own exclusive, worldwide rights to XENLETA and US rights to CONTEPO and we have out licensed the rights to XENLETA in Canada and China. We plan to continue to explore licensing of rights to XENLETA in other territories outside the United States. Our initial target patient population for XENLETA in the United States will consist of adult patients with moderate to severe CABP and the initial target population for CONTEPO will be hospitalized adult patients with complicated urinary tract infections and/or acute pyelonephritis. We are currently selling XENLETA in the United States with our own sales and marketing organization. If CONTEPO receives marketing approval from the FDA, we plan to commercialize it in the United States with our existing infrastructure although we may also consider supplemental internal or external sales resources. We believe CONTEPO has an innovative profile which, if approved, would support its adoption in the United States for adult cUTI patients treated in the hospital. XENLETA also has the opportunity to be adopted as outpatient transition of care from the hospital, or Emergency Department, or as an out-patient treatment in a community setting, each of which we believe represents a significant commercial opportunity. We are communicating CONTEPO's and XENLETA's differentiating characteristics and key attributes to clinicians, hospital pharmacies and payors with the goal of establishing favorable reimbursement as well as a favorable formulary status in targeted hospitals. Outside the United States we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with multiple third parties to commercialize XENLETA in such markets. We currently have a team of regional business directors performing market development activities and a targeted hospital based sales force in the field promoting XENLETA in addition to a Market Access team that is working with large payors, including managed care organizations to secure favorable formularly placement for XENLETA. Medical science liaisons are engaging with health care providers to serve as a resource for learning about XENLETA. Additionally, in late 2019, we started utilizing our experienced sales force to call on approximately 6,000 community health care professionals in areas with high levels of managed care coverage that are in close proximity to our target hospital accounts.

- ***Pursue the continued development of XENLETA in additional indications.*** We are evaluating the cost and benefits of the continued development of XENLETA for indications in addition to CABP. Pediatric oral formulation development is ongoing, and a Phase 1 clinical trial of intravenous lefamulin in pediatric patients is ongoing. We believe XENLETA may have the potential to treat acute bacterial skin and skin structure infection (ABSSSI), ventilator-associated bacterial pneumonia (VABP) or hospital-acquired bacterial pneumonia (HABP) and sexually transmitted infections (STIs). In addition, we may explore longer duration of treatment with XENLETA to support development of a treatment for osteomyelitis and prosthetic joint infections. We believe that XENLETA would be differentiated from other treatment options for these potential indications because of its novel mechanism of action, spectrum of activity, including activity against multi-drug resistant pathogens, achievement of substantial concentrations in relevant tissues, availability as both an IV and oral formulation and favorable safety and tolerability profile. We have evaluated these opportunities and will consider their development if and when there is adequate funding which meets our business and financial objectives.

- ***Continue the development of CONTEPO for a pediatric indication.*** We are continuing the development of CONTEPO for use in pediatric patients with cUTIs. In June 2018, we initiated a Phase 1, non-comparative, open-label study of the pharmacokinetics and safety of a single dose of CONTEPO in pediatric subjects less than 12 years of age. We anticipate completing enrollment of this study in late 2020.

- ***Evaluate business development opportunities and potential collaborations.*** We may expand our product pipeline through opportunistically in-licensing or acquiring the rights to complementary products, product candidates and technologies for the treatment of a range of infectious diseases or other products that could

utilize our commercial infrastructure. We plan to evaluate the merits of entering into collaboration agreements with other pharmaceutical or biotechnology companies that may contribute to our ability to efficiently advance our product candidates, build our product pipeline, concurrently advance a range of research and development programs and leverage our commercial infrastructure. Potential collaborations may provide us with funding and access to the scientific, development, regulatory and commercial capabilities of the collaborators. We expect to continue to explore opportunities from domestic and international governments, foundations, and non-governmental entities to provide additional funding and support for potential future development programs.

Background

Anti-Bacterial Market and Scientific Overview

Antibiotics that are active against both Gram-positive and Gram-negative bacteria are referred to as broad spectrum, while those that are active only against a select subset of Gram-positive or Gram-negative bacteria are referred to as narrow spectrum. Bacteria that cause infections are often referred to as bacterial pathogens. Because it often takes from 24 to 72 hours to definitively identify the particular bacterial pathogen causing an infection, and the difficulty associated with obtaining adequate bacterial cultures in some patients and infections, the causative pathogen(s) often remains unidentified. Since the introduction of antibiotics in the 1940s, numerous new antibiotic classes have been discovered and developed for therapeutic use. The development of new antibiotic classes and new antibiotics within a class is important because of the ability of bacteria to develop resistance to existing mechanisms of action of currently approved antibiotics. However, the pace of discovery and development of new antibiotic classes slowed considerably in the past few decades. The CDC estimates that the pathogens responsible for more than 70% of U.S. hospital infections are resistant to at least one of the antibiotics most commonly used to treat them. The CDC also estimated in 2019 that annually in the United States at least 2.8 million people become infected with bacteria that are resistant to antibiotics and at least 35,000 people die as a direct result of these infections.

Antibiotic resistance is primarily caused by genetic mutations in bacteria selected by exposure to antibiotics that do not kill all of the bacteria. In addition to mutated bacteria being resistant to the drug used for treatment, many bacterial strains can also become cross-resistant, meaning that they become resistant to multiple classes of antibiotics. As a result, the effectiveness of many antibiotics has declined, limiting physicians' options to treat serious infections and exacerbating a global health issue. For example, the WHO estimated in 2014 that people with infections caused by MRSA, a highly resistant form of bacteria, are 64% more likely to die than people with a non-resistant form of the bacteria. Resistance can increase the cost of healthcare because of the potential for lengthier hospital stays and more intensive care. Growing antibiotic resistance globally, together with the low level of investment in research and development, is considered one of the biggest global health threats. In 2010, the WHO stated that antibiotic resistance is one of the three greatest threats to human health. Partially in response to this threat, the U.S. Congress passed the GAIN Act in 2012, which provides incentives, including access to expedited FDA review for approval, fast track designation and five years of potential data exclusivity extension for the development of new QIDPs. Additional legislation is also being considered in the United States, including the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms Act of 2019 (DISARM), which is intended to establish a new reimbursement framework to enable product specific reimbursement to hospitals for anti-infective products. In addition, the Centers for Medicare Services, or CMS, has publicly stated that they are considering other actions within their administrative authority to improve the reimbursement rates for new generation anti-infectives.

In 2018, sales of antibiotics to treat humans totaled approximately $45 billion globally. Although judicious use of antibiotics is important to reduce the rate of antibiotic resistance, this approach alone cannot fully address the threat from increasing antibiotic resistance. New antibiotics, and particularly new antibiotic classes, are needed to ensure the availability of effective antibiotic therapy in the future.

Community-Acquired Bacterial Pneumonia (CABP)

Market Overview

The U.S. National Center for Health Statistics estimated that between 1988 and 1994 there were approximately 5.6 million cases of pneumonia per year in the United States. More recently, based on our combined analysis of the CDC's 2007 National Ambulatory Medical Care Survey, the National Hospital Ambulatory Medical Care Survey and 2013 data from the Healthcare Cost and Utilization Project we estimate that over 5.0 million adults are treated annually for CABP in the United States and that the majority of these adult CABP patients have their treatment initiated in a hospital, including emergency departments. According to the Healthcare Cost and Utilization Project, or HCUP, in 2013, approximately 3.1 million adults sought treatment in a U.S. hospital for CABP. In addition, in 2013, approximately 2.4 million adults were admitted to U.S. hospitals for in-patient care with a diagnosis of CABP and approximately 700,000 adults were seen in an emergency department at U.S. hospitals for treatment of CABP and then released.

Additionally, in 2014, based on CDC data approximately 50,000 patients died from CABP in the United States. Based on data collected from July 1, 2015 through June 30, 2018, on the Medicare.gov Hospital Compare website, the current national rate of readmissions for Medicare pneumonia patients is 16.6%, which is the percentage of patients who have had a recent hospital stay that must return to a hospital for unplanned care within 30 days of being discharged. The national average death rate for Medicare pneumonia patients, excluding Medicare Advantage plan data, is 15.6%, which is the percentage of patients who die, for any reason, within 30 days of admission to a hospital.

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

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

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

Causes of CABP

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

Chlamydophila pneumoniae, and *Legionella* species. In addition, IDSA notes the emergence of resistance to commonly utilized antibiotics for CABP, specifically drug-resistant *S. pneumoniae* and community-acquired MRSA, or CA-MRSA, as a major consideration in choosing empiric therapy. However, a majority of patients do not have a pathogen identified using routine diagnostic tests available to physicians.

Currently Available Treatment Options

In 2019, based on the most likely bacteria to cause CABP, IDSA and the American Thoracic Society, or ATS, updated their recommendations for the empiric treatment of non-severe hospitalized patients with CABP without risk factors for MRSA and *P. aeruginosa* with either:

- a combination of a cephalosporin plus a macrolide or
- monotherapy with a respiratory fluoroquinolone; or
- combination therapy with a β-lactam and doxycycline when macrolides or fluoroquinolones are contraindicated.

Given concerns over increasing drug resistance (macrolides) and safety issues (macrolides, fluoroquinolones), the guidelines noted a need for additional research of new therapeutic agents, like XENLETA, for hospitalized adults with CABP. As a new therapeutic agent for the treatment of CABP, we believe the treatment of CABP with XENLETA is consistent with the guidelines.

Regarding outpatient therapy, the updated guidelines now only conditionally recommend macrolide monotherapy for CABP patients with or without comorbidities or risk factors only if local pneumococcal macrolide resistance is less than 25% and reiterated that physicians need to be aware of the local susceptibility profiles of the common bacterial pathogens associated with CABP because of increasing resistance to first-line antibiotics. For example, rates of pneumococcal resistance to macrolides now exceed 25% in most areas of the US and resistance to tetracyclines (another first line outpatient recommended therapy) exceed 25% in some areas, while resistance in *M. pneumoniae* associated with severe disease has been recently reported by the CDC in the United States. Antibiotic resistance is widespread to various degrees throughout the world.

Limitations of Currently Available Treatment Options

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

Bacterial Resistance and Spectrum of Activity

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

Difficult, Inconvenient and Costly Regimens

Currently available antibiotics used to treat CABP and other serious infections can be difficult, inconvenient and costly to administer. Physicians typically prefer IV administration for patients hospitalized with more serious illness

to ensure adequate delivery of the drug. Many IV antibiotics are prescribed for seven to 14 days or more and patients can be hospitalized for much or all of this period or require in-home IV therapy. The diagnosis related group, or DRG, reimbursement system often used in the U.S. hospital setting pays a fixed fee for an episode of CABP that may not fully compensate hospitals for the duration of hospitalized care. Prolonged IV treatment that extends the period of hospitalization may cause hospital costs to increase in excess of the fixed reimbursement fee, resulting in significant negative financial impact on healthcare institutions. In addition, to address all likely bacterial pathogens in a patient with a more serious illness, IDSA guidelines recommend using a combination of antibiotics. Combination therapy presents the logistical challenge of administering multiple drugs with different dosing regimens and may increase the risk of drug-drug interactions. While IV treatment delivers the drug more rapidly than is typical orally, once a patient is stabilized, oral treatment with the same drug would allow for more convenient and cost-effective out-patient treatment. Because many commonly used antibiotics are only available in IV form, a switch to an oral therapy requires changing to a different antibiotic, which may be less effective for the patient due to the different mechanism of action of the drug prescribed upon discharge.

Adverse Effects

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

Our Solution : XENLETA for the treatment of CABP

We believe that XENLETA, which is the first new class of antibiotic approved by the FDA in nearly 20 years, can fill the current treatment gap by providing clinicans the ability to treat a patient with an IV antibiotic in the hospital setting and then discharging them on oral therapy, which provides significant advantages to the patients' health while potentially reducing the total cost of care to the hospital. Additionally, we believe a short course treatment with XENLETA oral monotherapy could benefit moderate to severe CABP patients treated in the Emergency Department, or ED, by potentially avoiding hospitalization or in the community by potentially avoiding an ED visit, thereby, reducing patient hospitalization exposure and related significant associated costs to managed care plans. We also believe XENLETA's novel mechanism of action provides for a low risk of resistance development and no cross resistance with other antibiotics.

cUTIs

Market Overview

Infections due to a bacterial pathogen that are resistant to one or multiple antibiotic classes have become increasingly common and present a risk to our fight against infectious diseases and the management of complications in vulnerable patients. According to the CDC, more than 2.8 million hospital infections caused by bacteria resistant to one or more antibiotics occur every year in the United States, and over 35,000 patients with an antibiotic-resistant pathogen die each year.

The prevalence of antibiotic-resistant bacteria is increasing and is considered a significant threat to global health. In particular, the CDC and the WHO consider antibiotic resistance to be an urgent and critical threat to human health. The prevalence of Beta-lactamase enzymes among Gram-negative pathogens threatens the usefulness of many Beta-lactam antibiotics and has resulted in greater reliance on last line antibiotics, including carbapenems.

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

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

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

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

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

Causes of cUTIs

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

Patients with pyelonephritis, regardless of underlying abnormalities of the urinary tract, are considered a subset of patients with cUTI.

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

Limitations of Currently Available Treatment Options

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

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

Our Solution: CONTEPO for the Treatment of cUTI

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

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

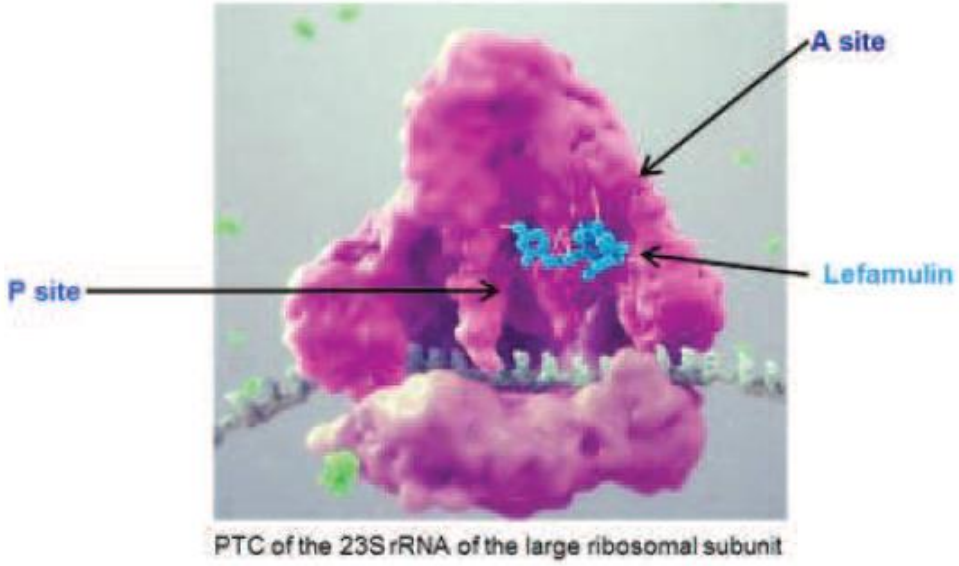
CONTEPO works differently than other IV antibiotics approved in the United States. CONTEPO inhibits an early step in bacterial cell wall synthesis, so the cell wall lacks integrity and the bacteria die quickly. We believe that because of its different mechanism of action, we have not observed any cross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

Our Product and Product Candidate

XENLETA

Overview

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



We believe that XENLETA is well suited to be used empirically as monotherapy for the treatment of respiratory tract infections, such as CABP, because of its spectrum of antibacterial activity against both the typical and

atypical pathogens causing CABP. XENLETA is a pleuromutilin antibacterial indicated for the treatment of adults with CABP caused by susceptible microorganisms. In addition, in preclinical studies, XENLETA showed potent antibacterial activity against a variety of Gram-positive bacteria, Gram-negative bacteria and atypical bacteria, including multi-drug resistant strains. In preclinical studies and in Phase 1 clinical trials, XENLETA achieved substantial concentrations in the epithelial lining fluid, or ELF, of the lung, the site infected during pneumonia. XENLETA also provides the ability to switch from IV to oral therapy and maintain therapy with the same antibacterial treatment. The efficacy of XENLETA in humans has been shown in a proof-of-concept clinical Phase 2 trial with 207 patients with ABSSSI (acute bacterial skin and skin structure infections) comparing two XENLETA doses (100 mg and 150 mg i.v. q12 h) with vancomycin (≥ 1,000 mg) over 5-14 days. This trial enrolled patients with severe skin and skin structure infections, excluding any patients with minor and uncomplicated infections. In total, 90.8 % of patients in the Modified Intent to Treat, or mITT population had *S. aureus* infection; 69.1 % of patients had MRSA. The results of the clinical Phase 2 trial in ABSSSI provided the first proof of concept for the systemic use of a pleuromutilin antibiotic for the treatment of serious bacterial infections in humans. Thereafter, the clinical program for XENLETA progressed with completion of two Phase 3 clinical trials in CABP (LEAP 1, LEAP 2). These trials demonstrated that XENLETA treatment, administered as IV only, IV to oral, and oral only regimens, was non-inferior to the standard of care moxifloxacin for the treatment of adults with CABP. Each trial provided independent evidence of the treatment effect and safety in this population with unmet medical need.

The FDA has designated each of the IV and oral formulations of XENLETA as a QIDP, which provides for the extension of statutory exclusivity periods in the United States for an additional five years upon FDA approval of the product for the treatment of CABP and granted fast track designation to these formulations of XENLETA. Fast track designation is granted by the FDA to facilitate the development and expedite the review of drugs that treat serious conditions and fill an unmet medical need. The fast track designation for the IV and oral formulations of XENLETA will allow for more frequent interactions with the FDA, the opportunity for a rolling review of any NDAs, eligibility for priority review and a shortening of the FDA's goal for taking action on a marketing application from ten months to six months. Two NDAs for IV and oral formulations of XENLETA for treatment of CABP were submitted to the FDA December 19, 2018 and were approved on August 19, 2019. We also submitted a marketing authorization application for XENLETA for the treatment of CABP in adults in Europe in May 2019. On June 24, 2019, we announced that the European Medicines Agency, or the EMA determined that our MAA for XENLETA is valid. Validation of the MAA confirms that the submission is sufficiently complete to begin the formal review process and an opinion of the EMA CHMP is anticipated in the second half of 2020.

We own exclusive, worldwide rights to XENLETA, other than our rights in People's Republic of China, Hong Kong, Macau, and Taiwan, which were licensed to Sinovant, and Canada, which was licensed to Sunovian. XENLETA is protected by issued patents in the United States, Europe and Japan covering composition of matter, which are scheduled to expire no earlier than 2028. We also have been granted patents for XENLETA relating to process and pharmaceutical crystalline salt forms in the United States, which are scheduled to expire no earlier than 2031 before any regulatory exclusivity such as QIPD or pediatric extensions are applied. In addition, we own a family of pending patent applications directed to pharmaceutical compositions of XENLETA, which if issued would be scheduled to expire no earlier than 2036.

Key Attributes of XENLETA

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

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

Based on our market research, we also believe that the availability of both IV and oral formulations of XENLETA, and an option to switch to oral treatment, could reduce the length of a patient's hospital stay and the overall cost of care.

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

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

Based on observations from our preclinical studies and clinical trials of XENLETA, as well as industry experience with pleuromutilins used in veterinary medicine over the last 40 years, we believe that XENLETA's novel mechanism of action is responsible for the low risk of cross-resistance observed with other antibiotic classes and a low propensity for development of bacterial resistance to XENLETA.

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

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

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

LEAP 1 (IV to Oral) Phase 3 Clinical Trial

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

The protocol defined different primary endpoints for the FDA and EMA to address regional differences in regulatory requirements for the development of antibacterial drugs to treat CABP. The FDA primary endpoint (EMA

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

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

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

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

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

Administration site reactions of any type occurred more frequently for XENLETA (7.7%) than moxifloxacin (3.7%). The most common individual TEAE was infusion site pain, affecting eight (2.9%) subjects in the XENLETA group, and no subjects in the moxifloxacin group. One subject in each treatment group had an infusion site reaction that led to discontinuation of study drug.

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

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

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

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

LEAP 2 (Oral Only) Phase 3 Clinical Trial

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

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

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

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

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

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

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

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

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

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

Phase 1 Pediatric Clinical Trial

Not unlike treatment of infectious diseases in adults, the management of pediatric infections has become more difficult due to the continuing rise in resistance in bacteria. Further complicating antimicrobial selection in the pediatric population is the need for agents to be very well tolerated and available in a final dosage form that can be easily administered to children. Based upon the *in vitro* antimicrobial spectrum of activity, along with the safety profile observed to date, we believe XENLETA is appropriate for evaluation for the treatment of a variety of pediatric infections, including those affecting the respiratory tract and skin and skin structure. We have an agreed Pediatric Investigation Plan, or PiP, and Pediatric Study Plan, or PSP, with the EMA and FDA, respectively. Pediatric oral formulation development is ongoing with initiation of a relative bioavailability and pharmacokinetic study with said oral formulation in 2019, and we initiated a Phase 1 clinical trial evaluating safety, tolerability and PK of intravenous XENLETA in pediatric patients in mid-2018.

Additional Potential Indications for XENLETA

STIs

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

In preclinical studies, XENLETA has shown high potency against *N. gonorrhoeae*, *C. trachomatis* and *M. genitalium*, including strains resistant to currently available antibacterial agents.

Osteomyelitis

The incidence of osteomyelitis, which is an infection of the bone, is increasing. The most common causative organism is *S. aureus*. In the United States, the prevalence of MRSA in these cases ranges from 33% to 55%. Up to 90% of cases of hematogenous osteomyelitis, most frequently in children, are caused by *S. aureus*. We believe that

XENLETA has the potential to be an effective treatment option for osteomyelitis. XENLETA has shown substantial tissue penetration and activity against the most common causative organism in all forms of osteomyelitis. We believe that based on the safety profile observed to date, XENLETA will be well tolerated for the long term use necessary for the treatment of both adult and pediatric patients with osteomyelitis. The current standard of care for these infections is treatment with vancomycin. We believe the ability to administer XENLETA by either the IV or oral route would provide a significant advantage over agents, such as vancomycin, that can only be administered by IV.

Prosthetic Joint Infections

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

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

CONTEPO Clinical Development Program

Overview

CONTEPO is under development in the United States for the treatment of cUTI, including AP. The clinical development plan for CONTEPO utilized a modernized dosing regimen to optimize coverage of the predominant pathogens in hospital infections, including strains recognized by the CDC as an urgent or serious antibiotic resistant threat to public health in the United States. The FDA has designated CONTEPO as a QIDP. We submitted an NDA for marketing approval of CONTEPO for the treatment of cUTI in adults in the United States, to the FDA in October 2018. The NDA submission is utilizing the 505(b)(2) regulatory pathway and is supported by a robust data package, including a pivotal Phase 2/3 clinical trial (known as ZEUS™), which met its primary endpoint of statistical non-inferiority to piperacillin/tazobactam in patients with cUTI, including acute pyelonephritis. The FDA granted us a PDUFA target action date of April 30, 2019 for CONTEPO, and received a Complete Response Letter from the FDA. The CRL requested that we address issues related to facility inspections and manufacturing deficiencies at one of our contract manufacturers prior to the FDA approving the NDA. The FDA did not request any new clinical data and did not raise any concerns with regard to the safety of CONTEPO. The NDA for CONTEPO was resubmitted based on the outcome and final minutes of a Type A meeting with the FDA. The FDA stated that our filing was a complete, class 2 response to the complete response letter the FDA issued on April 30, 2019. As a result, the FDA set a PDUFA date of June 19, 2020 for the completion of its review of the NDA resubmission.

Phase 2/3 Clinical Trial

The ZEUS Study was a multicenter, randomized, parallel-group, double-blind, pivotal Phase 2/3 clinical trial designed to evaluate safety, tolerability, efficacy and pharmacokinetics of CONTEPO compared to PIP-TAZ in the treatment of hospitalized adults with cUTI or AP. PIP-TAZ is a combination antibiotic consisting of a broad-spectrum antibiotic, piperacillin, plus a Beta-lactamase inhibitor, tazobactam, which extends the antibiotic spectrum of piperacillin to include many Beta-lactamase-producing bacteria that have acquired resistance to piperacillin alone. PIP-TAZ is widely used to treat serious Gram-negative infections. The primary objective of the ZEUS Study was to demonstrate that CONTEPO was non-inferior to PIP-TAZ in overall success based on clinical cure and microbiologic eradication in the microbiologic modified intent-to-treat, or m-MITT, population at the test-of-cure visit, or TOC, which occurred on the 19th to 21st day after completion of seven days of treatment with the study drug, or after up to 14 days of treatment for patients with concurrent bacteremia. The m-MITT population consisted of 362 patients, each of whom met the study's inclusion criteria, was randomized, received any amount of study drug, and had one or more baseline Gram-negative

pathogens growing at greater than or equal to 10(5) CFU/mL from an appropriately collected, pre-treatment baseline urine or blood sample. The primary endpoint was a composite of the investigator's determination of clinical cure, meaning complete resolution or significant improvement of signs and symptoms that were present at baseline and no new symptoms, such that no further antimicrobial therapy is warranted, plus microbiologic eradication, meaning that the baseline bacterial pathogen was reduced to less than 10(4) CFU/mL on urine culture and, if applicable, negative on repeat blood culture, both in the m-MITT population at TOC. Any missing or presumed eradications were classified as indeterminates, and conservatively counted as failures in the overall success analysis.

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

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

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

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

In the ZEUS Study, CONTEPO was non-inferior to PIP-TAZ for the primary efficacy outcome of overall success, which was defined as clinical cure and microbiologic eradication at TOC. Overall success occurred in 64.7% of CONTEPO patients and 54.5% of PIP-TAZ patients. The treatment difference between the CONTEPO and PIP-TAZ groups was 10.2%, with a 95% confidence interval (−0.4, 20.8). Additionally, the lower bound of the 95% confidence interval met the pre-specified non-inferiority margin of −15%, demonstrating that CONTEPO was non-inferior to PIP-TAZ in the study. In a post-hoc primary efficacy analysis using results of blinded PFGE molecular typing of urinary tract pathogens, this difference was even greater (69.0% CONTEPO patients compared to 57.3% PIP-TAZ patients, with a treatment difference of 11.7%, with a 95% confidence interval (1.3, 22.1). Overall success rates were driven by microbiologic eradication rates, as clinical cure rates were greater than 90% and treatment differences were small at TOC. Using the PFGE molecular typing, the microbiologic eradication rates in the m-MITT population at the TOC were 70.7% for patients receiving CONTEPO compared to 60.1% for patients receiving PIP-TAZ. These rates were consistent with those observed in some contemporary cUTI studies, and most patients with microbiologic persistence at TOC had

identifiable reasons or risk factors for persistence, such as functional or anatomical abnormalities of the urogenital tract, recent or indwelling urinary tract catheterization, elevated minimum inhibitory concentration, or MIC, to the study drug received, abbreviated study drug therapy, or other underlying co-morbidities. Of note, a majority of patients with microbiologic persistence at TOC were clinical cures at TOC, did not require rescue antimicrobial therapy, and remained sustained cures at LFU.

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

A total of 42.1% of CONTEPO patients and 32.0% of PIP-TAZ patients experienced at least one TEAE. Most TEAEs were mild or moderate in severity, and severe TEAEs were uncommon (2.1% of CONTEPO patients and 1.7% of PIP-TAZ patients). The most common TEAEs in both treatment groups were transient, asymptomatic laboratory abnormalities and gastrointestinal events. Treatment-emergent serious adverse events, or SAEs, were uncommon in both treatment groups (2.1% of CONTEPO patients and 2.6% of PIP-TAZ patients). There were no deaths in the study and one SAE in each treatment group was deemed related to the study drug (hypokalemia in a CONTEPO patient and renal impairment in a PIP-TAZ patient), leading to study drug discontinuation in the PIP-TAZ patient. Study drug discontinuations due to TEAEs were infrequent and similar between treatment groups (3.0% of CONTEPO patients and 2.6% of PIP-TAZ patients).

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

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

Phase 1 Pediatric Clinical Trial

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

Potential Additional Indications for CONTEPO

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

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

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

In August 2017, Zavante entered into an agreement with the United States National Institute of Allergy and Infectious Diseases, or NIAID, under which NIAID will conduct a clinical trial to assess CONTEPO's intrapulmonary penetration and pharmacokinetics in support of the product candidate's potential future development as a treatment for HABP and VABP. This bronchoalveolar lavage study, or the BAL study, will measure CONTEPO's pulmonary penetration by assessing drug concentrations in the lining of study subjects' bronchial pathways. Diffusion and saturation of antibiotics in patients' airways are considered important factors in assessing a drug's ability to effectively treat lower-respiratory tract infections. Prior preclinical and clinical investigations of IV fosfomycin have demonstrated that the product candidate penetrates rapidly into tissues and achieves clinically relevant concentrations in urine, soft tissues, lungs and other organs, supporting CONTEPO's potential versatility as an antibiotic treatment option. The Phase 1 BAL study is currently enrolling study subjects.

License Agreement with Sinovant Sciences

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

Under the Sinovant License Agreement, Sinovant and our subsidiaries established a joint development committee, or the JDC, to review and oversee development and commercialization plans in the Sinovant Territory. We received a $5.0 million upfront payment pursuant to the terms of the Sinovant License Agreement and were initially eligible for up to an additional $91.5 million in milestone payments upon the achievement of certain regulatory and commercial milestone events related to XENLETA for CABP, plus an additional $4.0 million in milestone payments if any Sinovant Licensed Product receives a second or any subsequent regulatory approval in the People's Republic of China. The first milestone was a $1.5 million payment for the submission of a clinical trial application by Sinovant to the Chinese Food and Drug Administration that was received in February 2019. Additionally, in connection with the FDA approval for XENLETA we received a $5.0 million milestone payment from Sinovant in the third quarter of 2019. The remaining milestone payments of $86.5 million are tied to additional regulatory approvals and annual sales targets. In addition, we are eligible to receive low double-digit royalties on sales, if any, of Sinovant Licensed Products in the Sinovant Territory.

Sinovant will be solely responsible for all costs related to developing, obtaining regulatory approval of and commercializing Sinovant Licensed Products in the Sinovant Territory and is obligated to use commercially reasonable

efforts to develop, obtain regulatory approval for, and commercialize Sinovant Licensed Product in the Sinovant Territory. We are obligated to use commercially reasonable efforts to supply, pursuant to supply agreements to be negotiated by the parties, to Sinovant sufficient supply of XENLETA for Sinovant to manufacture finished drug products for development and commercialization of the Sinovant Licensed Products in the Sinovant Territory.

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

License Agreement with Sunovion Pharmaceutics Canada Inc.

In March 2019, we entered into a license and commercialization agreement, or the Sunovion License Agreement, with Sunovion Pharmaceuticals Canada Inc., or Sunovion. As part of the Sunovion License Agreement, Nabriva Therapeutics Ireland DAC, our wholly owned subsidiary, granted Sunovion an exclusive license under certain patent rights, trademark rights and know-how to commercialize certain products containing XENLETA in the forms clinically developed by us or any of our affiliates, or the Sunovian Licensed Products, in Canada in all uses in humans in CABP and in any other indication for which the Sinovant Licensed Products have received regulatory approval in Canada.

Under the terms of the Sunovion License Agreement, we are entitled to receive an upfront payment, potential milestone payments upon the achievement of certain regulatory and sales milestone events and royalties on net sales, if any, of Sunovian Licensed Products in Canada. Sunovion is responsible for all costs related to developing, obtaining regulatory approval of, and commercializing the Sunovion Licensed Products in Canada.

Commercialization Strategy

Other than in greater China and Canada where we have licensed development and commercialization rights to XENLETA, we own exclusive, worldwide rights to XENLETA and U.S. rights to CONTEPO. Our initial target population for XENLETA consisted of patients with moderate to severe CABP whose antibiotic treatment is hospital-initiated. We received approval for XENLETA from the FDA in August 2019 and launched the product in September 2019. We utilize our own targeted hospital sales force and marketing organization and in early 2020 began to target high value primary care physicians in the community near our target hospitals. Based on our market research, we believe XENLETA has an innovative profile supporting adoption in the United States for adult hospital-initiated CABP patients, treated both as in-patients as well as outpatient-transition of care from the hospital to the community, which we believe represents a significant commercial opportunity. We believe that we will be able to effectively communicate XENLETA's differentiating characteristics and key attributes to clinicians, hospital pharmacies and payors with the goal of establishing favorable reimbursement for outpatients as well as a favorable formulary status in targeted hospitals. There is also a significant opportunity for XENLETA to be used in the community for CABP patients, given its versatile profile, and this may represent a future expanded use. Outside of the United States, we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize XENLETA.

Along with additional market research, we believe that medical education will be a key component of our commercialization efforts and, plan to invest in these activities to optimize the commercial potential of XENLETA. With a targeted initial prescribing base predominantly in the hospital setting, we expect that a targeted hospital sales and

marketing organization would be relatively smaller than competitors who are focused on both the hospital and community prescribing base. We believe that XENLETA's novel mechanism of action, status as the only member of a new class of systemically administered pleuromutilins and anticipated clinical profile will support its potential favorable reimbursement, its potential inclusion on formularies and in local and national treatment guidelines.

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

We own exclusive U.S. rights to CONTEPO. Our strategic intention, supported by CONTEPO's differentiated profile, is to establish CONTEPO as the standard of care in the United States for hospitalized patients with serious infections caused by suspected or confirmed MDR bacteria. We plan to use our existing hospital based sales force to promote CONTEPO to hospital-based healthcare professionals in key locations within the United States where MDR infections, including CRE, are concentrated. These include roughly 900 hospitals in high resistance locations such as New York City, Los Angeles and Chicago, and other major population centers. We also have a team of regional business directors and medical science liaisons in the field performing educational and market development activities, respectively, for XENLETA and CONTEPO.

Manufacturing

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

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

XENLETA

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

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

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

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

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

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

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

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

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

The Packaging Agreement has an initial five-year term ending December 31, 2023 and will automatically renew after the initial term for additional one-year terms unless either party gives notice of its intention to terminate the Packaging Agreement at least 90 days prior to the end of the then-current term. In addition, either party may terminate the Packaging Agreement for the other party's uncured material breach, in addition to other specified events, including with respect to bankruptcy proceedings and governmental actions, in each case subject to notice, cure periods and other conditions set forth in the Packaging Agreement.

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

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

XENLETA is a semi-synthetic organic compound of low molecular weight. The pleuromutilin core of the molecule is produced by fermentation and is manufactured on a significant scale by various manufacturers. The second part of the molecule is established from a readily accessible chiral starting material. The development stage production of XENLETA was carried out at a significant scale and we believe, if required, the synthetic route to XENLETA is amenable to further scale-up. The synthetic route does not require unusual, or specialized, equipment in the manufacturing process. Therefore, if any of our current or future drug substance manufacturers were to become unavailable for any reason, we believe there are a number of potential replacements, although delays may be incurred in identifying and qualifying such replacements.

CONTEPO

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

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

In addition, pursuant to the Three-Way Agreement, Zavante is required to (i) contract with one or more third party manufacturers to provide quantities of the Product required by Zavante for commercial sale in the United States, perform validation activities as required by the FDA, and obtain FDA approval of such third party manufacturer's facilities and quality systems; (ii) use commercially reasonable efforts to file an NDA within one year of its receipt of all Technical Documentation for the NDA from ERN and Ercros; (iii) obtain and own all trademarks to be used for the Product in the United States and (iv) bear the cost and manage all clinical trials necessary for obtaining FDA approval of the Product and keep ERN and Ercros updated regarding the progress of such clinical trials.

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

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

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

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

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

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

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

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

The ERN Supply Agreement contains, among other provisions, customary representations and warranties by the parties, a grant to each party by the other party of certain limited license rights to such other party's intellectual property

in connection with the parties' performance of the services under the ERN Supply Agreement, certain indemnification rights in favor of both parties and customary confidentiality provisions.

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

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

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

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

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

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

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

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

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

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, government agencies and private and public research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

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

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain marketing approvals for their products more rapidly than we obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected because in some cases insurers or other third-party payors seek to encourage the use of generic products. This may have the effect of making branded products less attractive, from a cost perspective, to buyers. XENLETA is priced at a significant premium over competitive generic products. This may make it difficult for us to replace existing therapies with XENLETA.

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

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

If approved, we expect CONTEPO will face competition from commercially available antibiotics such as ceftazidime-avibactam, meropenem-vaborbactam, tigecycline, plazomicin, from other product candidates currently in development for the treatment of cUTI, including AP, such as imipenem-relebactam (under Phase 3 clinical development by Merck), cefiderocol (owned by Shionogi and approved in 2019), tebipenem (under development by Spero), suilopenem (under development by Iterum Therapeutics) and LYS228 (under development by Boston Pharma), as well as generically available agents including carbapenems, aminoglycosides, and polymyxins.

Intellectual Property

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

As of January 31, 2020, we owned 23 different families of patents and patent applications, including 21 families directed to the various pleuromutilin derivatives as compositions of matter, processes for their manufacture, and their use in pharmaceutical compositions and methods of treating disease. The remaining two families are directed to ß-lactamase inhibitors and siderophore cephalosporin conjugates. Our patent portfolio includes 23 issued U.S. patents, 23 granted European patents and 19 granted Japanese patents, as well as patents in other jurisdictions. We also have pending patent applications in the United States, Europe, Japan and other countries and regions, including Asia, Australia, Eastern Europe, and South America, including notably Canada, Brazil, China, Israel, India and Taiwan among others.

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

As of January 31, 2020, our lead product, XENLETA, was protected by the following seven patent families:

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

- The second patent family includes patents and applications with claims that specifically recite XENLETA and/or its use in the treatment of microbial infections. This family includes two issued patents in each of the United States, Europe and Japan, as well as issued patents in 21 other jurisdictions and 5 pending patent applications in other jurisdictions, including one divisional application in the United States. The standard term for patents in this family expires in 2028. A patent term adjustment of 303 days has already been obtained in the United States for one patent. A patent term extension for this patent has been filed extending the term to 2033. A patent term extension application for the second United States patent has also been filed extending the term of this patent to 2032.

- The third patent family includes patents and applications with claims directed to the processes for the manufacture of XENLETA, crystalline intermediates useful in the processes, and the resulting crystalline salts. This family includes 21 granted patents including issued patents in the United States, Europe and Japan and 8 pending patent applications one in Europe 7 in other jurisdictions. The standard term for patents in this family expires in 2031. A patent term extension application for the United States patent has been filed extending the term to 2033.

- The fourth patent family includes patents and applications with claims directed to processes for the synthetic manufacture of crystalline intermediates useful in the manufacture of XENLETA. This family includes granted patents in Europe, the United States and Japan and granted patents in other jurisdictions. The standard term for patents in this family expires in 2031.

- The fifth patent family includes patents and applications with claims directed to pharmaceuticals and treatments for *Helicobacter* infection, including pleuromutilins, such as XENLETA. This family includes

issued patents in the United States, Europe and one other jurisdiction. The standard term for patents in this family expires in 2023. A patent term adjustment of 921 days has already been obtained for the U.S. patent.

- A further patent family is directed to pharmaceutical compositions of XENLETA and covers 1 granted patent and 16 pending patent applications in various jurisdictions such as the United States, Europe and Japan.

- The seventh patent family is directed to methods for purification of pleuromutilins and covers 11 pending patent applications in various jurisdictions.

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

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

Finally, we own one patent family directed to ß-lactamase inhibitor compounds and one patent application directed to siderophore cephalosporin conjugates. Patent applications in the ß-lactamase inhibitors family have been filed and granted in the United States and Europe. The standard term for patents in this family expires in 2030. An unpublished priority patent application for the siderophore cephalosporin conjugates has recently been filed in Europe.

Zavante holds two issued United States patents (U.S. 9,345,717 and U.S. 10,086,006) directed to methods for identifying dosing regimens that decrease the potential for on-therapy drug resistance. Zavante filed patent applications directed to dosing regimens of Fosfomycin in renally impaired patients. Additionally, Zavante has filed a patent application based on results from the ZEUS Study that relates to methods for treating patients with resistant bacterial infections and, specifically, Gram-negative bacterial infections. However, these patents may not ensure exclusivity through the patent terms and we may not be able to secure any additional patent protection. We plan to rely on regulatory protection afforded to CONTEPO™ through QIDP designation, data exclusivity, and market exclusivity where available.

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

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

Government Regulation

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

Review and Approval of Drugs in the United States

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

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

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of a new drug application, or NDA, summarizing available data to support the proposed approval of the new drug product for the proposed use;
- review of the product application by an FDA advisory committee, where appropriate or if applicable and as may be requested by the FDA;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing

Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;

- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of PDUFA fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, where applicable, and the potential to conduct post-approval studies required by the FDA.

Preclinical Studies

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

Companies usually must complete some long-term preclinical testing, such as animal tests of long term exposure and reproductive adverse events, and must also develop additional information about the chemistry and physical characteristics of the investigational product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the candidate product and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the candidate product does not undergo unacceptable deterioration over its shelf life.

The IND and IRB Processes

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

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

partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

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

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

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

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on its ClinicalTrials.gov website. Similar requirements for posting clinical trial information are present in the European Union (EudraCT) website: https://eudract.ema.europa/eu/ and other countries, as well.

Human Clinical Studies in Support of an NDA

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

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

- Phase 1: The drug is initially introduced into healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.

- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

- Phase 4: Post-approval studies, which are conducted following initial approval, are typically conducted to gain additional experience and data from treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

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

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

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

Expanded Access to an Investigational Drug for Treatment Use

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

When considering an IND application for expanded access to an investigational product with the purpose of treating a patient or a group of patients, the sponsor and treating physicians or investigators will determine suitability when all of the following criteria apply: patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational drug for the requested treatment will not interfere initiation, conduct, or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

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

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

Special Protocol Assessment Agreements

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

Specifically, under the FDCA, the FDA may meet with sponsors, provided certain conditions are met, for the purpose of reaching a SPA agreement on the design and size of clinical trials intended to form the primary basis of an efficacy claim in a marketing application. If a sponsor makes a reasonable written request to meet with the FDA for the purpose of reaching agreement on the design and size of a clinical trial, then the FDA will meet with the sponsor. If an agreement is reached, the FDA will reduce the agreement to writing and make it part of the administrative record. An agreement may not be changed by the sponsor or FDA after the trial begins, except with the written agreement of the sponsor and FDA, or if the director of the FDA reviewing division determines that “a substantial scientific issue essential

to determining the safety or effectiveness of the drug" was identified after the testing began. If a sponsor and the FDA meet regarding the design and size of a clinical trial and the parties cannot agree that the trial design is adequate to meet the goals of the sponsor, the FDA will clearly state the reasons for the disagreement in a letter to the sponsor.

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is subject to an application user fee, which for federal fiscal year 2020 is $2,942,965 for an application requiring clinical data. The sponsor of an approved NDA is also subject to an annual program fee, which for fiscal year 2020 is $325,424. Exceptions or waivers for these fees exist for a small company (fewer than 500 employees, including employees and affiliates) satisfying certain requirements and products with orphan drug designation for a particular indication are not subject to a fee provided there are no other intended uses in the NDA.

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

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

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

The FDA may refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and

under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions relating to approval of a new drug product.

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

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

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

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

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

With passage of the 21st Century Cures Act, or the Cures Act, in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such disease or condition. The benefits of a regenerative advanced therapy designation include early interactions with FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug when the product has an effect on an intermediate clinical endpoint that can be measured earlier

than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

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

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

Limited Population Antibacterial Drug Pathway

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

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

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific

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

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

Post-Approval Regulation

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with or without clinical data.

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

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

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

- injunctions or the imposition of civil or criminal penalties.

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

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

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

Section 505(b)(2) NDAs

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

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

Abbreviated New Drug Applications for Generic Drugs

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

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

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

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

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

Hatch-Waxman Patent Certification and the 30-Month Stay

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

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

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

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

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

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

Pediatric Studies and Exclusivity

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

patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

GAIN Exclusivity for Antibiotics

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

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

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

Patent Term Restoration and Extension

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

Regulation Outside the United States

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Although FDA approval for XENLETA has been obtained, we are required to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other

countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Regulation and Marketing Authorization in the European Union

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

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

Preclinical Studies

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

Clinical Trial Approval

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

In April 2014, the E.U. passed the new Clinical Trials Regulation, (EU) No 536/2014, which will replace the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the European Union, the new E.U. clinical trials legislation was passed as a regulation that is directly applicable in all E.U. member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation (EU) No 536/2014 becomes applicable. The Clinical Trials Directive 2001/20/EC will, however, still apply three years from the date of entry into application of the Clinical Trials Regulation to (i) clinical trials applications submitted before the entry into application and (ii) clinical trials applications submitted within one year after the entry into application if the sponsor opts for the old system. As of January 1, 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.

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

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

Marketing Authorization

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

Centralized Authorization Procedure

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

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

- medicinal products developed by means of one of the following biotechnological processes:
    - recombinant DNA technology;

- controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells; and
- hybridoma and monoclonal antibody methods;

- advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No 1394/2007 on advanced therapy medicinal products;
- medicinal products for human use containing a new active substance that, on the date of effectiveness of this regulation, was not authorized in the European Union, and for which the therapeutic indication is the treatment of any of the following diseases:
  - acquired immune deficiency syndrome;
  - cancer;
  - neurodegenerative disorder;
  - diabetes;
  - auto-immune diseases and other immune dysfunctions; and
  - viral diseases; and
- medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

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

Administrative Procedure

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

Conditional Approval

In specific circumstances, E.U. legislation (Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products), if (1) the risk-benefit balance of the product candidate is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Marketing Authorization Under Exceptional Circumstances

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

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

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

- The decentralized procedure allows applicants to file identical applications to several E.U. member states and receive simultaneous national approvals based on the recognition by E.U. member states of an assessment by a reference member state.

- The national procedure is only available for products intended to be authorized in a single E.U. member state.

- A mutual recognition procedure similar to the decentralized procedure is available when a marketing authorization has already been obtained in at least one E.U. member state.

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

Pediatric Studies

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

effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

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

Period of Authorization and Renewals

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

Regulatory Data Protection

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

Transparency

There is an increasing trend in the E.U. towards greater transparency and, while the manufacturing or quality information in marketing authorization dossiers is currently generally protected as confidential information, the EMA and national regulatory authorities are now liable to disclose much of the non-clinical and clinical information, including the full clinical study reports, in response to freedom of information requests after the marketing authorization has been granted. In October 2014, the EMA adopted a policy under which clinical study reports would be posted on the agency's website following the grant, denial or withdrawal of a marketing authorization application, subject to procedures for limited redactions and protection against unfair commercial use. Additional transparency provisions are contained in the new Clinical Trials Regulation (EU) No 536/2014 that will take effect in May 2016 at the earliest.

Regulatory Requirements After a Marketing Authorization has been Obtained

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

Pharmacovigilance and Other Requirements

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

Manufacturing

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

Marketing and Promotion

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

Patent Term Extension

To compensate the patentee for delays in obtaining a marketing authorization for a patented product, a supplementary certificate, or SPC, may be granted extending the exclusivity period for that specific product by up to five years. Applications for SPCs must be made to the relevant patent office in each E.U. member state and the granted certificates are valid only in the member state of grant. An application has to be made by the patent owner within six months of the first marketing authorization being granted in the European Union (assuming the patent in question has not expired, lapsed or been revoked) or within six months of the grant of the patent (if the marketing authorization is granted first). In the context of SPCs, the term "product" means the active ingredient or combination of active ingredients for a medicinal product and the term "patent" means a patent protecting such a product or a new manufacturing process or application for it. The duration of an SPC is calculated as the difference between the patent's filing date and the date of the first marketing authorization, minus five years, subject to a maximum term of five years.

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

Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the 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). Discussions between the United Kingdom and the European Union have so far mainly focused on finalizing withdrawal issues and transition agreements but have been extremely difficult to date. To date, only an outline of a trade agreement has been reached. Much remains open but the Prime Minister has indicated that the United Kingdom will not seek to extend the transitional period beyond the end of 2020. If no trade agreement has been reached before the end of the transitional period, there may be significant market and economic disruption. The Prime Minister has also indicated that the UK will not accept high regulatory alignment with the EU.

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. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

General Data Protection Regulation

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

Pharmaceutical Coverage, Pricing and Reimbursement

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

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

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

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

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

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with providers, consultants, third party payors and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, reporting of payments to physicians and teaching physicians and patient privacy laws and regulations and other healthcare laws and regulations

that may constrain business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal civil and criminal false claims laws, including the civil False Claims Act and civil monetary penalty laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the Foreign Corrupt Practices Act, or FCPA, which prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment;

- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the United States Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

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

Healthcare Reform

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

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

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;

- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- expanded the types of entities eligible for the 340B drug discount program;

- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;

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

- the Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs. However, the IPAB implementation has been not been clearly defined. PPACA provided that under certain circumstances, IPAB recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings; and

- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation from 2011 to 2019.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and will stay in effect through 2029 unless additional Congressional action is taken, and the American Taxpayer Relief Act of 2012, which, among other things, reduced

Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

Since enactment of the ACA, there have been, 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. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." The Congress may consider other legislation to replace elements of the ACA during the next Congressional session.

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

In addition, 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. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. The Trump Administration recently represented to the Court of Appeals considering this judgment that it does not oppose the lower court's ruling. On July 10, 2019, the Court of Appeals for the Fifth Circuit heard oral argument in this case. On December 18, 2019, that 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. On January 21, 2020, the U.S. Supreme Court declined to review this decision on an expedited basis. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Further, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform

government program reimbursement methodologies for drug products. For example, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on May 11, 2018, the Administration issued a plan to lower drug prices. Under this blueprint for action, the Administration indicated that the Department of Health and Human Services (HHS) will: take steps to end the gaming of regulatory and patent processes by drug makers to unfairly protect monopolies; advance biosimilars and generics to boost price competition; evaluate the inclusion of prices in drug makers' ads to enhance price competition; speed access to and lower the cost of new drugs by clarifying policies for sharing information between insurers and drug makers; avoid excessive pricing by relying more on value-based pricing by expanding outcome-based payments in Medicare and Medicaid; work to give Part D plan sponsors more negotiation power with drug makers; examine which Medicare Part B drugs could be negotiated for a lower price by Part D plans, and improving the design of the Part B Competitive Acquisition Program; update Medicare's drug-pricing dashboard to increase transparency; prohibit Part D contracts that include "gag rules" that prevent pharmacists from informing patients when they could pay less out-of-pocket by not using insurance; and require that Part D plan members be provided with an annual statement of plan payments, out-of-pocket spending, and drug price increases. In addition, on December 23, 2019, the Trump Administration published a proposed rulemaking that, if finalized, would allow states or certain other non-federal government entities to submit importation program proposals to FDA for review and approval. Applicants would be required to demonstrate their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. At the same time, FDA 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 authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Employees

As of January 31, 2020, we had 162 employees, 3 employees are located in Dublin, Ireland, 28 of our employees are located in Vienna, Austria and 131 of our employees are located in the U.S., with 49 located in King of Prussia, Pennsylvania, two located in San Diego, California and the remaining 80 employees in the field.

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

We consider our relations with our employees to be good.

Our Corporate Information

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

value per share, of Nabriva Ireland. The ordinary shares of Nabriva Ireland were issued on a one-for-ten basis to the holders of the Nabriva Austria common shares and on a one-for-one basis to the holders of the Nabriva Austria American Depositary Shares, or Nabriva Austria ADSs. On June 26, 2017, the ordinary shares of Nabriva Ireland began trading on the Nasdaq Global Market under the symbol "NBRV," the same symbol under which the Nabriva Austria ADSs were previously traded. This transaction was accounted for as a merger between entities under common control; accordingly, the historical financial statements of Nabriva Austria for periods prior to this transaction are considered to be the historical financial statements of Nabriva Ireland. Our executive offices are located at 25-28 North Wall Quay IFSC, Dublin 1, Ireland, and our telephone number is +353 1 649 2000.

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

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

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

Available Information

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

ITEM 1A. RISK FACTORS.

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

Risks Related to Our Financial Position and Need for Additional Capital

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

Since inception, we have incurred significant operating losses. Our net losses were $82.8 million for the year ended December 31, 2019, $114.8 million for the year ended December 31, 2018 and $74.4 million for the year ended December 31, 2017. As of December 31, 2019, we had an accumulated deficit of $476.7 million. To date, we have financed our operations primarily through the sale of our equity securities, convertible and term debt financings and

research and development support from governmental grants and loans and proceeds from our licensing agreements. We have devoted most of our efforts to research and development, including clinical trials and preparation for the commercial sale of our products. We have only recently begun to commercialize our first product, XENLETA (lefamulin), and have not developed any other drugs that have received regulatory approval. XENLETA is approved in the United States for the treatment of community-acquired bacterial pneumonia, or CABP, in adults. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years, including in connection with our regulatory approval efforts, supply chain investments and commercialization of XENLETA and, if it receives marketing approval, CONTEPO. The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year.

We also expect to continue to invest in critical pre-commercialization activities prior to potentially receiving marketing approval and making CONTEPO available to patients. In December 2019, we resubmitted the NDA for CONTEPO. The FDA has accepted our application and said that its PDUFA date is June 19, 2020. We cannot predict the outcome of any interactions with the FDA or when CONTEPO will receive marketing approval, if at all. If we obtain marketing approval of CONTEPO for cUTI, including AP, or another indication, we also expect to incur significant additional sales, marketing, distribution and manufacturing expenses.

On July 24, 2018, we completed our acquisition, or the Acquisition of Zavante. Upfront consideration in connection with the Acquisition was 8,152,092 of our ordinary shares, including the 815,186 ordinary shares that were initially held back but which were issued in July 2019 upon release of the Holdback Shares pursuant to the terms of the Agreement and Plan of Merger, dated July 23, 2018, or the Merger Agreement. Pursuant to the Merger Agreement, former Zavante stockholders are also entitled to receive from us up to $97.5 million in contingent consideration, consisting of the Approval Milestone Payment and the Net Sales Milestone Payment (each as defined below), subject to the terms and conditions of the Merger Agreement. In connection with the Acquisition, we assumed certain payment obligations under the Stock Purchase Agreement and Zavante manufacturing agreements acquired in the Acquisition. See "— *Risks Related to Our Acquisition of Zavante—We may fail to realize the anticipated benefits of our Acquisition of Zavante, those benefits may take longer to realize than expected, and we may encounter significant integration difficulties.*"

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

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

- establish and expand manufacturing arrangements with third parties; and

- add operational, financial and management information systems and personnel, including personnel to support our product development, our operations as a larger company following the Acquisition and our operations as a public company in addition to our commercialization efforts.

Our ability to generate profits from operations, and to become and remain profitable, depends on our ability to successfully develop and commercialize drugs that generate significant revenue. Based on our current plans, we do not expect to generate significant revenue unless and until we obtain marketing approval for CONTEPO, and successfully commercialize XENLETA and CONTEPO. In April 2019, the FDA issued a Complete Response Letter in connection with our NDA for CONTEPO for the treatment of cUTIs, including AP, stating that it was unable to approve the application in its current form. In December 2019, we resubmitted our NDA for CONTEPO to the FDA and in January 2020 the FDA acknowledged the resubmission and established a PDUFA date of June 19, 2020. We cannot predict whether CONTEPO will receive marketing approval. Our ability to generate significant revenue will require us to be successful in a range of challenging activities, including:

- obtaining marketing approval for CONTEPO;

- maintaining effective medical affairs, sales, marketing and distribution capabilities to effectively market and sell XENLETA and, if approved, CONTEPO, in the United States;

- establishing and maintaining collaboration, distribution or other marketing arrangements with third parties to commercialize XENLETA in markets outside the United States;

- protecting our rights to our intellectual property portfolio related to XENLETA and CONTEPO;

- establishing and maintaining arrangements for the manufacture of and obtaining commercial quantities of XENLETA and, if approved, CONTEPO; and

- negotiating and securing adequate reimbursement from third-party payors for XENLETA and, if approved, CONTEPO.

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

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

We expect to continue to incur substantial costs in connection with our ongoing activities, particularly as we continue the commercial launch of XENLETA and seek marketing approval for CONTEPO and, possibly, other product candidates and continue our research activities. Our expenses will increase if we suffer any regulatory delays or are required to conduct additional clinical trials to satisfy regulatory requirements.

Furthermore, we expect to continue to incur additional costs associated with operating as a public company and as a company with a commercial rather than a research and development focus. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or our commercialization efforts.

On March 11, 2020, we entered into an amendment, or the Amendment, to our Loan and Security Agreement, or the Loan Agreement, with Hercules Capital, Inc., or Hercules, as administrative agent, collateral agent and lender. Pursuant to the Amendment, we agreed to repay to Hercules between April 1, 2020 and April 3, 2020, $30.0 million of the $35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement, which we refer to as the Prepayment. We determined to enter into the Amendment following the effectiveness of a performance covenant in February 2020 under which we became obligated to either (1) achieve 80% of our net product revenue sales target over a trailing six-month period, or (2) maintain an amount of cash and cash equivalents in accounts pledged to Hercules plus a specified amount of eligible accounts receivables equal to the greater of the amount outstanding under the Loan Agreement or $40.0 million, which we refer to as the liquidity requirement. Under the Amendment, we and Hercules agreed to defer the end of term loan charge payment in the amount of approximately $2.3 million that would have otherwise become payable on the date of the Prepayment and to reduce the prepayment charge with respect to the Prepayment from $600,000 to $300,000 and to defer its payment, in each case, until June 1, 2023 or such earlier date on which all loans under the Loan Agreement are repaid or become due and payable. The Amendment also reset the revenue performance covenant to 70% of targeted revenue based on a revised net product revenue forecast and lowered our minimum liquidity requirement to $3.0 million in cash and cash equivalents, in each case, following the Prepayment. The new minimum liquidity requirement will not apply if CONTEPO receives regulatory approval from the U.S. Food and Drug Administration and we achieve at least 70% of our revised net product revenue targets under the Loan Agreement. Based on our current operating plans, immediately following the Prepayment, we expect that our existing cash resources and anticipated net product sales revenues will be sufficient to enable us to fund our operations, debt service obligations and capital expenditure requirements into the third quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate assumes, among other things, that we do not obtain any additional funding through grants and clinical trial support, collaboration agreements, or equity or debt financings. This estimate also assumes that our NDA for CONTEPO is approved on the PDUFA date and that we remain in compliance with the covenants and no event of default occurs under the Loan Agreement.

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

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

- the costs and timing of process development and manufacturing scale-up activities associated with XENLETA;
- the costs, timing and outcome of regulatory review of CONTEPO;
- the costs of commercialization activities for XENLETA and CONTEPO if we receive marketing approval for CONTEPO, including the costs and timing of product sales, marketing distribution and outsourced manufacturing capabilities, including the costs of building finished product inventory and its components in preparation of initial marketing of CONTEPO;
- revenue received from commercial sales of XENLETA and, subject to receipt of marketing approval, CONTEPO;
- the costs of developing XENLETA and CONTEPO for the treatment of additional indications;
- our ability to establish collaborations on favorable terms, if at all;
- the scope, progress, results and costs of product development of any other product candidates that we may develop;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;

- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property-related claims;
- the continued availability of Austrian governmental grants;
- the rate of the expansion of our physical presence in the United States and Ireland;
- interest expense on our debt and the eventual repayment of our debt obligations;
- the requirement to keep minimum cash balances per the terms of our debt obligations as well as our ability to remain in compliance with our debt covenants;
- the costs of operating as a company with a commercial rather than a research and development focus; and
- the costs of operating as a public company in the United States.

Our commercial revenues will be derived from sales of XENLETA, and from CONTEPO, if approved, or any other products that we successfully develop, in-license or acquire. XENLETA is our only product that is commercially available. XENLETA or, if approved, CONTEPO or any other product candidate that we develop, in-license or acquire may not achieve commercial success. If we fail to generate sufficient revenues from the sale of XENLETA or the commercialization of CONTEPO or any other product candidate that we successfully develop, in-license or acquire, we will need to obtain substantial additional financing to achieve our business objectives.

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

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

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

On June 25, 2019, we entered into an Open Market Sale Agreement℠, or the Jefferies ATM Agreement, with Jefferies LLC, or Jefferies, as agent, pursuant to which we may offer and sell ordinary shares, nominal value $0.01 per share, for aggregate gross sale proceeds of up to $50.0 million from time to time through Jefferies under an "at-the-market" offering program. As of the date of this filing, we have issued and sold an aggregate of 6,505,268 ordinary shares under the Jefferies ATM Agreement, for gross proceeds of $14.4 million, and net proceeds of $13.6 million, after deducting commissions and offering costs. We previously entered into a Controlled Equity Offering SM Sales Agreement, or the Cantor ATM Agreement, with Cantor Fitzgerald & Co. that we terminated effective as of June 24, 2019. The $12.2 million of ordinary shares that had been available for sale pursuant to the Cantor ATM Agreement remained unsold at the time of its termination. If a large number of our ordinary shares are sold in the public market after they become eligible for sale or if we make additional sales under our "at-the-market" offering program, the sales could cause dilution to our security holders, reduce the trading price of our ordinary shares and impede our ability to raise future capital.

In addition, in connection with the closing of the Acquisition, we issued 7,336,906 of our ordinary shares to former Zavante stockholders as initial upfront consideration and following the one year anniversary of the closing of the Acquisition on July 25, 2019, we issued an additional 815,186 ordinary shares to the former Zavante stockholders that had been subject to reduction in respect of certain indemnification and other obligations pursuant to the Merger Agreement. Such shares are able to be freely sold in the public market, subject to any requirements and restrictions, including any applicable volume limitations, imposed by Rule 144 under the Securities Act. In addition, the Merger Agreement provides that we may issue up to an additional $97.5 million in our ordinary shares to former Zavante stockholders upon the achievement of specified regulatory and commercial milestones in the future, and obligates us to provide registration rights with respect to the registration for resale of such additional ordinary shares that may become issuable upon the achievement of such milestones. The issuance of our ordinary shares to satisfy the milestone payments will cause dilution to our security holders, and the sale or resale of these shares in the public market, or the market's expectation of such sales, may result in an immediate and substantial decline in our stock price. Such a decline would adversely affect our investors and also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

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

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

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

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

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

As of December 31, 2019, under our Loan Agreement with Hercules, we had drawn down on the initial term loan advance under the Loan Agreement of $25.0 million and an additional $10.0 million advance that we became eligible to borrow following the approval by the FDA of the NDA for XENLETA. On March 11, 2020, we entered into the Amendment to the Loan Agreement pursuant to which we agreed to repay to Hercules between April 1, 2020 and April 3, 2020, $30.0 million of the $35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement. Following the Prepayment, there will remain outstanding $5.0 million in principal amount under the Loan Agreement, and we may request to borrow an additional $5.0 million subject to the lender's sole discretion.

All obligations under the Loan Agreement are secured by substantially all of our personal property, intellectual property and other assets owned or later acquired by us and our subsidiaries. This indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying

off or refinancing our outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including:

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

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

- the need to maintain minimum cash balances under specified circumstances, which restricts our ability to invest in the business and fund our operations.

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

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

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

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

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

- declare dividends or redeem or repurchase equity interests;

- incur additional indebtedness and liens;

- make loans and investments;

- engage in mergers, acquisitions and asset sales;

- undertake certain transactions with affiliates

- undergo a change in control;

- add or change business locations; and

- settle in cash potential milestone payment obligations that may become payable by us in the future to former security holders of Zavante.

We are also required to satisfy certain financial covenants, including an obligation to maintain specified minimum amounts of cash and cash equivalents in accounts pledged to Hercules. The Loan Agreement contains a performance covenant that became effective in February 2020 under which we became obligated to either (1) achieve 80% of our net product revenue sales target over the trailing six month period, or (2) maintain an amount of cash and cash equivalents in accounts pledged to Hercules plus a specified amount of eligible accounts receivables equal to the greater of the amount outstanding under the Loan Agreement or $40.0 million. Since we did not achieve our net product sales targets, we became obligated to maintain compliance with the liquidity requirement under the Loan Agreement. As a result, we entered into an Amendment to the Loan Agreement with Hercules. Under the Amendment, we and Hercules agreed to defer the end of term loan charge payment in the amount of approximately $2.3 million that would have otherwise become payable on the date of the Prepayment and to reduce the prepayment charge with respect to the Prepayment from $600,000 to $300,000 and to defer its payment, in each case, until June 1, 2023 or such earlier date on which all loans under the Loan Agreement are repaid or become due and payable. The Amendment also reset the revenue performance covenant to 70% of targeted revenue based on a revised net product revenue forecast and lowered our minimum liquidity requirement to $3.0 million in cash and cash equivalents following the Prepayment. The new minimum liquidity requirement will not apply if CONTEPO receives regulatory approval from the U.S. Food and Drug Administration and we achieve at least 70% of our revised net product revenue targets under the Loan Agreement.

These restrictive covenants may prevent us from undertaking an action that we feel is in the best interests of our business. In addition, if we were to breach any of these restrictive covenants, or if a material adverse effect as defined under the Loan Agreement occurs, Hercules could accelerate our indebtedness under the Loan Agreement or enforce its security interest against our assets, either of which would materially adversely affect our ability to continue to operate our business.

We and our Chief Executive Officer, Chief Medical Officer and Chief Financial Officer have been named as defendants in a lawsuit that could result in substantial costs and divert management's attention.

On May 8, 2019, a putative class action lawsuit was filed against us and our Chief Executive Officer. The complaint generally alleged that we and our Chief Executive Officer violated Sections 10(b) and/or 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements and omitting to disclose material facts concerning our submission of an NDA to the FDA for marketing approval of CONTEPO for the treatment of cUTI in the United States and the likelihood of such approval. The complaint sought unspecified damages, attorneys' fees, and other costs. On May 22, 2019, a second putative class action lawsuit was filed against us and our Chief Executive Officer. The allegations made in that complaint were similar to those made in the May 8 complaint, and the complaint sought similar relief. On May 24, 2019, the two actions were consolidated by the court. The court appointed a lead plaintiff and approved plaintiff's selection of lead counsel on July 22, 2019. On September 23, 2019, the plaintiff filed an amended complaint, adding our Chief Financial Officer and Chief Medical Officer as defendants. The amended compliant includes allegations similar to those made in the original complaints and seeks similar relief. Our pre-motion letter to dismiss the amended complaint was provided to the plaintiff on October 21, 2019, and plaintiff responded to us via letter on November 4, 2019. On November 18, 2019, we filed a pre-motion letter to dismiss with the Court, seeking leave to move to dismiss and setting forth why a motion to dismiss is warranted.

We and our Chief Executive Officer, Chief Financial Officer and Chief Medical Officer deny any and all allegations of wrongdoing and intend to vigorously defend against this lawsuit. We are unable, however, to predict the outcome of this matter at this time. Moreover, any conclusion of this matter in a manner adverse to us and for which we incur substantial costs or damages not covered by our directors' and officers' liability insurance would have a material adverse effect on our financial condition and business. In addition, the litigation could adversely impact our reputation and divert management and our board of directors' attention and resources from other priorities, including the execution of our business plan and strategies that are important to our ability to grow our business, any of which could have a material adverse effect on our business. Additional lawsuits may be filed.

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

As a company that carried out extensive research and development activities, we have benefited from the Austrian research and development support regime, under which we were eligible to receive a research premium from the Austrian government equal to 14% (12% for the fiscal years 2016 and 2017 and 10%, in the case of fiscal years prior to 2016) of a specified research and development cost base. Qualifying expenditures largely comprised research and development activities conducted in Austria, however, the research premium was also available for certain related third-party expenses with additional limitations. We received research premiums of $2.4 million for the year ended December 31, 2018 and $4.7 million for the year ended December 31, 2017. We have not received any research premium for our qualified 2019 expenditures as of December 31, 2019. As we increase our personnel and expand our business outside of Austria, we may not be able to continue to claim research premiums to the same extent as we have in previous years or at all, as some research and development activities may no longer be considered to occur in Austria. As research premiums that have been paid out already may be audited by the tax authorities, there is a risk that parts of the submitted cost base may not be considered as eligible and therefore repayments may have to be made.

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

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

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

Risks Related to Product Development and Commercialization

We depend heavily on the success of XENLETA, which the FDA has approved for oral and intravenous use for the treatment of CABP, and CONTEPO, which we are developing for cUTI, including AP. If we are unable to obtain marketing approval for CONTEPO, or if we fail in our commercialization efforts for XENLETA or CONTEPO, or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of XENLETA and, more recently, in CONTEPO. There remains a significant risk that we will fail to successfully develop CONTEPO for cUTI or any other indication and that we may fail to successfully commercialize XENLETA for CABP.

On August 19, 2019, the FDA approved the oral and intravenous formulations of XENLETA. We also submitted a marketing authorization application, or MAA, for XENLETA for the treatment of CAP in adults in Europe in May 2019. In mid-2018, we initiated a Phase 1, non-comparative, open-label study of the pharmacokinetics and safety of a single dose of IV XENLETA in pediatric subjects from birth to 18 years of age.

In June 2016, Zavante initiated the ZEUS Study. In April 2017, Zavante announced positive topline results of the ZEUS Study. We submitted an NDA for marketing approval of CONTEPO for the treatment of cUTI in adults in the United States, utilizing the FDA's 505(b)(2) pathway, in October 2018. In April 2019, the FDA issued a Complete Response Letter in connection with our NDA for CONTEPO for the treatment of cUTIs, including AP, stating that it was unable to approve the application in its current form. In December 2019, we resubmitted the NDA for CONTEPO. The FDA has accepted our application and scheduled the PDUFA date for June 19, 2020.

In June 2018, Zavante initiated a Phase 1, non-comparative, open label study of the pharmacokinetics and safety of a single dose of CONTEPO in pediatric subjects less than 12 years of age receiving standard of care antibiotic therapy for proven or suspected infection or peri operative prophylaxis. We anticipate completing enrollment in this study in late 2020. We also intend to continue to characterize the clinical pharmacology of CONTEPO.

We expect to incur significant additional sales, marketing, distribution and manufacturing expenses for the commercialization of XENLETA and, if approved, CONTEPO.

Our ability to generate meaningful product revenues will depend heavily on the successful commercialization of XENLETA and our obtaining marketing approval for CONTEPO. The success of XENLETA and, if approved, CONTEPO will depend on a number of factors, including the following:

- establishing and maintaining arrangements with third-party manufacturers for commercial supply and receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities;
- receipt of marketing approval from the FDA for CONTEPO for the treatment of cUTI, including AP;
- maintain an effective sales and marketing organization to successfully generate recurring sales of XENLETA and, if and when approved, CONTEPO;
- acceptance of XENLETA and, if and when approved, CONTEPO by patients, the medical community and third-party payors, including hospital formularies;
- achieving approval of favorable prescribing information;
- effectively competing with other therapies;
- maintaining a continued acceptable safety profile of XENLETA and CONTEPO following approval;
- securing contracts to allow XENLETA and, if approved, CONTEPO to be paid for by private and public health insurance plans;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- protecting our rights in our intellectual property portfolio; and
- obtaining and maintaining adequate distribution levels of XENLETA and CONTEPO at all appropriate trade channels.

Successful development of XENLETA and CONTEPO for the treatment of additional indications, if any, or for use in other patient populations and our ability to broaden the labels for XENLETA and, if approved, CONTEPO will depend on similar factors. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize XENLETA for CABP or for any other indication or CONTEPO for cUTI, including AP or for any other indication, which would materially harm our business.

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

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

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

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

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

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

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

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

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

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

We may not be able to initiate or continue clinical trials for our product candidates, including with respect to XENLETA, CONTEPO or any other product candidate that we develop, if we are unable to locate and enroll a sufficient

number of eligible patients to participate in these clinical trials. Some of our competitors have ongoing clinical trials for product candidates that could be competitive with XENLETA and CONTEPO, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors including:

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

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

If serious adverse or undesirable side effects are identified in XENLETA, CONTEPO or any other product candidate that we develop or following their approval and commercialization, we may need to modify, abandon or limit our development or marketing of that product or product candidate.

It is impossible to predict when or if the FDA, EMA or other regulators will view any of our product candidates as effective and safe in humans or if we will receive marking approval for any product candidates and it is impossible to ensure that safety or efficacy issues will not arise following the marketing approval. If our products or product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to modify or abandon their marketing or development or limit marketing or development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Similarly, if we are not able to comply with post-approval regulatory requirements, including safety requirements, with respect to XENLETA or any other approved product that we may develop, we could have the marketing approvals for such products withdrawn by regulatory authorities. Many compounds that initially showed

promise in clinical or earlier stage testing have later been found to cause side effects or other safety issues that prevented further development of the compound.

In the ZEUS Study, the incidence of premature discontinuation from study drug was low and similar in both treatment groups (6.0% in the CONTEPO treatment group and 3.9% in the PIP-TAZ treatment group). The incidence of premature discontinuation from study before the last follow-up visit, which occurred between Study Day 24 and 28, after completion of 7 days of study drug treatment (or up to 14 days of study drug treatment for patients with bacteremia at baseline), was 5.2% in the CONTEPO group and 0.9% in the PIP-TAZ group. Treatment-emergent adverse events occurred in 98 of 233 (42.1%) CONTEPO patients and 74 of 231 (32.0%) PIP-TAZ patients. Most treatment-emergent adverse events were mild or moderate in severity, and severe treatment-emergent adverse events were uncommon (2.1% of CONTEPO patients and 1.7% of PIP-TAZ patients). The most common treatment-emergent adverse events in both treatment groups were transient, asymptomatic laboratory abnormalities and gastrointestinal events. Treatment-emergent serious adverse events were uncommon in both treatment groups (2.1% of CONTEPO patients and 2.6% of PIP-TAZ patients). There were no deaths in the study and 1 treatment-emergent serious adverse event in each treatment group was deemed related to study drug (hypokalemia in a CONTEPO patient and renal impairment in a PIP-TAZ patient). Premature discontinuations from study drug due to treatment-emergent adverse events were infrequent and similar in both treatment groups (3.0% of CONTEPO patients and 2.6% of PIP-TAZ patients).

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

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

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

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

XENLETA and any other product candidate that receives marketing approval may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for such products and product candidates, if approved, may be smaller than we estimate.

XENLETA and any other product candidate that receives marketing approval may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current treatments for CABP, including generic options, are well established in the medical community, and

doctors may continue to rely on these treatments without XENLETA, CONTEPO or any of our other product candidates. In addition, our efforts to effectively communicate the differentiating characteristics and key attributes of XENLETA, CONTEPO or any of our other product candidates to clinicians and hospital pharmacies with the goal of establishing favorable hospital formulary status for XENLETA, CONTEPO or any of our other product candidates may fail or may be less successful than we expect. If XENLETA, CONTEPO or any of our other product candidates does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of our products and product candidates, if approved for commercial sale, will depend on a number of factors, including:

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

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

Our ability to negotiate, secure and maintain third-party coverage and reimbursement may be affected by political, economic and regulatory developments in the United States, the European Union and other jurisdictions. Governments continue to impose cost containment measures, and third-party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. If the level of reimbursement is below our expectations, our revenue and gross margins would be adversely affected.

Hospital formulary approval of XENLETA, CONTEPO or any future product candidates is an important component of our commercialization strategy. Accordingly, sales of XENLETA, CONTEPO or any future product candidates will depend substantially on the extent to which hospital formulary approval is obtained. Hospital formulary approval may depend upon several factors, including the determination that use of a product is:

- safe, effective and medically necessary;
- appropriate for the specific patient population;
- cost-effective; and

- neither experimental nor investigational.

Obtaining formulary approval from third-party payors can be an expensive and time-consuming process that will require us to provide supporting scientific, clinical and cost-effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to hospital formulary approval. We cannot be certain if and when we will obtain hospital formulary approval to allow us to sell XENLETA, CONTEPO or any future product candidates into our target markets. Even if we do obtain hospital formulary approval, third-party payors, such as government or private health care insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, drugs. Increasing efforts by hospitals in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit formulary approval. We have experienced and expect to continue to experience pricing pressures in connection with the sale of XENLETA in the hospital setting due to the trend toward reducing hospital costs, managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. These and other similar developments could significantly limit the degree of market acceptance of XENLETA, CONTEPO or any of our other product candidates that receive marketing approval. To address this uncertainty, in early 2020 we began to utilize our hospital based sales force to call upon approximately 6,000 high prescriber community doctors in an effort to potentially increase our penetration rates in the community setting while maintaining sales efforts in the hospital setting.

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

We have a limited sales, marketing, patient access and distribution infrastructure, and as a company we have limited experience in the sale, marketing or distribution of pharmaceutical products and XENLETA is the first product that we are commercializing. To achieve commercial success for XENLETA and any other approved product, we must either maintain an adequate sales, marketing, commercial operations, patient access and distribution organization or outsource these functions to third parties. We are currently commercializing XENLETA in the United States with our own targeted sales and marketing organization. In addition, we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize XENLETA in markets outside the United States. We plan to commercialize CONTEPO, if approved, on our own in the United States with the same commercial organization and targeted sales force, but we do not have the right to commercialize CONTEPO in any markets outside the United States.

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

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

- our inability to recruit, train and retain adequate numbers of effective sales, patient access, commercial operations and marketing personnel;

- our inability to recruit, train and retain adequate numbers of effective headquarter and field personnel;

- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe XENLETA or any future products and to have hospitals include XENLETA on hospital formularies;

- the lack of complementary products to be offered by sales personnel, which may put our sales representatives at a competitive disadvantage relative to sales representatives from companies with more extensive product lines;

- unforeseen costs and expenses associated with creating an independent sales, marketing, commercial operations, patient access and distribution organization; and

- a change in strategy resulting in the decrease or elimination of sales personnel.

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

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

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

There are a variety of available therapies marketed for the treatment of CABP and cUTI. Currently the treatment of CABP and cUTI is dominated by generic products. For hospitalized patients, combination therapy is frequently used in both CABP and cUTI. Many currently approved drugs are well-established therapies and are widely accepted by physicians, patients, medical association guidelines and third-party payors for the treatment of CABP. We also are aware of various drugs under development or recently approved by the FDA for the treatment of CABP. In June 2019, the FDA approved delafloxacin (marketed by Melinta) for the treamtment of CABP. We also are aware of various drugs under development for the treatment of CABP, including omadacycline which was launched in February 2019 by Paratek Pharmaceuticals Inc., and oral nafithromycin which is in Phase 2 clinical development by Wockhardt Ltd. If approved, we expect CONTEPO will face competition from commercially available antibiotics such as ceftazidime-avibactam, meropenem-vaborbactam, tigecycline, plazomicin, cefiderocol, from other product candidates currently in development for the treatment of cUTI, including AP, such as imipenem-relebactam (under Phase 3 clinical development by Merck), ETX0282-cefpodoxime proxetil (under development by Entasis Therapeutics), and LYS228 (under development by Boston Pharma), as well as generically available agents including carbapenems, aminoglycosides, and polymyxins.

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

product candidates are likely to be their efficacy, safety, convenience, price acceptance on hospital formularies and the availability of coverage and reimbursement from government and other third-party payors.

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

XENLETA, CONTEPO or any other product candidate may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

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

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

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs – particularly in the hospital - coverage may be more limited than the purposes for which the drug is approved by the applicable regulatory authority. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of

drugs from countries where they may be sold at lower prices than in the United States. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. In the European Union, reference pricing systems and other measures may lead to cost containment and reduced prices. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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

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

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

We maintain clinical trial liability insurance that covers bodily injury to patients participating in our clinical trials up to a $10.0 million annual aggregate limit and subject to a per event deductible. This amount of insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our product liability insurance coverage due to the FDA approval of XENLETA and potential approval of CONTEPO. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in the Medicaid Drug Rebate Program and a number of other federal and state government pricing programs in the United States in order to obtain coverage for XENLETA by certain government healthcare programs. These programs generally require us to pay rebates or provide discounts to certain private purchasers or government payers in connection with our products when dispensed to beneficiaries of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing and rebate calculations that we report on a monthly and quarterly basis to the government agencies that administer the programs. The terms, scope and complexity of these government pricing programs change frequently. We may also have reimbursement obligations or be subject to penalties if we fail to provide timely and accurate information to the government, pay the correct rebates or offer the correct discounted pricing. Changes to the price reporting or rebate requirements of these programs would

affect our obligations to pay rebates or offer discounts. Responding to current and future changes may increase our costs and the complexity of compliance, will be time-consuming, and could have a material adverse effect on our results of operations.

Risks Related to Our Dependence on Third Parties

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

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

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

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

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

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

- reliance on the third party for regulatory compliance and quality assurance;

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

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

In April 2019, the FDA issued a Complete Response Letter in connection with our NDA for CONTEPO for the treatment of cUTIs, including AP, stating that it was unable to approve the application in its current form. Specifically, the Complete Response Letter requested us to address issues related to facility inspections and manufacturing deficiencies at our API contract manufacturer prior to the FDA approving the NDA. In December 2019, we resubmitted the NDA for CONTEPO. The FDA has accepted our application and scheduled the PDUFA date for June 19, 2020. In addition to the facility inspections and manufacturing deficiencies at our API contract manufacturer that were identified in the Complete Response Letter we received from the FDA in connection with our NDA for CONTEPO, we have also been made aware that another one of our third-party manufacturers is currently subject to an open FDA Form 483, which relates to the IV fosfomycin that the third-party manufacturer is supplying to another company. If these manufacturering issues are not resolved to the FDA's satisfaction prior to the PDUFA date for CONTEPO, or if we or any of our third-party manufacturers or suppliers are the subject of any other open or unresolved regulatory inspections, inspection reports or FDA Form 483s identifying noncompliance with applicable regulations, we would be delayed in obtaining or fail to obtain regulatory approval of our product candidates, including CONTEPO.

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

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

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

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

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

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

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

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

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

We are commercializing XENLETA and, expect to commercialize CONTEPO, if approved, in the United States with our own targeted sales and marketing organization. Outside the United States, we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize XENLETA. For example, we have entered into a license agreement with Sinovant pursuant to which we granted Sinovant certain rights to manufacture and commercialize XENLETA in the People's Republic of China, Hong Kong, Macau and Taiwan and we have also entered into a license agreement with Sunovion pursuant to which we granted Sunovion certain rights to commercialize XENLETA in Canada. We also may seek third-party collaborators for development and commercialization of other product candidates or for XENLETA for indications other than CABP.

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

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

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

For example, under our license agreement with Sinovant, if any court, tribunal or governmental agency in the People's Republic of China, Hong Kong, Macau or Taiwan determines that the exclusive license granted to Sinovant pursuant to the license agreement is not sufficiently exclusive such that Sinovant does not have sufficient rights to enforce the licensed patent rights in such territories, we and our subsidiary, Nabriva Therapeutics GmbH, have agreed to

take such commercially reasonable steps as Sinovant reasonably requests to grant Sinovant such rights. If a court in such jurisdictions were to determine that our license to Sinovant was not sufficiently exclusive and that Sinovant did not have the rights to enforce the licensed patent rights in the licensed territories, Sinovant may require us to take such actions that it deems reasonable but that we do not and which may have a material adverse effect on our business, including requiring us to make changes to our organizational structure that may result in adverse tax and other consequences, or to conduct other activities that may cause us to incur significant expenses.

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

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

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

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

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

We enter into various contracts in the normal course of our business in which we agree to indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and

other research agreements, we typically agree to indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sub licensees' exercise of rights under the agreement. With respect to our commercial agreements, we have agreed to indemnify our vendors from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party. With respect to consultants, we typically agree to indemnify them from claims arising from the good faith performance of their services.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage or not covered by insurance, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator or other third party to indemnify us and the collaborator or other third party is denied insurance coverage or otherwise does not have assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

A widespread outbreak of an illness or other health issue, such as the Coronavirus outbreak, could negatively affect various aspects of our business, including our supply chain, and make it more difficult and expensive to meet our obligations to our customers, and could result in reduced demand from our customers.

Our operations are susceptible to a widespread outbreak of an illness or other health issue, such as the recent outbreak of the coronavirus disease 2019 (COVID-19), or Coronavirus, resulting in thousands of confirmed cases in China and many additional cases identified in other countries, which may result in Coronavirus impacting countries in which we or our collaborators conduct business. The recent outbreak of Coronavirus has caused the Chinese government to implement quarantines and significant restrictions on travel. The Chinese government has also implemented work restrictions that prohibit many employees from going to work. These quarantines, travel bans, and other restrictions have been put in place on a national level. In addition, many countries have placed significant bans on travel to and from China, with many countries and airlines suspending flights to and from mainland China.

As a result of illness outbreaks, including Coronavirus, businesses can be shut down, supply chains can be interrupted, slowed, or rendered inoperable, and individuals can become ill, quarantined, or otherwise unable to work and/or travel due to health reasons or governmental restrictions. This may negatively impact our community sales efforts as it could result in our sales force having limited access to our target hospitals and health care physician offices. Additionally, certain of the activities of our collaborator, Sinovant, have been delayed in China. If these delays continue and impact Sinovant's efforts to develop and commercialize lefamulin in China, our receipt of future milestone payments or potential royalties on sales of the Sinovant Licensed Products may be delayed. Portions of our supply chain extend through China and Europe. If Coronavirus continues to spread, this may affect the ability of our third-party manufacturers to supply XENLETA, CONTEPO or any future product candidates. We also expect that, in connection with its review of the NDA for CONTEPO, the FDA may inspect the facilities of our third-party manufacturers in Europe. On March 10, 2020, the FDA announced that it would restrict travel of its employees to Europe for inspections as a result of the spread of Coronavirus. As a result of this decision, the timing of the FDA's review of our NDA for CONTEPO may be delayed.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology, products and product candidates, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize technology, products and product candidates similar or identical to ours, and our ability to successfully commercialize our technology, products and 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 technology, products and product candidates. We seek to protect our proprietary position by filing patent applications in the United States, Europe and in certain additional foreign jurisdictions related to our novel technologies, products and product candidates that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects

of our research and development output before it is too late to obtain patent protection. Moreover, if we license technology, products or product candidates from third parties in the future, these license agreements may not permit us to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering this intellectual property. These agreements could also give our licensors the right to enforce the licensed patents without our involvement, or to decide not to enforce the patents at all. Therefore, in these circumstances, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. We also may not pursue or obtain patent protection in all major markets or may not obtain protection that enables us to prevent the entry of third parties onto the market. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our U.S. patents or pending U.S. patent applications, or that we were the first to file for patent protection of such inventions.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, reexamination, *inter partes* review, post grant review, interference proceedings or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology, products or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products or product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or

identical technology, products and product candidates, or limit the duration of the patent protection of our technology, products and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

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

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

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

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

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

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

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

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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

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

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

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

Our trademark applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

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

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

XENLETA, CONTEPO, and any other product candidates that we develop, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and, in the case of XENLETA, by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. On August 19, 2019, we received approval from the FDA to market the oral and intravenous formulations of XENLETA to treat CABP in the United States. We have not received approval to market XENLETA in any jurisdiction other than the United States or for any other indication, and we have not received approval to market CONTEPO or any of our other product candidates from regulatory authorities in any jurisdiction, and we do not intend to seek approval to market CONTEPO outside the United States. In April 2019, the FDA issued a Complete Response Letter in connection with our NDA for CONTEPO for the treatment of cUTIs, including AP, stating that it was unable to approve the application in its current form. Specifically, the Complete Response Letter requested us to address issues related to facility inspections and manufacturing deficiencies at our API contract manufacturer prior to the FDA approving the NDA. In December 2019, we resubmitted the NDA for CONTEPO. The FDA has accepted our application and scheduled the PDUFA date for June 19, 2020. In addition to the facility inspections and manufacturing deficiencies at our API contract manufacturer that were identified in the Complete Response Letter we received from the FDA in connection with our NDA for CONTEPO, we have also been made aware that another one of our third-party manufacturers is currently subject to an open FDA Form 483, which relates to the IV fosfomycin that the third-party manufactuer is supplying to another company. If these manufacturing issues are not resolved to the FDA's satisfaction prior to the PDUFA date for CONTEPO, or if we or any of our third-party manufacturers or suppliers are the subject of any other open or unresolved regulatory inspections, inspection reports or FDA Form 483s identifying noncompliance with applicable regulations, we would be delayed in obtaining or fail to obtain regulatory approval of our product candidates, including CONTEPO.

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

The process of obtaining marketing approvals is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application.

For example, on June 23, 2016, the electorate in the United Kingdom 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). Discussions between the United Kingdom and the European Union have so far mainly focused on finalizing withdrawal issues and transition agreements but have been extremely difficult to date. To date, only an outline of a trade agreement has been reached. Much remains open but the Prime Minister has indicated that the United Kingdom will not seek to extend the transitional period beyond the end of 2020. If no trade agreement has been reached before the end of the transitional period, there may be significant market and economic disruption. The Prime Minister has also indicated that the UK will not accept high regulatory alignment with the EU.

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. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

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

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

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

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

approvals in those countries or in any other countries, and marketing approvals and pricing approvals do not ensure that reimbursement will be obtained.

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

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

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

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

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

The FDA and other federal and state agencies, including the U.S. Department of Justice, or DOJ, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of such requirements may lead to investigations alleging violations of the Food, Drug and Cosmetic Act and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws. Accordingly, we may not promote XENLETA in the United States for use in any indications other than the treatment of CABP, and all promotional claims must be consistent with the FDA-approved labeling of XENLETA.

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

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

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

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

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

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

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

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

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

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

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

If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the FDA's goal to review an application is six months, rather than the standard review period of ten months. CONTEPO was granted priority review by the FDA, and we may also request priority review for other product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or thereafter.

Designation of CONTEPO as a Qualified Infectious Disease Product does not assure FDA approval of this product candidate.

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

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

We submitted an NDA for marketing approval of CONTEPO for the treatment of cUTI in adults in the United States in October 2018, and we resubmitted the NDA in December 2019, utilizing Section 505(b)(2) of the Food, Drug and Cosmetic Act, or the FDCA, which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

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

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

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

If the FDA does not conclude that CONTEPO, or any of our other product candidates for which we may utilize the 505(b)(2) pathway, satisfies the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates, including CONTEPO, under Section 505(b)(2) are not as we expect, the approval pathway for CONTEPO and any of our other product candidates for which we may utilize the 505(b)(2) pathway will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

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

In December 2016, the 21st Century Cures Act, or the Cures Act was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

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

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

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any of our products, including XENLETA, and product candidates, including CONTEPO, for which we obtain marketing approval. Our future arrangements with healthcare providers, physicians and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute XENLETA and any other products for which we obtain marketing approval. Restrictions under applicable federal, state, and foreign healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at a minimum of $11,181 and a maximum of $22,363 per false claim;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians and teaching hospitals, with data collection beginning in August 2013; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, and foreign anti-corruption laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers.

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

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our

operations could adversely affect our financial results. We have developed and implemented a corporate compliance program designed to ensure that we will market and sell any approved products in compliance with all applicable laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

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

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA. Among the provisions of the ACA of potential importance to our business and our product candidates are the following:

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

- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report product samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in April 2013 and, due to subsequent legislative amendments to the statutes, will stay in effect through 2029 unless additional Congressional action is taken, and the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

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

Congress has repeatedly tried to repeal, replace and amend the ACA in recent years. With enactment of the legislation commonly referred to as the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the “individual mandate” for the ACA. The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” The Congress may consider other legislation to replace elements of the ACA during the next Congressional session.

The Trump Administration has also taken executive actions to undermine or delay implementation of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys Generals filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled

that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. This decision is under review by the U.S. Supreme Court during its current term. The full effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

In addition, the Centers for Medicare & Medicaid Services, or CMS, has proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. On November 30, 2018, CMS announced a proposed rule that would amend the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the proposed rule changes would allow Medicare Advantage plans to use pre authorization, or PA, and step therapy, or ST, for six protected classes of drugs, with certain exceptions, permit plans to implement PA and ST in Medicare Part B drugs; and change the definition of "negotiated prices" in the regulations. It is unclear whether these proposed changes will be accepted, and if so, what effect such changes will have on our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

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. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. The Trump Administration recently represented to the Court of Appeals considering this judgment that it does not oppose the lower court's ruling. On July 10, 2019, the Court of Appeals for the Fifth Circuit heard oral argument in this case. On December 18, 2019, that 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. On January 21, 2020, the U.S Supreme Court declined to review this decision on an expedited basis. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

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

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

examine which Medicare Part B drugs could be negotiated for a lower price by Part D plans, and improving the design of the Part B Competitive Acquisition Program; update Medicare's drug-pricing dashboard to increase transparency; prohibit Part D contracts that include "gag rules" that prevent pharmacists from informing patients when they could pay less out-of-pocket by not using insurance; and require that Part D plan members be provided with an annual statement of plan payments, out-of-pocket spending, and drug price increases. In addition, on December 23, 2019, the Trump Administration published a proposed rulemaking that, if finalized, would allow states or certain other non-federal government entities to submit importation program proposals to FDA for review and approval. Applicants would be required to demonstrate their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. At the same time, FDA 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 authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

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

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

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

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

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the trade control laws.

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

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

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

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

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

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

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

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

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

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from computer viruses, 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, third-party vendors and/or business partners, or from cyber-attacks by malicious third parties. 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, unauthorized access to or deletion of files, social engineering and other means to affect the service reliability and threaten the confidentially, 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.

System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our drug development programs and commercialization activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our product research, development and commercialization efforts could be delayed.

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

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

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

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

Risks Related to Our Acquisition of Zavante

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

On July 24, 2018, we completed the Acquisition, of Zavante pursuant to the Merger Agreement. Our ability to realize the anticipated benefits of the Acquisition will depend, to a large extent, on our ability to integrate Zavante and CONTEPO into our business and business strategy and realize anticipated growth opportunities and synergies. The integration process has been, and we expect will continue to be, complex, costly and time-consuming. As a result, we

have been, and in the future will be, required to devote significant management attention and resources to integrating Zavante into our business and CONTEPO into our business strategy. The integration process may be disruptive to our business and the expected benefits may not be achieved within the anticipated time frame, or at all. The failure to meet the challenges involved and to realize the anticipated benefits of the Acquisition could cause an interruption of, or a loss of momentum in, our development and commercialization efforts, including with respect to XENLETA and CONTEPO, and could adversely affect our business, financial condition and results of operations.

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

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

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

Upfront consideration for the Acquisition was comprised of 8,152,092 of our ordinary shares, including the 815,186 ordinary shares that were initially held back but which were issued in July 2019 upon release of the Holdback Shares pursuant to the terms of the Merger Agreement. Pursuant to the Merger Agreement, former Zavante stockholders are also entitled to receive from us, subject to the terms and conditions of the Merger Agreement, up to $97.5 million in contingent consideration, of which $25.0 million would become payable upon the first approval of a new drug application from the FDA, for CONTEPO for any indication, or the Approval Milestone Payment, and an aggregate of up to $72.5 million would become payable upon the achievement of specified net sales milestones, or the Net Sales Milestone Payments, with the first commercial milestone becoming payable when CONTEPO exceeds $125.0 million in net sales in a calendar year. At our Extraordinary General Meeting of Shareholders held in October 2018, our shareholders approved the issuance of ordinary shares in settlement of potential milestone payment obligations that may

become payable in the future to former Zavante stockholders, including the Approval Milestone Payment which will be settled in our ordinary shares. We also now have the right to settle the Net Sales Milestone Payments in ordinary shares, except as otherwise provided in the Merger Agreement. The issuance of our ordinary shares in connection with the closing of the Acquisition was dilutive to our existing shareholders, and the future issuance of our ordinary shares to satisfy our milestone payment obligations would be further dilutive to our then existing shareholders.

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

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

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

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

Risks Related to Employee Matters

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

We are highly dependent on the principal members of our management and commercial teams. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain “key person” insurance on any of our

executive officers. The unplanned loss of the services of any of these persons might impede the achievement of our research, development and commercialization objectives.

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

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

We have significantly increased the number of our employees and the scope of our operations, particularly in the areas of technical operations, supply chain, medical affairs and sales and marketing and we may continue to add staff to these areas. To manage any possible future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. In addition, our growth in connection with the Acquisition, including expansion of our business operations in connection with the Acquisition, has imposed added responsibilities on members of our management, including the need to recruit, hire, retain, motivate and integrate additional employees and business operations.

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

Risks Related to Ownership of Our Ordinary Shares

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

Our ordinary shares began trading on the Nasdaq Global Market on June 26, 2017. Given the limited trading history of our ordinary shares, there is a risk that an active trading market for our ordinary shares will not be sustained, which could put downward pressure on the market price of our ordinary shares and thereby affect the ability of our security holders to sell their shares.

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

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

- our ability to successfully commercialize the oral and intravenous formulations of XENLETA for the treatment of CABP and the intravenous formulation of CONTEPO, if approved;
- our ability to successfully implement our proposed business strategy;
- the success of competitive products or technologies;

- results of clinical trials of our product candidates or those of our competitors;
- regulatory delays and greater government regulation of potential products due to adverse events;
- regulatory or legal developments in the United States, the European Union and other countries or regions;
- 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 discover, develop, acquire or in-license additional product candidates or products;
- one or more of our manufacturers or suppliers could have an event which causes an unforeseen disruption of the manufacture or supply of our product candidates;
- our ability to comply with the restrictive covenants under our Loan Agreement and avoid an event of default that may lead to an acceleration of the amounts due under the Loan Agreement;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- perception and market performance of companies that are perceived to be similar to us:
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- activism by any single large shareholder or combination of shareholders;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation has often been instituted against that company. We also may face securities class-action litigation if we cannot obtain regulatory approvals for or if we otherwise fail to successfully commercialize XENLETA, CONTEPO if approved, or any of our other product candidates or if our securities experience volatility for any reason. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management’s attention and resources. For example, we and our Chief Executive Officer, Chief Medical Officer and Chief Financial Officer have been named as defendants in a purported class action lawsuit following our announcement in April 2019 that the FDA issued a Complete Response Letter in connection with our NDA for CONTEPO for injection for the treatment of cUTIs, including AP, stating that it was unable to approve the application in its current form. See *“—Risks Related to Our Financial Position and Need for Additional Capital— We and our Chief Executive Officer, Chief Medical Officer and Chief Financial Officer have been named as defendants in a lawsuit that could result in substantial costs and divert management’s attention.*”

The number of shares of ordinary shares underlying our outstanding warrants is significant in relation to our currently outstanding ordinary shares, which could have a negative effect on the market price of our ordinary shares and make it more difficult for us to raise funds through future equity offerings.

As part of our December 2019 registered direct offering, we issued warrants to purchase an aggregate of up to 13,793,106 shares of ordinary shares at an exercise price of $1.90 per share. As of December 31, 2019, all of these warrants remained outstanding and, upon exercise in full of these warrants, the shares issuable upon exercise would represent a significant portion of our outstanding ordinary shares. Each warrant is initially exercisable six months following the date of issuance, which was December 24, 2019, and will expire on the three-year anniversary of the date on which such warrants became initially exercisable. We have registered the issuance of shares upon exercise of these warrants under a registration statement under the Securities Act of 1933, as amended, and, accordingly, such shares can be freely sold into the public market upon issuance, subject to volume limitations applicable to affiliates. Sales of these shares could cause the market price of our ordinary shares to decline significantly. Furthermore, if our share price rises, the holders of these warrants may be more likely to exercise their warrants and sell a large number of shares, which could negatively impact the market price of our ordinary shares and reduce or eliminate any appreciation in our share price that might otherwise occur.

We may also find it more difficult to raise additional equity capital while these warrants are outstanding. At any time during which these warrants are likely to be exercised, we may be unable to obtain additional equity capital on more favorable terms from other sources. In addition, the exercise of these warrants would result in a significant increase in the number of our outstanding ordinary shares, which could have the effect of significantly diluting the interest of our current shareholders, and following such exercise the former holders of such warrants could have significant influence over our company as a result of the ordinary shares they acquire upon such exercise.

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

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

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

Sales of a substantial number of our ordinary shares, or the perception in the market that these sales could occur, could reduce the market price of our ordinary shares. We had 94,545,116 ordinary shares outstanding as of December 31, 2019. To the extent any of these shares are sold into the market, particularly in substantial quantities, the market price of our ordinary shares could decline.

Future issuances of ordinary shares pursuant to our equity incentive plans could also result in a reduction in the market price of our ordinary shares. We have filed registration statements on Form S-8 registering all of the ordinary shares that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance and once vested, subject to volume, notice and manner of sale limitations applicable to affiliates. The majority of ordinary shares that may be issued under our equity compensation plans remain subject to vesting in tranches over a four-year period. As of December 31, 2019, an aggregate of 3,406,233 options to purchase our ordinary shares had vested and become exercisable although these options all have an exercise price that is higher than the recent market trading prices of our ordinary shares.

In addition, on June 25, 2019 we entered into the Jefferies ATM Agreement with Jefferies, as agent, pursuant to which we may offer and sell ordinary shares for aggregate gross sale proceeds of up to $50.0 million from time to time through Jefferies under an “at-the-market” offering program. As of the date of this filing, we have issued and sold an aggregate of 6,505,268 ordinary shares under the Jefferies ATM Agreement, for gross proceeds of $14.4 million, and net proceeds of $13.6 million, after deducting commissions and offering costs. We previously entered into the Cantor ATM Agreement with Cantor Fitzgerald & Co. that we terminated effective as of June 24, 2019. As of the effective date of the

termination of the Cantor ATM Agreement, we had issued and sold an aggregate of 10,316,190 of our ordinary shares pursuant to the Cantor ATM Agreement for aggregate gross proceeds of $37.8 million and net proceeds to us of $36.3 million, after deducting commissions and offering expenses payable by us.

Moreover, as part of our December 2019 registered direct offering, we issued warrants to purchase an aggregate of up to 13,793,106 shares of ordinary shares at an exercise price of $1.90 per share. As of December 31, 2019, all of these warrants remained outstanding and, upon exercise in full of these warrants, the shares issuable upon exercise would represent a significant portion of our outstanding ordinary shares. Each warrant is initially exercisable six months following the date of issuance, which was December 24, 2019, and will expire on the three-year anniversary of the date on which such warrants became initially exercisable. We have registered the issuance of shares upon exercise of these warrants under a registration statements under the Securities Act of 1933, as amended, and, accordingly, such shares can be freely sold into the public market upon issuance, subject to volume limitations applicable to affiliates. Sales of these shares, or the perception that sales of these shares could occur, could cause the market price of our ordinary shares to decline significantly. Furthermore, if our share price rises, the holders of these warrants may be more likely to exercise their warrants and sell a large number of shares, which could negatively impact the market price of our ordinary shares and reduce or eliminate any appreciation in our share price that might have otherwise occurred.

If a large number of our ordinary shares are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our ordinary shares and impede our ability to raise future capital.

Upfront consideration for the Acquisition was comprised of 8,152,092 of our ordinary shares, including 815,186 ordinary shares that were initially held back but which were issued in July 2019 upon release of the Holdback Shares pursuant to the terms of the Merger Agreement. Such shares are able to be freely sold in the public market, subject to any requirements and restrictions, including any applicable volume limitations, imposed by Rule 144 under the Securities Act. In addition, the Merger Agreement provides that we may issue up to an additional $97.5 million in our ordinary shares to former Zavante stockholders upon the achievement of specified regulatory and commercial milestones in the future, and obligates us to provide registration rights with respect to the registration for resale of such additional ordinary shares that may become issuable upon the achievement of such milestones.

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

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

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

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

- exemptions from the requirements to obtain a non-binding advisory vote on executive compensation or a shareholder approval of any golden parachute arrangements.

We may choose to take advantage of some, but not all, of the available exemptions. We may take advantage of these provisions until December 31, 2020 or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earlier to occur of: the last day of the fiscal year in which we have more than $1.07 billion (as may be inflation-adjusted by the SEC from time-to-time) in annual revenues; the date we qualify as a “large accelerated filer,” with more than $700 million in market value of our share capital held by non-affiliates; or the issuance by us of more than $1 billion of non-convertible debt over a three-year period.

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

We are also a "smaller reporting company" as defined in Rule 12b-2 promulgated under the Exchange Act. We may remain a smaller reporting company until we have a non-affiliate public float in excess of $250 million and annual revenues in excess of $100 million, or a non-affiliate public float in excess of $700 million, each as determined on an annual basis. Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements.

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

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

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

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

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

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

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

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, as an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm until we are no longer an emerging growth company. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

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

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

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

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

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

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

We are exposed to risks related to currency exchange rates.

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

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

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

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

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

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

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

In addition, our articles of association authorize us to issue, without the approval of our shareholders, one or more classes or series of preferred shares having such designation, powers, preferences and relative, participating, optional and other special rights, including preferences over our ordinary shares respecting dividends and distributions, as our board of directors generally may determine. The terms of one or more classes or series of preferred shares could dilute the voting power or reduce the value of our ordinary shares. Similarly, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred shares could affect the residual value of the ordinary shares. Additionally, we may issue and sell our ordinary shares under our Jefferies ATM Agreement from time to time, and we may issue additional ordinary shares as contingent consideration upon the achievement of certain regulatory and commercialization milestones, subject to the terms and conditions of the Merger Agreement. See *"—Risks Related to Ownership of our Ordinary Shares —Substantial future sales of our ordinary shares in the public market, or the perception that these sales could occur, could cause the price of our ordinary shares to decline significantly, even if our business is doing well."*

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

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

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

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

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

We are subject to the Irish Takeover Panel Act, 1997, Takeover Rules, 2013. Under those Irish Takeover Rules, the board is not permitted to take any action that might frustrate an offer for our ordinary shares once the board has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as (i) the issue of ordinary shares, options or convertible securities, (ii) material acquisitions or disposals, (iii) entering into contracts other than in the ordinary course of business or (iv) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which the board has reason to believe an offer is or may be imminent. These provisions may give the board less ability to control negotiations with hostile offerors and protect the interests of holders of ordinary shares than would be the case for a corporation incorporated in a jurisdiction of the United States.

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

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

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

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

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

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

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

The IRS may not agree with the conclusion that we should be treated as a foreign corporation for U.S. federal tax purposes.

Although we are incorporated in Ireland, the IRS may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal tax purposes pursuant to Section 7874 of the Code. For U.S. federal tax purposes, a corporation generally is considered a tax resident in the jurisdiction of its organization or incorporation. Because we are an Irish incorporated entity, we would be classified as a foreign corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 of the Code provides an exception under which a foreign incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal tax purposes. New statutory and/or regulatory provisions under Section 7874 of the Code or otherwise could be enacted that adversely affect our status as a foreign corporation for U.S. federal tax purposes, and any such provisions could have prospective or retroactive application to us and our shareholders.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage points change (by value) in the ownership of its equity by certain significant shareholders over a rolling three year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future and/or subsequent shifts in our stock ownership, some of which would be outside our control. If our ability to use our net operating losses and other tax attributes is limited by ownership changes, we may be unable to utilize a material portion of our net operating losses and other tax attributes.

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

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

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

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

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

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

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

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

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

Irish capital acquisitions tax, or CAT, could apply to a gift or inheritance of our ordinary shares irrespective of the place of residence, ordinary residence or domicile of the parties. This is because our ordinary shares will be regarded as property situated in Ireland. The person who receives the gift or inheritance has primary liability for CAT. Gifts and inheritances passing between spouses are exempt from CAT. Children have a tax-free threshold of €335,000 in respect of taxable gifts or inheritances received from their parents.

Our business and operations could be negatively affected if we become subject to shareholder activism, which could cause us to incur significant expense, hinder execution of our business strategy and impact our stock price.

Shareholder activism, which takes many forms and arises in a variety of situations, has been increasingly prevalent. If we become the subject of certain forms of shareholder activism, such as proxy contests, the attention of our management and our board of directors may be diverted from execution of our business strategy. Such shareholder activism could give rise to perceived uncertainties as to our future strategy, adversely affect our relationships with business partners and make it more difficult to attract and retain qualified personnel. Also, we may incur substantial costs, including significant legal fees and other expenses, related to activist shareholder matters. Our stock price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any shareholder activism.

We may be classified as a passive foreign investment company for one or more of our taxable years, which may result in adverse U.S. federal income tax consequence to U.S. holders.

A corporation organized outside the United States generally will be classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes (1) in any taxable year in which (A) at least 75% of its gross income is passive income or (B) on average at least 50% of the gross value of its assets is attributable to assets that produce passive income or are held for the production of passive income, and (2) as to a given holder who was a holder in such taxable year and regardless of such corporation's income or asset composition, in any subsequent taxable year, unless certain elections are made by that holder that allow the holder to discontinue that classification as to that holder, generally at a substantial tax cost to that holder. Passive income for this purpose generally includes dividends, interest, royalties, rents and gains from commodities and securities transactions and from sales of property that produced, or was held for the production of, passive income (or no income).

Based on our gross income and average value of our gross assets for each relevant taxable year, and given the nature of our business, we do not believe that we were a "passive foreign investment company," or PFIC, for U.S. federal income tax purposes for any such taxable year from our initial public offering through the year ended December 31, 2019. Our status in any taxable year (determined without regard to our status in any prior taxable year) will depend

on our assets and activities in that year, and because this is a factual determination made annually after the end of the year, there can be no assurance that we will not be considered a PFIC for the current taxable year or any other taxable year. In particular, in many cases the gross value of our assets may be inferred from the market price of our ordinary shares, which may fluctuate considerably given that market prices of biotechnology companies can be especially volatile. In other cases, factors external to our specific circumstances may make the presumptive relationship between the gross value of our assets and our market capitalization unreliable, in which case the gross value of our individual assets, based upon valuation methods suitable for use in U.S. federal tax matters (the choice of which may vary from taxable year to taxable year), will govern the determination of our status.

If we were to be treated as a PFIC for the taxable year ending December 31, 2019, or any other taxable year during which a U.S. holder held or holds our ordinary shares, certain adverse U.S. federal income tax consequences could apply to the U.S. holder. We currently intend to make available the information necessary to permit a U.S. holder to make a valid qualified electing fund, or QEF, election, which may mitigate some of the adverse U.S. federal income tax consequences that could apply to a U.S. holder of ordinary shares if it is determined that we are a PFIC for a given taxable year. However, we may choose not to provide such information at a future date.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Facilities

Our facilities consist of approximately 2,900 square meters of leased laboratory and office space in Vienna, Austria. We lease approximately 15,000 square feet of office space in King of Prussia, Pennsylvania. We also lease office space in Dublin, Ireland and San Diego, California. We believe that suitable additional or alternative space will be available in the future on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

On May 8, 2019, a putative class action lawsuit was filed against the Company and its Chief Executive Officer in the United States District Court for the Southern District of New York, captioned Larry Enriquez v. Nabriva Therapeutics PLC, and Ted Schroeder, No. 19-cv-04183. The complaint purported to be brought on behalf of shareholders who purchased the Company's securities between November 1, 2018 and April 30, 2019. The complaint generally alleged that the Company and its Chief Executive Officer violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements and omitting to disclose material facts concerning the Company's submission of an NDA to the FDA for marketing approval of CONTEPO for the treatment of cUTI in the United States and the likelihood of such approval. The complaint sought unspecified damages, attorneys' fees, and other costs.

On May 22, 2019, a second putative class action lawsuit was filed against the Company and its Chief Executive Officer in the United States District Court for the Southern District of New York, captioned Anthony Manna v. Nabriva Therapeutics PLC, and Ted Schroeder, No. 19-cv-04713. The complaint purported to be brought on behalf of shareholders who purchased the Company's securities between November 1, 2018 and April 30, 2019. The allegations made in the Manna complaint were similar to those made in the Enriquez complaint, and the Manna complaint sought similar relief. On May 24, 2019, these two lawsuits were consolidated by the court. The court appointed a lead plaintiff and approved plaintiff's selection of lead counsel on July 22, 2019.

On September 23, 2019, plaintiff filed an amended complaint, adding the Company's Chief Financial Officer and Chief Medical Officer as defendants; the amended complaint purports to be brought on behalf of shareholders who purchased the Company's securities between January 4, 2019 through April 30, 2019, and otherwise includes allegations similar to those made in the original complaints and seeks similar relief. The Company's pre-motion letter to dismiss the amended complaint was due to plaintiff on October 21, 2019, and plaintiff responded to the Company via a letter on

November 4, 2019. On November 18, 2019, the Company filed a pre-motion letter to dismiss with the Court, seeking leave to move to dismiss and setting forth why a motion to dismiss is warranted.

The Company denies any and all allegations of wrongdoing and intends to vigorously defend against this lawsuit. The Company is unable, however, to predict the outcome of this matter at this time. Moreover, any conclusion of this matter in a manner adverse to the Company and for which it incurs substantial costs or damages not covered by the Company's directors' and officers' liability insurance would have a material adverse effect on its financial condition and business. In addition, the litigation could adversely impact the Company's reputation and divert management's attention and resources from other priorities, including the execution of its business plan and strategies that are important to the Company's ability to grow its business, any of which could have a material adverse effect on the Company's business.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

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

Stockholders

As of January 31, 2020, there were 32 holders of record of our ordinary shares. The number of record holders may not be representative of the number of beneficial owners because many of our ordinary shares are held by depositories, brokers or other nominees.

Securities Authorized for Issuance Under Equity Compensation Plans

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

Dividend Policy

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

Recent Sales of Unregistered Securities

We did not sell any of our equity securities or any options, warrants, or rights to purchase our equity securities during the year ended December 31, 2019 that were not registered under the Securities Act of 1933, as amended, or the Securities Act, and that have not otherwise been described in a Current Report on Form 8-K or a Quarterly Report on Form 10-Q.

Purchase of Equity Securities

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

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below for the years ended December 31, 2017, 2018 and 2019 and as of December 31, 2018 and 2019 have been derived from our audited consolidated financial statements which have been prepared in accordance with generally accepted accounting practices in the United States and included elsewhere in this Annual Report. Financial data set forth below for the years ended December 31, 2015 and 2016 and as of December 31, 2015, 2016 and 2017 have been derived from the audited consolidated financial statements not included in this Annual Report. The following selected consolidated financial data should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and the notes thereto included elsewhere in this Annual Report on Form 10-K. The selected financial data in this section

are not intended to replace our consolidated financial statements and the related notes. Our historical results are not necessarily indicative of the results that may be expected in the future.

(in thousands)	Year ended December 31, 2015	2016	2017	2018	2019
Consolidated Operations Data:					
Revenues	$ 3,767	$ 6,482	$ 5,319	$ 9,656	$ 9,481
Operating Expenses:					
Cost of product sales	—	—	—	—	(70)
Research and development	(23,604)	(47,994)	(49,615)	(82,288)	(26,415)
Selling, general and administrative	(7,921)	(13,535)	(29,472)	(41,743)	(62,485)
Total operating expenses	(31,525)	(61,529)	(79,087)	(124,031)	(88,970)
Loss from operations	**(27,758)**	**(55,047)**	**(73,768)**	**(114,375)**	**(79,489)**
Other income (expense):					
Other income (expense), net	2,427	(783)	492	(272)	215
Interest income	14	343	318	49	255
Interest expense	(22,092)	(75)	(43)	(133)	(3,644)
Loss before income taxes	**(47,409)**	**(55,562)**	**(73,001)**	**(114,731)**	**(82,663)**
Income tax (expense) benefit	445	672	(1,355)	(49)	(101)
Net Loss	**$ (46,964)**	**$ (54,890)**	**$ (74,356)**	**$ (114,780)**	**$ (82,764)**
Loss per share					
Basic and Diluted	$ (4.80)	$ (2.56)	$ (2.49)	$ (2.26)	$ (1.12)
Weighted average number of shares:					
Basic and Diluted	10,583,950	21,478,320	29,830,669	50,795,768	74,199,482

(in thousands)	As of December 31, 2015	2016	2017	2018	2019
Consolidated Balance Sheet Data:					
Cash and cash equivalents, restricted cash and short-term investments	$ 111,440	$ 83,884	$ 86,879	$ 102,228	$ 86,586
Total assets	117,711	93,240	95,763	110,418	94,113
Long-term liabilities	84	107	435	23,982	36,200
Total liabilities	9,005	15,984	13,695	41,788	52,839
Accumulated deficit	(171,426)	(204,842)	(279,198)	(393,978)	(476,742)
Total stockholder’s equity	108,706	77,256	82,068	68,630	41,274

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

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

Overview

We are a biopharmaceutical company engaged in the research, development and commercialization of novel anti-infective agents to treat serious infections. In August 2019, our first product was approved by the U.S. Food and Drug Administration, or FDA, and we made it available in the United States in September 2019 under the brand name XENLETA. XENLETA (lefamulin) is a first-in-class semi-synthetic pleuromutilin antibiotic for systematic administration in humans discovered and developed by our team. It inhibits the synthesis of bacterial protein, which is required for bacteria to grow by binding with high affinity, high specificity and at molecular targets that are different than other antibiotic classes. Based on results from two global, Phase 3 clinical trials, we believe that XENLETA is well-positioned for use as a first-line monotherapy for the treatment of CABP due to its novel mechanism of action, targeted spectrum of activity, resistance profile, achievement of substantial drug concentration in lung tissue and fluid, availability of oral and intravenous, or IV, formulations and a generally well-tolerated safety profile. We believe XENLETA represents a potentially important new treatment option for the five to six million adults in the United States diagnosed with CABP each year.

We currently have a team of regional business directors and medical science liaisons in the field performing educational and market development activities. In connection with our commercial launch of XENLETA, we hired a targeted hospital-based sales force to promote XENLETA which we also intend to utilize to market CONTEPO, if approved.

We also submitted a marketing authorization application, or MAA, for XENLETA for the treatment of CABP in adults in Europe in May 2019. On June 24, 2019, we announced that the European Medicines Agency, or the EMA, determined that our MAA for XENLETA is valid. Validation of the MAA confirms that the submission is sufficiently complete to begin the formal review process and an opinion of the EMA Committee for Medicinal Products for Human Use (CHMP) is anticipated in the second half of 2020.

We submitted a new drug application, or NDA, for marketing approval of CONTEPO for the treatment of cUTI in adults in the United States, utilizing the FDA's 505(b)(2) pathway, in October 2018. The FDA has granted fast track designation to CONTEPO under the Generating Antibiotics Incentives Now Act, or the GAIN Act. In April 2019, the FDA issued a Complete Response Letter, or CRL, in connection with our NDA for CONTEPO for the treatment of cUTI, including AP, stating that is was unable to approve the application in its current form. Specifically, the CRL requested that we address issues related to facility inspections and manufacturing deficiencies at our API contract manufacturer. We held a "Type A" meeting with the FDA in July 2019 to discuss its findings and resubmitted our NDA seeking marketing approval for CONTEPO in December 2019. The FDA acknowledged the resubmission in January 2020 and has established a PDUFA date of June 19, 2020. However, we cannot predict when CONTEPO will receive marketing approval, if at all.

Since inception, we have incurred significant operating losses. As of December 31, 2019, we had an accumulated deficit of $476.7 million. To date, we have financed our operations primarily through equity offerings, convertible and term debt financings and research and development support from governmental grants and proceeds from our licensing agreements. We have devoted substantially all of our efforts to research and development, including clinical trials as well as preparing for the commercial launch of XENLETA. Our ability to generate profits from operations depends on our ability to successfully develop and commercialize drugs that generate significant revenue.

We expect to continue to incur significant expenses and have negative cash flows for at least the next several years. Our expenses will increase if we suffer any regulatory delays or are required to conduct additional clinical trials to satisfy regulatory requirements. If we obtain marketing approval for CONTEPO or any other product candidate that we develop, in-license or acquire, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Based on our current forecasts and plans, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional capital may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs and commercialization efforts.

Market conditions for antibiotic companies continue to be challenging as evidenced by the bankruptcy of two organizations engaged in the research and development and commercialization of antibiotics in 2019. The cost of capital has risen significantly for others and us. On December 20, 2019, we issued 13.8 million ordinary shares and 13.8 million warrants with an exercise price of $1.90 per share that generated gross proceeds of $20.1 million. In addition, on March 11, 2020, we entered into an amendment, or the Amendment, to our Loan and Security Agreement, or the Loan Agreement, with Hercules Capital, Inc., or Hercules, as administrative agent, collateral agent and lender. Pursuant to the Amendment, we agreed to repay to Hercules between April 1, 2020 and April 3, 2020, $30.0 million of the $35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement, which we refer to as the Prepayment. See "—Liquidity and Capital Resources."

On March 1, 2017, Nabriva Therapeutics plc, or Nabriva Ireland, was incorporated in Ireland under the name Hyacintho 2 plc, and was renamed to Nabriva Therapeutics plc on April 10, 2017, in order to effectuate the change of the jurisdiction of incorporation of the ultimate company of the group from Austria to Ireland. Nabriva Ireland replaced Nabriva Therapeutics AG, or Nabriva Austria, as the ultimate parent company on June 23, 2017, following the conclusion of a tender offer, or the Exchange Offer, in which holders of 98.6% of the outstanding share capital of Nabriva Austria exchanged their holdings for ordinary shares, $0.01 nominal value per share, of Nabriva Ireland, which we refer to as the Redomiciliation Transaction. The ordinary shares of Nabriva Ireland were issued on a one-for-ten basis to the holders of the Nabriva Austria common shares and on a one-for-one basis to the holders of the Nabriva Austria American Depositary Shares, or Nabriva Austria ADSs, participating in the Exchange Offer. On June 26, 2017, the ordinary shares of Nabriva Ireland began trading on the Nasdaq Global Market under the symbol "NBRV," the same symbol under which the Nabriva Austria ADSs were previously traded. This transaction was accounted for as a merger between entities under common control; accordingly, the historical financial statements of Nabriva Austria for periods prior to this transaction are considered to be the historical financial statements of Nabriva Ireland. As of August 18, 2017, 100% of Nabriva Austria share capital had been exchanged for ordinary shares of Nabriva Ireland.

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

Acquisition of Zavante

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

Upon the closing of the Acquisition, or the Closing, we issued 7,336,906 of our ordinary shares to former Zavante stockholders, which together with the 815,186 ordinary shares that were issued in July 2019 upon release of the Holdback Shares (as defined below) constituted approximately 19.9% of our ordinary shares outstanding as of immediately prior to the Closing, or the Upfront Shares.

Pursuant to the Merger Agreement, former Zavante stockholders and other equity holders, in the aggregate and subject to the terms and conditions of the Merger Agreement, will also be entitled to receive from us up to $97.5 million in contingent consideration, of which $25.0 million would become payable upon the first approval of an NDA from the FDA, for fosfomycin for injection for any indication, or the Approval Milestone Payment, and an aggregate of up to $72.5 million would become payable upon the achievement of specified sales milestones, or the Net Sales Milestone Payments with the first commercial milestone becoming payable when CONTEPO exceeds $125 million in net sales in a calendar year.

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

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

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

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

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

We expensed the acquired intellectual property as of the acquisition date as in-process research and development with no alternative future uses. For the year ended December 31, 2018, we recorded an in-process research and development expense of $32.0 million which represented $26.9 million for the fair value of the Upfront Shares, $4.9 million of transaction costs and $0.2 million of net liabilities assumed.

License Agreement with Sinovant Sciences, Ltd.

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

Under the Sinovant License Agreement, Sinovant and our subsidiaries have established a joint development committee, or the JDC, to review and oversee development and commercialization plans in the Sinovant Territory. We received a $5.0 million upfront payment pursuant to the terms of the Sinovant License Agreement and were initially eligible for up to an additional $91.5 million in milestone payments upon the achievement of certain regulatory and commercial milestone events related to lefamulin for CABP, plus an additional $4.0 million in milestone payments if any Sinovant Licensed Product receives a second or any subsequent regulatory approval in the People's Republic of China. The first milestone was a $1.5 million payment for the submission of a Clinical Trial Application, or CTA, by Sinovant to the Chinese Food and Drug Administration that was received in February 2019. We received an additional $5.0 million milestone payment from Sinovant in the third quarter of 2019 due to the receipt of approval for XENLETA from the FDA in August 2019. The remaining milestone payments of $86.5 million are tied to additional regulatory approvals and annual sales targets. In addition, we are eligible to receive low double-digit royalties on sales, if any, of Sinovant Licensed Products in the Sinovant Territory.

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

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

We identified two performance obligations at inception: (1) the delivery of the licenses to Sinovant; and, (2) the participation in the JDC. The $5.0 million non-refundable upfront payment was allocated entirely to the delivery of the licenses as the JDC deliverable was deemed to be de minimis. In addition, since the first $1.5 million milestone payment is related to a submission of the CTA that is in the control of the parties', we recorded such milestone as variable consideration allocated to the licenses at the inception of the arrangement as we believed it was probable to be met and payment was received in February 2019. The future regulatory and commercial milestone payments will be recorded during the period the milestone is probable of achievement.

License Agreement with Sunovion Pharmaceutics Canada Inc.

In March 2019, we entered into a license and commercialization agreement, or the Sunovion License Agreement, with Sunovion Pharmaceuticals Canada Inc., or Sunovion. As part of the Sunovion License Agreement,

Nabriva Therapeutics Ireland DAC, our wholly owned subsidiary, granted Sunovion an exclusive license under certain patent rights, trademark rights and know-how to commercialize certain products containing lefamulin in the forms clinically developed by us or any of our affiliates, or the Sunovion Licensed Products, in Canada in all uses in humans in community-acquired bacterial pneumonia and in any other indication for which the Sunovion Licensed Products have received regulatory approval in Canada.

We have identified the delivery of the exclusive license to Sunovion as the one material performance obligation at inception. We have determined that the Sunovion License Agreement provides for a distinct license of functional intellectual property that Sunovion has obtained control of. The non-refundable upfront payment of $1.0 million that we received in connection with the Sunovion License Agreement was allocated entirely to the delivery of the license.

Any future regulatory and commercial milestone payments under the Sunovion License Agreement will be recorded during the period the milestone is probable of achievement.

Financial Operations Overview

Revenue

In September 2019 we had our commercial launch of XENLETA. During 2019, we recorded $1.5 million of product revenues net as XENLETA was purchased by our wholesale customers. Future product revenues will be generated by the amount and frequency of reorders from our wholesale customers based on the ultimate consumption patterns from the end users of XENLETA. Our initial sales of XENLETA in the third quarter of 2019 exceeded our expectations for product availability at our distributors. Our distribution partners continue to primarily utilize their existing inventory to satisfy product demand which in turn impacted sales in the fourth quarter of 2019 and is expected to similarly impact sales during the first quarter of 2020.

Our revenue for the year ended December 31, 2019 included $5.0 million of collaboration revenues from the Sinovant License Agreement related to the approval of XENLETA, and our revenue for the year ended December 31, 2018 included a $5.0 million non-refundable upfront payment received as consideration for entering into the Sinovant License Agreement as well as $1.5 million of variable consideration related to a future milestone payment that we believed was probable to be met and was ultimately received in February 2019. Revenue also includes governmental research premiums, non-refundable government grants and the benefit of government loans at below-market interest rates, which are more fully described below under “Critical Accounting Policies”.

Research and Development Expenses

Research and development expenses represented 62.7%, 66.3% and 29.7% of our total operating expenses for the years ended December 31, 2017, 2018 and 2019, respectively.

For each of our research and development programs, we incur both direct and indirect expenses. Direct expenses include third party expenses related to these programs such as expenses for manufacturing services (prior to our products receiving FDA approval, after which time these costs are capitalized in inventory until product is sold), non-clinical and clinical studies and other third party development services. Indirect expenses include salaries and related costs, including stock-based compensation, for personnel in research and development functions, infrastructure costs allocated to research and development operations, costs associated with obtaining and maintaining intellectual property associated with our research and development operations, laboratory consumables, consulting fees related to research and development activities and other overhead costs. We utilize our research and development staff and infrastructure resources across multiple programs, and many of our indirect costs historically have not been specifically attributable to a single program. Accordingly, we cannot state precisely our total indirect costs incurred on a program-by-program basis.

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

(in thousands)	Year Ended December 31, 2018	2019
Direct Costs		
XENLETA	$ 20,685	$ 7,765
CONTEPO	3,423	2,977
NDA filing fee refund	—	(2,589)
Other programs and initiatives	53	1,412
Indirect Costs	26,079	16,850
In-process research and development	32,048	—
Total	**$ 82,288**	**$ 26,415**

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

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

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

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses represented 37.3%, 33.7% and 70.3% of our total operating expenses for the years ended December 31, 2017, 2018 and 2019 respectively.

Selling, general and administrative expenses consist primarily of salaries and related costs, including stock-based compensation not related to research and development activities for personnel in our finance, information technology, commercial, medical affairs and administrative functions. Selling, general and administrative expenses also

include costs related to professional fees for auditors, lawyers and tax advisors and consulting fees not related to research and development operations, as well as functions that are partly or fully outsourced by us, such as accounting, payroll processing and information technology.

We expect selling, general and general administrative expenses to increase in 2020 compared to 2019 related to the expansion of staff primarily related to our commercial sales force for the commercialization of XENLETA which took place in September 2019.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the end of the reporting period, as well as the reported revenues and expenses during the reporting periods. We base our estimates on our limited historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing at the end of this filing. However, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

Revenue Recognition

Under Accounting Standards Codification, or ASC, 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied as services are rendered.

The transaction price that we recognize as revenue reflects the amount we expect with the sale and transfer of control of the product to our customers. Once the customer takes control of the product, our performance obligation under the sale contract is complete and revenue is recorded net of applicable reserves for various types of variable consideration. The types of variable consideration are as follows and are further described in Note 2 in our Consolidated Financial Statements.

- Fees-for-service
- Product returns
- Chargebacks and rebates
- Government rebates
- Commercial payer and other rebates
- Group Purchasing Organizations ("GPO") administration fees
- Voluntary patient assistance programs

In determining the amounts of variable consideration, we must make significant judgments and estimates. In assessing the amount of net revenue to record, we consider both the likelihood and the magnitude of the revenue reversal. Actual amounts of consideration ultimately received may differ significantly from our estimates. If actual results in the future vary from our estimates, we adjust our estimates which would affect net product revenue and earnings in the period such variances become known.

Research Premium and Grant Revenue

As a company that carries out research and development activities, we benefit from the Austrian research and development support regime, under which we are eligible to receive a research premium from the Austrian government equal to 12% of a specified research and development cost base. Qualifying expenditures largely comprise research and development activities conducted in Austria, however, the research premium is also available for certain related third-party expenses with additional limitations. We recorded research premiums of $4.8 million, $2.6 million and $1.3 million for the years ended December 31, 2017, 2018, and 2019, respectively. We have not received any research premium for our qualified 2019 expenditures as of December 31, 2019. We recognize the research premium, as long as we have incurred research and development expenses. Significant judgment is required in determining which expenditures are eligible to be included in the research and development costs base and such costs are subject to review by the Austrian government.

Research and Development Expenses

Research expenses are defined as costs incurred for current or planned investigations undertaken with the prospect of gaining new scientific or technical knowledge and understanding. Development expenses are defined as costs incurred for the application of research findings or specialist knowledge to production, production methods, services or goods prior to the commencement of commercial production or use. We expense all research and development costs as incurred.

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with preclinical development activities;
- the production of preclinical and clinical trial materials;
- CROs in connection with clinical trials; and,
- investigative sites in connection with clinical trials.

Implications of Being an Emerging Growth Company

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

- an exemption from compliance with the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002 on the design and effectiveness of our internal controls over financial reporting;

- reduced disclosure about the company's executive compensation arrangements; and
- exemptions from the requirements to obtain a non-binding advisory vote on executive compensation or a shareholder approval of any golden parachute arrangements.

We may take advantage of these provisions until December 31, 2020. We would cease to be an emerging growth company upon the earlier to occur of: the last day of the fiscal year in which we have more than $1 billion in annual revenues (as may be inflation adjusted by the SEC from time-to-time); the date we qualify as a "large accelerated filer," with at least more than $700 million in market value of our share capital held by nonaffiliates; or the issuance by us of more than $1 billion of non-convertible debt over a three-year period. We may choose to take advantage of some, but not all, of the available benefits under the JOBS Act. We have taken advantage of some reduced reporting burdens in this Annual Report. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

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

We expect to incur increased costs once we no longer qualify as an emerging growth company due to the increased reporting requirements and requirement to obtain an auditor attestation report under Section 404 of the Sarbanes-Oxley Act.

Results of Operations

Comparison of Years Ended December 31, 2018 and 2019

(in thousands)	Year Ended December 31, 2018	2019	Change
Consolidated Operations Data:			
Revenues	$ 9,656	$ 9,481	$ (175)
Costs and Expenses:			
Cost of product sales	—	(70)	(70)
Research and development expenses	(82,288)	(26,415)	55,873
Selling, general and administrative expenses	(41,743)	(62,485)	(20,742)
Total operating expenses	(124,031)	(88,970)	35,061
Loss from operations	**(114,375)**	**(79,489)**	**34,886**
Other income (expense):			
Other income (expense), net	(272)	215	487
Interest income (expense), net	(84)	(3,389)	(3,305)
Loss before income taxes	**(114,731)**	**(82,663)**	**32,068**
Income tax expense	(49)	(101)	(52)
Net loss	**$ (114,780)**	**$ (82,764)**	**$ 32,016**

Revenues

Revenues decreased by $0.2 million from $9.7 million for the year ended December 30, 2018 to $9.5 million for the year ended December 31, 2019, primarily due to a $1.4 million decrease in research premiums and government grants provided to us by the Austrian government as a result of a decrease in our research and development expenses for which we can receive grant revenue and a $0.3 million decrease in collaboration revenue, partially offset by a $1.5 million increase in product revenue, net.

Cost of Product Sales

Cost of product sales primarily represents direct and indirect manufacturing costs of our XENLETA product. Prior to the FDA approval of XENLETA on August 19, 2019, the inventory costs for the product were expensed as research and development expenses since the approval was outside of our control and therefore not considered probable. As such, the majority of the expenses incurred for our initial inventories of XENLETA has been previously expensed. As a result, we anticipate that our cost of product sales will remain at relatively low levels for a period of time until our initial pre-launch inventory stock is sold by our customers based on end user consumption demand.

Research and Development Expenses

Research and development expenses decreased by $55.9 million from $82.3 million for the year ended December 31, 2018 to $26.4 million for the year ended December 31, 2019. The decrease was primarily due to a charge of $32.0 million for in-process research and development expenses associated with the acquisition of Zavante assets during the year ended December 31, 2018, a $4.6 million decrease in research consulting fees, a $8.1 million decrease of filing and other fees inclusive of a $2.6 million NDA filing fee refund for CONTEPO in 2019, a $10.6 million decrease in research materials and purchased services related to the development of lefamulin, a $1.2 million decrease in staff costs due to the reduction of employees and $0.1 million decrease in infrastructure and other expenses, partly offset by a $0.7 million increase in stock-based compensation expense.

Selling, General and Administrative Expenses

Selling, general and administrative expense increased by $20.7 million from $41.7 million for the year ended December 31, 2018 to $62.5 million for the year ended December 31, 2019. The increase was due to a $8.6 million increase in staffing expense, primarily for our commercial sales force in connection with the product launch of XENLETA in September 2019, a $5.9 million increase in advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees, a $3.9 million increase in stock-based compensation expense, a $1.1 million increase in legal fees, a $1.0 million increase in travel expenses, and a $0.6 million increase in infrastructure costs, partly offset by a $0.3 million decrease in other corporate costs.

Other Income (Expense), net

Other income (expense), net decreased by $0.5 million from $0.3 million of expense for the year ended December 31, 2018, to $0.2 million income for the year ended December 31, 2019 primarily due to re-measurements of our foreign currency cash balances.

Interest Income (Expense), net

During the year ended December 31, 2019, net interest expense increased over the prior year due to interest expense on our loan with Hercules that was entered into in December 2018.

Income Tax Expense

Our income tax expense was $49,000 for the year ended December 31, 2018 compared to $101,000 for the year ended December 31, 2019.

Comparison of Years Ended December 31, 2017 and 2018

(in thousands)	Year Ended December 31, 2017	2018	Change
Consolidated Operations Data:			
Revenues	$ 5,319	$ 9,656	$ 4,337
Costs and Expenses:			
Research and development expenses	(49,615)	(82,288)	(32,673)
Selling, general and administrative expenses	(29,472)	(41,743)	(12,271)
Total operating expenses	(79,087)	(124,031)	(44,944)
Loss from operations	**(73,768)**	**(114,375)**	**(40,607)**
Other income (expense):			
Other income (expense), net	492	(272)	(764)
Interest income (expense), net	275	(84)	(359)
Loss before income taxes	**(73,001)**	**(114,731)**	**(41,730)**
Income tax benefit	(1,355)	(49)	1,306
Net loss	**$ (74,356)**	**$ (114,780)**	**$ (40,424)**

Revenues

Revenues increased by $4.3 million from $5.3 million for the year ended December 30, 2017 to $9.7 million for the year ended December 31, 2018, primarily due to the $5.0 million upfront payment received from our Sinovant License Agreement, as well as a $1.5 million of variable consideration related to a future milestone payment pursuant to the Sinovant License Agreement that we believed was probable to be met. Grant revenue from research premiums provided to us by the Austrian government decreased by $2.2 million as a result of a decrease in our research and development expenses for which we can receive grant revenue.

Research and Development Expenses

Research and development expenses increased by $32.7 million from $49.6 million for the year ended December 31, 2017 to $82.3 million for the year ended December 31, 2018. The increase was primarily due to a $32.0 million increase for in-process research and development expenses associated with the acquisition of Zavante assets, a $6.5 million increase in research consulting fees, a $6.5 million increase associated with the payment of the NDA fees to the FDA for lefamulin and CONTEPO, a $1.9 million increase in staff costs due to the addition of employees, a $0.3 million increase in travel and other research and development costs, partly offset by a $13.9 million decrease in research materials and purchased services related to the development of lefamulin and a $0.7 million decrease in stock-based compensation expense.

Selling, General and Administrative Expenses

Selling, general and administrative expense increased by $12.3 million from $29.5 million for the year ended December 31, 2017 to $41.7 million for the year ended December 31, 2018. The increase was primarily due to a $2.6 million increase of advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees, a $9.6 million increase in staff costs due to the addition of employees, a $0.1 million increase in stock-based compensation expense, a $1.0 million increase in other corporate costs, a $0.7 million increase in travel expenses, and a $0.4 million increase in infrastructure costs, partly offset by a $2.2 million decrease in legal fees.

Other Income (Expense), net

Other income (expense), net decreased by $0.8 million from $0.5 million income for the year ended December 31, 2017, to $0.3 million expense for the year ended December 31, 2018 primarily due to re-measurements of our foreign currency account balances.

Interest Income (Expense), net

During the year ended December 31, 2018, net interest expense increased over the prior year due to lower interest earned on cash and cash equivalents.

Income Tax Expense

Our income tax expense was $1.4 million for the year ended December 31, 2017 compared to $49,000 for the year ended December 31, 2018. The change to income tax expense was primarily due to the recognition of a valuation allowance on deferred tax assets in 2017.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and generated negative cash flows from our operations. To date, we have financed our operations through the sale of equity securities, convertible and term debt financings, research and development support from governmental grants and loans and proceeds from licensing agreements.

In December 2019, we entered into a securities purchase agreement with certain institutional investors pursuant to which we agreed to issue and sell in a registered direct offering an aggregate of 13,793,106 ordinary shares and accompanying warrants to purchase up to an aggregate of 13,793,106 ordinary shares. Each share in the offering was issued and sold together with an accompanying warrant at a combined price of $1.45. The gross proceeds to us from the offering, before deducting the placement agent's fees and other offering expenses payable by us, was $20.0 million. Each warrant has an exercise price of $1.90 per share, is initially exercisable six months following the date of issuance, which was December 24, 2019, and will expire on the three-year anniversary of the date on which the warrant becomes initially exercisable.

On June 25, 2019, we entered into an Open Market Sale Agreement℠, or the Jefferies ATM Agreement, with Jefferies LLC, or Jefferies, as agent, pursuant to which, from time to time, we may offer and sell ordinary shares for aggregate gross sale proceeds of up to $50.0 million through Jefferies by any method permitted that is deemed an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. As of December 31, 2019, we have issued and sold and aggregate of 6,505,268 ordinary shares pursuant to the Jefferies ATM Agreement and received gross proceeds of $14.4 million and net proceeds of $13.6 million, after deducting commissions to Jefferies and other offering expenses. As of the date of this filing, we may issue and sell ordinary shares for gross proceeds of up to $35.6 million under the Jefferies ATM Agreement.

In December 2018, we announced the closing of up to a $75.0 million term loan with Hercules, or the Loan Agreement, $25.0 million of which was funded on the day of closing. Under the terms of the loan, in addition to the $25.0 million received at closing, we borrowed an additional $10.0 million in connection with the approval by the FDA of the NDA for XENLETA. On March 11, 2020, we entered into an amendment, or the Amendment, to our Loan and Security Agreement, or the Loan Agreement, with Hercules Capital, Inc., or Hercules, as administrative agent, collateral agent and lender. Pursuant to the Amendment, we agreed to repay to Hercules between April 1, 2020 and April 3, 2020, $30.0 million of the $35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement, which we refer to as the Prepayment. We determined to enter into the Amendment following the effectiveness of a performance covenant in February 2020 under which we became obligated to either (1) achieve 80% of our net product revenue sales target over a trailing six month period, or (2) maintain an amount of cash and cash equivalents in accounts pledged to Hercules plus a specified amount of eligible accounts receivables equal to the greater of the amount outstanding under the Loan Agreement or $40.0 million, which we refer to as the liquidity requirement. Since we did not achieve our net product sales targets, we became obligated to maintain compliance with the liquidity requirement. Under the Amendment, we and Hercules agreed to defer the end of term loan charge payment in the amount of approximately $2.3 million that would have otherwise become payable on the date of the Prepayment and to reduce the prepayment charge with respect to the Prepayment from $600,000 to $300,000 and to defer its payment, in each case, until June 1, 2023 or such earlier date on which all loans under the Loan Agreement are repaid or become due and payable. The Amendment also reset the revenue performance covenant to 70% of targeted revenue based on a revised net product revenue forecast

and lowered our minimum liquidity requirement to $3.0 million in cash and cash equivalents, in each case, following the Prepayment. The new minimum liquidity requirement will not apply if CONTEPO receives regulatory approval from the U.S. Food and Drug Administration and we achieve at least 70% of our revised net product revenue targets under the Loan Agreement. Following the Prepayment, there will remain outstanding $5.0 million in principal amount under the Loan Agreement, and we may request to borrow an additional $5.0 million subject to the lender's sole discretion.

In July 2018, we completed an underwritten public offering of 18,181,818 ordinary shares at a public offering price of $2.75 per share, resulting in gross proceeds of $50.0 million and net proceeds to us of $46.3 million, after deducting underwriting discounts and commissions and offering expenses.

In March 2018, we entered into a Controlled Equity Offering℠ Sales Agreement, or the Cantor ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, pursuant to which, from time to time, we could previously offer and sell our ordinary shares having aggregate gross proceeds of up to $50.0 million through Cantor. We terminated the Cantor ATM Agreement effective as of June 24, 2019. We did not incur any penalties as a result of the termination of the Cantor ATM Agreement. As of the effective date of the termination of the Cantor ATM Agreement, we had issued and sold an aggregate of 10,316,190 of our ordinary shares pursuant to the Cantor ATM Agreement for aggregate gross proceeds of $37.8 million and net proceeds of $36.3 million, after deducting commissions and offering expenses. The $12.2 million of ordinary shares that had been available for sale pursuant to the Cantor ATM Agreement remained unsold at the time of its termination.

In September 2017, we completed an underwritten public offering of 9,411,765 ordinary shares at a public offering price of $8.50 per share, resulting in gross proceeds of $80.0 million and net proceeds to us of $73.3 million, after deducting underwriting discounts and commissions and offering expenses.

Cash Flows

Comparison of Years Ended December 31, 2018 and 2019

The following table summarizes our cash flows for the years ended December 31, 2018 and 2019:

(in thousands)	Year Ended December 31, 2018	2019
Net cash (used in) provided by:		
Operating activities	$ (72,723)	$ (71,892)
Investing activities	(4,604)	331
Financing activities	92,923	56,075
Effects of foreign currency translation on cash	(362)	(106)
Net increase (decrease) in cash, cash equivalents and restricted cash	**$ 15,234**	**$ (15,592)**

Operating Activities

Cash flow used in operating activities decreased by $0.8 million from $72.7 million for the year ended December 31, 2018 to $71.9 million for the year ended December 31, 2019 primarily due to a $5.0 million decrease in net loss, after adjustments for non-cash amounts included in net loss and higher working capital of $4.2 million primarily due to changes in accrued expenses and other current liabilities.

Investing Activities

Cash flow provided by investing activities decreased by $4.9 million from $4.6 million of cash used for the year ended December 31, 2018 to $0.3 million cash provided for the year ended December 31, 2019 primarily due to transaction costs related to the acquisition of Zavante assets in 2018.

Financing Activities

Cash flow provided by financing activities decreased by $36.8 million from $92.9 million for the year ended December 31, 2018 to $56.1 million for the year ended December 31, 2019 primarily due to net proceeds of $26.9 million related to sales of our ordinary shares under our ATM Agreements, net proceeds of $18.8 million from our December 2019 registered direct offering of ordinary shares a $10.0 million advance under our December 2019 Loan Agreement with Hercules and $0.4 million proceeds from our employee stock purchase plan.

Comparison of Years Ended December 31, 2017 and 2018

The following table summarizes our cash flows for the years ended December 31, 2017 and 2018:

	Year ended December 31,	
(in thousands)	**2017**	**2018**
Net cash (used in) provided by:		
Operating activities	$ (69,348)	$ (72,723)
Investing activities	49,749	(4,604)
Financing activities	72,219	92,923
Effect of foreign currency translation on cash	1,371	(362)
Net increase (decrease) in cash, cash equivalents and restricted cash	**$ 53,991**	**$ 15,234**

Operating Activities

Cash flow used in operating activities increased by $3.4 million from $69.3 million for the year ended December 31, 2017 to $72.7 million for the year ended December 31, 2018 primarily due to a $8.7 million increase in net loss, after adjustments for non-cash amounts included in net loss and higher working capital of $5.3 million primarily due to changes in accrued expenses and other current liabilities.

Investing Activities

Cash flow provided by investing activities decreased by $54.4 million from $49.7 million of cash provided for the year ended December 31, 2017 to $4.6 million cash used for the year ended December 31, 2018 primarily due to a $51.0 million decrease in proceeds from sale of available-for-sale financial assets to fund operational cash outflows and $4.3 million in transaction costs related to the acquisition of Zavante assets.

Financing Activities

Cash flow provided by financing activities increased by $20.7 million from $72.2 million for the year ended December 31, 2017 to $92.9 million for the year ended December 31, 2018 primarily due to net proceeds of $24.2 million related to sales of our ordinary shares under our ATM Agreement, net proceeds of $46.3 million from our July 2018 public offering of ordinary shares and the $25.0 million advance under our December 2018 Loan Agreement with Hercules.

Operating and Capital Expenditure Requirements

We anticipate that our expenses will increase as we expect to incur significant additional commercialization expenses related to product sales, marketing, distribution and manufacturing. In addition, our expenses will increase if we suffer any regulatory delays or are required to conduct additional clinical trials to satisfy regulatory requirements.

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

- expand our medical affairs, sales, marketing and distribution infrastructure and build up inventory of finished product and its components to commercialize any product candidates for which we have or may receive marketing approval;
- establish and expand manufacturing arrangements with third parties;
- initiate or continue the research and development of lefamulin and CONTEPO for additional indications and of our other product candidates;
- seek to discover and develop additional product candidates;
- seek marketing approval for any product candidates that successfully complete clinical development;
- in-license or acquire other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- expand our physical presence in the United States and Ireland; and,
- add operational, financial and management information systems and personnel, including personnel to support our product development, our operations as a public company and our commercialization efforts.

As described above, on March 11, 2020, we entered into an Amendment to our Loan Agreement with Hercules. Pursuant to the Amendment, we agreed to repay to Hercules between April 1, 2020 and April 3, 2020, $30.0 million of the $35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement, which we refer to as the Prepayment. Under the Amendment, we and Hercules agreed to defer the end of term loan charge payment in the amount of approximately $2.3 million that would have otherwise become payable on the date of the Prepayment and to reduce the prepayment charge with respect to the Prepayment from $600,000 to $300,000 and to defer its payment, in each case, until June 1, 2023 or such earlier date on which all loans under the Loan Agreement are repaid or become due and payable. The Amendment also reset the revenue performance covenant to 70% of targeted revenue based on a revised net product revenue forecast and lowered our minimum liquidity requirement to $3.0 million in cash and cash equivalents, in each case, following the Prepayment. The new minimum liquidity requirement will not apply if CONTEPO receives regulatory approval from the U.S. Food and Drug Administration and we achieve at least 70% of our revised net product revenue targets under the Loan Agreement. Based on our current operating plans, immediately following the Prepayment, we expect that our existing cash resources and anticipated net product sales revenues will be sufficient to enable us to fund our operations, debt service obligations and capital expenditure requirements into the third quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate assumes, among other things, that we do not obtain any additional funding through grants and clinical trial support, collaboration agreements, or equity or debt financings. This estimate also assumes that our NDA for CONTEPO is approved on the PDUFA date and that we remain in compliance with the covenants and no event of default occurs under the Loan Agreement.

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

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

- the costs and timing of process development and manufacturing scale-up activities associated with XENLETA and CONTEPO;

- the costs, timing and outcome of regulatory review of lefamulin in Europe and for any other indications and CONTEPO;
- the costs of commercialization activities for XENLETA and potentially CONTEPO if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities, including the costs of building finished product inventory and its components in preparation of initial marketing of CONTEPO, if approved;
- the commercial success of XENLETA and the amount and frequency of reorders by our wholesaler customers;
- subject to receipt of marketing approval, revenue received from commercial sales of CONTEPO;
- the costs of developing XENLETA and CONTEPO for the treatment of additional indications;
- our ability to establish collaborations on favorable terms, if at all;
- the scope, progress, results and costs of product development of any other product candidates that we may develop;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property-related claims;
- the continued availability of Austrian governmental grants;
- the need to satisfy interest and principal obligations under our term loan with Hercules as well as the loan covenants contained in our Loan Agreement;
- the rate of the expansion of our physical presence in the United States and Ireland; and
- the costs of operating as a public company in the United States.

Conducting clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. Our commercial revenues, if any, will be derived from sales of XENLETA, CONTEPO or any other products that we successfully develop, in-license or acquire. In addition, XENLETA and, if approved, CONTEPO or any other product candidate that we develop, in-license or acquire may not achieve commercial success. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

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

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

Capital Expenditures

Capital expenditures were $0.2 million for the year ended December 31, 2018 and we made no significant capital investments during the year ended December 31, 2019. We also made no significant investments in intangible assets during the years ended December 31, 2018 and 2019. Currently, there are no material capital projects planned in 2020.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, other than our operating lease obligations for our facilities in Austria, Ireland and the United States.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to a variety of financial risks in the ordinary course of our business: market risk, credit risk and liquidity risk. Our overall risk management program focuses on preservation of capital given the unpredictability of financial markets. These market risks are principally limited to interest rate and foreign currency fluctuations.

Market Risk

We do not have any significant credit risk exposure to any single counterparty or any group of counterparties having similar characteristics. The credit risk on liquid funds (bank accounts, cash balances, marketable securities and term deposits) is limited because the counterparties are banks with high credit ratings from international credit rating agencies. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes.

We are exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the euro and the British pound. Our functional currency is the U.S. dollar, but we receive payments and acquire materials, in each of these other currencies. We have not established any formal practice to manage the foreign exchange risk against our functional currency. However, we attempt to minimize our net exposure by buying or selling foreign currencies at spot rates upon receipt of new funds to facilitate committed or anticipated foreign currency transactions.

Interest rate risk may arise from short-term or long-term debt. Our outstanding indebtedness with Hercules bears interest at the greater of 9.80% and 9.80% plus the prime rate of interest minus 5.50%. Based on the current prime rate, our outstanding indebtedness with Hercules bears interest at 9.80%. If the prime rate increases to over 5.50%, the interest on our loan with Hercules will increase.

Liquidity Risk

Since our inception, we have incurred net losses and generated negative cash flows from our operations. Subsequent to our recent agreement with Hercules to repay the majority of our indebtedness, we anticipate based on our current operating plans, that our existing cash, cash equivalents and short-term investments as of the date of this filing, as well as anticipated net product revenues and research premiums from the Austrian government for our qualified research and development expenditures will be sufficient to enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into the third quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This

estimate assumes, among other things, that we do not obtain any additional funding through grants and clinical trial support, collaboration agreements or equity or debt financings.

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

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

There can be no assurance that we will be successful in acquiring additional capital at a level sufficient to fund our operations or on terms favorable to us. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce to eliminate our research and development programs or our commercialization efforts.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements, together with the report of our independent registered public accounting firm, appear on pages F-1 through F-33 of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

We have carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) under the supervision and the participation of the company’s management, which is responsible for the management of the internal controls, and which includes our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively). The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon our evaluation of our disclosure controls and procedures as of December 31, 2019, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable level of assurance.

Management's Annual Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that: (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and board of directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(e) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled "*Internal Control—Integrated Framework (2013)*" published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2019, the end of our most recent fiscal year.

Our independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. For as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) that occurred during the three months ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

The information set forth below is included herein for the purpose of providing the disclosure required under "Item 1.01 – Entry into a Material Definitive Agreement" and "Item 2.03 – Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant" of Form 8-K.

On December 20, 2018, we entered into a Loan and Security Agreement, or the Loan Agreement, with Nabriva Therapeutics Ireland DAC, our direct subsidiary, certain of our other subsidiaries from time to time party thereto, any bank and other financial institution or entity from time to time party thereto, which we collectively refer to as Lender, and Hercules Capital, Inc., or Hercules, in its capacity as administrative agent and collateral agent for itself and Lender, pursuant to which a term loan of up to an aggregate principal amount of $75.0 million became available to us and Nabriva Therapeutics Ireland DAC, subject to the terms and conditions of the Loan Agreement. On March 11, 2020, we

certain of our subsidiaries entered into an amendment, or the Amendment to the Loan Agreement. Pursuant to the Amendment, we agreed to repay to Hercules between April 1, 2020 and April 3, 2020, $30.0 million of the $35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement, which we refer to as the Prepayment. We determined to enter into the Amendment following the effectiveness of a performance covenant in February 2020 under which we became obligated to either (1) achieve 80% of our net product revenue sales target over a trailing six-month period, or (2) maintain an amount of cash and cash equivalents in accounts pledged to Hercules plus a specified amount of eligible accounts receivable equal to the greater of the amount outstanding under the Loan Agreement or $40.0 million, which we refer to as the liquidity requirement. Under the Amendment, we and Hercules agreed to defer the end of term loan charge payment in the amount of approximately $2.3 million that would have otherwise become payable on the date of the Prepayment and to reduce the prepayment charge with respect to the Prepayment from $600,000 to $300,000 and to defer its payment, in each case, until June 1, 2023 or such earlier date on which all loans under the Loan Agreement are repaid or become due and payable. The Amendment also reset the revenue performance covenant to 70% of targeted revenue based on a revised net product revenue forecast and lowered our minimum liquidity requirement to $3.0 million in cash and cash equivalents, in each case, following the Prepayment. The new minimum liquidity requirement will not apply if CONTEPO receives regulatory approval from the U.S. Food and Drug Administration and we achieve at least 70% of our revised net product revenue targets under the Loan Agreement. Following the Prepayment, the Company may request to borrow an additional $5.0 million subject to the Hercules' sole discretion.

The term loan bears interest at an annual rate equal to the greater of 9.80% and 9.80% plus the prime rate of interest minus 5.50%. The Loan Agreement provided for interest-only payments through July 1, 2021, which may be incrementally extended from time to time upon the occurrence of certain conditions through January 1, 2022, and repayment of the aggregate outstanding principal balance of the term loan thereafter in monthly installments through June 1, 2023, or the Maturity Date. In addition, we are required to pay a fee of 6.95% of the aggregate amount of advances under the Loan Agreement at the Maturity Date. At our option, we may elect to prepay any portion of the outstanding term loan that is greater than or equal to $5.0 million by paying such portion of the principal balance and all accrued and unpaid interest thereon, plus a prepayment charge equal to the following percentage of the principal amount being prepaid: (i) 3.0% if the term loan is prepaid during the first 12 months following the initial closing, (ii) 2.0% if the term loan is prepaid after 12 months following the initial closing but before 24 months following the initial closing and (iii) 1.0% if the term loan is prepaid any time thereafter but prior to the Maturity Date. We are also required to satisfy certain financial covenants.

The foregoing descriptions of the Amendment and the Loan Agreement do not purport to be complete and are qualified in their entirety by reference to the Amendment and the Loan Agreement, as applicable, filed as exhibits to this Form 10-K.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Board of Directors

Set forth below are the names and certain biographical information about each member of our board of directors as of March 1, 2020. The information presented includes each director's principal occupation and business experience for at least the past five years and the names of other public companies of which he or she has served as a director during the past five years.

Name	Age	Position
Daniel Burgess(1)(3)	58	Director, Chairman of the Board
Theodore Schroeder	64	Director, Chief Executive Officer
Colin Broom, MD	64	Director
Carrie Bourdow(2)	57	Director
Mark Corrigan, MD(2)(3)	62	Director
Charles A. Rowland, Jr.(1)(2)	61	Director
George H. Talbot, MD(3)	71	Director
Stephen Webster(1)(3)	58	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

Daniel Burgess has served on our board of directors since June 23, 2017. Mr. Burgess was a member of the supervisory board of Nabriva Austria and served as its chairman from October 2016 until the Redomiciliation. Mr. Burgess has been a venture partner at SV Health Investors (SV) since 2014. As part of his work with SV, Mr. Burgess has been acting as the chief executive officer of Therini Bio, Inc., a private therapeutics company, since May 2019. He was previously president and chief executive officer of Rempex Pharmaceuticals, an antibiotics company he co-founded in 2011 and that was subsequently sold to The Medicines Company (now Novartis) in 2013. Prior to this, Mr. Burgess was president and chief executive officer of Mpex Pharmaceuticals from 2007 until its acquisition by Aptalis Inc. (now AbbVie Inc.) in 2011. Prior to his time at Mpex, Mr. Burgess served in various senior operating roles for other biotechnology companies. In addition, he serves as a member of the boards of directors of Cidara Therapeutics, Inc., a public biotechnology company; Arbutus Biopharma Corp., a public biotechnology company; and several private healthcare companies. Mr. Burgess was a member of the board of directors of Santarus, Inc., from 2004 until its acquisition in 2014 by Salix Pharmaceuticals Inc. He received his B.A. in economics from Stanford University and an M.B.A. from Harvard University. We believe Mr. Burgess is qualified to serve as a director because of his expertise and experience as an executive in the pharmaceutical industry, his service on other boards of directors and his educational background.

Theodore Schroeder has served on our board of directors and as chief executive officer since July 24, 2018. During the last 30 years, Mr. Schroeder has been focused on drug development and commercialization in both large and small pharmaceutical companies. Most recently, he served as president, chief executive officer and director of Zavante Therapeutics from June 2015 until its acquisition by Nabriva Therapeutics in July 2018. Mr. Schroeder co-founded Cadence Pharmaceuticals in 2004 and previously held leadership roles at Elan Pharmaceuticals, Dura Pharmaceuticals and earlier in his career, Bristol-Myers Squibb. He currently serves on the board of Cidara Therapeutics, Otonomy and Collegium Pharmaceutical. He is a former chair of BIOCOM, the California life sciences trade association and in 2014, he was named the EY Entrepreneur of the Year for the San Diego region and was listed as a national finalist. He received a bachelor's degree in management from Rutgers University. We believe Mr. Schroeder is qualified to serve as a director because of his expertise and experience as an executive in the pharmaceutical industry, his service on other boards of directors and his educational background.

Colin Broom has served on our board of directors since June 23, 2017. Dr. Broom has served as the chief executive officer of Pulmotect, Inc., a private biotechnology company, since September 2019. Dr. Broom was previously our chief executive officer from April 12, 2017 until July 24, 2018, and the chief executive officer of Nabriva Austria from August 2014 until the Redomiciliation. Prior to joining Nabriva Austria, he served as chief scientific officer at ViroPharma Incorporated from 2004 until it was acquired by Shire plc in 2014. Dr. Broom served as vice president of clinical development and medical affairs in Europe for Amgen Inc. from 2000 to 2003 and previously held several leadership positions with Hoechst Marion Roussel (now Sanofi), SmithKline Beecham and Glaxo (now GlaxoSmithKline). Dr. Broom served as a member of the board of directors of NPS Pharmaceuticals, Inc. from 2009 until its acquisition by Shire in 2015. He is a member of the U.K. Royal College of Physicians and a fellow of the Faculty of Pharmaceutical Medicine. Dr. Broom received his B.Sc. from University College, London and M.B.B.S. from St. George's Hospital Medical School, London. We believe that Dr. Broom is qualified to serve as a director due to his extensive experience in all stages of drug development and commercialization.

Carrie Bourdow has served on our board of directors since June 23, 2017. Ms. Bourdow has been the President, Chief Executive Officer, and member of the Trevena Board of Directors since October 2018. She has served in various senior positions at Trevena since May 2015. She joined Trevena as Chief Commercial Officer and was appointed Executive Vice President and Chief Operating Officer in January 2018. Prior to joining Trevena, Ms. Bourdow was Vice President of Marketing at Cubist Pharmaceuticals, Inc., from 2013 until its acquisition by Merck & Co., Inc. in January 2015. At Cubist, Ms. Bourdow led launch strategy, marketing, reimbursement, and operations for acute care hospital pharmaceuticals. Prior to Cubist, Ms. Bourdow served for more than 20 years at Merck & Co., Inc., where she held positions of increasing responsibility across multiple therapeutic areas. Ms. Bourdow also serves as a director of Sesen Bio, Inc., a publicly traded pharmaceutical company. Ms. Bourdow holds a B.A. degree from Hendrix College and an M.B.A. from Southern Illinois University. We believe Ms. Bourdow is qualified to serve as a director due to her extensive experience in the biopharmaceutical industry, including her experience with anti-infectives and with the commercialization of new drugs.

Mark Corrigan has served on our board of directors since June 23, 2017. Dr. Corrigan previously served on the supervisory board of Nabriva Austria from October 2016 until the Redomiciliation. Dr. Corrigan has been the chief executive officer of Correvio Pharma Corporation (formerly Cardiome Pharma), a public biopharmaceutical company, since March 2019. From April 2016 until March 2019, Dr. Corrigan was president of research and development of Tremeau Pharmaceuticals Inc. Dr. Corrigan served as president and chief executive officer of Zalicus, Inc. from January 2010 until July 2014. Previously, Dr. Corrigan was executive vice president of research and development at the specialty pharmaceutical company Sepracor Inc., and prior to this, he spent 10 years with Pharmacia & Upjohn, most recently as group vice president of Global Clinical Research and Experimental Medicine. Dr. Corrigan currently serves on the boards of directors of Correvio Pharma Corporation, Wave Life Science, a public biotechnology company, and Tremeau Pharmaceuticals, a private company. He previously served as chairman of the boards of directors of Novelion Therapeutics, Inc., BlackThorn Therapeutics, Inc., and EPIRUS Biopharmaceuticals, Inc. and as a director of CoLucid Pharmaceuticals, Inc., Cubist Pharmaceuticals, Inc., and Avanair Pharmaceuticals, Inc. Dr. Corrigan holds an M.D. from the University of Virginia and received specialty training in psychiatry at Maine Medical Center and Cornell University. We believe Dr. Corrigan is qualified to serve as a director due to his extensive experience in the biopharmaceutical industry as both an executive and a board member and because of his education and training.

George H. Talbot has served on our board of directors since June 23, 2017. Dr. Talbot previously served on the supervisory board of Nabriva Austria from 2009 until the Redomiciliation. Dr. Talbot has been the principal at Talbot Advisors LLC, a biopharmaceutical company consultancy, since 2007 and prior to that, from 2000 to 2006. From 2006 to 2007, he served as chief medical officer and executive vice president of Cerexa, Inc. prior to its acquisition by Forest Laboratories, Inc. Dr. Talbot also worked closely with Calixa Therapeutics, Inc. and Durata Therapeutics, Inc., prior to their acquisitions by Cubist Pharmaceuticals, Inc. and Actavis plc, respectively. He was an initial member of the Infectious Diseases Society of America's Antimicrobial Availability Task Force ("Bad Bugs, No Drugs") and recently completed a seven-year tenure as co-chair of the Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium Projects for Endpoint Development in Acute Bacterial Skin and Skin Structure Infections, Community-acquired Bacterial Pneumonia, and Hospital-acquired Bacterial Pneumonia/Ventilator-associated Bacterial Pneumonia, which made evidence-based recommendations to the Food and Drug Administration for its Guidance development in these indications. Dr. Talbot received his B.A. from Wesleyan University, his M.D. from the Yale

University School of Medicine, and his Infectious Diseases fellowship training at the University of Pennsylvania. After serving as a faculty member of the Infectious Diseases Section at the University of Pennsylvania, he joined the anti-infectives group at Rhone-Poulenc-Rorer in 1990. We believe that Dr. Talbot is qualified to serve as a director due to his education, training and extensive experience in the biopharmaceutical industry.

Charles A. Rowland, Jr. has served on our board of directors since June 23, 2017. Mr. Rowland previously served on the supervisory board of Nabriva Austria from January 2015 until the Redomiciliation. Mr. Rowland served as chief executive officer of Aurinia Pharmaceuticals Inc. from April 2016 to January 2017. Mr. Rowland previously served as vice president and chief financial officer of ViroPharma Incorporated from 2008 until it was acquired by Shire plc in 2014. Prior to joining ViroPharma, Mr. Rowland served as executive vice president and chief financial officer, as well as interim co-chief executive officer, for Endo Pharmaceuticals Inc. from 2006 to 2008 and chief financial officer at Biovail Corporation from 2004 to 2006. He previously held finance and operational positions of increasing responsibility at Breakaway Technologies, Inc., Pharmacia, Novartis International AG and Bristol-Myers Squibb Company. Mr. Rowland currently serves as a member of the board of directors for Blueprint Medicines Corporation, a public biopharmaceutical company, Viking Therapeutics, a public, clinical-stage biopharmaceutical company, and Orchard Therapeutics, a public, clinical-stage biopharmaceutical company. In addition, Mr. Rowland serves as a member of the board of directors for Generation Bio, a privately held biopharmaceutical company. Previously, he served on the board of directors at Idenix Pharmaceuticals, Inc., Vitae Pharmaceuticals, Inc., Bind Therapeutics Inc. and Aurinia Pharmaceuticals Inc. Mr. Rowland received his B.S. from Saint Joseph's University and M.B.A. from Rutgers University. We believe that Mr. Rowland is qualified to serve as a director due to his extensive experience in pharmaceutical operations and all areas of finance and accounting.

Stephen Webster has served on our board of directors since June 23, 2017. Mr. Webster previously served on the supervisory board of Nabriva Austria from October 2016 until the Redomiciliation. Mr. Webster served as the chief financial officer of Spark Therapeutics from July 2014 until its acquisition by Roche Holdings, Inc. in December 2019. He was previously senior vice president and chief financial officer of Optimer Pharmaceuticals, Inc. from June 2012 until its acquisition by Cubist Pharmaceuticals in November 2013. Prior to this, Mr. Webster served as senior vice president and chief financial officer of Adolor Corporation, also acquired by Cubist, from 2008 to 2011. Previously, Mr. Webster served as managing director, Investment Banking Division, Health Care Group for Broadpoint Capital Inc. (formerly First Albany Capital). He also was a co-founder and served as president and chief executive officer of Neuronyx, Inc. Prior to this, Mr. Webster held positions of increasing responsibility, including as director, Investment Banking Division, Health Care Group, for PaineWebber Incorporated. Mr. Webster is currently a member of the board of directors of Viking Therapeutics, Inc and NextCure, Inc. He holds an A.B. in economics from Dartmouth College and an M.B.A. from the University of Pennsylvania. We believe that Mr. Webster is qualified to serve as a director due to his extensive experience in the biopharmaceutical industry, particularly his service as a chief financial officer and in other executive management roles.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates under a charter that has been approved by our board. Copies of the committee charters are posted under the heading "Corporate Governance" on the Investor section of our website, which is located at http://investors.nabriva.com.

Audit Committee

Our audit committee consists of Charles A. Rowland, Jr., Daniel Burgess and Stephen Webster. Stephen Webster is the chair of the audit committee. The audit committee oversees our accounting and financial reporting processes and the audits of our consolidated financial statements. The audit committee is responsible for, among other things:

- making recommendations to our board regarding the ratification by the annual general meeting of shareholders of our independent auditors;

- overseeing the work of the independent auditors, including resolving disagreements between management and the independent auditors relating to financial reporting;
- pre-approving all audit and non-audit services permitted to be performed by the independent auditors;
- reviewing the independence and quality control procedures of the independent auditors;
- reviewing and approving all proposed related-party transactions;
- discussing the annual audited consolidated and statutory financial statements with management;
- annually reviewing and reassessing the adequacy of our audit committee charter;
- meeting separately with the independent auditors to discuss critical accounting policies, recommendations on internal controls, the auditor's engagement letter and independence letter and other material written communications between the independent auditors and the management; and
- attending to such other matters as are specifically delegated to our audit committee by our board from time to time.

Our Board has determined that Charles A. Rowland, Jr. and Stephen Webster are "audit committee financial experts" as defined in the applicable SEC rules.

Compensation Committee

Our compensation committee consists of Charles A. Rowland, Jr., Mark Corrigan and Carrie Bourdow. Charles A. Rowland, Jr. is the chair of the compensation committee. The compensation committee assists the board in reviewing and approving or recommending our compensation structure, including all forms of compensation relating to our directors and management. The compensation committee is responsible for, among other things:

- reviewing and making recommendations to the board with respect to compensation of our board of directors and management;
- reviewing and approving the compensation, including equity compensation, change-of-control benefits and severance arrangements, of our chief executive officer, chief financial officer and such other members of our management as it deems appropriate;
- overseeing the evaluation of our management;
- reviewing periodically and making recommendations to our board with respect to any incentive compensation and equity plans, programs or similar arrangements;
- exercising the rights of our board under any equity plans, except for the right to amend any such plans unless otherwise expressly authorized to do so; and
- attending to such other matters as are specifically delegated to our compensation committee by our board from time to time.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Daniel Burgess, Mark Corrigan, George Talbot and Stephen Webster. Daniel Burgess is the chair of the nominating and corporate governance committee. The nominating and corporate governance committee assists the board in selecting individuals qualified to become our

directors and in determining the composition of the board and its committees. The nominating and corporate governance committee is responsible for, among other things:

- recommending to the board persons to be nominated for election or re-election to the board at any meeting of shareholders;
- overseeing the board's annual review of its own performance and the performance of its committees; and
- developing and recommending to the board a set of corporate governance guidelines.

Executive Officers

The following table sets forth information regarding our executive officers as of March 1, 2020:

Name	Age	Position
Theodore Schroeder	64	Chief Executive Officer
Robert Crotty	46	General Counsel and Secretary
Steven Gelone	52	President and Chief Operating Officer
Francesco Maria Lavino	46	Chief Commercial Officer
Jennifer Schranz	55	Chief Medical Officer
Gary Sender	57	Chief Financial Officer

In addition to the biographical information for Mr. Schroeder, which is set forth above under "Board of Directors," set forth below is certain biographical information about Drs. Gelone and Schranz, and Messrs. Crotty, Lavino and Sender:

Robert Crotty has served as our general counsel and secretary since June 23, 2017. Mr. Crotty joined Nabriva Austria as general counsel and secretary prior to the Redomiciliation on June 14, 2017. Previously, Mr. Crotty served as vice president, general counsel, chief compliance officer and secretary of Vernalis Therapeutics, Inc. from January 2016 to June 2017. Prior to joining Vernalis, Mr. Crotty held several positions at Dendreon Corporation from April 2012 to July 2015, including president, general counsel and secretary from February 2015 to July 2015, executive vice president, general counsel and secretary from March 2014 to February 2015, and vice president, assistant general counsel and assistant secretary from April 2012 to February 2014. Before Dendreon, Mr. Crotty was senior counsel at NPS Pharmaceuticals from 2009 until 2012 and at ImClone Systems, Inc. from 2006 to 2009. Prior to going in-house, Mr. Crotty was an associate at Morgan, Lewis & Bockius and Norton Rose Fulbright. Mr. Crotty received his B.A. from Princeton University and J.D. from University of Pennsylvania.

Steven Gelone has served as our president and chief operating officer since July 24, 2018. Dr. Gelone previously served as Nabriva Austria's chief development officer and head of business development from 2014 until the Redomiciliation, our chief development officer from the Redomiciliation until June 30, 2017 and our chief scientific officer from June 30, 2017 until July 24, 2018. Prior to joining Nabriva Austria, he served as head of clinical research and development at Spark Therapeutics, Inc. in 2014 and vice president of clinical and preclinical development at ViroPharma Incorporated from 2005 to 2014. Dr. Gelone also served as director of medical affairs at Vicuron Pharmaceuticals from 2002 to 2003 and director of clinical pharmacology and experimental medicine at GlaxoSmithKline Pharmaceuticals from 2000 to 2002. Dr. Gelone received his B.S. Pharm. and Pharm.D. from Temple University.

Francesco Maria Lavino has served as our chief commercial officer since July 10, 2017. Previously, Mr. Lavino served as associate vice president and global brand leader for the anti-infective portfolio at Merck & Co. from September 2015 to July 2017. Prior to Merck, Mr. Lavino was vice president of international marketing for Cubist Pharmaceuticals from December 2013 until September 2015. Before joining Cubist, Mr. Lavino spent 10 years with Merck & Co. in various roles, including serving as executive director and global brand leader for Merck's anti-fungal portfolio from January 2011 to November 2013. Mr. Lavino began his career in pharmaceutical sales at UCB S.A. and

3M Company in Italy. He has a B.A. in Pharmacy from the Federico II University of Napoli, Italy and an M.B.A. from SDA Bocconi School of Management in Milan, Italy.

Jennifer Schranz has served as our chief medical officer since March 21, 2018. Previously, Dr. Schranz served as vice president, clinical research and development, global development team lead, for hereditary angioedema at Shire plc from January 2014 until March 2018. Prior to Shire, Dr. Schranz served as vice president of clinical development for ViroPharma, Inc. from March 2011 until January 2014. Before joining ViroPharma, Dr. Schranz was vice president, clinical research at Cempra, Inc., where she was responsible for clinical and regulatory strategy. Earlier in her career, Dr. Schranz worked in clinical development and medical affairs at several pharmaceutical companies, including Wyeth (now Pfizer), Vicuron Pharmaceuticals, Inc. (now Pfizer), GlaxoSmithKline plc, and Merck & Co. Inc. Dr. Schranz completed two years of biology and psychology at McMaster University prior to acceptance and subsequent completion of an M.D. from the University of Toronto, where she completed her internal medicine training and was a fellow in infectious diseases.

Gary Sender has served as our chief financial officer since April 12, 2017. Mr. Sender previously served as our chief financial officer from May 2016 until the Redomiciliation. Prior to joining Nabriva Austria, he served as chief financial officer and executive vice president at Synergy Pharmaceuticals from 2015 to 2016. From 2009 until 2015, Mr. Sender served as senior vice president, Finance at Shire plc., supporting its Specialty Pharmaceuticals business and subsequently its Global Commercial businesses. At Shire he was responsible for financial management and support of all commercial areas of Shire's Specialty Pharmaceutical and Rare Disease businesses, with an emphasis on resource allocation, financial forecasting, business cases and mergers and acquisitions. Prior to joining Shire, Mr. Sender was the founding CFO of Tengion, Inc. Mr. Sender also spent 15 years in a number of leadership roles within Merck. Mr. Sender is currently a member of the board of directors of Schrödinger, Inc. Mr. Sender received his B.S. from Boston University and an M.B.A from Carnegie-Mellon University.

Code of Business Conduct and Ethics

Our Code of Business Conduct and Ethics is applicable to all of our directors, officers and employees and is available on our website at http://investors.nabriva.com/corporate-governance/governance-overview. Our Code of Business Conduct and Ethics provides that our directors, officers and employees are expected to avoid any action, position or interest that conflicts with the interests of our company or gives the appearance of a conflict. We expect that any amendment to this code, or any waivers of its requirements, will be disclosed on our website. Information contained on, or that can be accessed through, our website is not incorporated by reference into this document, and you should not consider information on our website to be part of this document.

ITEM 11. EXECUTIVE COMPENSATION

The following discussion provides the amount of compensation paid, and benefits in-kind granted, by us and our subsidiaries to the members of our board of directors and certain executives for services provided in all capacities to us and our subsidiaries for the year ended December 31, 2019.

Executive and Director Compensation Processes

Our executive compensation program is administered by the compensation committee of our board of directors, subject to the oversight and approval of our full board of directors. Our compensation committee reviews our executive compensation practices on an annual basis and based on this review approves, or, as appropriate, makes recommendations to our board of directors for approval of our executive compensation program.

In designing our executive compensation program, our compensation committee considers publicly available compensation data for national and regional companies in the biotechnology/pharmaceutical industry to help guide its executive compensation decisions at the time of hiring and for subsequent adjustments in compensation. Since 2016, our compensation committee has retained Radford, a part of Aon Hewitt, a business unit of Aon plc, as its independent compensation consultant, to provide comparative data on executive compensation practices in our industry and to advise on our executive compensation program generally. The committee also has retained Radford for guidelines and review

of non-employee director compensation. Although our compensation committee considers the advice and guidelines of Radford as to our executive compensation program, our compensation committee ultimately makes its own decisions about these matters. In the future, we expect that our compensation committee will continue to engage independent compensation consultants to provide additional guidance on our executive compensation programs and to conduct further competitive benchmarking against a peer group of publicly traded companies.

Our director compensation program is administered by our board of directors with the assistance of the compensation committee. The compensation committee conducts an annual review of director compensation and makes recommendations to the board of directors with respect thereto.

Summary Compensation Table

Our "named executive officers" for the year ended December 31, 2019 were as follows: Mr. Schroeder, our chief executive officer, Dr. Schranz, our chief medical officer and Dr. Gelone, our president and chief operating officer. The following table sets forth information regarding compensation awarded to, earned by or paid to our named executive officers for the periods presented.

Name and principal position	Year	Salary($)	Share Awards ($)(1)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)(2)	All Other Compensation ($)(3)	Total ($)
Theodore Schroeder	2019	560,000	310,175	478,367	119,250	28,372	1,496,164
Chief Executive Officer	2018	220,360	529,500	1,739,100	—	20,380	2,509,340
Jennifer Schranz	2019	436,200	99,750	261,555	151,200	33,450	982,155
Chief Medical Officer							
Steven Gelone	2019	472,100	200,925	309,859	181,420	13,976	1,178,280
President and Chief	2018	426,104	225,255	546,738	126,822	15,116	1,340,035
Operating Officer							

(1) The amounts reported in the "Share Awards" and "Option Awards" columns reflect the aggregate grant-date fair value of share-based compensation awarded during the year computed in accordance with the provisions of ASC Topic 718. See Note 11 to the consolidated financial statements regarding assumptions underlying the valuation of equity awards.

(2) The amounts reported in the "Non-Equity Incentive Plan Compensation" column represent awards to our named executive officers under our annual cash bonus program.

(3) The compensation included in the "All Other Compensation" column consists of amounts we contributed to our 401(k) plan and medical insurance premiums paid by us on behalf of such individual.

Narrative Disclosure to Summary Compensation Table

Base Salary

In 2019, we paid annualized base salaries of $560,000 to Mr. Schroeder; $436,200 to Dr. Schranz; and $472,100 to Dr. Gelone. In 2018, we paid annualized base salaries of $530,000 to Mr. Schroeder; $400,000 to Dr. Schranz; and $450,000 to Dr. Gelone upon the closing of the Zavante acquisition.

In January 2020, our board of directors, following approval and recommendation from the compensation committee and consistent with the recommendations of the compensation committee's independent compensation consultant, approved an increase to the base salaries of our named executive officers for 2020 as follows: $576,800 for Mr. Schroeder, $449,300 for Dr. Schranz and $486,300 for Dr. Gelone. The board also approved 2020 base salaries for Mr. Crotty, our general counsel and secretary, of $392,200, Mr. Lavino, our chief commercial officer, of $384,500 and

Mr. Sender, our chief financial officer, of $409,200, which also were consistent with the recommendation of the compensation committee's independent consultant.

None of our named executive officers is currently party to an employment agreement or other agreement or arrangement that provides for automatic or scheduled increases in base salary.

Annual Performance-Based Compensation

Our executive officers, which include the named executive officers, participate in our performance-based bonus program. All annual cash bonuses for our executives under the performance-based bonus program are tied to the achievement of strategic and operational corporate goals for the company, which are set by the compensation committee and approved by the board. There are no discretionary individual goals under the bonus program. The 2019 strategic and operational goals for Nabriva related to the following objectives:

- regulatory approvals
- commercialization of our product candidates
- finance, specifically fundraising;
- business development;
- operating infrastructure; and,
- chemistry, manufacturing, and control (CMC).

Under their respective employment agreements, the annual target bonus for Mr. Schroeder is 60% of his current base salary, the annual target bonus for Dr. Gelone is 45% of his current base salary and the annual target bonus for each of Dr. Schranz, Mr. Sender, Mr. Crotty and Mr. Lavino is 40% of their respective current base salaries.

At a meeting held in December 2019, our compensation committee reviewed the accomplishments of the named executive officers as measured against the aforementioned 2019 goals. The compensation committee reviewed whether each goal had been obtained and the weight such goals should be given in determining the bonus payout for 2019 performance. Based on its review, the compensation committee recommended an 90% payout of the target bonuses for 2019, which were paid in February 2020. Accordingly, the 2019 bonus payouts were $277,200 for Mr. Schroeder, $157,032 for Dr. Schranz and $191,201 for Dr. Gelone.

Equity Incentive Awards

We believe that equity grants provide our executive officers with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executive officers and our shareholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incents our executive officers to remain in our employment during the vesting period. Accordingly, our board of directors periodically reviews the equity incentive compensation of our executive officers, which includes the named executive officers, and from time to time may grant equity incentive awards to them in the form of stock options or restricted stock units, or RSUs. We also generally make stock option grants to new executive officers in connection with the commencement of their employment.

We have historically granted stock options with exercise prices that are set at no less than the fair market value of the underlying award on the date of grant, as determined by contemporaneous valuations and reviewed, and approved by our compensation committee or our board.

Effective as of February 6, 2020, our board of directors granted stock options under the 2020 Share Incentive Plan to Mr. Schroeder, Dr. Schranz, and Dr. Gelone subject to shareholder approval; provided that if such shareholder approval is not obtained, the options will remain outstanding and convert into a cash-settled share appreciation right. The stock options will vest over a four year period beginning on February 6, 2020. Twenty five percent (25%) of the options will vest on February 6, 2021, and the remaining seventy five percent (75%) will vest on a monthly pro rata basis over the remaining vesting period. Each of the option awards had an exercise price $1.35 per share, which was the closing sale price of our ordinary shares on the Nasdaq Global Market on the grant date. Mr. Schroeder, Dr. Schranz, and Dr. Gelone were also granted Restricted Stock Units, or RSUs under our 2017 Share Incentive Plan. The RSUs vest over a four year period beginning on February 6, 2020. Twenty five percent (25%) of the RSUs will vest of February 6, 2021, and the remaining seventy five percent (75%) will vest on a monthly pro rata basis over the remaining vesting period.

The following table sets forth the number of our ordinary shares issuable upon exercise of the share awards granted to our named executive officers in 2020:

Name	Option Award (#)	RSU Award (#)
Theodore Schroeder	687,500	343,800
Steven Gelone	310,000	155,000
Jennifer Schranz	210,000	105,000

On January 31, 2019, our board of directors granted stock options under the 2017 Share Incentive Plan to Mr. Schroeder, Dr. Schranz and Dr. Gelone. The options vest over a four year period beginning on January 31, 2019. Twenty five percent (25%) of the options vested on January 31, 2020, and the remaining seventy five percent (75%) will vest on a monthly pro rata basis over the remaining vesting period. Each of the option awards had an exercise price of $1.90 per share, which was the closing sale price of our ordinary shares on the Nasdaq Global Market on the grant date. Mr. Schroeder, Dr. Schranz and Dr. Gelone were also granted Restricted Stock Units, or RSUs. The RSUs vest over a four year period beginning on January 31, 2019. Twenty five percent (25%) of the RSUs vested on January 31, 2020, and the remaining seventy five percent (75%) will vest on a monthly pro rata basis over the remaining vesting period.

The following table sets forth the number of our ordinary shares issuable upon exercise of the share awards granted to our named executive officers in 2019:

Name	Option Award (#)	RSU Award (#)
Theodore Schroeder	429,800	163,250
Steven Gelone	278,400	105,750
Jennifer Schranz	235,000	52,500

Outstanding Equity Awards as of December 31, 2019

The following table sets forth information regarding outstanding stock options and RSUs held by our named executive officers as of December 31, 2019:

	Option Awards				Share Awards			
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares of units of stock that have not vested ($)	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested ($)
Theodore Schroeder	301,042	548,958 (1)	3.53	07/25/2028	150,000 (12)	198,000	163,200 (13)	215,424
	—	429,800 (2)	1.90	01/31/2029	—	—	—	—
Jennifer Schranz	65,625	84,375 (3)	5.03	03/31/2028	—	—	52,500 (13)	69,300
	—	235,000 (4)	1.90	01/31/2029	—	—	—	—
Steven Gelone	88,790	— (5)	7.21	07/05/2025	—	—	11,250 (14)	14,850
	53,571	2,329 (6)	8.34	02/04/2026	—	—	16,000 (14)	21,120
	80,042	32,958 (7)	8.50	02/07/2027	—	—	105,750 (13)	139,590
	47,917	52,083 (8)	6.47	01/31/2028	—	—	—	—
	27,448	50,052 (9)	3.53	07/25/2028	—	—	—	—
	2,500	5,000 (10)	2.49	02/08/2028	—	—	—	—
	—	278,400 (11)	1.90	01/31/2029	—	—	—	—

(1) Mr. Schroeder's option to purchase 850,000 of our ordinary shares vests over four years, with 25% of the options vesting on July 25, 2019, and the remaining 75% of the option vesting on a monthly pro rata basis over the remaining three years of the vesting period.

(2) Mr. Schroeder's option to purchase 429,800 of our ordinary shares vests over four years, with 25% of the options vesting on January 31, 2020, and the remaining 75% of the option vesting on a monthly pro rata basis over the remaining three years of the vesting period.

(3) Dr. Schranz's option to purchase 150,000 of our ordinary shares vests over four years, with 25% of the options vesting on March 31, 2019, and the remaining 75% of the option vesting on a monthly pro rata basis over the remaining three years of the vesting period.

(4) Dr. Schranz's option to purchase 235,000 of our ordinary shares vests over four years, with 25% of the options vesting on January 31, 2020, and the remaining 75% of the option vesting on a monthly pro rata basis over the remaining three years of the vesting period.

(5) Dr. Gelone's option to purchase 88,790 of our ordinary shares vests over four years, with 25% of the options vesting on May 31, 2016, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.

(6) Dr. Gelone's option to purchase 55,900 of our ordinary shares vests over four years, with 25% of the options vesting on February 28, 2017, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.

(7) Dr. Gelone's option to purchase 113,000 of our ordinary shares vests over four years, with 25% of the options vesting on February 28, 2018, and the remaining 75% of the option vesting on a monthly pro rata basis over the remaining three years of the vesting period.

(8) Dr. Gelone's option to purchase 100,000 of our ordinary shares vests over four years, with 25% of the options vesting on January 31, 2019, and the remaining 75% of the option vesting on a monthly pro rata basis over the remaining three years of the vesting period.

(9) Dr. Gelone's option to purchase 77,500 of our ordinary shares vests over four years, with 25% of the options vesting on July 25, 2019, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.

(10) Dr. Gelone's option to purchase 7,500 of our ordinary shares vests over four years, with 25% of the options vesting on August 2, 2019, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.

(11) Dr. Gelone's option to purchase 278,400 of our ordinary shares vests over four years, with 25% of the options vesting on January 31, 2020, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.

(12) Mr. Schroeder's RSUs will vest as follows: 50% of the RSUs will vest upon Board certification of the receipt of FDA approval of a new drug application for each of (x) lefamulin and (y) CONTEPO for any indication, and 50% of his RSUs will vest on the first anniversary of such Board certification, provided, in each case, that Mr. Schroeder is performing services to Nabriva US on the applicable vesting dates. Since the FDA did not approve the NDA for both lefamulin and CONTEPO by January 31, 2020, the RSUs have terminated in full.

(13) Mr. Schroeder's, Dr. Schranz´s and Dr. Gelone's RSUs vest over four years, with 25% of the options vesting on January 31, 2020, and the remaining 75% of the option vesting on a monthly pro-rata basis over the remaining three years of the vesting period.

(14) Dr. Gelone's vesting of the RSUs is subject to the FDA approval of an NDA for lefamulin. Fifty percent (50%) of each RSU award vested upon FDA approval of an NDA for lefamulin, and the remaining fifty percent (50%) will vest on the one-year anniversary of such approval.

Employment Agreements with Executive Officers

Agreement with Theodore Schroeder, Chief Executive Officer and Director

Mr. Schroeder was appointed our chief executive officer and entered into an employment agreement dated and effective as of July 23, 2018. He was appointed to our board on August 1, 2018. His employment agreement continues until terminated in accordance with its terms, as described below.

Pursuant to his employment agreement, Mr. Schroeder receives an annual base salary of $530,000 and is eligible to receive an annual performance bonus targeted at 50% of his annual base salary, with the actual amount of such bonus, if any, to be determined by the Board. For 2018, Mr. Schroeder's bonus was pro-rated to reflect his 2018 service to us. Mr. Schroeder is also eligible to receive equity awards at such times and on such terms and conditions as the Board may determine and is also entitled to participate in any and all benefit programs that we make available to our executive officers, for which he may be eligible, under the plan documents governing such programs.

Pursuant to his employment agreement, the Board also approved the grant to Mr. Schroeder, effective as of the first business day immediately following his employment commencement date (the "Grant Date"), of a non-statutory stock option to purchase 850,000 ordinary shares at an exercise price per share equal to the closing price per share of the Company's ordinary shares on the Nasdaq Global Select Market on the Grant Date. The option award has a ten-year term and vests over a four-year period, with 25% of the shares underlying the award vesting on the first anniversary of his employment commencement date and the remaining 75% of the shares underlying the option award to vest monthly over the subsequent 36-month period. In addition, the Board approved the grant to Mr. Schroeder, effective as of the Grant Date, of 150,000 performance-based restricted share units (the "Schroeder PRSUs"). The Schroeder PRSUs vest

as follows: 50% of the Schroeder PRSUs will vest upon Board certification of the receipt of FDA approval of a new drug application for each of (x) lefamulin and (y) CONTEPO for any indication, and 50% of the Schroeder PRSUs will vest on the first anniversary of such Board certification, provided, in each case, that Mr. Schroeder is performing services for us on the applicable vesting dates. Since the FDA did not approve both NDAs for lefamulin and CONTEPO by January 31, 2020, the Schroeder PRSUs award has terminated in full. The option being granted to Mr. Schroeder and the Schroeder PRSUs were awarded outside of our 2017 Share Incentive Plan as an inducement material to Mr. Schroeder's entering into employment with us in accordance with Nasdaq Stock Market Listing Rule 5635(c)(4).

The employment agreement, and Mr. Schroeder's employment, may be terminated as follows: (1) upon Mr. Schroeder's death or "disability" (as disability is defined in his employment agreement); (2) at our election, with or without "cause" (as cause is defined in his employment agreement); and (3) at Mr. Schroeder's election, with or without "good reason" (as good reason is defined in his employment agreement).

In the event of the termination of Mr. Schroeder's employment by us without cause, including as a result of a termination of his employment for good reason prior to, or more than twelve months following, a "change in control" (as change in control is defined in his employment agreement), Mr. Schroeder will be entitled to his base salary that has accrued and to which he is entitled as of the termination date. In addition, subject to his execution and nonrevocation of a release of claims in our favor and his continued compliance with his proprietary rights, non-disclosure and developments agreement with us, he is entitled to (1) continued payment of his base salary, in accordance with our regular payroll procedures, for a period of 18 months (2) provided he is eligible for and timely elects to continue receiving group medical insurance under COBRA and the payments would not result in the violation of nondiscrimination requirements of applicable law, payment by us of the portion of health coverage premiums we pay for similarly-situated, active employees who receive the same type of coverage, for a period of up to 18 months following his date of termination, (3) a lump sum payment equal to any earned but unpaid annual bonus for a previously completed calendar year and (4) a lump sum payment equal to a prorated annual bonus for the year in which Mr. Schroeder's employment is terminated based on the number of days he provided services to us during the year in which his employment is terminated.

In the event of the termination of Mr. Schroeder's employment by us without cause, including as a result of a termination of his employment for good reason prior to, or by him for good reason within twelve months following a change in control, subject (as described above with respect to certain payments), to his execution and nonrevocation of a release of claims in our favor and his continued compliance with his proprietary rights, non-disclosure and developments agreement with us, Mr. Schroeder would be entitled to the same payments and benefits as described in the preceding paragraph, except that, in lieu of a pro-rated annual bonus payment, he would be entitled to receive a lump sum payment equal to 100% of his target bonus for the year in which his employment is terminated and he shall also be entitled to full vesting acceleration of his then-unvested equity awards, whether granted under the 2017 Share Incentive Plan, 2020 Share Incentive Plan or any successor equity incentive plan or as an inducement to his employment, such that his equity awards become fully exercisable and non-forfeitable as of the termination date.

If Mr. Schroeder's employment is terminated for any other reason, including as a result of his death or disability, for cause, or voluntarily by Mr. Schroeder without good reason, our obligations under the employment agreement cease immediately, and Mr. Schroeder is only entitled to his base salary that has accrued and to which he is entitled as of the termination date and solely if his employment is terminated as a result of his death or disability, subject to his execution and nonrevocation of a release of claims in our favor and his continued compliance with his proprietary rights, non-disclosure and developments agreement with us, he or his estate, as applicable, is entitled to any earned but unpaid annual bonus from a previously completed calendar year.

As a condition of his employment, Mr. Schroeder signed a proprietary rights, non-disclosure and developments agreement.

Agreements with other Executive Officers

Mr. Sender was appointed chief financial officer of Nabriva Austria and entered into an employment agreement dated and effective as of May 2, 2016. He was appointed our chief financial officer on April 12, 2017. Dr. Gelone was appointed chief development officer and entered into an employment agreement dated and effective as of December 1,

2014, which was amended and restated as of May 26, 2016 and further amended on restated on July 24, 2018. Mr. Crotty was appointed general counsel and secretary of Nabriva Austria and entered into an employment agreement dated and effective as of June 14, 2017. Dr. Gelone was appointed as our chief development officer and Mr. Crotty was appointed our general counsel and secretary effective as of June 23, 2017. Dr. Gelone was subsequently appointed our chief scientific officer on June 30, 2017, and our president and chief operating officer on July 24, 2018. Dr. Schranz was appointed our chief medical officer and entered into an employment agreement dated and effective as of March 21, 2018. Mr. Lavino was appointed our chief commercial officer and entered into an employment agreement dated and effective as of July 10, 2017. Each of these employment agreements provides that such executive officer is an at-will employee, and his or her employment with us can be terminated by the respective executive officer or us at any time and for any reason.

The employment agreements and the employment of each of Mr. Sender, Dr. Gelone, Mr. Crotty, Dr. Schranz and Mr. Lavino may be terminated in one of three ways: (1) upon the death or "disability" (as disability is defined in the applicable employment agreement) of such executive officer; (2) at our election, with or without "cause" (as cause is defined in the applicable employment agreement); and (3) at such executive officer's election, with or without "good reason" (as good reason is defined in the applicable employment agreement).

In the event of the termination of such executive officer's employment by us without cause or by him or her for good reason prior to, or more than twelve months following, a "change in control" (as change in control is defined in the applicable employment agreement), such executive officer will be entitled to his or her base salary that has accrued and to which he or she is entitled as of the termination date. In addition, subject to such executive officer's execution and nonrevocation of a release of claims in our favor and his or her continued compliance with his or her proprietary rights, non-disclosure and developments agreement with us, such executive officer is entitled to (1) continued payment of such executive officer's base salary, in accordance with our regular payroll procedures, for a period of 12 months, (2) provided he or she is eligible for and timely elects to continue receiving group medical insurance under COBRA and the payments would not result in the violation of nondiscrimination requirements of applicable law, payment by us of the portion of health coverage premiums we pay for similarly-situated, active employees, who receive the same type of coverage, for a period of up to 12 months following the date of termination, (3) a lump sum payment equal to any earned but unpaid annual bonus for a previously completed calendar year and (4) a lump sum payment equal to a prorated annual bonus for the year in which such executive officer's employment is terminated based on the number of days such executive officer provided services to us during the year in which such executive officer's employment is terminated.

In the event of the termination of the executive officer's employment by us without cause or by him or her for good reason within twelve months following a change in control, subject (as described above with respect to certain payments) to such executive officer's execution and nonrevocation of a release of claims in our favor and his or her continued compliance with his or her proprietary rights, non-disclosure and developments agreement with us, such executive officer will be entitled to the same payments and benefits as described in the preceding paragraph, except that, in lieu of a pro-rated annual bonus payment, such executive officer will be entitled to receive a lump sum payment equal to 100% of such executive officer's target bonus for the year in which his or her employment is terminated, and such executive officer shall also be entitled to full vesting acceleration of his or her then-unvested equity awards, whether granted under the 2017 Share Incentive Plan, 2020 Share Incentive Plan or any successor equity incentive plan, such that his or her equity awards become fully exercisable and non-forfeitable as of the termination date.

If such executive officer's employment is terminated for any other reason, including as a result of his or her death or disability, for cause, or voluntarily by such executive officer without good reason, our obligations under the applicable employment agreement cease immediately, and such executive officer is only entitled to his or her base salary that has accrued and to which he or she is entitled as of the termination date and, solely if such executive officer's employment is terminated as a result of his or her death or disability and subject to his or her execution and nonrevocation of a release of claims in our favor and his or her continued compliance with his or her proprietary rights, non-disclosure and developments agreement with us, such executive officer or the estate of such executive officer, as applicable, is entitled to any earned but unpaid annual bonus from a previously completed calendar year.

The base salaries of our executive officers are reviewed by our compensation committee and the board of directors in the first quarter of each fiscal year and any adjustment to such base salary is retroactively effective to the

first day of such fiscal year. In addition, such executive officers are eligible for an annual discretionary bonus of 40% of their current base salary. Each executive officer is also eligible to receive equity awards at such times and on such terms and conditions as the Board may determine and is also entitled to participate in any and all benefit programs that we make available to our executive officers, for which he or she may be eligible, under the plan documents governing such programs.

As a condition to their employment, each of Mr. Sender, Dr. Gelone, Mr. Crotty, Dr. Schranz and Mr. Lavino signed a proprietary rights, non-disclosure and developments agreement.

Equity Incentive Plans

In this section, we describe our 2020 Share Incentive Plan, 2017 Share Incentive Plan and Stock Option Plan 2015. Prior to the Redomiciliation, Nabriva Austria granted awards to eligible recipients under the Stock Option Plan 2015. In connection with the Redomiciliation, both plans were amended to take account of certain requirements under Irish law and assumed by us, with each option to acquire one Nabriva Austria common share becoming an option to acquire ten of our ordinary shares on the same terms and conditions. We currently make share awards to eligible recipients solely under our 2017 Share Incentive Plan.

2020 Share Incentive Plan

On March 4, 2020, our board of directors, subject to shareholder approval, adopted the 2020 Share Incentive Plan, or the 2020 Plan. The 2020 Plan has not yet been approved by our shareholders and will be submitted for shareholder approval at our 2020 Annual General Meeting of Shareholders. The number of ordinary shares initially reserved for issuance under the 2020 Plan is 1,837,500 ordinary shares. Prior to submitting the 2020 Plan to our shareholders for approval at the 2020 Annual General Meeting of Shareholders, our board of directors plans to amend the 2020 Plan to increase the number of shares reserved for issuance thereunder.

The 2020 Plan provides for the grant of incentive share options, nonstatutory share options, share appreciation rights, restricted share awards, restricted share units, other share-based and cash-based awards and performance awards.

To date, option awards to purchase 1,837,500 ordinary shares have been granted under the 2020 Plan. Such awards will automatically convert to cash-settled share appreciation rights if our shareholders do not approve the 2020 Plan at our 2020 Annual General Meeting of Shareholders.

The 2020 Plan is administered by the board of directors. The exercise or measurement prices, vesting periods, performance goals and other award restrictions are determined at the discretion of the board of directors, except that the exercise price or measurement price per share of options or share appreciation rights may not be less than 100% of the fair market value of the ordinary shares on the date of grant, provided that if the board of directors approves the grant of an option or a share appreciation right with an exercise or measurement price to be determined on a future date, the exercise or measurement price may not be less than 100% of the fair market value of the ordinary shares on such future date. No share option or share appreciation right will be granted under the 2020 Plan with a term in excess of ten years.

If, during the term of the 2020 Plan, there is a change in our share capital or a restructuring measure which has an effect on our share capital, such as a share split or reverse share split, the board of directors will make equitable adjustments to the price or the amount of outstanding awards.

The 2020 Plan also contains provisions addressing the consequences of any reorganization event. A reorganization event is defined as (a) any merger or consolidation of ours with or into another entity as a result of which all of our ordinary shares are converted into or exchanged for the right to receive cash, securities or other property, or are canceled, (b) any transfer or disposition of all of our ordinary shares for cash, securities or other property pursuant to a share exchange or other transaction or (c) any liquidation or dissolution of ours; any one of which, (a), (b) or (c), may be effected pursuant to the laws of the Republic of Ireland.

The 2020 Plan provides that, if a reorganization event occurs, the board of directors may take one or more of the following actions with respect to all or any outstanding awards other than restricted shares on such terms as the board of directors determines: (1) provide that such awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (2) upon written notice to a participant, provide that all of the participant's unvested awards will be forfeited immediately prior to the consummation of such reorganization event and/or that all of the participant's unexercised awards will terminate immediately prior to the consummation of such reorganization event unless exercised by the participant (to the extent then exercisable) within a specified period following the date of such notice, (3) provide that outstanding awards will become exercisable, realizable, or deliverable, or restrictions applicable to an award will lapse, in whole or in part prior to or upon such reorganization event, (4) in the event of a reorganization event under the terms of which holders of our ordinary shares will receive, upon consummation thereof, a cash payment for each share surrendered in the reorganization event, or the Acquisition Price, make or provide for a cash payment to participants with respect to each award held by a participant equal to (A) the number of ordinary shares subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event) multiplied by (B) the excess, if any, of (I) the Acquisition Price over (II) the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award, (5) provided that, in connection with our liquidation or dissolution, awards will convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings) and (6) any combination of the foregoing. Our board of directors is not obligated to treat all awards, all awards held by a participant, or all awards of the same type, identically.

No award may be granted under the 2020 Plan after the date that is ten years from the date the 2020 Plan is approved by our shareholders. Our board of directors may, at any time, amend, suspend or terminate the 2020 Plan or any portion thereof. However, if shareholder approval is required, including by application of Irish law or the terms of the 2020 Plan, the board of directors may not effect such modification or amendment without such approval.

2017 Share Incentive Plan

The 2017 Share Incentive Plan permits the award of share options, share appreciation rights, or SARs, restricted shares, restricted share units or RSUs, and other share-based awards to our employees, officers, directors, consultants and advisers. Our board of directors will administer the 2017 Share Incentive Plan. As of January 31, 2020, under our 2017 Share Incentive Plan, there were options to purchase an aggregate of 4,422,139 of our ordinary shares at a weighted average exercise price of $3.55 per share, 1,051,686 restricted stock units outstanding with a weighted average grant date fair value of $2.74 per share, and 1,635,981ordinary shares available for future issuance under the plan. Shares covered by awards under the 2017 Share Incentive Plan that expire or are terminated, surrendered, or cancelled without having been fully exercised or are forfeited in whole or in part or that result in any shares not being issued will again be available for the grant of awards under the 2017 Share Incentive Plan (subject, in the case of incentive share options, to any limitations under the Internal Revenue Code, or the Code).

Options and SARs granted under the 2017 Share Incentive Plan may not have an exercise price or measurement price, respectively, that is less than 100% of the fair market value of our ordinary shares on the date of grant; provided, however, that if our board of directors approves the grant of an option or SAR with an exercise price or measurement price to be determined on a future date, such price may not be less than 100% of the fair market value of our ordinary shares on such future date. Such options and SARs will be exercisable at such times and subject to such terms and conditions as the board may specify in the applicable option or SAR agreement. No option or SAR will be granted with a term in excess of ten years.

Restricted shares and RSUs granted under the 2017 Share Incentive Plan will determine the terms and conditions of restricted shares and RSUs, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

If, during the term of the 2017 Share Incentive Plan, there is a change in our capital or a restructuring measure which has an effect on our capital, such as a share split or reverse share split, which change or measure results in a

change in the value of the share-based awards outstanding under the 2017 Share Incentive Plan, the board will make appropriate adjustments to the price or the amount of such outstanding awards.

The 2017 Share Incentive Plan also contains provisions addressing the consequences of any reorganization event. A reorganization event is defined as (a) any merger or consolidation of us with or into another entity as a result of which all of our ordinary shares are converted into or exchanged for the right to receive cash, securities or other property, or are cancelled, (b) any transfer or disposition of all of our ordinary shares for cash, securities or other property pursuant to a share exchange or other transaction or (c) our liquidation or dissolution; any one of which, (a), (b) or (c), may be effected pursuant to the laws of the Republic of Ireland.

The 2017 Share Incentive Plan provides that, if a reorganization event occurs, the board of directors may take one or more of the following actions to all or any outstanding awards other than restricted shares on such terms as the board of directors determines: (1) provide that such awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (2) upon written notice to a participant, provide that all of the participant's unvested awards will be forfeited immediately prior to the consummation of such reorganization event and/or that all of the participant's unexercised awards will terminate immediately prior to the consummation of such reorganization event unless exercised by the participant (to the extent then exercisable) within a specified period following the date of such notice, (3) provide that outstanding awards will become exercisable, realizable, or deliverable, or restrictions applicable to an award will lapse, in whole or in part prior to or upon such reorganization event, (4) in the event of a reorganization event under the terms of which holders of our ordinary shares will receive, upon consummation thereof, a cash payment for each share surrendered in the reorganization event, which we refer to as the Acquisition Price, make or provide for a cash payment to participants with respect to each award held by a participant equal to (A) the number of ordinary shares subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event) multiplied by (B) the excess, if any, of (I) the Acquisition Price over (II) the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award, (5) provide that, in connection with our liquidation or dissolution, awards will convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings) and (6) any combination of the foregoing. Our board is not obligated to treat all awards, all awards held by a participant, or all awards of the same type, identically.

No award may be granted under the 2017 Share Incentive Plan after the earlier of September 14, 2027 and shareholder approval of the 2020 Plan. The board of directors may, at any time, amend, suspend or terminate the 2017 Share Incentive Plan or any portion thereof. However, if shareholder approval is required, including by application of Irish law, the board may not effect such modification or amendment without such approval.

Stock Option Plan 2015

The Stock Option Plan 2015 provided for the grant of options to purchase our ordinary shares to our employees, including executive officers, and to directors. As of January 31, 2020, under our Stock Option Plan 2015, there were options to purchase an aggregate of 2,289,904 of our ordinary shares at a weighted average exercise price of $8.33 per share and no ordinary shares were available for issuance under the plan. Following the approval of the 2017 Share Incentive Plan by our shareholders on September 15, 2017, we ceased granting awards under the Stock Option Plan 2015, Unless the context specifically indicates otherwise, references to our Stock Option Plan 2015 in this Annual Report on Form 10-K refer to the Stock Option Plan 2015, as amended and adopted by us.

Options granted under the Stock Option Plan 2015 entitle beneficiaries thereof to purchase our ordinary shares at an exercise price equal to 100% of the fair market value per share on the beneficiary's date of participation, which following the Redomiciliation was derived from the closing sale price of our ordinary shares on the Nasdaq Global Market. Options granted under the Stock Option Plan 2015 generally vest over four years from the beneficiary's date of participation. Typically, 25% of the options subject to a particular grant vest on the last day of the last calendar month of the first year of the vesting period, and the remaining 75% vests on a monthly pro-rata basis over the second, third and fourth years of the vesting period (i.e., 2.083% per month). Any alternative vesting period determined by us is subject to

approval by our executive officers, board of directors or shareholders, in accordance with any applicable voting requirements.

The Stock Option Plan 2015 provides that, if a liquidity event (as defined below) occurs, all options outstanding under the Stock Option Plan 2015 will be assumed (or substantially equivalent awards will be substituted by an acquiring or succeeding corporation (or an affiliate of the acquiring or succeeding corporation)), and any then-unvested options shall continue to vest in accordance with the beneficiary's original vesting schedule. If a beneficiary is terminated due to a good leaver event (within the meaning of the Stock Option Plan 2015), on or prior to the first anniversary of the date of the liquidity event, the beneficiary's options will be immediately exercisable in full as of the date of such termination. If the acquiring or succeeding corporation (or an affiliate of the acquiring or succeeding corporation) refuses to assume the options outstanding under the Stock Option Plan 2015 or to substitute substantially equivalent options therefor, all then-unvested options under the Stock Option Plan 2015 will automatically vest in full upon the liquidity event. For purposes of the Stock Option Plan 2015, a liquidity event generally refers to an exclusive license of or the sale, lease or other disposal of all or substantially all of our assets, a sale or other disposal (but not a pledge) of 50% or more of our shares, a merger or consolidation of us with or into any third party, or our liquidation, winding up or other form of dissolution of us.

Unless otherwise specifically permitted in an option agreement or resolved upon by the board of directors, the exercise of vested options is permitted under the Stock Option Plan 2015 only during specified periods and on specified terms in the case of a liquidity event or following an initial public offering occurring during the term of the option. A beneficiary is entitled to exercise vested options at any time during the remaining term of the option while the beneficiary is providing services to us, and within the three-month period following a termination of the beneficiary's services due to a good leaver event. Options granted under the Stock Option Plan 2015 will have a term of no more than ten years from the beneficiary's date of participation.

If, during the term of the Stock Option Plan 2015, there is a change in our capital or a restructuring measure which has an effect on our capital, such as a stock split or reverse stock split, which change or measure results in a change in the value of the options outstanding under the Stock Option Plan 2015, the board may make appropriate adjustments to the price or the amount of such outstanding options.

The board of directors may, at any time, amend, suspend or terminate the Stock Option Plan 2015 in whole or in part. However, if shareholder approval is required, including by application of Irish law, the board may not effect such modification or amendment without such approval.

401(k) Plan

We maintain a defined contribution employee retirement plan for our U.S.-based employees. Our 401(k) plan is intended to qualify as a tax-qualified plan under Section 401 of the Internal Revenue Code, so that contributions to our 401(k) plan, and income earned on such contributions, are not taxable to participants until withdrawn or distributed from the 401(k) plan. Our 401(k) plan provides that each participant may contribute up to 100% of his or her pre-tax compensation, up to a statutory limit, which is $19,000 for 2019. Participants who are at least 50 years old can also make "catch-up" contributions, which in 2019 may be up to an additional $6,000 above the statutory limit. Under our 401(k) plan, each employee is fully vested in his or her deferred salary contributions. Employee contributions are held and invested by the plan's trustee, subject to participants' ability to give investment directions by following certain procedures. We match 100.0% of the first 3.0% of the employee's voluntary contribution to the 401(k) plan and 50.0% of the next 2.0% contributed by the employee.

Risk Considerations in Our Compensation Program

Our compensation committee has reviewed and evaluated the philosophy and standards on which our compensation plans have been developed and implemented across our company. It is our belief that our compensation programs do not encourage inappropriate actions or risk taking by our executive officers. We do not believe that any risks arising from our employee compensation policies and practices are reasonably likely to have a material adverse

effect on our company. In addition, we do not believe that the mix and design of the components of our executive compensation program encourage management to assume excessive risks.

DIRECTOR COMPENSATION

Summary Compensation Table

The following table sets forth a summary of the compensation earned by the non-employee members of the board of directors for the year ended December 31, 2019.

Name	Fees Earned or Paid in Cash ($)(1)	Option Awards ($)(2)(3)	Total ($)
Daniel Burgess	85,645	46,900	132,545
Colin Broom	39,129	46,900	86,029
George Talbot	43,462	46,900	90,362
Charles Rowland, Jr.	60,789	46,900	107,689
Stephen Webster	61,427	46,900	108,327
Mark Corrigan	49,786	46,900	96,686
Carrie Bourdow	45,468	46,900	92,368

(1) Fees earned consist of gross director retainer fees which were subject to income tax withholdings in Ireland.

(2) The amounts reported in the “Option Awards” column reflect the aggregate fair value of share-based compensation awarded during 2019 computed in accordance with the provisions of ASC Topic 718. See Note 11 to the consolidated financial statements regarding assumptions underlying the valuation of equity awards.

(3) Represents the grant of an option to purchase 35,000 of our ordinary shares vesting with respect to all of the shares on the last date of the month of the first anniversary of the grant date.

Director Compensation Arrangements

Effective as of October 31, 2018, our board of directors adopted a non-employee director compensation policy, which provided for the following:

- each new non-employee director receives an initial grant of an option to purchase 70,000 of our ordinary shares upon his or her initial election to the board of directors;
- each non-employee director receives an annual grant of an option to purchase 35,000 of our ordinary shares on the date of our annual general meeting of shareholders;
- each non-employee director receives an annual cash fee of $40,000;
- the chairman of our board of directors receives an additional annual cash fee of $30,000;
- each non-employee director who is a member of the audit committee receives an additional annual cash fee of $10,000 ($20,000 for the audit committee chair);
- each non-employee director who is a member of the compensation committee receives an additional annual cash fee of $7,500 ($15,000 for the compensation committee chair); and
- each non-employee director who is a member of the nominating and corporate governance committee receives an additional annual cash fee of $5,000 ($10,000 for the nominating and corporate governance committee chair).

The board of directors approved the annual grants to non-employee directors for the 2019 fiscal year on July 31, 2019.

On December 16, 2019, our board of directors approved an amendment to our non-employee director compensation policy. Effective as of December 16, 2019, the amendment increased the initial grant of an option to purchase our ordinary shares to new non-employee directors upon their initial election to the board of directors to 105,000 ordinary shares and increased the annual grant of an option to purchase our ordinary shares to 35,000 ordinary shares and 17,500 restricted stock units.

The stock options to be granted to our non-employee directors under our non-employee director compensation policy have an exercise price equal to the fair market value of our ordinary shares on the date of grant and will expire ten years after the date of grant. The initial stock options granted to newly elected director vest, subject to such director's continued service on the board, over a three-year period on a monthly pro-rata basis at the end of each successive month following the date of the initial grant. The annual stock options granted to directors will vest, subject to such director's continued service on the board, fully on the last date of the month of the first anniversary of the grant date. The annual restricted stock units awarded to directors will vest, subject to such director's continued service on the board, fully on the last date of the month of the first anniversary of the grant date.

Under our non-employee director compensation policy, the annual cash fees are payable in arrears in four equal quarterly installments payable the week following the end of each quarter. Each non-employee director is also entitled to reimbursement for reasonable travel and other expenses incurred in connection with attending meetings of the board of directors and any committee on which he or she serves or otherwise in direct service of the company.

Compensation Committee Interlocks and Insider Participation

For the fiscal year ended December 31, 2019, the members of our compensation committee were Carrie Bourdow, Mark Corrigan and Charles Rowland Jr. No member of our compensation committee is, or has been, an officer or employee of ours or any subsidiary of ours. None of our executive officers served as a director or a member of a compensation committee (or other committee serving an equivalent function) of any other entity that had one or more executive officers serving as a director or member of our compensation committee during the year ended December 31, 2019.

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

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of January 31, 2020 by:

- each of our directors and director nominees;
- each of our "named executive officers";
- all of our directors and executive officers as a group; and
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our ordinary shares.

The percentages in the columns entitled "Percentage of Shares Beneficially Owned" are based on a total of 94,545,116 ordinary shares outstanding as of January 31, 2020.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our ordinary shares. Our ordinary shares subject to options that are currently

exercisable or exercisable within 60 days of January 31, 2020 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the ordinary shares beneficially owned by them, subject to community property laws, where applicable. Except as otherwise set forth below, the address of the beneficial owner is c/o Nabriva Therapeutics plc, 25-28 North Wall Quay, Dublin 1, Ireland.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Directors and Named Executive Officers:		
Daniel Burgess(1)	120,400	* %
George H. Talbot(2)	136,840	* %
Mark Corrigan(3)	69,400	* %
Stephen Webster(4)	77,400	* %
Charles A. Rowland, Jr.(5)	128,200	* %
Carrie Bourdow(6)	57,056	* %
Colin Broom(7)	921,420	* %
Steven Gelone(8)	477,944	* %
Theodore Schroeder(9)	639,898	* %
Jennifer Schranz(10)	171,605	* %
All current directors and executive officers as a group (13 individuals)(11)	3,521,470	3.62 %
5% Shareholders:		
FMR LLC(12)	6,131,900	6.49 %

* Less than one percent.

(1) Consists of (i) 36,000 ordinary shares and (ii) 84,400 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2020.

(2) Consists of (i) 47,640 ordinary shares and (ii) 89,200 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2020.

(3) Consists of 69,400 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2020.

(4) Consists of (i) 8,000 ordinary shares and (ii) 69,400 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2020.

(5) Consists of (i) 53,000 ordinary shares and (ii) 75,200 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2020.

(6) Consists of 57,056 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2020.

(7) Consists of (i) 208,750 ordinary shares directly owned by Dr. Broom and (ii) 712,670 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2020.

(8) Consists of (i) 71,116 ordinary shares, (ii) 402,422 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2020 and (iii) 4,406 ordinary shares issuable upon the vesting of restricted stock units within 60 days of January 31, 2020.

(9) Consists of (i) 153,571 ordinary shares, (ii) 479,525 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2020 and (iii) 6,802 ordinary shares issuable upon the vesting of restricted stock units within 60 days of January 31, 2020.

(10) Consists of (i) 25,875 ordinary shares, (ii) 143,542 ordinary shares issuable upon exercise of stock options exercisable within 60 days of January 31, 2020 and (iii) 2,188 ordinary shares issuable upon the vesting of restricted stock units within 60 days of January 31, 2020.

(11) Consists of (i) 428,540 ordinary shares and (ii) 1,439,916 ordinary shares issuable upon exercise of stock options within 60 days of January 31, 2020.

(12) Based solely on information provided in a Schedule 13G filed by FMR LLC on February 7, 2020. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act ("Fidelity Funds") advised by Fidelity Management & Research Company ("FMR Co"), a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. FMR Co carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. FMR LLC reports that it holds sole dispositive power with respect to 6,131,900 shares. The address of FMR LLC is 245 Summer Street, Boston, Massachusetts 02210.

Securities Authorized for Issuance under Equity Compensation Plans

The following table contains information about our equity compensation plans as of December 31, 2019. As of December 31, 2019, we had four equity compensation plans: the 2017 Share Incentive Plan, the Stock Option Plan 2015 and the 2018 Employee Share Purchase Plan, each of which were approved by our shareholders and the 2020 Share Incentive Plan which has been adopted by our board of Directors and which we expect to submit to our shareholders for approval at our 2020 annual general meeting. In addition, from time to time, the compensation committee grants inducement equity awards to individuals as an inducement material to the individual's entry into employment with us within the meaning of Nasdaq Listing Rules, including pursuant to our 2019 Inducement Share Incentive Plan, or the Inducement Plan, that was adopted by our board of directors without shareholder approval.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a)) (c)
Equity compensation plans approved by security holders	7,614,944 (1)	$ 5.18 (2)	1,634,766 (3)
Equity compensation plans not approved by security holders	1,605,650 (4)	2.95 (2)	1,394,350 (5)
Total	9,220,594	$ 4.79 (2)	3,029,116

(1) Includes ordinary shares underlying awards outstanding under our 2017 Share Incentive Plan and our Stock Option Plan 2015.

(2) Only share option awards were used in computing the weighted-average exercise price.

(3) Includes ordinary shares available for issuance under our 2017 Share Incentive Plan and 2018 Employee Share Purchase Plan.

(4) Represents an option award and a performance-based restricted share unit award granted to Mr. Schroeder on July 25, 2018, as an inducement material to Mr. Schroeder's acceptance of employment with the company in accordance with Nasdaq Listing Rule 5635(c)(4), other inducement awards made in accordance with Nasdaq Listing Rule 5635(c)(4) under our 2019 Inducement Plan and ordinary shares underlying option and RSU awards made under our 2020 Share Incentive Plan.

(5) Includes ordinary shares available for issuance under our 2019 Inducement Share Incentive Plan.

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

Board Determination of Independence

Applicable Nasdaq rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the Nasdaq rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under applicable Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. To be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of the director, including any consulting, advisory or other compensatory fee paid by such company to the director; and (2) whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In July 2019, our board of directors undertook a review of the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board has determined that each of our directors, with the exception of Colin Broom and Theodore Schroeder, is an "independent director" as defined under applicable Nasdaq rules, including, in the case of all the members of our audit committee, the independence criteria set forth in Rule 10A-3 under the Exchange Act, and in the case of all the members of our compensation committee, the independence criteria set forth in Rule 10C-1 under the Exchange Act. In making such determination, our board considered the relationships that each such director has with us, including each of the transactions described below in "—Board Policies—Related Person Transactions—Certain Relationships and Related Transactions," and all other facts and circumstances that our board deemed relevant in make such independence determination. Mr. Schroeder is not an independent director because he is our chief executive officer, and Dr. Broom is not an independent director because he was employed as our chief executive officer during the past three years.

Board Policies

Related Person Transactions

Our board of directors has adopted written policies and procedures for the review of any transaction, arrangement or relationship in which the company is a participant, the amount involved exceeds the lesser of $120,000 and one percent of the average of the our total assets at year-end for the last two completed fiscal years and one of our executive officers, directors, director nominees or 5% shareholders, or their immediate family members, each of whom we refer to as a "related person," has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a "related person transaction," the related person must report the proposed related person transaction to our chief financial officer or general counsel. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by our audit committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the committee will review, and, in its discretion, may ratify the related person transaction. The policy also permits the chair of the audit committee to review and, if deemed appropriate, approve proposed related person transactions that arise between committee meetings, subject to ratification by the committee at its next meeting. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the audit committee after full disclosure of the related person's interest in the transaction. As appropriate for the circumstances, the audit committee will review and consider:

- the related person's interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person's interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of our business;
- whether the terms of the transaction are no less favorable to us than terms that could have been reached with an unrelated third party;
- the purpose of, and the potential benefits to us of, the transaction; and
- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of such transaction.

Our audit committee may approve or ratify the transaction only if it determines that, under all of the circumstances, the transaction is in our best interests. Our audit committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC's related person transaction disclosure rule, our board of directors has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- interests arising solely from the related person's position as an executive officer of another entity, whether or not the person is also a director of the entity, that is a participant in the transaction where the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity, the

related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction and the amount involved in the transaction is less than the greater of $200,000 or 5% of the annual gross revenues of the company receiving payment under the transaction; and

- a transaction that is specifically contemplated by provisions of our memorandum and articles of association.

The policy provides that transactions involving compensation of our executive officers shall be reviewed and approved by our compensation committee in the manner specified in the compensation committee's charter.

In addition, under our Code of Business Conduct and Ethics, our directors, executive officers and employees have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest.

Certain Relationships and Related Transactions

Since January 1, 2018, we have engaged in the following transactions with our executive officers, directors and holders of more than 5% of our voting securities, and affiliates of our executive officers, directors and 5% shareholders. We believe that all of the transactions described below were made on terms no less favorable to us than could have been obtained from unaffiliated third parties:

July 2018 Financing

In July 2018, we completed an underwritten offering for the sale of an aggregate of 18,181,818 ordinary shares. In connection with such offerings, our 5% shareholders, purchased an aggregate of 8,715,000 ordinary shares at a purchase price of $2.75 per ordinary share.

5% Shareholders:	**Number of Shares Acquired**
Entities affiliated with Vivo Capital	2,545,000
Novo A/S	1,815,000
Longitude Ventures Partners	1,815,000
Frazier Healthcare Partners	1,815,000
OrbiMed Private Investments V, L.P.	725,000

At-the-Market Offering

In March 2018, Wellington Management Group LLP, purchased an aggregate of 3,414,100 of our ordinary shares at a purchase price of $5.50 per share under our "at-the-market" offering program. Following such purchase, Wellington Management Group LLP beneficially owned more than 5% of our outstanding share capital.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table sets forth, for each of the years indicated, the aggregate fees billed or expected to be billed to us for services rendered by KPMG LLP, or KPMG.

	Year Ended December 31,	
(in thousands)	2019	2018
Audit Fees (1)	$ 605	$ 889
Tax Fees(2)	40	23
All Other Fees	40	—
Total	$ 685	$ 912

(1) Includes fees related to services associated with our at-the-market facility, July 2018 public offering and Zavante acquisition.

(2) Fees related to services rendered on tax compliance, tax advice and tax planning.

Pre-Approval Policies and Procedures

Our audit committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by our independent registered public accounting firm. This policy generally provides that we will not engage our independent registered public accounting firm to render audit or non-audit services unless the service is specifically approved in advance by our audit committee or the engagement is entered into pursuant to a de minimis exception in accordance with applicable SEC rules.

All of the services provided to us by KPMG during the last two fiscal years were approved by the audit committee.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) (1) Financial Statements: See Index to Consolidated Financial Statements on page F-1.
(2) No financial statement schedules have been filed as part of this Annual Report on Form 10-K because they are not applicable, not required or because the information is otherwise included in our financial statements or notes thereto.
(3) The exhibits listed on the Exhibit Index set forth immediately following Item 16 are filed or furnished as part of this Annual Report. The Exhibit Index is incorporated herein by reference.

ITEM 16. FORM 10-K SUMMARY

None

EXHIBIT INDEX

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit Number	
2.1*	Agreement and Plan of Merger dated as of July 23, 2018, by and among Nabriva Therapeutics plc, Zuperbug Merger Sub I, Inc., Zuperbug Merger Sub II, Inc., Zavante Therapeutics, Inc. and Cam Gallagher, solely in his capacity as Stockholder Representative	8-K	00137558	07/25/2018	2.1	
3.1	Memorandum and Articles of Association of Nabriva Therapeutics plc.	8-K	00138132	06/26/2017	3.1	
4.1	Description of the Registrant's Securities Registered under Section 12 of the Exchange Act					X
10.1	Form of Indemnification Agreement.	8-K	00138132	06/26/2017	10.1	
10.2#	2017 Share Incentive Plan, as Amended.	10-Q	00137558	11/09/2017	10.2	
10.3#	Stock Option Plan 2007, as Amended.	8-K	00138132	06/26/2017	10.2	
10.4#	Stock Option Plan 2015, as Amended.	8-K	00138132	6/26/2017	10.3	
10.5	Lease Agreement, dated March 16, 2007, by and between Nabriva Therapeutics AG and CONTRA Liegenschaftsverwaltung GmbH	F-1	333205073	06/18/15	10.4	
10.6	Sublease Agreement, dated July 7, 2015, by and between Nabriva Therapeutics AG and Card Connect, LLC	F-1	333205073	8/24/15	10.11	
10.7#	Employment Agreement dated May 2, 2016 by and between Nabriva Therapeutics US, Inc. and Gary Sender	6-K	00137558	08/09/16	10.2	
10.8#	Employment Agreement, dated June 14, 2017, by and between Nabriva Therapeutics US, Inc. and Robert Crotty.	10-Q	00137558	08/07/2017	10.4	

10.9#	Employment Agreement, dated July 6, 2017, by and among the Registrant, Nabriva Therapeutics US, Inc. and Francesco M. Lavino.	10-Q	00137558	08/07/2017	10.5	
10.10#	Form of Restricted Share Unit Agreement under the 2017 Share Incentive Plan (Share Withholding)					X
10.11#	Form of Restricted Share Unit Agreement under the 2017 Share Incentive Plan (Automatic Sale)	8-K	00137558	02/02/2018	10.1	
10.12#	Form of Share Option Agreement under the 2017 Share Incentive Plan	8-K	00137558	02/02/2018	10.2	
10.13**	Manufacturing Services Agreement, dated May 8, 2017, by and between Patheon UK Limited and Nabriva Therapeutics AG	10-K	03/16/2018	03/16/2018	10.16	
10.14**	Master Agreement for the Manufacture, Packaging and Supply of Products, dated August 7, 2017, by and between ALMAC Pharma Services Limited and Nabriva Therapeutics Ireland DAC	10-K	03/16/2018	03/16/2018	10.17	
10.15**	Key Intermediate Supply Agreement, dated of August 28, 2017 by and among Nabriva Therapeutics Ireland DAC, and SEL Biochem Xinjiang Co., Ltd, and Fountain International Development Holding Limited	10-K	03/16/2018	03/16/2018	10.18	
10.16	Open Market Sale Agreement℠, dated June 25, 2019, by and between Nabriva Therapeutics plc and Jefferies LLC	8-K	00137558	06/25/2019	1.1	
10.17**	License Agreement, dated March 26, 2018, by and among Nabriva Therapeutics Ireland DAC, Sinovant Sciences, Ltd., Nabriva Therapeutics GmbH and Roivant Sciences, Ltd.	10-Q	00137558	05/08/2018	10.2	
10.18	Transition, Separation and Release of Claims Agreement, by and between Nabriva Therapeutics US, Inc. and Colin Broom, dated as of July 23, 2018	8-K	00137558	07/25/2018	10.1	
10.19#	Employment Agreement, by and between Nabriva Therapeutics US, Inc. and Theodore Schroeder, dated as of July 23, 2018	8-K	00137558	07/25/2018	10.2	
10.20	Consulting Agreement, by and between Nabriva Therapeutics US, Inc. and Colin Broom, dated as of July 24, 2018 (included as Attachment A to Exhibit 10.1)	8-K	00137558	07/25/2018	10.1	
10.21	Form of Inducement Option Award Agreement.	S-8	333226330	07/25/2018	99.2	
10.22	Form of Inducement Performance-Based Share Award Agreement.	S-8	333226330	07/25/2018	99.3	

10.23	Stock Purchase Agreement by and among SG Pharmaceuticals, Inc., the Sellers named on Annex A, and Julia Feliciano, as Sellers' Representative, dated as of May 5, 2015	10-Q	00137558	11/06/2018	10.4
10.24**	License Agreement by and between ICPD Holdings, LLC and Evelyn J. Ellis-Grosse and Zavante Therapeutics, Inc., dated as of March 1, 2014	10-Q	00137558	11/06/2018	10.5
10.25	Office Lease by and between AGP Sorrento R&D, LP and Zavante Therapeutics, Inc., dated as of June 16, 2016	10-Q	00137558	11/06/2018	10.6
10.26**	Manufacturing and Supply Agreement by and between Zavante Therapeutics, Inc. and Ercros, S.A., dated as of July 28, 2016	10-Q	00137558	11/06/2018	10.7
10.27**	Amended and Restated Three-Way Agreement by and between Laboratorios ERN, S.A, Ercros, S.A., and Zavante Therapeutics, Inc., dated as of July 28, 2016	10-Q	00137558	11/06/2018	10.8
10.28**	Amended and Restated Pharmaceutical Manufacturing and Exclusive Supply Agreement by and between Laboratorios ERN, S.A. and Zavante Therapeutics, Inc. dated as of July 28, 2016, as amended	10-Q	00137558	11/06/2018	10.9
10.29**	Manufacturing and Supply Agreement by and between Zavante Therapeutics, Inc. and Fisiopharma, S.r.l., dated as of April 25, 2017	10-Q	00137558	11/06/2018	10.10
10.30**	Commercial Packaging Agreement by and between Zavante Therapeutics, Inc. and AndersonBrecon Inc., d/b/a PCI of Illinois, dated as of December 26, 2017	10-Q	00137558	11/06/2018	10.11
10.31**	Packaging and Supply Agreement by and between Sharp Corporation and Nabriva Therapeutics US, Inc., dated as of August 30, 2018	10-Q	00137558	11/06/2018	10.12
10.32#	Second Amended and Restated Employment Agreement by and between Nabriva Therapeutics US, Inc. and Steven Gelone, dated as of July 24, 2018	10-Q	00137558	11/06/2018	10.13
10.33#	2018 Employee Share Purchase Plan	DEF 14A	00137558	06/19/2018	99.1
10.34**	Loan and Security Agreement, dated as of December 20, 2018, by and among Nabriva Therapeutics plc, Nabriva Therapeutics Ireland DAC, certain other subsidiaries of Nabriva Therapeutics plc from time to time party thereto, any bank and other financial institution or entity from time to time party thereto and Hercules Capital, Inc, as administrativeagent and collateral agent.	10-K	001-37558	3/12/2019	10.35

10.35#	Employment Agreement, by and between Nabriva Therapeutics US, Inc. and Jennifer Schranz, dated as of March 21, 2018	10-K	001-37558	3/12/2019	10.36	
10.36**	Agreement for the Commercial Supply of Products by and between Arran Chemical Company Limited and Nabriva Therapeutics Ireland DAC, dated as of November 12, 2018	10-K	001-37558	3/12/2019	10.37	
10.37**	Active Pharmaceutical Ingredient Supply Agreement by and between Nabriva Therapeutics Ireland DAC and Hovione Limited, dated as of November 23, 2018.	10-K	001-37558	3/12/2019	10.38	
10.38	2019 Inducement Share Incentive Plan	S-8	333-230216	3/12/2019	99.1	
10.39	First Amendment to Loan and Security Agreement, dated as of September 26, 2019, by and among Nabriva Therapeutics Public Limited Company, Nabriva Therapeutics Ireland Designated Activity Company, Nabriva Therapeutics GmbH, Nabriva Therapeutics US, Inc., Zavante Therapeutics, Inc., and Hercules Capital, Inc.	10-Q	001-37558	11/12/2019	10.1	
10.40	Second Amendment to Loan and Security Agreement, dated as of January 8, 2020, by and among Nabriva Therapeutics Public Limited Company, Nabriva Therapeutics Ireland Designated Activity Company, Nabriva Therapeutics GmbH, Nabriva Therapeutics US, Inc., Zavante Therapeutics, Inc., and Hercules Capital, Inc.					X
10.41	Third Amendment to Loan and Security Agreement, dated as of March 11, 2020, by and among Nabriva Therapeutics Public Limited Company, Nabriva Therapeutics Ireland Designated Activity Company, Nabriva Therapeutics GmbH, Nabriva Therapeutics US, Inc., Zavante Therapeutics, Inc., and Hercules Capital, Inc.					X
10.42	2020 Share Incentive Plan					X
10.43	Form of Share Option / Cash Settled Share Appreciation Right Agreement under the 2020 Share Incentive Plan					X
21.1	Subsidiaries of Nabriva Therapeutics plc					X
23.1	Consent of KPMG LLP					X
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X

31.2	Certification of principal financial officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
101.INS	XBRL Instance Document	X
101.SCH	XBRL Taxonomy Extension Schema Document	X
101.CAL	XBRL Taxonomy Calculation Linkbase Document	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	XBRL Taxonomy Label Linkbase Document	X
101.PRE	XBRL Taxonomy Presentation Linkbase Document	X

Management contract or compensatory plan or arrangement filed in response to Item 15(a)(3) of the Instructions to the Annual Report on Form 10-K.

* Confidential treatment was granted for certain portions that are omitted from this exhibit. The omitted information has been filed separately with the U.S. Securities and Exchange Commission (the "SEC") pursuant to the registrant's application for confidential treatment. In addition, schedules have been omitted from this exhibit pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule will be furnished supplementally to the SEC upon request; provided, however, that the registrant may request confidential treatment for any document so furnished.

** Confidential treatment has been 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.

SIGNATURES

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

NABRIVA THERAPEUTICS PLC

Date: March 12, 2020

By: /s/ THEODORE SCHROEDER
Theodore Schroeder
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ THEODORE SCHROEDER Theodore Schroeder	Director, Chief Executive Officer (Principal Executive Officer)	March 12, 2020
/s/ GARY SENDER Gary Sender	Chief Financial Officer (Principal Financial and Accounting Officer)	March 12, 2020
/s/ DANIEL BURGESS Daniel Burgess	Chairman of the Board	March 12, 2020
/s/ COLIN BROOM Colin Broom	Director	March 12, 2020
/s/ CARRIE BOURDOW Carrie Bourdow	Director	March 12, 2020
/s/ GEORGE TALBOT George Talbot	Director	March 12, 2020
/s/ CHARLES A. ROWLAND JR. Charles A. Rowland Jr.	Director	March 12, 2020
/s/ STEPHEN WEBSTER Stephen Webster	Director	March 12, 2020
/s/ MARK CORRIGAN Mark Corrigan	Director	March 12, 2020

INDEX TO FINANCIAL STATEMENTS

Nabriva Therapeutics plc
Audited Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
Nabriva Therapeutics plc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Nabriva Therapeutics plc and subsidiaries (the Company) as of December 31, 2018 and 2019, the related consolidated statements of operations and comprehensive income (loss), changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2019, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ KPMG LLP

We have served as the Company's auditor since 2017.

Philadelphia, Pennsylvania
March 12, 2020

NABRIVA THERAPEUTICS plc

Consolidated Balance Sheets

(in thousands, except share data)	As of December 31, 2018	As of December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 102,003	$ 86,019
Restricted cash	—	392
Short-term investments	225	175
Accounts receivable, net and other receivables	3,871	2,744
Contract asset	1,500	—
Inventory	—	682
Prepaid expenses	1,154	1,158
Total current assets	108,753	91,170
Property, plant and equipment, net	1,139	2,474
Intangible assets, net	98	91
Long-term receivables	428	378
Total assets	**$ 110,418**	**$ 94,113**
Liabilities and equity		
Current liabilities:		
Accounts payable	$ 3,304	$ 4,673
Accrued expense and other current liabilities	14,502	11,966
Total current liabilities	17,806	16,639
Non-current liabilities		
Long-term debt	23,718	34,502
Other non-current liabilities	264	1,698
Total non-current liabilities	23,982	36,200
Total liabilities	**41,788**	**52,839**
Commitments and contingencies (Note 17)		
Stockholders' Equity:		
Ordinary shares, nominal value $0.01, 1,000,000,000 ordinary shares authorized at December 31, 2019; 67,019,094 and 94,545,116 issued and outstanding at December 31, 2018 and December 31, 2019, respectively	670	945
Preferred shares, par value $0.01, 100,000,000 shares authorized at December 31, 2019; None issued and outstanding	—	—
Additional paid in capital	461,911	517,044
Accumulated other comprehensive income	27	27
Accumulated deficit	(393,978)	(476,742)
Total stockholders' equity	**68,630**	**41,274**
Total liabilities and stockholders' equity	**$ 110,418**	**$ 94,113**

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

NABRIVA THERAPEUTICS plc

Consolidated Statements of Operations and Comprehensive Income (Loss)

(in thousands, except share and per share data)	Year ended December 31, 2017	2018	2019
Revenues:			
Product revenue, net	$ —	$ —	$ 1,538
Collaboration revenue	—	6,500	6,210
Research premium and grant revenue	5,319	3,156	1,733
Total revenue	5,319	9,656	9,481
Operating expenses:			
Cost of product sales	—	—	(70)
Research and development expenses	(49,615)	(82,288)	(26,415)
Selling, general and administrative expenses	(29,472)	(41,743)	(62,485)
Total operating expenses	(79,087)	(124,031)	(88,970)
Loss from operations	**(73,768)**	**(114,375)**	**(79,489)**
Other income (expense):			
Other income (expense), net	492	(272)	215
Interest income	318	49	255
Interest expense	(43)	(133)	(3,644)
Loss before income taxes	**(73,001)**	**(114,731)**	**(82,663)**
Income tax expense	(1,355)	(49)	(101)
Net loss	**(74,356)**	**(114,780)**	**(82,764)**
Other comprehensive income (loss), net of tax			
Unrealized losses on available-for-sale securities	(26)	—	—
Reclassification to net income	43	—	—
Other comprehensive income, net of tax	17	—	—
Comprehensive loss	**$ (74,339)**	**$ (114,780)**	**$ (82,764)**
Loss per share			
Basic and Diluted ($ per share)	**$ (2.49)**	**$ (2.26)**	**$ (1.12)**
Weighted average number of shares:			
Basic and Diluted	**29,830,669**	**50,795,768**	**74,199,482**

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

NABRIVA THERAPEUTICS plc

Consolidated Statements of Changes in Stockholders' Equity

(in thousands)	Common Stock/Ordinary Shares	Amount	Additional paid in capital	Accumulated other comprehensive income	Accumulated deficit	Total Stockholders' Equity
January 1, 2017	**2,720**	**$ 2,939**	**$ 279,149**	**$ 10**	**$ (204,842)**	**$ 77,256**
Issuance of ordinary shares	9,412	94	79,906	—	—	80,000
Exercise of stock options	54	3	51	—	—	54
Equity transaction costs	—	—	(6,635)	—	—	(6,635)
Redomiciliation share exchange	24,522	(2,669)	2,669	—	—	—
Stock-based compensation expense	—	—	5,732	—	—	5,732
Other comprehensive income, net of tax	—	—	—	17	—	17
Net loss	—	—	—	—	(74,356)	(74,356)
December 31, 2017	**36,708**	**367**	**360,872**	**27**	**(279,198)**	**82,068**
Issuance of ordinary shares	22,974	230	73,989	—	—	74,219
Equity transaction costs	—	—	(4,933)	—	—	(4,933)
Stock-based compensation expense	—	—	5,154	—	—	5,154
Shares issued in connection with the acquisition of Zavante Therapeutics, Inc.	7,337	73	26,829	—	—	26,902
Net loss	—	—	—	—	(114,780)	(114,780)
December 31, 2018	**67,019**	**670**	**461,911**	**27**	**(393,978)**	**68,630**
Issuance of ordinary shares and warrants	25,838	258	47,824	—	—	48,082
Equity transaction costs	—	—	(2,794)	—	—	(2,794)
Stock-based compensation expense	—	—	9,748	—	—	9,748
Shares issued in connection with the vesting of restricted stock units	659	7	(7)	—	—	—
Shares issued in connection with the employee stock purchase plan	214	2	370	—	—	372
Shares issued in connection with the acquisition of Zavante Therapeutics, Inc.	815	8	(8)	—	—	—
Net loss	—	—	—	—	(82,764)	(82,764)
December 31, 2019	**94,545**	**$ 945**	**$ 517,044**	**$ 27**	**$ (476,742)**	**$ 41,274**

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

NABRIVA THERAPEUTICS plc

Consolidated Statements of Cash Flows

(in thousands)	Year Ended December 31, 2017	2018	2019
Cash flows from operating activities			
Net loss	$ (74,356)	$ (114,780)	$ (82,764)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash other income/expense, net	(1,371)	362	(40)
Non-cash interest income	—	45	22
Non-cash interest expense	—	(104)	519
Depreciation and amortization expense	432	510	396
Amortization of right-of-use assets	—	—	374
Stock-based compensation	5,732	5,154	9,748
In-process research and development in connection with acquisition	—	32,048	—
Deferred income taxes	1,410	—	—
Other, net	131	14	48
Changes in operating assets and liabilities:			
(Increase)/decrease in long-term receivables	(5)	(3)	50
(Increase)/decrease in accounts receivable, net and other receivables and prepaid expenses	(223)	1,139	2,582
Increase in inventory	—	—	(682)
Increase/(decrease) in accounts payable	2,585	(2,969)	1,310
Increase/(decrease) in accrued expenses and other liabilities	(3,778)	5,742	(3,209)
Increase/(decrease) in other non-current liabilities	96	61	(172)
Increase/(decrease) in income tax liabilities	(1)	58	(74)
Net cash used in operating activities	(69,348)	(72,723)	(71,892)
Cash flows from investing activities			
Purchases of plant and equipment and intangible assets	(1,173)	(229)	(61)
Purchases of term deposits	(30)	(115)	—
Changes in restricted cash	—	—	392
Proceeds from sales of property, plant and equipment	2	—	—
Transaction costs related to Zavante acquisition, net of cash acquired	50,950	(4,260)	—
Net cash provided by (used in) investing activities	49,749	(4,604)	331
Cash flows from financing activities			
Proceeds from equity offerings and warrants	80,000	50,000	20,138
Proceeds from at-the-market facility	—	24,219	27,944
Proceeds from long-term debt, net of issuance costs	228	23,545	9,980
Proceeds from exercise of stock options	83	—	—
Proceeds from employee share purchase plan	—	—	372
Equity transaction costs	(8,092)	(4,841)	(2,359)
Net cash provided by financing activities	72,219	92,923	56,075
Effects of foreign currency translation on cash and cash equivalents	1,371	(362)	(106)
Net increase/(decrease) in cash, cash equivalents and restricted cash	53,991	15,234	(15,592)
Cash, cash equivalents, and restricted cash at beginning of year	32,778	86,769	102,003
Cash, cash equivalents and restricted cash at end of year	$ 86,769	$ 102,003	$ 86,411
Supplemental disclosure of cash flow information:			
Interest paid	$ (1)	$ (7)	$ (2,560)
Taxes paid	$ (5)	$ (4)	$ (11)
Equity transaction costs included in accounts payable and accrued expenses	$ 28	$ 120	$ 555

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

NABRIVA THERAPEUTICS plc

Notes to the Consolidated Financial Statements

(in thousands, except per share data)

1. Organization and Business Activities

Nabriva Therapeutics plc (“Nabriva Ireland”), together with its wholly owned and consolidated subsidiaries, Nabriva Therapeutics GmbH (“Nabriva Austria”), Nabriva Therapeutics US, Inc., and Nabriva Therapeutics Ireland DAC, (collectively, “Nabriva”, or the “Company”) is a biopharmaceutical company engaged in the commercialization and development of novel anti-infective agents to treat serious infections. The Company’s headquarters are located at 25-28 North Wall Quay, Dublin, Ireland.

On September 9, 2019, the Company announced that the oral and intravenous (“IV”) formulations of XENLETA (lefamulin) are available in the United States for the treatment of community-acquired bacterial pneumonia (“CABP”) through major specialty distributors. This followed the approval by the U.S. Food and Drug Administration (FDA) of the Company’s New Drug Application (NDA) for XENLETA on August 19, 2019 for the treatment of adults with community-acquired bacterial pneumonia (CABP). XENLETA is the first oral and IV treatment in the pleuromutilin class of antibiotics available for the systematic administration in humans.

On June 24, 2019, the Company announced that the European Medicines Agency ("EMA") determined that the Company's Marketing Authorization Application ("MAA") for the IV and oral formulations of lefamulin was valid. Validation of the MAA confirms that the submission is sufficiently complete to begin the formal review process and an opinion of the EMA Committee for Medicinal Products for Human Use ("CHMP") is anticipated in the second half of 2020.

The EMA's review of the application will follow the centralized marketing authorization procedure. If approved by the EMA, XENLETA will receive marketing authorization in all member states of the European Union ("EU"), as well as in Norway, Liechtenstein and Iceland (and the UK, in the event they exit the EU). If approved, Nabriva intends to work with a commercial partner to make XENLETA available to patients in the EU.

On July 23, 2018, the Company entered into an Agreement and Plan of Merger (the “Merger Agreement”) for the acquisition of Zavante Therapeutics Inc., (“Zavante”) a biopharmaceutical company focused on developing CONTEPO (fosfomycin for injection). CONTEPO is potentially a first-in-class epoxide antibiotic for IV administration in the United States. The Company is developing CONTEPO IV for complicated urinary tract infections (“cUTI”) and may potentially develop XENLETA and CONTEPO for additional indications. In April 2019, the FDA issued a Complete Response Letter (“CRL”) in connection with the Company’s NDA for CONTEPO for the treatment of cUTIs, including acute pyelonephritis, stating that it was unable to approve the application in its current form. The CRL requests that issues related to facility inspections and manufacturing deficiencies at Nabriva’s active pharmaceutical ingredient contract manufacturer be addressed prior to the FDA approving the NDA. The Company requested a “Type A” meeting with the FDA to discuss its findings and this meeting occurred in July 2019. As the FDA did not request any new clinical data and did not raise any other concerns with regard to the safety or efficacy of CONTEPO in the CRL, the purpose of the meeting was to discuss and gain clarity on the issues related to facility inspections and manufacturing deficiencies at one of Nabriva's contract manufacturers that were described in the CRL and other matters pertaining to the steps required for the resubmission of the NDA for CONTEPO. The Company resubmitted its NDA in December 2019 and the FDA acknowledged the resubmission in January 2020 and established a PDUFA date of June 19, 2020. However, the Company cannot predict when CONTEPO will receive marketing approval, if at all.

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

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

Throughout these notes to the consolidated financial statements, unless the context requires otherwise, all references to "Nabriva", "the Company," or similar terms on or prior to June 23, 2017 (the effective date of the Redomiciliation Transaction), refer to the predecessor of the Company, Nabriva Austria, together with its subsidiaries.

Liquidity

Since its inception, the Company has incurred net losses and generated negative cash flows from its operations which has resulted in a significant accumulated deficit to date. The Company has financed its operations through the sale of equity securities, convertible and term debt financings and research and development support from governmental grants and proceeds from its licensing agreements. As of December 31, 2019, the Company had cash and cash equivalents, restricted cash and short-term investments of $86.6 million.

The Company follows the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 205-40, *Presentation of Financial Statements — Going Concern* ("ASC 205-40"), which requires management to assess the Company's ability to continue as a going concern for one year after the date the consolidated financial statements are issued.

The Company expects to seek additional funding in future periods for purposes of enhancing the commercial launch of XENLETA and potential launch of CONTEPO. While the Company has raised capital in the past, the ability to raise capital in future periods is not considered probable, as defined under the accounting standards. As such, under the requirements of ASC 205-40, management may not consider the potential for future capital raises in their assessment of the Company's ability to meet its obligations for the next twelve months.

If the Company is not able to secure adequate additional funding in future periods, the Company may make reductions in certain expenditures. This may include liquidating assets and suspending or curtailing planned programs. The Company may also have to delay, reduce the scope of, suspend or eliminate one or more research and development programs or its commercialization efforts.

The Company's expenses will increase if it suffers any regulatory delays or is required to conduct additional clinical trials to satisfy regulatory requirements. The Company has incurred and expects to continue to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing for XENLETA and, if approved, CONTEPO, including the recent hiring of a dedicated sales force. It is uncertain when, if ever, the Company will generate sufficient revenues from product sales to achieve profitability.

As a result, based on the Company's available cash resources, the minimum cash required under the Loan and Security Agreement (the "Loan Agreement") with Hercules Capital, Inc., and in accordance with the requirements of ASC 205-40, management has concluded that substantial doubt exists about the Company's ability to continue as a going concern for one year from the date these financial statements are issued. A failure to raise the additional funding or to effectively implement cost reductions could harm the Company's business, results of operations and future prospects.

As discussed in Note 19, the Company has agreed to repay $30.0 million of the $35.0 million in aggregate principal amount of debt outstanding debt under the Loan Agreement subsequent to December 31, 2019. Based on its current operating plans, immediately following such repayment, the Company expects that its existing cash, cash equivalents and short-term investments as of the date of this filing and anticipated net product revenues, will be sufficient to enable the Company to fund its operating expenses, debt service obligations and capital expenditure requirements into the third quarter of 2020. The Company has based this estimate on assumptions that may prove to be wrong, and the Company could use its capital resources sooner than expected. This estimate assumes, among other things, that the Company does not obtain any additional funding through grants and clinical trial support, collaboration agreements or equity or debt financings. This estimate also assumes that the Company's NDA for CONTEPO is

approved on the PDUFA date and that it remains in compliance with the covenants and no event of default occurs under the Loan Agreement. The consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the continuity of operations, the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

On June 25, 2019, the Company entered into an Open Market Sale Agreement℠ (the "Jefferies ATM Agreement") with Jefferies, pursuant to which, from time to time, the Company may offer and sell ordinary shares, for aggregate gross sale proceeds of up to $50.0 million through Jefferies by any method permitted that is deemed an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. The Company also filed a prospectus supplement with the Securities and Exchange Commission in connection with the Offering under the Company's shelf Registration Statement on Form S-3 (File No. 333-219567), which became effective on August 10, 2017.

As of December 31, 2019, the Company has issued and sold an aggregate of 6,505,268 ordinary shares pursuant to the Jefferies ATM Agreement and received gross proceeds of $14.4 million and net proceeds of $13.6 million, after deducting commissions to Jefferies and other offering expenses. As of the date of this filing, the Company may issue and sell ordinary shares for gross proceeds of up to $35.6 million.

In December 2019, the Company sold to certain institutional investors in a registered direct offering an aggregate of 13,793,106 ordinary shares (the "Shares"), and accompanying warrants to purchase up to an aggregate of 13,793,106 ordinary shares (the "Warrants," and together with the Shares, the "Securities"). Each Share was issued and sold together with an accompanying Warrant at a combined price of $1.45. The gross proceeds to the Company from the offering, before deducting the placement agent's fees and other offering expenses payable by the Company were $20.1 million. Each Warrant has an exercise price of $1.90 per share, is initially exercisable six months following the date of issuance (the "Initial Exercise Date") and will expire on the three-year anniversary of the Initial Exercise Date.

2. Summary of Significant Accounting Policies

Basis of Preparation

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("US GAAP") and US Securities and Exchange Commission ("SEC") regulations for annual reporting. The consolidated financial statements include the accounts of Nabriva Therapeutics plc and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Functional Currency Transactions and Balances

In preparing the consolidated financial statements, transactions in currencies other than the U.S. dollar are recognized at the exchange rates prevailing at the dates of the transactions. Foreign currency exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the consolidated statements of operations and comprehensive income (loss).

Use of Estimates

The preparation of consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the amount of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers highly liquid investments with original maturities of three months or less to be cash equivalents.

Restricted Cash

The Company classifies funds contributed by its employees to its Employee Stock Purchase Plan (See Note 11) as restricted in nature since these amounts can only be utilized to purchase Company stock at the end of each six month offering period. Prior to the conclusion of the offering period, employees can request reimbursement of the funds they previously contributed and if they leave the Company prior to the end of the offering period the funds are returned to the employee.

Short-term Investments

The Company has designated its investments in securities as available-for-sale securities and measures these securities at their respective fair values. Investments that mature in one year or less are classified as short-term available-for-sale securities. Investments that are not considered available for use in current operations are classified as long-term available-for-sale securities. Changes in the fair value of available-for-sale investments are recognized in other comprehensive income (loss).

Inventory

Inventory is stated at the lower of cost or estimated net realizable value. Inventory is valued on a first-in, first-out basis and consists primarily of material costs, third-party manufacturing costs, and related transportation costs along the Company's supply chain. The Company capitalizes inventory upon regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are recorded as research and development expense. Costs of drug product to be consumed in any current or future clinical trials will continue to be recognized as research and development expense and costs of sample inventory is recorded as selling, general and administrative expense. The Company reviews inventories for realization on a quarterly basis and would record provisions for estimated excess, slow-moving and obsolete inventory, as well as inventory with a carrying value in excess of net realizable value when necessary.

The components of our inventory at December 31, 2019 are as follows:

(in thousands)	
Raw materials	$ —
Work in process	498
Finished goods	184
Total Inventory	**$ 682**

Property, Plant and Equipment

Property, plant and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. The estimated useful lives of property, plant and equipment are as follows: 3-5 years for IT equipment, 5-10 years for laboratory equipment and 3-10 years for other plant and office equipment. The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at each reporting date. When assets are sold or otherwise disposed of, the difference between the net proceeds, if any, and the net carrying amount of the asset is recognized as a gain or a loss in other operating income or expenses.

Intangible Assets and Other Long-lived Assets

Intangible assets, such as acquired computer software licenses, are capitalized on the basis of the costs incurred to acquire the software and bring it into use. These costs are amortized on a straight-line basis over their estimated useful lives (3-10 years).

Long-lived assets are assessed for potential impairment when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recovered. An impairment loss would be

recognized when undiscounted cash flows expected to be generated by an asset, is less than its carrying amount. The impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value and recognized in these financial statements.

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 as one operating segment, which is the commercialization and development of novel anti-infective agents to treat serious and life-threatening infections.

Revenue Recognition—The Company recognizes revenue from sales of its commercial products in accordance with ASC 606, *Revenue from Contracts with Customers* ("ASC 606").

Net Product Revenue

Beginning in September 2019, the Company began selling its XENLETA product principally to a limited number of specialty distributors in the United States. The distributors place orders with the Company for sufficient quantities of its products to maintain an appropriate level of inventory based on its customers' anticipated purchase volumes and demand. The Company recognizes revenue once it has transferred physical possession of the goods and the distributor obtains legal title to the product. Payment terms between Nabriva and its customers are generally approximately 60 days from the invoice date. In addition to distribution agreements with customers, the Company enters into arrangements with health care providers and payers that provide for government mandated and/or privately negotiated rebates, chargebacks and discounts with respect to the purchase of its product.

The transaction price that the Company recognizes as revenue reflects the amount it expects to be entitled to in connection with the sale and transfer of control of product to its customers. At the time that the Company's customers take control of the product, which is when the Company's performance obligation under the sales contracts is complete, the Company records product revenues net of applicable reserves for various types of variable consideration. The types of variable consideration are as follows:

- Fees-for-service
- Product returns
- Chargebacks and rebates
- Government rebates
- Commercial payer and other rebates
- Group Purchasing Organizations ("GPO") administration fees
- Voluntary patient assistance programs

In determining the amounts of certain allowances and accruals, the Company must make significant judgments and estimates. For example, in determining these amounts, the Company estimates prescription demand from the specialty pharmacies, hospital demand, buying patterns by hospitals, hospital systems and/or group purchasing organizations and the levels of inventory held by specialty distributors and customers. The Company also analyzes third party end usage product consumption patterns to gauge demand for its products. Making these determinations involves analyzing third party industry data to determine whether trends in historical channel distribution patterns will predict future product sales. The Company receives data periodically from its specialty distributors and customers on inventory

levels and historical channel sales mix, and the Company considers this data when determining the amount of the allowances and accruals for variable consideration, however given the recent launch of its XENLETA product this data is limited.

In assessing the amount of net revenue to record, the Company considers both the likelihood and the magnitude of the revenue reversal. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known. The specific considerations the Company uses in estimating these amounts related to variable consideration associated with the Company's products are as follows:

Fees-for-service – The Company offers discounts and pays certain distributor service fees which are recorded as a reduction of revenue in the period the related product revenue is recognized. The Company does not consider the fees separate from the distributors' purchase of the product. The Company records its fee-for-service accruals based on distributors' purchases and the applicable discount rate.

Product returns – Generally, the Company's customers have the right to return products during the 18-month period beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. Since the Company currently does not have history of XENLETA returns, the Company estimated returns based on industry data for comparable products in the market. As the Company distributes its product and establishes historical sales over a longer period of time (i.e., two to three years), the Company will be able to place more reliance on historical purchasing, demand and return patterns of its customers when evaluating its reserves for product returns. The Company's XENLETA product has a thirty-six-month shelf life.

The Company's customers also have the right to return excess inventory on new products that do not yield forecasted sales. The Company recently launched XENLETA and underlying demand has been below its expectations, particularly in the hospital for its IV product. To the extent the Company's customers determine that the quantities they purchased are in excess of their customers demand, product returns could increase in excess of what the Company has currently reserved which would result in a reduction to net revenues in future periods.

At the end of each reporting period for any of its products, the Company may decide to constrain revenue for product returns based on information from various sources, including channel inventory levels and dating and sell-through data, the expiration dates of product currently being shipped, price changes of competitive products and introductions of generic products.

Chargebacks and rebates – Although the Company primarily sells products to specialty distributors in the United States, the Company also enters into agreements with hospitals and retail pharmacies, either directly or through group purchasing organizations acting on behalf of their members, in connection with the purchase of product. Based on these agreements, certain of the Company's customers have the right to receive a discounted price on product purchases. The Company typically provides a credit to its specialty distributors customers (i.e., chargeback), representing the difference between the customer's acquisition list price and the discounted price. The calculation of the accrual for chargebacks and rebates is based on estimates of claims and their associated cost that the Company expects to receive associated with product sales that have been recognized as revenue but remain in the distribution channel as inventory at the end of each reporting period.

Government rebates –The Company is subject to discount obligations primarily under state Medicaid and Medicare programs. The Company estimates its Medicaid and Medicare rebates based upon a range of possible outcomes that are probability-weighted for the estimated payer mix. These reserves are recorded in the same period the related product revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is included in accrued expenses on the consolidated balance sheet. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The calculation of the accrual for government rebates is based on estimates of claims and their associated cost that the Company expects to receive associated with product sales that have been recognized as revenue but remain in the distribution channel as inventory at the end of each reporting period.

Commercial payer and other rebates – The Company contracts with certain private payer organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of XENLETA and contracted formulary status. The Company estimates these rebates and records reserves for such estimates in the same period the related revenue is recognized. Currently, the reserve for customer payer rebates considers future utilization based on third party studies of payer prescription data; the utilization is applied to product that remains in the distribution and retail pharmacy channel inventories at the end of each reporting period. The calculation of the accrual for commercial payer and other rebates is based on estimates of claims and their associated cost that the Company expects to receive associated with product sales that have been recognized as revenue but remain in the distribution channel as inventory at the end of each reporting period.

GPO administration fees – The Company contracts with GPOs and pays administration fees related to contacting and membership management services provided. In assessing if the consideration paid to the GPO should be recorded as a reduction in the transaction price, the Company determines whether the payment is for a distinct good or service or a combination of both. Since GPO fees are not specifically identifiable, the Company does not consider the fees separate from the purchase of the product. Additionally, the GPO services generally cannot be provided by a third party. Because of these factors, the consideration paid is considered a reduction of revenue.

Patient assistance – The Company offers certain voluntary patient assistance programs for prescriptions, such as co-pay assistance programs, which are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product sales that have been recognized as revenue but remains in the distribution channel as inventory at the end of each reporting period.

At the end of each reporting period, the Company will adjust its variable consideration estimates for product returns, chargebacks, and rebates when the Company believes actual experience may differ from current estimates.

The following table summarizes balances and activity of product revenue allowances and reserves:

	Total
Balance at December 31, 2018	$ —
Provision related to current period sales	635
Adjustment related to prior period sales	—
Credit or payments made during the period	(101)
Balance at December 31, 2019	$ 534

Cost of Product Sales

Cost of product sales consists primarily of the direct and indirect manufacturing costs for XENLETA. All manufacturing costs incurred prior to XENLETA's approval in the United States on August 19, 2019 were expensed in research and development expense. Costs incurred after the approval date were capitalized as inventory.

Research Premium and Grant Revenue

Grant revenue comprises (a) the research premium from the Austrian government, (b) grants received from the Vienna Business Promotion Fund (*Wiener Wirtschaftsförderungsfonds, or WWFF*), (c) grants received from the Austrian Research Promotion Agency (*Österreichische Forschungsförderungsgesellschaft, or FFG*), and (d) the benefit of government loans at below-market interest rates.

The research premium the Company receives from the Austrian government is calculated at a specified percent of specified research and development cost base. The Company recognizes the research premium as long as it has incurred research and development expenses. The WWFF grant is paid out through the landlord in the form of a monthly reduction in lease payments and is recognized over the period from grant date in March 2010 until end of the lease

termination waiver term in December 2017. All grants are non-refundable as long as the conditions of the grant are met. Nabriva is and has been in full compliance with the conditions of the grants and all related regulations.

Research and Development Expenses

All research and development costs are expensed as incurred. Research and development costs included direct personnel and material costs, related overheads, depreciation of equipment used for research or development purposes; costs for clinical research; costs for the utilization of third parties' patents for research and development purposes and other taxes related to research facilities.

Share-based Payments

The Company measures the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award in accordance with ASC 718, *Compensation—Stock Compensation*. The fair value of stock options is estimated using the Black-Scholes option pricing model. All grants under share-based payment programs are accounted for at fair value and that cost is recognized over the period during which an employee is required to provide service in exchange for the award—the requisite service period (vesting period). The Company accounts for forfeitures as incurred. Compensation expense for options granted to non-employees is determined as the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of awards granted to non-employees is re-measured each period until the related service is complete.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, the Company determines deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that it believes that these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If the Company determines that it would be able to realize its deferred tax assets in the future in excess of their net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

In recognizing the benefit of tax positions, the Company has taken or expects to take, the Company determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

The Company's policy is to record interest and penalties related to tax matters in income tax expense.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act makes broad and complex changes to the U.S. tax code, including, but not limited to, reducing the top U.S. federal corporate tax rate from 35 percent to 21 percent; eliminating the corporate alternative minimum tax ("AMT") and changing how existing AMT credits can be realized; creating the base erosion anti-abuse tax ("BEAT"), a new minimum tax; creating a new limitation on deductible interest expense; and, changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017.

The Tax Act reduced the U.S. corporate income tax rate from 35% to 21%, effective January 1, 2018. Deferred tax assets and liabilities were measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. As a result of the reduction in the U.S. corporate income tax rate from 35% to 21% under the Tax Act, the Company revalued the ending net deferred tax assets and liabilities of our U.S. subsidiary at December 31, 2017.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date.

Adopted as of the current period:

In February 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. On January 1, 2019, the Company adopted the new lease standard using the optional transition method under which comparative financial information has not been restated and will continue to apply the provisions of the previous lease standard in its annual disclosures for the comparative periods. In addition, the new lease standard provides a number of optional practical expedients in transition. The Company elected the package of practical expedients. As such, the Company did not have to reassess whether expired or existing contracts are or contain a lease; and did not have to reassess the lease classifications or reassess the initial direct costs associated with expired or existing leases.

The new lease standard also provides practical expedients for an entity's ongoing accounting. The Company elected the short-term lease recognition exemption under which the Company will not recognize right of use (“ROU”) assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases. The Company elected the practical expedient to not separate lease and non-lease components for certain classes of assets (office buildings).

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease ROU assets, other current liabilities, and operating lease liabilities on the Company’s consolidated balance sheet as of December 31, 2019. Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the remaining lease term as of January 1, 2019. Since none of the Company’s lease agreements provide an implicit rate, the Company estimated an incremental borrowing rate over the lease term based on the information available at January 1, 2019 in determining the present value of lease payments. Operating lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectations regarding the terms. Variable lease costs such as operating costs and property taxes are expensed as incurred.

On January 1, 2019, the Company recognized ROU assets and lease liabilities of approximately $2.0 million on its consolidated balance sheet using an estimated incremental borrowing rate of 9.8%. This ROU asset is recorded in property, plant and equipment, net and the ROU liability is recorded in other non-current liabilities.

Pronouncements to be adopted in future periods:

In August 2018, the FASB issued ASU No. 2018-15, “*Customer’s Accounting for Implementation Cost Incurred in a Cloud Computing Arrangement That Is a Service Contract*” (“ASU 2018-15”). Under the new guidance, customers will apply the same criteria for capitalizing implementation costs as they would for an arrangement that has a software license. This will result in certain implementation costs being capitalized; the associated amortization charge will, however, be recorded as an operating expense. Under the previous guidance, costs incurred when implementing a cloud computing arrangement deemed to be a service contract were recorded as an operating expense when incurred. ASU 2018-15 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Entities can choose to adopt the new guidance prospectively to eligible costs incurred on or after the date

the guidance is first applied or retrospectively. The Company does expect the impact of the adoption of ASU 2018-15 on its consolidated financial statements to be material.

3. Short-term investments

The Company's short-term investments were as follows:

	As of December 31, 2019			
(in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Term deposits	$ 175	$ —	$ —	$ 175
Total	**$ 175**	**$ —**	**$ —**	**$ 175**

	As of December 31, 2018			
(in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Available for sale securities	$ 50	$ —	$ —	$ 50
Term deposits	175	—	—	175
Total	**$ 225**	**$ —**	**$ —**	**$ 225**

As of December 31, 2019 and 2018, the Company's short-term investments were classified as available-for-sale and comprised of certain term deposits with maturities in excess of 90 days.

4. Fair Value Measurement

US GAAP establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows:

- Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly (as prices) or indirectly (as exchange rates).
- Level 3: Valuation techniques that include inputs for the asset or liability that are not based on observable market data (those are unobservable inputs) and significant to the overall fair value measurement.

The following table presents the financial instruments measured at fair value and classified by level according to the fair value measurement hierarchy:

(in thousands)	Level 1	Level 2	Level 3	Total
December 31, 2019				
Assets:				
Cash equivalent:				
Money market funds	$ 15,050	$ —	$ —	$ 15,050
Short term investments:				
Term deposits	175	—	—	175
Total Assets	**$ 15,225**	**$ —**	**$ —**	**$ 15,225**

(in thousands)	Level 1	Level 2	Level 3	Total
December 31, 2018				
Assets:				
Cash equivalent:				
Money market funds	$ 50	$ —	$ —	$ 50
Short term investments:				
Term deposits	175	—	—	175
Total Assets	**$ 225**	**$ —**	**$ —**	**$ 225**

There were no transfers between Level 1 and 2 in the years ended December 31, 2019 and 2018. There were no changes in valuation techniques during the years ended December 31, 2019 and 2018.

As of December 31, 2019 and 2018, the Company did not hold any financial instruments as liabilities that were held at fair value. Other receivables and accounts payable are carried at their historical cost which approximates fair value due to their short-term nature.

5. Accounts receivable, net and other receivables

Accounts receivable, net and other receivables include the following:

	As of December 31	
(in thousands)	2018	2019
Research premium	$ 2,657	$ 1,530
VAT and other taxes	1,024	403
Receivables from grant revenue	104	2
Other receivables	86	809
Total accounts receivable, net and other receivables	**$ 3,871**	**$ 2,744**

6. Property, Plant and Equipment

Property, plant and equipment was comprised of the following:

	As of December 31	
(in thousands)	2018	2019
IT equipment	$ 1,079	$ 1,060
Laboratory equipment	3,392	3,375
ROU asset	—	1,647
Other equipment	124	165
	4,595	**6,247**
Less: Accumulated depreciation	**(3,456)**	**(3,773)**
Property, plant and equipment, net	**$ 1,139**	**$ 2,474**

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities include the following:

(in thousands)	As of December 31, 2018	As of December 31, 2019
Research and development related costs	$ 5,032	$ 1,347
Payroll and related costs	7,427	6,327
Accounting, tax and audit services	398	420
Other	1,645	3,872
Total other current liabilities	**$ 14,502**	**$ 11,966**

8. Debt

In December 2018, the Company entered into the Loan Agreement by and among the Company, Nabriva Therapeutics Ireland DAC, and certain other subsidiaries of the Company and Hercules Capital, Inc. ("Hercules"), pursuant to which a term loan of up to an aggregate principal amount of $75.0 million is available to the Company. The Loan Agreement initially provided for an initial term loan advance of $25.0 million, which was funded in December 2018, and, at the Company's option and subject to the occurrence of the funding conditions described below and other customary funding conditions, five additional term loan advances comprised of the following; 1) $10.0 million ("Tranche 2 Advance"), 2) $5.0 million ("Tranche 3 Advance"), 3) $10.0 million ("Tranche 4 Advance"), 4) $15.0 million ("Tranche 5 Advance") and 5) $5.0 million ("Tranche 6 Advance"). The Tranche 2 Advance became available upon the approval by the FDA of the NDA for lefamulin. The Tranche 3, 4, 5 and 6 Advances are no longer available as their contingencies were not achieved. The Company may request a term loan advance of $5.0 million prior to December 31, 2021 subject to Hercules's sole discretion. See Note 19 for a discussion of a repayment and amendment to its Loan Agreement that occurred in March 2020.

The term loan bears interest at an annual rate equal to the greater of 9.80% or 9.80% plus the prime rate of interest minus 5.50%. The Loan Agreement provided for interest-only payments through July 1, 2021 and repayment of the outstanding principal balance of the term loan thereafter in monthly installments through June 1, 2023 (the "Maturity Date"). In addition, the Company is required to pay a fee of 6.95% of the aggregate amount of advances under the Loan Agreement at the Maturity Date (the "End of Term Fee"). At the Company's option, the Company may elect to prepay any portion of the outstanding term loan that is greater than or equal to $5.0 million by paying such portion of the principal balance and all accrued and unpaid interest thereon plus a prepayment charge equal to the following percentage of the principal amount being prepaid: (i) 3.0% if the term loan is prepaid during the first 12 months following the initial closing, (ii) 2.0% if the term loan is prepaid after 12 months following the initial closing but before 24 months following the initial closing and (iii) 1.0% if the term loan is prepaid any time thereafter but prior to the Maturity Date. The Company is also required to satisfy certain financial covenants, including an obligation to maintain a minimum of $10.0 million of cash and cash equivalents in accounts pledged to Hercules. Additionally, the Loan Agreement contains a performance covenant, which became effective in February 2020, that requires the Company to either (1) achieve 80% of its net product revenue sales target over a trailing six month period, or (2) maintain an amount of cash and cash equivalents in accounts pledged to Hercules plus a specified amount of eligible accounts receivables equal to the greater of the amount outstanding under the Loan Agreement or $40.0 million. The Company was in compliance with all of its Loan Agreement covenants at December 31, 2019.

The Company's obligations under the Loan Agreement are guaranteed by all current and future subsidiaries of the Company, and each of the Company and its subsidiaries has granted Hercules a security interest in all of their respective personal property, intellectual property and other assets owned or later acquired. The Loan Agreement also contains certain events of default, representations, warranties and covenants of the Company and its subsidiaries. For example, the Loan Agreement contains representations and covenants that, subject to exceptions, restrict the Company's and its subsidiaries' ability to do the following, among things: declare dividends or redeem or repurchase equity interests; incur additional indebtedness and liens; make loans and investments; engage in mergers, acquisitions and asset sales; certain transactions with affiliates; undergo a change in control; add or change business locations or settle in cash potential milestone payment obligations that may become payable by the Company in the future to former security holders of Zavante.

The Loan Agreement also grants Hercules or its nominee an option to purchase up to an aggregate of $2.0 million of the Company's equity securities, or instruments exercisable for or convertible into equity securities, sold to investors in any private financing upon the same terms and conditions afforded to such other investors for as long as there are amounts outstanding under the Loan Agreement.

The Company incurred $1.3 million of costs in connection with the Loan Agreement which along with the initial fee of $0.7 million paid to Hercules were recorded as debt issuance cost and are being amortized as interest expense using the effective interest method over the term of the loan. The End of Term Fee is being accrued as additional interest expense using the effective interest method over the term of the loan.

Long-term debt as December 31, 2018 and 2019 consisted of the following:

(in thousands)	As of December 31 2018	As of December 31 2019
Term loan payable	$ 25,000	$ 35,000
End of term fee	—	443
Unamortized debt issuance costs	(1,990)	(1,742)
Carrying value of term loan	23,010	33,701
Other long-term debt	708	801
Total long-term debt	**$ 23,718**	**$ 34,502**

Maturities of long-term debt (inclusive of the End of Term Fee) as of December 31, 2019 were as follows:

(in thousands)	
2020	$ —
2021	8,895
2022	17,450
2023	11,889

9. Stockholders' Equity

On December 20, 2019, the Company sold to certain institutional investors in a registered direct offering an aggregate of 13,793,106 ordinary shares (the "Shares"), and accompanying warrants to purchase up to an aggregate of 13,793,106 ordinary shares (the "Warrants"). Each Share was issued and sold together with an accompanying Warrant at a combined price of $1.45. The gross proceeds to the Company from the offering, before deducting the placement agent's fees and other offering expenses payable by the Company were $20.1 million. Each Warrant has an exercise price of $1.90 per share, is initially exercisable six months following the date of issuance (the "Initial Exercise Date") and will expire on the three-year anniversary of the Initial Exercise Date.

On June 25, 2019, the Company entered into an Open Market Sale Agreement℠ (the "Jefferies ATM Agreement") with Jefferies, pursuant to which, from time to time, the Company may offer and sell ordinary shares, for aggregate gross sale proceeds of up to $50.0 million through Jefferies by any method permitted that is deemed an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. The Company also filed a prospectus supplement with the Securities and Exchange Commission in connection with the Offering under the Company's shelf Registration Statement on Form S-3 (File No. 333-219567), which became effective on August 10, 2017. As of December 31, 2019, the Company has issued and sold an aggregate of 6,505,268 ordinary shares pursuant to the Jefferies ATM Agreement and received gross proceeds of $14.4 million and net proceeds of $13.6 million, after deducting commissions to Jefferies and other offering expenses. As of the date of this filing, the Company may issue and sell ordinary shares for gross proceeds of up to $35.6 million.

On July 31, 2018, the Company completed an underwritten public offering of 18,181,818 ordinary shares at a public offering price of $2.75 per share, resulting in gross proceeds of $50.0 million and net proceeds to the Company of $46.3 million, after deducting underwriting discounts and commissions and offering expenses.

In March 2018, the Company entered into a Controlled Equity Offering℠ Sales Agreement (the "ATM Agreement"), with Cantor Fitzgerald & Co. ("Cantor"), pursuant to which, from time to time, the Company may offer and sell its ordinary shares having aggregate gross proceeds of up to $50.0 million through Cantor. The Company terminated the Cantor ATM Agreement effective as of June 24, 2019. The Company did not incur any penalties as a result of the termination of the Cantor ATM Agreement. As of the effective date of the termination of the Cantor ATM Agreement, the Company had issued and sold an aggregate of 10,316,190 of our ordinary shares pursuant to the Cantor ATM Agreement for aggregate gross proceeds of $37.8 million and net proceeds of $36.3 million, after deducting commissions and offering expenses. The $12.2 million of ordinary shares that had been available for sale pursuant to the Cantor ATM Agreement remained unsold at the time of its termination.

On September 22, 2017 the Company completed an underwritten public offering of 9,411,765 ordinary shares at a public offering price of $8.50 per share, resulting in gross proceeds of $80.0 million and net proceeds to the Company of $73.3 million, after deducting underwriting discounts and commissions and offering expenses.

10. Revenue

Our revenues which are described in Note 1 consist of the following categories.

	Year ended December 31,		
(in thousands)	2017	2018	2019
Product revenue, net	$ —	$ —	$ 1,538
Collaboration revenues	—	6,500	6,210
Research premium	4,842	2,594	1,311
Government grants	369	562	422
Grants from WWFF	108	—	—
Total	**$ 5,319**	**$ 9,656**	**$ 9,481**

11. Share-Based Payments

Stock Option Plan 2015

On April 2, 2015, the Company's shareholders, management board and supervisory board adopted the Stock Option Plan 2015 (the "SOP 2015") and the shareholders approved an amended and restated version of the SOP 2015 on June 30, 2015. An amendment to the amended and restated SOP 2015 was approved by the shareholders on July 22, 2015. SOP 2015 became effective on July 3, 2015 upon the registration with the commercial register in Austria of the conditional capital increase approved by the shareholders on June 30, 2015. The SOP 2015 initially provided for the grant of options for up to 95,000 Nabriva Austria common shares to the Company's employees, including members of the management board, and to members of the supervisory board. Following the closing of the initial public offering of the Company, the overall number of options increased to 177,499 Nabriva Austria common shares. Following approval by the Company's shareholders at its 2016 annual general meeting, the number of shares available for issuance under the SOP 2015 was increased to 346,235 Nabriva Austria common shares.

Each vested option grants the beneficiary the right to acquire one share in the Company. The vesting period for the options is four years following the grant date. On the last day of the last calendar month of the first year of the vesting period, 25% of the options attributable to each beneficiary are automatically vested. During the second, third and fourth years of the vesting period, the remaining 75% of the options vest on a monthly pro rata basis (i.e. 2.083% per month). Options granted under the SOP 2015 have a term of no more than ten years from the beneficiary's date of participation.

The following table summarizes information regarding our stock option awards under the SOP 2015:

	2017		2018		2019		
Stock Option Plan 2015	Options	Weighted average exercise price in $ per share	Options	Weighted average exercise price in $ per share	Options	Weighted average exercise price in $ per share	Aggregate intrinsic value
Outstanding as of January 1	1,794,360	7.83	3,044,899	8.35	2,842,913	8.34	
Granted	1,458,300	9.02	—	—	—	—	
Exercised	—	—	—	—	—	—	
Forfeited	(207,761)	8.60	(201,986)	8.41	(552,319)	8.40	
Outstanding as of December 31,	**3,044,899**	**8.35**	**2,842,913**	**8.34**	**2,290,594**	**8.33**	**$ —**
Vested and exercisable as of December 31,	**989,656**	**7.68**	**1,844,590**	**8.10**	**1,984,911**	**8.20**	**$ —**

No options were exercised during the years ended December 31, 2017, 2018 or 2019.

The Company has 2,290,594 option grants outstanding at December 31, 2019 with exercise prices ranging from $4.06 per share to $11.00 per share and a weighted average remaining contractual life of 6.4 years.

Stock-based compensation expense under the SOP 2015 was $5.6 million, $3.2 million and $4.0 million for the years ended December 31, 2017, 2018 and 2019, respectively. The weighted average fair value of the options granted during the year ended December 31, 2017 was $5.05 per share. No options have been awarded during the years ended December 31, 2018 or 2019.

The grant date fair value of each option grant was estimated throughout the year using the Black-Scholes option-pricing model using the following assumptions:

Input parameters	2017
Expected volatility	55.6% - 62.0%
Expected term of options	6.1 years
Risk-free interest rate	1.9% - 2.1%
Expected dividend yield	—

Due to the limited trading history for the Company's shares, the expected price volatility was based on historical trading volatility for a set of publicly traded peer companies under consideration of the remaining life of the options. The risk free interest is based on the average yield on U.S. treasury securities that corresponds to the expected term of the options in effect at the time of grant.

As of December 31, 2019, there was $1.6 million of unrecognized compensation expense, related to unvested options granted under the SOP 2015 Plan, which will be recognized over the weighted average remaining vesting period of 1.3 years.

2017 Share Incentive Plan

On July 26, 2017, the Company’s board of directors adopted the 2017 Share Incentive Plan (the “2017 Plan”) and the shareholders approved the 2017 Plan at the Company’s Extraordinary General Meeting of Shareholders on September 15, 2017. Following shareholder approval of the 2017 Plan, the Company ceased making awards under the SOP 2015, and future awards will be made under the 2017 Plan. However, all outstanding awards under SOP 2015 will remain in effect and continue to be governed by the terms of the SOP 2015. The 2017 Plan permits the award of share options (both incentive and nonstatutory options), share appreciation rights (“SARs”), restricted shares, restricted share units (“RSUs”), and other share-based awards to the Company’s employees, officers, directors, consultants and advisers. The 2017 Plan is administered by the Company’s board of directors.

Under the 2017 Plan, the number of ordinary shares that will be reserved for issuance will be the sum of (1) 3,000,000 ordinary shares; plus (2) a number of ordinary shares (up to 3,438,990 ordinary shares) which is equal to the sum of the number of the Company’s ordinary shares then available for issuance under the SOP 2015 and the number of ordinary shares subject to outstanding awards under the SOP 2015 that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual increase, to be added on the first day of each fiscal year beginning in the fiscal year ending December 31, 2018 and continuing until, and including, the fiscal year ending December 31, 2027, equal to the least of (i) 2,000,000 ordinary shares, (ii) 4% of the number of outstanding ordinary shares on such date and (iii) an amount determined by the board of directors.

At December 31, 2019, 1,634,766 ordinary shares were available for future issuance under the 2017 Plan.

Options and SARs granted will be exercisable at such times and subject to such terms and conditions as the board may specify in the applicable option agreement; provided, however, that no option or SAR will be granted with a term in excess of ten years. The board will also determine the terms and conditions of restricted shares and RSUs, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

The following table summarizes information regarding our stock option awards under the 2017 Plan at December 31, 2019:

	2017		2018		2019		
2017 Plan	Options	Weighted average exercise price in $ per share	Options	Weighted average exercise price in $ per share	Options	Weighted average exercise price in $ per share	Aggregate intrinsic value
Outstanding as of January 1	—	—	294,100	6.92	2,398,425	5.41	
Granted	294,100	6.92	2,199,225	5.27	2,463,300	1.95	
Exercised	—	—	—	—	—	—	
Forfeited	—	—	(94,900)	6.75	(439,061)	4.79	
Outstanding as of December 31,	**294,100**	**6.92**	**2,398,425**	**5.41**	**4,422,664**	**3.55**	—
Vested and exercisable as of December 31,	**—**	**—**	**119,287**	**6.88**	**1,120,280**	**5.53**	—

There were no options exercised during the years ended December 31, 2017, 2018 and 2019.

The Company has 4,422,664 option grants outstanding at December 31, 2019 with exercise prices ranging from $1.46 per share to $8.35 per share and a weighted average remaining contractual life of 8.7 years.

Stock-based compensation expense under the 2017 Plan was $0.1 million, $1.8 million and $2.6 million for the years ended December 31, 2017, 2018 and 2019, respectively. The weighted average fair value of the options granted during years ended December 31, 2017, 2018 and 2019 was $3.98, $3.06 and $1.14 per share, respectively, based on a Black Scholes option pricing model using the following assumptions:

Input parameters	2017	2018	2019
Range of expected volatility	59.5% - 63.0%	59.8% - 61.4%	61.4% - 63.1%
Expected term of options (in years)	6	6.1	6.0
Range of risk-free interest rate	1.9% - 2.3%	2.6% - 3.0%	1.9% - 2.6%
Dividend yield	—	–	—

As of December, 2019, there was $4.9 million of total unrecognized compensation expense, related to unvested options granted under the 2017 Plan, which will be recognized over the weighted-average remaining vesting period of 2.7 years.

Restricted Stock Units (“RSUs”)

During 2019, the Company granted RSUs to certain employees that vest over a period of four years with 25% vesting upon the first anniversary of the grant date and on a monthly pro rata basis thereafter over the remaining three years. As of December 31, 2019, there were 479,000 of such RSUs outstanding. For the year ended December 31, 2019, $0.2 million of stock-based compensation expense was recognized for these RSUs.

During 2018, the Company granted RSUs to certain employees where vesting of the RSUs was subject to FDA approval of an NDA for XENLETA. Fifty percent (50%) of each RSU award vested upon FDA approval, and the remaining fifty percent (50%) will vest on the one- year anniversary of such approval. As of December 31, 2019, a total of 170,400 RSUs have vested and were issued and there were 161,175 of such RSUs outstanding. In connection with the FDA approval that was received in August 2019, the Company recognized compensation expense of $1.4 million during the year ended December 31, 2019. No compensation expense was recognized on these awards prior to this date as it was determined that approval was not probable since it was outside of the Company’s control.

Also during 2018, the Company granted RSUs to certain employees that will vest in three six-month increments beginning in May 2019 and ending in May 2020. As of December 31, 2019, a total of 487,181 RSUs have vested and were issued and there were 225,911 of such RSUs outstanding. During the years ended December 31, 2018 and 2019, $0.2 million and $1.1 million of compensation expense was recognized for these RSUs.

The Company also granted 35,600 RSUs in 2018 to certain employees where vesting of the RSUs is subject to FDA approval of an NDA for CONTEPO. Fifty percent (50%) of each RSU award will vest upon FDA approval, and the remaining fifty percent (50%) will vest on the one- year anniversary of such approval. As of December 31, 2019, a total of 35,600 of such RSUs are outstanding.

The following table summarizes information regarding our restricted stock unit awards under the 2017 Plan at December 31, 2019:

	2018		2019	
2017 Plan	RSUs	weighted average fair value per share	RSUs	weighted average fair value per share
Outstanding as of January 1	—	—	1,222,100	3.31
Granted	1,241,450	3.36	479,000	1.90
Vested and issued	—	—	(657,581)	3.18
Forfeited	(19,350)	6.47	(141,833)	2.79
Outstanding as of December 31	**1,222,100**	**3.31**	**901,686**	**3.69**

The Company has total unrecognized compensation costs of $2.4 million associated with RSUs which are expected to be recognized over the awards average remaining vesting period of 0.8 years. The fair value of RSU's that vested during the year ended December 31, 2019 was $2.1 million.

2019 Inducement Share Incentive Plan

On March 12, 2019, the Company's board of directors adopted the 2019 Inducement Share Incentive Plan (the "2019 Inducement Plan") and, subject to the adjustment provisions of the 2019 Inducement Plan, reserved 2,000,000 ordinary shares for issuance pursuant to equity awards granted under the 2019 Inducement Plan. In accordance with Nasdaq Listing Rule 5635(c)(4), awards under the 2019 Inducement Plan may only be made to individuals who were not previously employees or non-employee directors of the Company (or following such individuals' bona fide period of non-employment with the Company), as an inducement material to the individuals' entry into employment with the Company.

At December 31, 2019, 1,394,350 ordinary shares were available for future issuance under the 2019 Inducement Plan.

Options and SARs granted will be exercisable at such times and subject to such terms and conditions as the board may specify in the applicable option agreement; provided, however, that no option or SAR will be granted with a term in excess of ten years. The board will also determine the terms and conditions of restricted shares and RSUs, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

The following table summarizes information regarding the Company's stock option awards under the 2019 Inducement Plan for the year ended December 31, 2019:

2019 Plan	Options	Weighted average exercise price in $ per share	Aggregate intrinsic value
Outstanding as of January 1, 2019	—	—	
Granted	703,150	2.22	
Exercised	—	—	
Expired			
Forfeited	(97,500)	2.69	
Outstanding as of December 31, 2019	**605,650**	**2.14**	**$ —**
Vested and exercisable as of December 31, 2019	**—**	**—**	**$ —**

Stock-based compensation expense under the 2019 Inducement Plan was $77,000 for the year ended December 31, 2019. The weighted average fair value of the options granted during the year ended December 31, 2019 was $1.30 per share. The options granted during the year ended December 31, 2019 were valued based on a Black Scholes option pricing model using the following assumptions. The significant inputs into the model were as follows:

Input parameters	
Range of expected volatility	61.6% - 63.7%
Expected term of options (in years)	6.1
Range of risk-free interest rate	1.4% - 2.3%
Dividend yield	—

The weighted average remaining contractual life of the options as of December 31, 2019 is 9.6 years.

As of December 31, 2019, there was $0.7 million of total unrecognized compensation expense, related to unvested options granted under the 2019 Inducement Plan, which will be recognized over the weighted-average remaining vesting period of 3.3 years.

Inducement Awards Outside of the 2019 Inducement Plan

In July 2018, the Company granted a non-statutory option to purchase 850,000 of its ordinary shares and 150,000 performance-based RSUs to the Company's newly appointed Chief Executive Officer (the "CEO"). These equity awards were granted outside of the 2017 Plan, were approved by the Company's compensation committee and board of directors and were made as an inducement material to the CEO entering into employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4). The exercise price per share for the share option is $3.53 per share, and the option award has a ten-year term and will vest over a four-year period, with 25% of the shares underlying the award vesting on the first anniversary of the grant date and the remaining 75% of the shares underlying the option award to vest monthly over the subsequent 36-month period. The performance-based RSUs are subject to vesting as follows: 50% will vest upon certification by the board of directors of the receipt of approval by the FDA of an NDA for each of lefamulin and CONTEPO for any indication, and 50% will vest on the first anniversary of such certification by the board of directors, provided, in each case, the CEO is performing services to the Company on the applicable vesting dates. If the FDA does not approve an NDA for both lefamulin and CONTEPO by January 31, 2020, the performance-based RSUs will terminate in full. Since CONTEPO was not approved by this date the award was forfeited. The Company also issues non-statutory options to new employees upon the commencement of their employment.

Stock-based compensation expense was $0.2 million and $0.4 million for the year ended December 31, 2018 and December 31, 2019. The performance-based RSUs granted to our CEO had a grant date fair value of $3.53 per share (although no expense was recognized as FDA approval was not considered probable) and the options granted to our CEO had a grant date fair value of $2.05 per share based on a Black Scholes option pricing model using the following assumptions.

Input parameters	
Expected volatility	59.8 %
Expected term of options (in years)	6.1
Range of risk-free interest rate	2.9 %
Dividend yield	—

The weighted average remaining contractual life of the options as of December 31, 2019 is 8.6 years.

As of December 31, 2019, there was $1.1 million of total unrecognized compensation expense, related to unvested inducement award options granted, which will be recognized over the weighted-average remaining vesting period of 2.6 years.

Our share-based compensation expense has been allocated to research and development and selling, general and administrative expenses in the Consolidated Statement of Operations and Comprehensive Loss as follows:

	Year ended December 31,		
(in thousands)	**2017**	**2018**	**2019**
Research and development	$ 2,128	$ 1,406	$ 2,138
Selling, general and administrative	3,604	3,748	7,610
Total	**$ 5,732**	**$ 5,154**	**$ 9,748**

The Company recognizes the impact of forfeitures as they occur and issues new shares to satisfy share based compensation arrangements upon the exercise of stock options or vesting of restricted shares.

Employee Stock Purchase Plan

The Company's board of directors adopted, and in August 2018 Company's stockholders approved, the 2018 employee stock purchase plan (the "2018 ESPP"). The maximum aggregate number of shares of ordinary shares that may be purchased under the 2018 ESPP is 500,000 shares, (the "ESPP Share Pool"), subject to adjustment as provided for in the 2018 ESPP. The ESPP Share Pool represented 0.75% of the total number of shares of ordinary shares outstanding as of December 31, 2018. The 2018 ESPP allows eligible employees to purchase shares at a 15% discount to the then current market price of the Company's ordinary shares during certain offering periods, which will be six -month periods commencing November 1 and ending April 30 and commencing May 1 and ending October 31 of each year. The first offering under the 2018 ESPP commenced on November 1, 2018. Expense recorded under the ESPP was not material for the year ended December 31, 2018 and was $0.1 million for the year ended December 31, 2019.

12. Post-employment benefit obligations

As required under Austrian labor law, the Company makes contributions to a state plan classified as defined contribution plan (Mitarbeitervorsorgekasse) for its employees in Austria. Monthly contributions to the plan are 1.53% of salary with respect to each employee and are recognized as expense in the period incurred. For the years ended December 31, 2017, 2018 and 2019, contributions costs were $58,000, $68,000 and $68,000, respectively.

For employees of Nabriva Therapeutics US, Inc., the Company makes contributions to a defined contribution plan as defined in subsection 401(k) of the Internal Revenue Code. The Company matches 100% of the first 3% of the employee's voluntary contribution to the plan and 50% of the next 2% contributed by the employee. Contributions are recognized as expense in the period incurred. In the years ended December 31, 2017, 2018 and 2019, contributions were $213,000, $448,000 and $710,000, respectively.

13. Income tax expense

Loss before income taxes attributable to domestic and international operations, consists of the following:

(in thousands)	Year ended December 31 2017	2018	2019
Domestic	$ (66,109)	$ (113,699)	$ (78,761)
Foreign	(6,892)	(1,032)	(3,902)
Loss before income taxes	$ (73,001)	$ (114,731)	$ (82,663)

Income tax expense consists of the following:

(in thousands)	Year ended December 31 2017	2018	2019
Current tax			
Domestic	$ —	$ —	$ —
Foreign	55	(49)	(101)
Deferred tax			
Domestic	—	—	—
Foreign	(1,410)	—	—
Total income tax expense	$ (1,355)	$ (49)	$ (101)

The reconciliation to our effective tax rate from the Irish statutory income tax rate of 12.5% for the years ended December 31, 2017, 2018 and 2019 is as follows:

(% of pre-tax income)	Year ended December 31 2017	2018	2019
Statutory income tax rate	12.5 %	12.5 %	12.5 %
Non-deductible expenses	(0.8)	(0.1)	(0.1)
Income not subject to tax	0.9	0.3	0.3
Impairment	1.4	—	—
Tax credits	0.2	0.1	0.4
Foreign rate differential	21.0	(3.1)	0.6
In-process research and development	—	(3.5)	0.0
Tax audit assessments	—	—	(11.8)
Other	(1.4)	0.2	0.8
Valuation allowance	(35.6)	(6.5)	(2.8)
Effective income tax rate	(1.8)%	(0.1)%	(0.1)%

The following table summarizes the components of deferred income tax balances:

(in thousands)	As of December 31, 2018	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 91,995	$ 94,014
Tax loss on liquidation of subsidiary	6,245	5,024
Equity compensation	2,473	4,182
Non-deductible reserves	203	395
Total deferred tax assets	100,916	103,615
Valuation allowance	(100,832)	(103,185)
Net deferred tax assets	84	430
Deferred tax liabilities:		
Financial liabilities	55	48
Property, plant and equipment	29	382
Total deferred tax liability	84	430
Deferred tax, net	$ —	$ —

The table below summarizes changes in the deferred tax valuation allowance:

(in thousands)	Year ended December 31, 2017	2018	2019
Balance at beginning of year	$ (54,114)	$ (80,087)	$ (100,832)
Tax benefit	(25,973)	(7,301)	(2,353)
Acquired tax attributes	—	(13,444)	—
Balance at end of year	**$ (80,087)**	**$ (100,832)**	**$ (103,185)**

The following table summarizes carryforwards of net operating losses as of December 31, 2019.

(in thousands)	Amount	Expiration
Ireland	$ 187,631	Indefinite
Austria	$ 223,827	Indefinite
United States	$ 10,403	Indefinite
United States	$ 35,680	2033

Due to uncertainty regarding the ability to realize the benefit of deferred tax assets primarily relating to net operating loss carryforwards and the fact that the Company is in a three year pretax cumulative loss position, a full valuation allowance has been established.

On the basis of this evaluation, as of December 31, 2017, 2018 and 2019, the Company has recorded a valuation allowance of $80.1 million, $100.8 million and $103.2 million, respectively, to recognize only the portion of the deferred tax asset that is more likely than not to be realized. The amount of the deferred tax asset considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period are reduced or increased or if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to subjective evidence such as our projections for growth.

The Tax Cuts and Jobs Act (the “TCJA”) was enacted on December 22, 2017 and became effective January 1, 2018. The Tax Act had significant changes to U.S. tax law, lowering U.S. corporate income tax rates, implementing a territorial tax system, and modified the taxation of other income and expense items.

The TCJA reduces the U.S. corporate income tax rate from 35% to 21%, effective January 1, 2018. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. As a result of the reduction in the U.S. corporate income tax rate from 35% to 21% under the TCJA, the Company revalued the ending net deferred tax assets and liabilities of its U.S.

subsidiary as of December 31, 2017. The tax impact of the revaluation of these deferred tax assets, net was $0.8 million, which was wholly offset by a corresponding reduction in the valuation allowance for these net deferred tax assets resulting in no impact to income tax expense.

At December 31, 2018, the Company had no uncertain tax positions and did not expect any material increase or decrease in income tax expense related to examinations or changes in uncertain tax positions. At December 31, 2019, the Company received a tax assessment from the government in Austria resulting in a change of deferred tax assets. The assessment does not result in a cash settlement.

The Company files income tax returns in Ireland. In addition, the Company's foreign subsidiaries file separate income tax returns in Austria and the United States and state jurisdictions in which they are located. Tax years 2017 and forward remain open for examination for Ireland tax purposes and 2015 and forward remain open for examination for Austrian tax purposes and years 2016 and forward remain open for examination for United States tax purposes.

The Company's policy is to record interest and penalties related to tax matters in income tax expense.

14. Earnings (Loss) per Share

Basic and diluted loss per share

Basic and diluted loss per share is calculated by dividing the net loss attributable to shareholders by the weighted average number of shares outstanding during the year. Diluted net loss per share is the same as basic net loss per share during the periods presented as the effects of the Company's common stock equivalents are antidilutive and thus not included in the calculation.

	Year ended December 31,		
(in thousands, except per share data)	**2017**	**2018**	**2019**
Net loss for the period	$ (74,356)	$ (114,780)	$ (82,764)
Weighted average number of shares outstanding	29,830,669	50,795,768	74,199,482
Basic and diluted loss per share	**$ (2.49)**	**$ (2.26)**	**$ (1.12)**

The following ordinary share equivalents were excluded from the calculations of diluted loss per share as their effect would be anti-dilutive:

	Year ended December 31		
	2017	**2018**	**2019**
Stock option awards	3,338,999	6,091,338	8,168,908
Restricted stock units	—	1,372,100	1,051,686

15. Acquisition of Zavante

On July 24, 2018, the Company acquired Zavante. The acquisition was completed on July 24, 2018 (the "Closing"). In connection with the Closing, the Company issued 7,336,906 Company ordinary shares to former Zavante stockholders, which together with the 815,186 ordinary shares that were issued in July 2019 upon release of the Holdback Shares (as defined below) constitute approximately 19.9% of the Company ordinary shares outstanding as of immediately prior to the Closing (the "Upfront Shares").

Pursuant to the Merger Agreement, former Zavante stockholders and other equity holders, in the aggregate and subject to the terms and conditions of the Merger Agreement, will also be entitled to receive from the Company up to $97.5 million in contingent consideration, of which $25.0 million would become payable upon the first approval of a NDA from the FDA for CONTEPO for any indication (the "Approval Milestone Payment") and an aggregate of up to

$72.5 million would become payable upon the achievement of specified sales milestones (the "Net Sales Milestone Payments").

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

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

The Company accounted for the acquisition of Zavante as an asset acquisition as the arrangement did not meet the definition of a business pursuant to the guidance prescribed in ASC Topic 805, *Business Combinations* because the transaction resulted in the acquisition of the exclusive rights to IV fosfomycin in the U.S. which is a single identifiable asset and represented substantially all the fair value of the assets acquired.

The Company expensed the acquired intellectual property as of the acquisition date as in- process research and development with no alternative future uses. The Company recorded an in-process research and development expense of $32.0 million which represents $26.9 million for the fair value of the Upfront Shares, $4.8 million of transaction costs and $0.2 million of net liabilities assumed.

In addition, the Company assumed certain liabilities and obligations, including contractual liabilities and obligations, that were assumed by the Company upon closing of the acquisition. See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations Acquisition of Zavante" for further information regarding the agreements that were assumed by the Company.

16. Sinovant and Sunovion License Agreements

Sinovant License Agreement

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

Under the Sinovant License Agreement, Sinovant and the Company's subsidiaries have established a joint development committee (the "JDC'), to review and oversee development and commercialization plans in the Territory. The Company received a non-refundable $5.0 million upfront payment pursuant to the terms of the Sinovant License Agreement and will be eligible for up to an additional $91.5 million in milestone payments upon the achievement of certain regulatory and commercial milestone events related to lefamulin for CABP, plus an additional $4.0 million in milestone payments if any Sinovant Licensed Product receives a second or any subsequent regulatory approval in the People's Republic of China. The first milestone was a $1.5 million payment for the submission of a clinical trial

application (“CTA”), by Sinovant to the Chinese Food and Drug Administration, which was received in the first quarter of 2019. Additionally, in connection with the FDA approval for lefamulin the Company received a $5.0 million milestone payment in the third quarter of 2019. The remaining milestone payments of $86.5 million are tied to additional regulatory approvals and annual sales targets. The Company will also be eligible to receive low double-digit royalties on sales, if any, of Sinovant Licensed Products in the Territory. The Company has recorded the payments received to date as collaboration revenue in the consolidated statements of operations. The future regulatory and commercial milestone payments will be recorded during the period the milestones become probable of achievement.

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

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

Sunovion License Agreement

In March 2019, the Company entered into the Sunovion License Agreement with Sunovion. As part of the Sunovion License Agreement, Nabriva Therapeutics Ireland DAC, the Company’s wholly owned subsidiary, granted Sunovion an exclusive license under certain patent rights, trademark rights and know-how to commercialize the Licensed Products in Canada in all uses in humans in community-acquired bacterial pneumonia and in any other indication for which the Licensed Products have received regulatory approval in Canada. Under the Sunovion License Agreement, Sunovion and DAC will establish a joint development committee (the “Sunovian JDC”), to review and oversee regulatory approval and commercialization plans in the Territory. Sunovion will be solely responsible for all costs related to obtaining regulatory approval of and commercializing Licensed Products in the Territory and is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize Licensed Product in the Territory.

The Company has identified two performance obligations at inception: (1) the delivery of the exclusive license to Sunovion, which the Company has determined is a distinct license of functional intellectual property that Sunovion has obtained control of; and, (2) the participation in the Sunovian JDC. The $1.0 million non-refundable upfront payment was allocated entirely to the delivery of the license as the Sunovian JDC deliverable was deemed to be de minimis. Any future regulatory and commercial milestone payments under the Sunovion License Agreement will be recorded during the period the milestones become probable of achievement.

17. Commitments and Contingencies

Leases

The Company leases office spaces in King of Prussia, Pennsylvania, San Diego, California, Dublin, Ireland and laboratory and office space in Vienna, Austria under agreements previously classified as operating leases.

The lease agreement in King of Prussia, Pennsylvania expires on December 15, 2023 and does not include any renewal options. The agreement provides for an initial monthly base amount plus annual escalations through the term of the lease.

The lease agreement in San Diego, California expired on June 30, 2019 and was not renewed by the Company. In May 2019, the Company entered into a month-to-month sublease agreement for office space for two employees in San Diego, California.

For the lease agreement in Vienna Austria, the Company can terminate the lease without the landlord's consent and without paying a termination penalty by giving six months' notice to the landlord. The agreement provides for a monthly base fixed amount. The Company is in the process of determining the appropriate space needed in the building based on its needs. As a result, the Company may negotiate a new lease or evaluate additional or alternate spaces. As such, the Company has classified the agreement as a short-term lease. During the third quarter of 2019, the Company subleased certain space at its leased cost.

In March 2019, the Company entered into a lease agreement for office space in Dublin, Ireland which expires on April 30, 2021. The agreement can be automatically renewed by both parties equal to the current lease term but for no less than three months. The agreement provides for a monthly based fixed amount of 7,000 euros beginning on the commencement date which was in May 2019.

In addition to the monthly base amounts under the lease agreements, the Company is required to pay its proportionate share of real estate taxes and operating expenses during the lease term for the King of Prussia lease.

Lease expense was $1.3 million, $1.4 million, and $1.5 million for the years ended December 31, 2017, 2018 and 2019, respectively.

As of December 31, 2019, the lease term of the King of Prussia operating leases was 4.0 years and the discount rate was 9.8%.

As of December 31, 2019, other information related to the operating leases were as follows:

Operating Cash Flow Supplemental Information:

(in thousands)		**December 31, 2019**
Cash paid for amounts included in the measurement of the operating lease liabilities	$	515
Right-of-use assets obtained in exchange for operating lease obligations	$	1,647

The following table sets forth by year the required future payments of operating lease liabilities:

(in thousands)		**December 31, 2019**
2020	$	507
2021		515
2022		522
2023		533
Total lease payments		2,077
Less imputed interest		(368)
Present value of operating lease liabilities		1,709

Future minimum contractual obligations and commitments at December 31, 2019 are as follows:

	Year ending December 31,						
(in thousands)	Total	2020	2021	2022	2023	2024	Thereafter
Operating lease obligations	$ 3,222	$ 1,647	$ 546	$ 522	$ 507	$ —	$ —
Other contractual commitments	52,406	10,274	9,043	9,690	9,911	6,744	6,744
Total	**$ 55,628**	**$ 11,921**	**$ 9,589**	**$ 10,212**	**$ 10,418**	**$ 6,744**	**$ 6,744**

In addition to the agreements described above, the Company has other contractual commitments related primarily to contracts entered into with contract manufacturing organizations and contract research organizations in connection with the commercial manufacturing of Xenleta and other research and development activities. The estimated payments to the service providers included in the table above are based solely on the estimated work to be performed by them to complete manufacturing and other activities along with the anticipated achievement of milestones included within the agreements. Also, some of these contracts are subject to early termination clauses exercisable at the discretion of the Company.

Legal Proceedings

On May 8, 2019, a putative class action lawsuit was filed against the Company and its Chief Executive Officer in the United States District Court for the Southern District of New York, captioned Larry Enriquez v. Nabriva Therapeutics PLC, and Ted Schroeder, No. 19-cv-04183. The complaint purported to be brought on behalf of shareholders who purchased the Company's securities between November 1, 2018 and April 30, 2019. The complaint generally alleged that the Company and its Chief Executive Officer violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements and omitting to disclose material facts concerning the Company's submission of an NDA to the FDA for marketing approval of CONTEPO for the treatment of cUTI in the United States and the likelihood of such approval. The complaint sought unspecified damages, attorneys' fees, and other costs.

On May 22, 2019, a second putative class action lawsuit was filed against the Company and its Chief Executive Officer in the United States District Court for the Southern District of New York, captioned Anthony Manna v. Nabriva Therapeutics PLC, and Ted Schroeder, No. 19-cv-04713. The complaint purported to be brought on behalf of shareholders who purchased the Company's securities between November 1, 2018 and April 30, 2019. The allegations made in the Manna complaint were similar to those made in the Enriquez complaint, and the Manna complaint sought similar relief. On May 24, 2019, these two lawsuits were consolidated by the court. The court appointed a lead plaintiff and approved plaintiff's selection of lead counsel on July 22, 2019.

On September 23, 2019, plaintiff filed an amended complaint, adding the Company's Chief Financial Officer and Chief Medical Officer as defendants; the amended complaint purports to be brought on behalf of shareholders who purchased the Company's securities between January 4, 2019 through April 30, 2019, and otherwise includes allegations similar to those made in the original complaints and seeks similar relief. The Company's pre-motion letter to dismiss the amended complaint was due to plaintiff on October 21, 2019, and plaintiff responded to the Company via a letter on November 4, 2019. On November 18, 2019, the Company filed a pre-motion letter to dismiss with the Court, seeking leave to move to dismiss and setting forth why a motion to dismiss is warranted.

The Company denies any and all allegations of wrongdoing and intends to vigorously defend against this lawsuit. The Company is unable, however, to predict the outcome of this matter at this time. Moreover, any conclusion of this matter in a manner adverse to the Company and for which it incurs substantial costs or damages not covered by the Company's directors' and officers' liability insurance would have a material adverse effect on its financial condition and business. In addition, the litigation could adversely impact the Company's reputation and divert management's attention and resources from other priorities, including the execution of its business plan and strategies that are important to the Company's ability to grow its business, any of which could have a material adverse effect on the Company's business.

The Company has no other contingent liabilities in respect of legal claims arising in the ordinary course of business.

18. Selected Quarterly Financial Information (Unaudited)

The table summarizes the unaudited consolidated financial results of operations for the quarters ended:

(amounts in thousands, except per share data)	March 31	June 30	September 30	December 31
2019 Quarter Ended				
Revenues	$ 1,703	$ 525	$ 6,920	$ 333
Operating expenses	(20,947)	(21,501)	(24,119)	(22,403)
Loss from operations	(19,244)	(20,976)	(17,199)	(22,070)
Other income (expense)	(819)	(776)	(625)	(954)
Income tax (expense) benefit	(154)	45	29	(21)
Net loss	(20,217)	(21,707)	(17,795)	(23,045)
Basic and diluted loss per share	**$ (0.29)**	**$ (0.30)**	**$ (0.24)**	**$ (0.29)**
2018 Quarter Ended				
Revenues	$ 7,551	$ 847	$ 461	$ 797
Operating expenses	(20,415)	(18,554)	(53,386)	(31,676)
Loss from operations	(12,864)	(17,707)	(52,925)	(30,879)
Other income (expense)	28	(129)	(51)	(204)
Income tax (expense) benefit	(506)	48	151	259
Net loss	(13,342)	(17,788)	(52,825)	(30,824)
Basic and diluted loss per share (1)	**$ (0.36)**	**$ (0.44)**	**$ (0.90)**	**$ (0.46)**

(1) Net loss per share amounts may not agree to the per share amounts for the full year due to the use of weighted average shares for each period.

19. Subsequent Events

On March 11, 2020, the Company entered into an amendment (the “Amendment”) to its Loan Agreement with Hercules. Pursuant to the Amendment, the Company agreed to repay to Hercules between April 1, 2020 and April 3, 2020, $30.0 million of the $35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement (the “Prepayment”). The Company determined to enter into the Amendment following the effectiveness of a performance covenant in February 2020 under which it became obligated to either (1) achieve 80% of its net product revenue sales target over a trailing six month period, or (2) maintain an amount of cash and cash equivalents in accounts pledged to Hercules plus a specified amount of eligible accounts receivables equal to the greater of the amount outstanding under the Loan Agreement or $40.0 million (the “Liquidity Requirement”). Since the Company did not achieve its net product sales targets, it became obligated to maintain compliance with the Liquidity Requirement. Under the Amendment, the Company and Hercules agreed to defer the end of term loan charge payment in the amount of approximately $2.3 million that would have otherwise become payable on the date of the Prepayment and to reduce the prepayment charge with respect to the Prepayment from $600,000 to $300,000 and to defer its payment, in each case, until June 1, 2023 or such earlier date on which all loans under the Loan Agreement are repaid or become due and payable. The Amendment also reset the revenue performance covenant to 70% of targeted revenue based on a revised net product revenue forecast and lowered the Company’s minimum liquidity requirement to $3.0 million in cash and cash equivalents, in each case, following the Prepayment. The new minimum liquidity requirement will not apply if CONTEPO receives regulatory approval from the U.S. Food and Drug Administration and the Company achieves at least 70% of its revised net product revenue targets under the Loan Agreement. Following the Prepayment, the Company may request to borrow an additional $5.0 million subject to the Hercules’ sole discretion.

DESCRIPTION OF SECURITIES REGISTERED UNDER SECTION 12 OF THE EXCHANGE ACT

The following description of registered securities of Nabriva Therapeutics plc (“us,” “our,” “we” or the “Company”) is intended as a summary only and therefore is not a complete description. This description is based upon, and is qualified by reference to, our memorandum and articles of association and applicable provisions of the Irish Companies Act. You should read our memorandum and articles of association, which are filed as Exhibit 3.1 to the Annual Report on Form 10-K of which this Exhibit 4.1 is a part, for the provisions that are important to you.

Capital Structure

Authorized Share Capital

Our authorized share capital consists of 1,000,000,000 ordinary shares of $0.01 each and 100,000,000 preferred shares of $0.01 each with a liquidation preference per preferred share as determined by the directors.

We may issue shares subject to the maximum authorized share capital contained in our memorandum and articles of association. The authorized share capital may be increased or reduced (but not below the number of issued ordinary shares or preferred shares, as applicable) by a resolution approved by a simple majority of the votes of our shareholders cast at a general meeting (referred to under Irish law as an "ordinary resolution") (unless otherwise determined by the directors). The shares comprising our authorized share capital may be divided into shares of any nominal value.

The rights and restrictions to which the ordinary shares are subject are prescribed in our articles of association. Our articles of association entitle our board of directors, without shareholder approval, to determine the terms of our preferred shares. Preferred shares may be preferred as to dividends, rights upon liquidation or voting in such manner as our board of directors may resolve. The preferred shares may also be redeemable at the option of the holder of the preferred shares or at our option, and may be convertible into or exchangeable for shares of any of our other class or classes, depending on the terms of such preferred shares.

Irish law does not recognize fractional shares held of record. Accordingly, our articles of association do not provide for the issuance of fractional shares, and our official Irish register will not reflect any fractional shares.

Whenever an alteration or reorganization of our share capital would result in any of our shareholders becoming entitled to fractions of a share, our board of directors may, on behalf of those shareholders that would become entitled to fractions of a share, arrange for the sale of the shares representing fractions and the distribution of the net proceeds of sale in due proportion among the shareholders who would have been entitled to the fractions.

Pre-emption Rights, Share Warrants and Share Options

Under Irish law certain statutory pre-emption rights apply automatically in favor of shareholders where shares are to be issued for cash. However, we have opted out of these pre-emption rights in our articles of association as permitted under Irish company law. Irish law requires this opt-out to be renewed every five years by a resolution approved by not less than 75% of the votes of our shareholders cast at a general meeting (referred to under Irish law as a "special resolution"). If the opt-out is not renewed, shares issued for cash must be offered to our existing shareholders on a *pro rata* basis to their existing shareholding before the shares can be issued to any new shareholders. The statutory pre-emption rights do not apply where shares are issued for non-cash consideration (such as in a share-for-share acquisition) and do not apply to the issue of non-equity shares (that is, shares that have the right to participate only up to a specified amount in any income or capital distribution) or where shares are issued pursuant to an employee stock option or similar equity plan.

Our memorandum and articles of association provide that, subject to any shareholder approval requirement under any laws, regulations or the rules of any stock exchange to which we are subject, our board of directors is authorized, from time to time, in its discretion, to grant such persons, for such periods and upon such terms as our board of directors deems advisable, options to purchase such number of shares of any class or classes or of any

series of any class as our board of directors may deem advisable, and to cause warrants or other appropriate instruments evidencing such options to be issued. The Irish Companies Act provides that directors may issue share warrants or options without shareholder approval once authorized to do so by the articles of association. We are subject to the rules of the Nasdaq Global Market that require shareholder approval of certain equity plans and share issuances. Our board of directors may authorize the issuance of shares upon exercise of warrants or options without shareholder approval or authorization (up to the relevant authorized share capital limit).

Under Irish law, we are prohibited from allotting shares without consideration. Accordingly, at least the nominal value of the shares issued underlying any restricted share award, restricted share unit, performance share award, bonus share or any other share based grant must be paid pursuant to the Irish Companies Act.

Dividends

Under Irish law, dividends and distributions may only be made from distributable reserves. Distributable reserves generally means accumulated realized profits, so far as not previously utilized by distribution or capitalization, less accumulated realized losses, so far as not previously written off in a reduction or reorganization of capital, and includes reserves created by way of capital reduction. In addition, no distribution or dividend may be made unless our net assets are equal to, or in excess of, the aggregate of our called up share capital plus undistributable reserves and the distribution does not reduce our net assets below such aggregate. Undistributable reserves include the undenominated capital, the amount by which our accumulated unrealized profits, so far as not previously utilized by any capitalization, exceed our accumulated unrealized losses, so far as not previously written off in a reduction or reorganization of capital and any other reserve that we are prohibited from distributing by applicable law.

The determination as to whether or not we have sufficient distributable reserves to fund a dividend must be made by reference to our "relevant financial statements." The "relevant financial statements" are either the last set of unconsolidated annual audited financial statements or other financial statements properly prepared in accordance with the Irish Companies Act. The relevant financial statements must be filed in the Companies Registration Office (the official public registry for companies in Ireland).

Consistent with Irish law, our articles of association authorize our board of directors to declare interim dividends without shareholder approval out of funds lawfully available for the purpose, to the extent they appear justified by profits and subject always to the requirement to have distributable reserves at least equal to the amount of the proposed dividend. Our board of directors may also recommend a dividend to be approved and declared by our shareholders at a general meeting. Our board of directors may direct that the payment be made by distribution of assets, shares or cash and no dividend declared or paid may exceed the amount recommended by the directors. Dividends may be paid in U.S. dollars or any other currency.

Our board of directors may deduct from any dividend payable to any shareholder any amounts payable by such shareholder to us in relation to our shares.

Our board of directors may also authorize the issuance of shares with preferred rights to participate in our declared dividends. The holders of preferred shares may, depending on their terms, rank senior to our ordinary shares in terms of dividend rights and/or be entitled to claim arrears of a declared dividend out of subsequently declared dividends in priority to ordinary shareholders.

Share Repurchases, Redemptions and Conversions

Overview

Our memorandum and articles of association provide that, in general, any ordinary shares which we have agreed to acquire shall be deemed to be a redeemable share. Accordingly, for Irish company law purposes, the repurchase of ordinary shares by us may technically be effected as a redemption of those shares as described below under "—Repurchases and Redemptions by Nabriva." If our articles of association did not contain such provision, all repurchases by us would be subject to many of the same rules that apply to purchases of our shares by

subsidiaries described below under "—Purchases by Subsidiaries of Nabriva," including the shareholder approval requirements described below and the requirement that any on-market purchases be effected on a "recognized stock exchange."

Repurchases and Redemptions by Nabriva

Under Irish law, a company may issue redeemable shares and redeem them out of distributable reserves or, if the company proposes to cancel the shares on redemption, the proceeds of a new issue of shares for that purpose. We may only issue redeemable shares if the nominal value of the issued share capital that is not redeemable is not less than 10% of the nominal value of our total issued share capital. All redeemable shares must also be fully-paid and the terms of redemption of the shares must provide for payment on redemption. Based on the provision of our articles described above, shareholder approval will not be required to redeem our shares.

We may also be given an additional general authority by our shareholders to purchase our own shares on-market, which would take effect on the same terms and be subject to the same conditions as applicable to purchases by our subsidiaries as described below.

Our board of directors may also issue preferred shares which may be redeemed at either our option or the option of the shareholder, depending on the terms of such preferred shares. Please see "—Authorized Share Capital."

Repurchased and redeemed shares may be cancelled or held as treasury shares. The nominal value of treasury shares held by us at any time must not exceed 10% of the nominal value of our issued share capital. We may not exercise any voting rights in respect of any shares held as treasury shares. Treasury shares may be cancelled by us or re-issued subject to certain conditions.

Purchases by Subsidiaries of Nabriva

Under Irish law, an Irish or non-Irish subsidiary may purchase our shares either as overseas market purchases on a recognized stock exchange such as the Nasdaq or off-market. For a subsidiary of ours to make market purchases of our shares, our shareholders must provide general authorization for such purchase by way of ordinary resolution. However, as long as this general authority has been granted, no specific shareholder authority for a particular market purchase by a subsidiary of our shares is required.

For an off-market purchase by a subsidiary of ours, the proposed purchase contract must be authorized by special resolution of the shareholders before the contract is entered into. The person whose shares are to be bought back cannot vote in favor of the special resolution and, for at least 21 days prior to the special resolution being passed, the purchase contract must be on display or must be available for inspection by shareholders at our registered office from the date of the notice of the meeting at which the resolution approving the contract is to be proposed.

In order for a subsidiary of ours to make an on-market purchase of our shares, such shares must be purchased on a "recognized stock exchange." The Nasdaq Global Market, on which our ordinary shares are listed, is specified as a recognized stock exchange for this purpose by Irish company law.

The number of shares held by our subsidiaries at any time will count as treasury shares and will be included in any calculation of the permitted treasury share threshold of 10% of the nominal value of our issued share capital. While a subsidiary holds shares of ours, it cannot exercise any voting rights in respect of those shares. The acquisition of our shares by a subsidiary of ours must be funded out of distributable reserves of the subsidiary.

Lien on Shares, Calls on Shares and Forfeiture of Shares

Our articles of association provide that we will have a first and paramount lien on every share for all debts and liabilities of any shareholder to the company, whether presently due or not, payable in respect of such share. Subject to the terms of their allotment, our board of directors may call for any unpaid amounts in respect of any shares to be paid, and if payment is not made within 14 days after notice demanding payment, we may sell the

shares. These provisions are standard inclusions in the articles of association of an Irish company limited by shares and will only be applicable to our shares that have not been fully paid up.

Consolidation and Division; Subdivision

Under our articles of association, we may, by ordinary resolution (unless our board of directors determines otherwise), consolidate and divide all or any of our issued share capital into a smaller number of shares of larger nominal value than our existing shares or subdivide all or any of our issued share capital into smaller amounts than is fixed by our memorandum of association, provided that the proportion between the amount paid for such share and the amount, if any, unpaid on each reduced share after the subdivision remains the same.

Reduction of Share Capital

We may, by ordinary resolution (unless our board of directors determines otherwise), reduce our authorized but unissued share capital in any way. We also may, by special resolution and subject to confirmation by the Irish High Court, reduce or cancel our issued share capital in any manner permitted by the Irish Companies Act.

Annual Meetings of Shareholders

We are required to hold an annual general meeting within 18 months of incorporation and at intervals of no more than 15 months thereafter, provided that an annual general meeting is held in each calendar year following the first annual general meeting and no more than nine months after our fiscal year-end. Subject to Section 176 of the Irish Companies Act, all general meetings may be held outside of Ireland.

Notice of an annual general meeting must be given to all of our shareholders and to our auditors. Our articles of association provide for a minimum notice period of 21 clear days (i.e. 21 days excluding the day when the notice is given or deemed to be given and the day of the event for which it is given or on which it is to take effect), which is the minimum permitted under Irish law.

The only matters which must, as a matter of Irish company law, be transacted at an annual general meeting are the consideration of the statutory financial statements, report of the directors, report of the statutory auditors, review by the members of the company's affairs and the appointment or re-appointment of the statutory auditors.

At any annual general meeting, only such business may be conducted as has been brought before the meeting:

- in the notice of the meeting;
- by or at the direction of our board of directors;
- in certain circumstances, at the direction of the Irish High Court;
- as required by law; or
- that the chairman of the meeting determines is properly within the scope of the meeting.

In addition, and subject to compliance with our articles of association, shareholders entitled to vote at an annual general meeting may propose business to be considered thereat.

Extraordinary General Meetings of Shareholders

Our extraordinary general meetings may be convened by (i) our board of directors, (ii) on requisition of the shareholders holding not less than 10% of our paid up share capital carrying voting rights, (iii) on requisition of our auditors; or (iv) in exceptional cases, by order of the Irish High Court. Extraordinary general meetings are generally held for the purpose of approving shareholder resolutions as may be required from time to time. At any extraordinary general meeting, only such business will be conducted as is set forth in the notice thereof or is proposed pursuant to and in accordance with the procedures and requirements set out in the articles of association.

Notice of an extraordinary general meeting must be given to all of our shareholders and to our auditors. Under Irish law and our articles of association, the minimum notice periods are 21 clear days' notice in writing for an extraordinary general meeting to approve a special resolution and 14 clear days' notice in writing for any other extraordinary general meeting.

In the case of an extraordinary general meeting convened by our shareholders, the proposed purpose of the meeting must be set out in the requisition notice. Upon receipt of any such valid requisition notice, our board of directors has 21 days to convene a meeting of our shareholders to vote on the matters set out in the requisition notice. This meeting must be held within two months of the receipt of the requisition notice. If our board of directors does not convene the meeting within such 21-day period, the requisitioning shareholders, or any of them representing more than one half of the total voting rights of all of them, may themselves convene a meeting, which meeting must be held within three months of our receipt of the requisition notice.

If our board of directors becomes aware that our net assets are not greater than half of the amount of our called-up share capital, our directors must convene an extraordinary general meeting of our shareholders not later than 28 days from the date that the fact is known to a director.

Quorum for General Meetings

Our articles of association provide that no business shall be transacted at any general meeting unless a quorum is present. One or more shareholders present in person or by proxy at any meeting of shareholders holding not less than a majority of the issued and outstanding shares entitled to vote at the meeting in question will constitute a quorum for such meeting.

Voting

Our articles of association provide that all votes will be decided on a poll and that our board of directors or the chairman may determine the manner in which the poll is to be taken and the manner in which the votes are to be counted.

Every shareholder is entitled to one vote for each ordinary share that he or she holds as of the record date for the general meeting. Voting rights may be exercised by shareholders registered in our share register as of the record date for the general meeting or by a duly appointed proxy, which proxy need not be a shareholder. Where interests in shares are held by a nominee trust company, this company may exercise the rights of the beneficial holders on their behalf as their proxy. All proxies must be appointed in the manner prescribed by our articles of association, which provide that our board of directors may permit shareholders to notify us of their proxy appointments electronically.

In accordance with our articles of association, our directors may from time to time authorize the issuance of preferred shares. These preferred shares may have such voting rights as may be specified in the terms of such preferred shares (e.g., they may carry more votes per share than ordinary shares). Treasury shares or shares of ours that are held by our subsidiaries will not be entitled to be voted at general meetings of shareholders.

Irish company law requires special resolutions of the shareholders at a general meeting to approve certain matters. Examples of matters requiring special resolutions include:

- amending the objects or memorandum of association;
- amending the articles of association;
- approving a change of name;
- authorizing the entering into of a guarantee or provision of security in connection with a loan, quasi-loan or credit transaction to a director or connected person;
- opting out of pre-emption rights on the issuance of new shares;
- re-registration from a public limited company to a private company;
- purchase of own shares off-market;
- reduction of issued share capital;

- sanctioning a compromise/scheme of arrangement;
- resolving that the company be wound up by the Irish courts;
- resolving in favor of a shareholders' voluntary winding-up;
- re-designation of shares into different share classes;
- setting the re-issue price of treasury shares; and
- variation of class rights attaching to classes of shares (where our articles of association do not provide otherwise).

Neither Irish law nor any of our constituent document places limitations on the right of non-resident or foreign owners to vote or hold our shares.

Variation of Rights Attaching to a Class or Series of Shares

Under our articles of association and the Irish Companies Act, any variation of class rights attaching to our issued shares must be approved by an ordinary resolution passed at a general meeting of the shareholders of the affected class or with the consent in writing of the holders of a majority of the issued shares of that class of shares entitled to vote on such variation. The rights conferred upon the holder of any pre-existing issued shares shall not be deemed to be varied by the issuance of any preferred shares.

The provisions of our articles of association relating to general meetings apply to general meetings of the holders of any class of shares except that the necessary quorum is determined in reference to the shares of the holders of the class. Accordingly, for general meetings of holders of a particular class of shares, a quorum consists of one or more shareholders present in person or by proxy holding not less than a majority of the issued and outstanding shares of the class entitled to vote at the meeting in question.

Inspection of Books and Records

Under Irish law, shareholders have the right to: (i) receive a copy of our memorandum and articles of association and any act of the Irish Government which alters our memorandum; (ii) inspect and obtain copies of the minutes of general meetings and any resolutions; (iii) inspect and receive a copy of the register of shareholders, register of directors and secretaries, register of directors' interests and other statutory registers maintained by us; (iv) receive copies of statutory financial statements and directors' and auditors' reports which have previously been sent to shareholders prior to an annual general meeting; and (v) receive statements of financial position of any subsidiary of ours which have previously been sent to shareholders prior to an annual general meeting for the preceding ten years. Our auditors will also have the right to inspect all of our books, records and vouchers. The auditors' report must be circulated to the shareholders with our financial statements prepared in accordance with Irish law, 21 clear days before the annual general meeting and must be read to the shareholders at our annual general meeting.

Acquisitions

An Irish public limited company may be acquired in a number of ways, including:

- a court-approved scheme of arrangement under the Irish Companies Act. A scheme of arrangement with shareholders requires a court order from the Irish High Court and the approval of a majority in number representing 75% in value of the shareholders present and voting in person or by proxy at a meeting called to approve the scheme;
- through a tender or takeover offer by a third party, in accordance with the Irish Takeover Rules and the Irish Companies Act, for all of our shares. Where the holders of 80% or more of our shares (excluding any shares already beneficially owned by the bidder) have accepted an offer for their shares, the remaining shareholders may also be statutorily required to transfer their shares, unless, within one month, the non-tendering shareholders can obtain an Irish court order otherwise providing. If the bidder does not exercise its "squeeze-out" right, then the non-accepting shareholders also have a statutory right to require the bidder to acquire their shares on the same terms as the original offer, or such other terms as the bidder and the non-tendering shareholders may agree or on such term as an

Irish court, on application of the bidder or non-tendering shareholder, may order. If our shares were to be listed on Euronext Dublin or another regulated stock exchange in the European Union, the aforementioned 80% threshold would be increased to 90%;

- by way of a transaction with an EU-incorporated company under the EU Cross-Border Mergers Directive 2019/2121. Such a transaction must be approved by a special resolution and by the Irish High Court. If we are being merged with another EU company under the EU Cross-Border Mergers Directive 2019/2121 and the consideration payable to our shareholders is not all in the form of cash, our shareholders may be entitled to require their shares to be acquired at fair value; and
- by way of a merger with another Irish company under the Irish Companies Act which must be approved by a special resolution and by the Irish High Court.

Appraisal Rights

Generally, under Irish law, shareholders of an Irish company do not have dissenters' or appraisal rights. Under the European Communities (Cross-Border Merger) Regulations 2008, as amended, governing the merger of an Irish company limited by shares and a company incorporated in the European Economic Area (the European Economic Area includes all member states of the European Union and Norway, Iceland and Liechtenstein) and the other company is the surviving entity, a shareholder (i) who voted against the special resolution approving the transaction or (ii) of a company in which 90% of the shares are held by the other party to the transaction has the right to request that the company acquire its shares for cash at a price determined in accordance with the share exchange ratio set out in the acquisition agreement. In addition, a dissenting shareholder in a successful tender offer for an Irish company may, by application to the Irish High Court, object to the compulsory squeeze-out provisions.

Disclosure of Interests in Shares

Under the Irish Companies Act, our shareholders must notify us if, as a result of a transaction, the shareholder will become interested in 3% or more of our shares or if, as a result of a transaction, a shareholder who was interested in 3% or more of our shares ceases to be so interested. Where a shareholder is interested in 3% or more of our shares, the shareholder must notify us of any alteration of his or her interest that brings his or her total holding through the nearest whole percentage number, whether an increase or a reduction. The relevant percentage figure is calculated by reference to the aggregate nominal value of the shares in which the shareholder is interested as a proportion of the entire nominal value of our issued share capital (or any such class of share capital in issue). Where the percentage level of the shareholder's interest does not amount to a whole percentage, this figure may be rounded down to the next whole number. We must be notified within five business days of the transaction or alteration of the shareholder's interests that gave rise to the notification requirement. If a shareholder fails to comply with these notification requirements, the shareholder's rights in respect of any of our shares it holds will not be enforceable, either directly or indirectly. However, such person may apply to the court to have the rights attaching to such shares reinstated.

In addition to these disclosure requirements, we, under the Irish Companies Act, may, by notice in writing, require a person whom we know or have reasonable cause to believe to be, or at any time during the three years immediately preceding the date on which such notice is issued to have been, interested in shares comprised in our relevant share capital to: (i) indicate whether or not it is the case and (ii) where such person holds or has during that time held an interest in our ordinary shares, to provide additional information, including the person's own past or present interests in our shares. If the recipient of the notice fails to respond within the reasonable time period specified in the notice, we may apply to court for an order directing that the affected shares be subject to certain restrictions, as prescribed by the Irish Companies Act, as follows:

- any transfer of those shares, or in the case of unissued shares any transfer of the right to be issued with shares and any issue of shares, will be void;
- no voting rights will be exercisable in respect of those shares;
- no further shares will be issued in right of those shares or in pursuance of any offer made to the holder of those shares; and
- no payment will be made of any sums due from us on those shares, whether in respect of capital or otherwise.

The court may also order that shares subject to any of these restrictions be sold with the restrictions terminating upon the completion of the sale.

In the event we are in an offer period pursuant to the Irish Takeover Rules, accelerated disclosure provisions apply for persons holding an interest in our securities of 1.0% or more.

Irish Takeover Rules

A transaction in which a third party seeks to acquire 30% or more of our voting rights will be governed by the Irish Takeover Panel Act 1997 and the Irish Takeover Rules made thereunder and will be regulated by the Irish Takeover Panel. The "General Principles" of the Irish Takeover Rules and certain important aspects of the Irish Takeover Rules are described below.

General Principles

The Irish Takeover Rules are built on the following General Principles, which will apply to any transaction regulated by the Irish Takeover Panel:

- in the event of an offer, all holders of securities of the target company should be afforded equivalent treatment and, if a person acquires control of a company, the other holders of securities must be protected;
- the holders of the securities in the target company must have sufficient time and information to enable them to reach a properly informed decision on the offer;
- where it advises the holders of securities, the board of the target company must give its views on the effects of implementation of the offer on employment, conditions of employment and the locations of the target company's places of business;
- the board of the target company must act in the interests of the company as a whole and must not deny the holders of securities the opportunity to decide on the merits of the offer;
- false markets must not be created in the securities of the target company, the bidder or of any other company concerned by the offer in such a way that the rise or fall of the prices of the securities becomes artificial and the normal functioning of the markets is distorted;
- a bidder must announce an offer only after ensuring that he or she can fulfil in full, any cash consideration, if such is offered, and after taking all reasonable measures to secure the implementation of any other type of consideration;
- a target company must not be hindered in the conduct of its affairs for longer than is reasonable by an offer for its securities; and
- a substantial acquisition of securities (whether such acquisition is to be effected by one transaction or a series of transactions) shall take place only at an acceptable speed and shall be subject to adequate and timely disclosure.

Mandatory Bid

Under certain circumstances, a person who acquires shares or other voting rights in us may be required under the Irish Takeover Rules to make a mandatory cash offer for our remaining outstanding shares at a price not less than the highest price paid for the shares by the acquirer (or any parties acting in concert with the acquirer) during the previous 12 months. This mandatory bid requirement is triggered if an acquisition of shares would increase the aggregate holding of an acquirer (including the holdings of any parties acting in concert with the acquirer) to shares representing 30% or more of our voting rights, unless the Irish Takeover Panel otherwise consents. An acquisition of shares by a person holding (together with its concert parties) shares representing between 30% or more of our voting rights would also trigger the mandatory bid requirement if, after giving effect to the acquisition, the percentage of the voting rights held by that person (together with its concert parties) would increase by 0.05% within a 12-month period. Any person (excluding any parties acting in concert with the holder) holding shares representing more than 50% of the voting rights of a company is not subject to these mandatory offer requirements in purchasing additional securities.

Voluntary Bid; Requirements to Make a Cash Offer and Minimum Price Requirements

If a person makes a voluntary offer to acquire outstanding ordinary shares of ours, the offer price must be no less than the highest price paid for our shares by the bidder or its concert parties during the three-month period prior to the commencement of the offer period. The Irish Takeover Panel has the power to extend the "look back" period to 12 months if the Irish Takeover Panel, taking into account the General Principles, believes it is appropriate to do so.

If the bidder or any party acting in concert with it has acquired our ordinary shares (i) during the period of 12 months prior to the commencement of the offer period which represent more than 10% of our total ordinary shares or (ii) at any time after the commencement of the offer period, the offer must be in cash (or accompanied by a full cash alternative) and the price per ordinary share must not be less than the highest price paid by the bidder or any party acting in concert with it during, in the case of (i), the 12-month period prior to the commencement of the offer period and, in the case of (ii), the offer period. The Irish Takeover Panel may apply this rule to a bidder who, together with any party acting in concert with it, has acquired less than 10% of our total ordinary shares in the 12-month period prior to the commencement of the offer period if the Irish Takeover Panel, taking into account the General Principles, considers it just and proper to do so.

An offer period will generally commence from the date of the first announcement of the offer or proposed offer.

Substantial Acquisition Rules

The Irish Takeover Rules also contain rules governing substantial acquisitions of shares which restrict the speed at which a person may increase his or her holding of shares and rights over shares to an aggregate of between 15% and 30% of our voting rights. Except in certain circumstances, an acquisition or series of acquisitions of shares or rights over shares representing 10% or more of our voting rights is prohibited if such acquisition(s), when aggregated with shares or rights already held, would result in the acquirer holding 15% or more but less than 30% of our voting rights and such acquisitions are made within a period of seven days. These rules also require accelerated disclosure of acquisitions of shares or rights over shares relating to such holdings.

Anti-Takeover Provisions

Shareholder Rights Plan

Our articles of association expressly authorize our board of directors to adopt a shareholder rights plan, subject to applicable law.

Frustrating Action

Under the Irish Takeover Rules, our board of directors is not permitted to take any action which might frustrate an offer for our shares once our board of directors has received an approach which may lead to an offer or has reason to believe an offer is imminent, subject to certain exceptions. Potentially frustrating actions such as (i) the issue of shares, options or convertible securities, (ii) material acquisitions or disposals, (iii) entering into contracts other than in the ordinary course of business or (iv) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any time during which our board of directors has reason to believe an offer is imminent. Exceptions to this prohibition are available where:

- the action is approved by our shareholders at a general meeting; or
- the Irish Takeover Panel has given its consent, where:
  - it is satisfied the action would not constitute frustrating action;
  - our shareholders that hold 50% of the voting rights state in writing that they approve the proposed action and would vote in favor of it at a general meeting;
  - the action is taken in accordance with a contract entered into prior to the announcement of the offer; or

- the decision to take such action was made before the announcement of the offer and either has been at least partially implemented or is in the ordinary course of business.

Further Provisions

Our articles of association provide that, subject to certain exceptions, we may not engage in certain business combinations with any person that acquires beneficial ownership of 15% or more of our outstanding voting shares for a period of three years following the date on which the person became a 15% shareholder unless: (i) a committee of our disinterested directors approved the business combination; and (ii) in certain circumstances, the business combination is authorized by a special resolution of disinterested shareholders.

Certain other provisions of Irish law or our memorandum and articles of association may be considered to have anti-takeover effects, including those described under the following captions: "—Capital Structure—Authorized Share Capital," "—Pre-emption Rights, Share Warrants and Share Options" and "—Disclosure of Interests in Shares."

Insider Dealing

The Irish Takeover Rules also provide that no person, other than the bidder, who is privy to confidential price-sensitive information concerning an offer made in respect of the acquisition of a company (or a class of its securities) or a contemplated offer shall deal in relevant securities of the target during the period from the time at which such person first has reason to suppose that such an offer, or an approach with a view to such an offer being made, is contemplated to the time of (i) the announcement of such offer or approach or (ii) the termination of discussions relating to such offer, whichever is earlier.

Corporate Governance

Our articles of association allocate authority over the day-to-day management of the company to our board of directors. Our board of directors may delegate any of its powers, authorities and discretions (with power to sub-delegate) to any committee, or delegate to any director, officer or member of management of ours or any of our subsidiaries such of its powers as it considers desirable to be exercised by him or her, but regardless, the directors will remain responsible, as a matter of Irish law, for the proper management of the affairs of the company. Committees may meet and adjourn as they determine proper. Unless otherwise determined our board of directors, the quorum necessary for the transaction of business at any committee meeting shall be a majority of the members of the committee.

Appointment of Directors

The Irish Companies Act provides for a minimum of two directors. Our articles of association provide that the number of directors will be not less than two and not more than 12. The authorized number of directors within the prescribed range will be determined solely by our board of directors and does not require approval or ratification by the shareholders in a general meeting. Our directors will be elected by way of an ordinary resolution at a general meeting save that directors in contested elections will be elected by a plurality of the votes of the shares present in person or represented by proxy at the relevant general meeting and entitled to vote on the election of directors. If the number of the directors is reduced below the fixed minimum number, the remaining director or directors may appoint an additional director or additional directors to make up such minimum or may convene a general meeting for the purpose of making such appointment. Casual vacancies may be filled by our board of directors.

No person may be appointed director unless nominated in accordance with our articles of association. Our articles of association provide that, with respect to an annual or extraordinary general meeting of shareholders, nominations of persons for election to our board of directors may be made by (i) the affirmative vote our board of directors or a committee thereof, (ii) any shareholder who is entitled to vote at the meeting and who has complied with the advance notice procedures provided for in our articles of association, or (iii) with respect to election at an extraordinary general meeting requisitioned in accordance with section 178 of the Irish Companies Act, by a shareholder who holds ordinary shares or other shares carrying the general right to vote at general meetings of the

company and who makes such nomination in the written requisition of the extraordinary general meeting in accordance with our articles of association and the Irish Companies Act relating to nominations of directors and the proper bringing of special business before an extraordinary general meeting.

Removal of Directors

Under the Irish Companies Act, the shareholders may, by an ordinary resolution, remove a director from office before the expiration of his or her term at a meeting held on no less than 28 days' notice and at which the director is entitled to be heard. The power of removal is without prejudice to any claim for damages for breach of contract (e.g., employment contract) that the director may have against the company in respect of his or her removal.

Our board of directors may fill any vacancy occurring on the board of directors. If our board of directors fills a vacancy, the director shall hold office until the next election of directors and until his or her successor shall be elected. A vacancy on our board of directors created by the removal of a director may be filled by our board of directors.

Director Interested Transactions

Under the Irish Companies Act and our articles of association, a director who has an interest in a proposal, arrangement or contract is required to declare the nature of his or her interest at the first opportunity either (i) at a meeting of the board at which such proposal, arrangement or contract is first considered (provided such director knows this interest then exists, or in any other case, at the first meeting of the board after learning that he or she is or has become so interested) or (ii) by providing a general notice to the directors declaring that he or she is to be regarded as interested in any proposal, arrangement or contract with a particular person, and after giving such general notice will not be required to give special notice relating to any particular transaction. Provided the interested director makes such required disclosure, he or she shall be counted in determining the presence of a quorum at a meeting regarding the relevant proposal, arrangement or contract and will be permitted to vote on such proposal, arrangement or contract.

Pursuant to our articles of association, it is within the directors' sole discretion to determine their compensation.

Duration; Dissolution; Rights upon Liquidation

Our duration will be unlimited. We may be dissolved and wound up at any time by way of a shareholders' voluntary winding up or a creditors' winding up. In the case of a shareholders' voluntary winding-up, a special resolution of shareholders is required. We may also be dissolved by way of court order on the application of a creditor, or by the Companies Registration Office as an enforcement measure where we have failed to file certain returns. We may also be dissolved by the Director of Corporate Enforcement in Ireland where the affairs of the company have been investigated by an inspector and it appears from the report or any information obtained by the Director of Corporate Enforcement that we should be wound up.

The rights of the shareholders to a return of our assets on dissolution or winding up, following the settlement of all claims of creditors, are prescribed in our articles of association or the terms of any preferred shares issued by the directors from time to time. The holders of preferred shares in particular may have the right to priority in a dissolution or winding up. Pursuant to our articles of association, subject to the priorities of any creditors, the assets will be distributed to ordinary shareholders in proportion to the paid-up nominal value or credited as paid up value of the shares held at the commencement of the winding up. Our articles of association provide that our ordinary shareholders are entitled to participate *pro rata* in a winding up, but their right to do so may be subject to the rights of any preferred shareholders to participate under the terms of any series or class of preferred shares.

Uncertificated Shares

Unless otherwise provided for by our board of directors or the rights attaching to or by the terms of issue of any particular shares, or to the extent required by any exchange, depositary or any operator of any clearance or

settlement system or by law, holders of our ordinary shares will not have the right to require us to issue certificates for their shares.

No Sinking Fund

Our shares have no sinking fund provisions.

Transfer and Registration of Shares

The transfer agent maintains our share register, and registration in the share register will be determinative of membership in us. A shareholder of ours who only holds shares beneficially will not be the holder of record of such shares. Instead, the depositary or other nominee will be the holder of record of those shares. Accordingly, a transfer of shares from a person who holds such shares beneficially to a person who also holds such shares beneficially through a depositary or other nominee will not be registered in our official share register, as the depositary or other nominee will remain the record holder of any such shares.

A written instrument of transfer is required under Irish law in order to register on our official share register any transfer of shares (i) from a person who holds such shares directly to any other person, (ii) from a person who holds such shares beneficially to a person who holds such shares directly or (iii) from a person who holds such shares beneficially to another person who holds such shares beneficially where the transfer involves a change in the depositary or other nominee that is the record owner of the transferred shares. An instrument of transfer is also required for a shareholder who directly holds shares to transfer those shares into his or her own broker account (or vice versa). Such instruments of transfer may give rise to Irish stamp duty, which must be paid prior to registration of the transfer on our official Irish share register. However, a shareholder who directly holds shares may transfer those shares into his or her own broker account (or vice versa) without giving rise to Irish stamp duty provided there is no change in the ultimate beneficial ownership of the shares as a result of the transfer and the transfer is not made in contemplation of a sale of the shares.

Any transfer of our shares that is subject to Irish stamp duty will not be registered in the name of the buyer unless an instrument of transfer is duly stamped and provided to our transfer agent. Our articles of association allow us, in our absolute discretion, to create an instrument of transfer and pay (or procure the payment of) any stamp duty, which is the legal obligation of a buyer. In the event of any such payment, we are (on behalf of ourselves or our affiliates) entitled to (i) seek reimbursement from the buyer or seller (at its discretion), (ii) set-off the amount of the stamp duty against future dividends payable to the buyer or seller (at its discretion) and (iii) claim a lien against the shares on which it has paid stamp duty. Parties to a share transfer may assume that any stamp duty arising in respect of a transaction in our shares has been paid unless one or both of such parties is otherwise notified by us.

Our memorandum and articles of association delegate to our secretary (or such other person as may be nominated by the secretary for this purpose) the authority to execute an instrument of transfer on behalf of a transferring party.

In order to help ensure that the official share register is regularly updated to reflect trading of our shares occurring through normal electronic systems, we intend to regularly produce any required instruments of transfer in connection with any transactions for which we pay stamp duty (subject to the reimbursement and set-off rights described above). In the event that we notify one or both of the parties to a share transfer that we believe stamp duty is required to be paid in connection with the transfer and that we will not pay the stamp duty, the parties may either themselves arrange for the execution of the required instrument of transfer (and may request a form of instrument of transfer from us for this purpose) or request that we execute an instrument of transfer on behalf of the transferring party in a form determined by us. In either event, if the parties to the share transfer have the instrument of transfer duly stamped (to the extent required) and then provide it to our transfer agent, the buyer will be registered as the legal owner of the relevant shares on our official Irish share register (subject to the matters described below).

The directors may suspend registration of transfers from time to time, not exceeding 30 days in aggregate each year.

NABRIVA THERAPEUTICS PLC

RESTRICTED SHARE UNIT AGREEMENT
GRANTED UNDER 2017 SHARE INCENTIVE PLAN

This Restricted Share Unit Agreement (this "**Agreement**") is made between Nabriva Therapeutics plc, a public limited company organized under the laws of Ireland (the "**Company**"), and the Participant pursuant to the 2017 Share Incentive Plan (the "**Plan**").

NOTICE OF GRANT

I. Participant Information

Participant:	
Participant Address:	

II. Grant Information

Grant Date:	
Number of Restricted Share Units:	

III. Vesting Table

Vesting Date	Number of Restricted Share Units that Vest

This Agreement includes this Notice of Grant and the following Exhibits and Schedules, which are expressly incorporated by reference in their entirety herein:

Exhibit A – General Terms and Conditions
Exhibit B – Nabriva Therapeutics plc 2017 Share Incentive Plan
Schedule 1 – Vesting Schedule
Schedule 2 – Additional Terms and Conditions

IN WITNESS WHEREOF, the parties hereto have executed this Agreement.

NABRIVA THERAPEUTICS PLC

Name:
Title:

PARTICIPANT

Name:

Restricted Share Unit Agreement
2017 Share Incentive Plan

EXHIBIT A

GENERAL TERMS AND CONDITIONS

For valuable consideration, receipt of which is acknowledged, the parties hereto agree as follows:

1. Award of Restricted Share Units. This Agreement evidences the grant by the Company, on the grant date (the "**Grant Date**") set forth in the Notice of Grant that forms part of this Agreement (the "**Notice of Grant**"), to the Participant, subject to the terms and conditions set forth in this Agreement and in the Company's 2017 Share Incentive Plan (the "**Plan**"), of an award with respect to the number of restricted share units (the "**RSUs**") set forth in the Notice of Grant. Each RSU represents the right to receive one ordinary share of the Company (an "**Ordinary Share**") upon vesting of the RSU, subject to the terms and conditions set forth herein.

2. Vesting.

(a) The RSUs shall vest in accordance with the Vesting Table set forth in the Notice of Grant.

(b) Upon the vesting of the RSUs, the Company will deliver to the Participant, for each RSU that becomes vested, one Ordinary Share, subject to the payment of any taxes pursuant to Section 4. Each Ordinary Share will be delivered to the Participant as soon as practicable following each vesting date, but in any event within 30 days of such date.

3. Forfeiture of Unvested RSUs Upon Cessation of Service.

In the event that the Participant ceases to perform services to the Company for any reason or no reason, with or without cause, all of the RSUs that are unvested as of the time of such cessation shall be forfeited immediately and automatically to the Company, without the payment of any consideration to the Participant, effective as of such cessation. The Participant shall have no further rights with respect to the unvested RSUs or any Ordinary Shares that may have been issuable with respect thereto. If the Participant provides services to a subsidiary of the Company, any references in this Agreement to provision of services to the Company shall instead be deemed to refer to service with such subsidiary.

4. Tax Matters.

(a) Acknowledgments; No Section 83(b) Election. The Participant acknowledges that he or she is responsible for obtaining the advice of the Participant's own tax advisors with respect to the award of RSUs and the Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents with respect to any or all income tax, social insurance, payroll tax, payment on account or other tax-related items related to participation in the Plan and legally applicable to the Participant ("**Tax-Related Items**")

relating to the RSUs. The Participant understands that the Participant (and not the Company) shall be responsible for the Participant's Tax-Related Items that may arise in connection with the grant, vesting and/or settlement of the RSUs, the subsequent sale of Ordinary Shares acquired pursuant to such settlement and the receipt of dividends. The Participant acknowledges that no election under Section 83(b) of the Internal Revenue Code, as amended, is available with respect to RSUs and that the Company is under no obligation to structure the terms of the grant or any aspect of the RSUs to reduce or eliminate the Participant's liability for Tax-Related Items or achieve any particular tax result. Further, if the Participant becomes subject to tax in more than one jurisdiction between the Grant Date and the date of any relevant taxable event, as applicable, the Participant acknowledges that the Company may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

(b) Withholding. The Participant acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Participant any federal, state, local or other Tax-Related Items of any kind (including Tax-Related Items of jurisdictions outside the United States, as applicable) required by law to be withheld with respect to the RSUs. The Participant may satisfy such Tax-Related Items by instructing the Company to withhold a number of Ordinary Shares having a fair market value (valued in the manner determined by (or in a manner approved by) the Board) on the applicable vesting date equal to the Tax-Related Items, based on minimum statutory withholding rates for federal and state tax purposes, including payroll taxes, that are applicable to such supplemental taxable income. If the Participant does not instruct the Company to withhold Ordinary Shares to satisfy any applicable Tax-Related Items, then the Participant agrees that if under applicable law the Participant will owe Tax-Related Items at such time on any portion of the Award the Company shall be entitled to satisfy the obligations with regard to all Tax-Related Items by one or a combination of the following:

(1) immediate payment from the Participant of the amount to be withheld by the Company; or
(2) withholding from wages or other cash compensation otherwise paid to the Participant by the Company on the applicable vesting date.

The Company shall not deliver any Ordinary Shares to the Participant until it is satisfied that all required withholdings have been made and the Participant has complied with the above obligations in connection with Tax-Related Items.

5. Transfer Restrictions; Clawback.

(a) The Participant shall not sell, assign, transfer, pledge, hypothecate or otherwise dispose of or encumber, by operation of law or otherwise (collectively "transfer") any RSUs, or any interest therein. The Company shall not be required to treat as the owner of any RSUs or issue any Ordinary Shares to any transferee to whom such RSUs have been transferred in violation of any of the provisions of this Agreement.

(b) In accepting this award, the Participant agrees to be bound by any clawback policy that the Company may adopt in the future.

6. Data Privacy.

(a) Consent. The Participant hereby acknowledges and consents to the collection, use, processing and/or transfer by the Company of Personal Data as defined and described in this Section 6. The Participant is not obliged to consent, however a failure to provide consent, or the withdrawal of consent at any time, may impact the Participant's ability to participate in the Plan. The Participant accepts that the consent provided pursuant to this Section 6 includes consent to any transfer of Personal Data throughout the world.

(b) Information Collected. The Company and/or the Participant's employer collects and maintains certain personal information about the Participant that may include name, home address and telephone number, date of birth, social security number or other government or employer-issued identification number, salary grade, hire data, salary, citizenship, job title, any Ordinary Shares of the Company, or details of all RSUs or any other entitlement to Ordinary Shares awarded, canceled, vested, or unvested (collectively "**Personal Data**").

(c) Uses made of Data. The Company may use, process and/or transfer Personal Data among other group companies to implement, administer and/or manage the Participant's participation in the Plan. The Company may further use, process, analyze and/or transfer Personal Data for its overall administration, management and/or improvement of the Plan and/or to comply with any applicable laws and regulations. The Company maintains technical, administrative and physical safeguards designed to protect Personal Data.

(d) Disclosure of Data. The Company may share and/or transfer Personal Data, in electronic or other format, to selected third parties including but not limited to the Plan's service provider. Such third parties assist in the implementation, administration and/or management of the Plan or the Participant's participation in the Plan, for example to facilitate the holding of shares of stock on Participant's behalf or to process the Participant's election to deposit shares of stock acquired pursuant to the Plan with a broker or other third party. Third parties retained by the Company may use the Personal Data as authorized by the Company to provide the requested services in accordance with the requirements of data protection legislation. Third parties may be located throughout the world, including but not limited to the United States. Third parties often maintain their own published policies that describe their privacy and security practices. The Company is not responsible for the privacy or security practices of any third parties.

(e) Participant Rights. The Participant may request access to, rectification, erasure, portability or restriction of their Personal Data, or object to the processing of their Personal Data at any time by contacting the Company and/or the Plan's service provider. Participant shall have the right to obtain and reuse their Personal Data as provided to the Company. The Company will respond to any such request in writing, or orally if requested, as soon as practicable and in any event not more than one month after receipt of such request. The Company may request proof of identification to verify such a request.

7. Rights as a Shareholder. The Participant shall have no rights as a shareholder of the Company with respect to any Ordinary Shares that may be issuable with respect to the RSUs until the issuance of the Ordinary Shares to the Participant following the vesting of the RSUs.

8. Provisions of the Plan. This Agreement is subject to the provisions of the Plan (including the provisions relating to amendments to the Plan), a copy of which is attached hereto as Exhibit B.

9. Miscellaneous.

(a) No Right to Continued Service/Compensation for Loss. The Participant acknowledges and agrees that, notwithstanding the fact that the vesting of the RSUs is contingent upon his or her continued service to the Company, this Agreement does not constitute an express or implied promise of continued service relationship with the Participant or confer upon the Participant any rights with respect to a continued service relationship with the Company. Under no circumstances will the Participant ceasing to be an employee of the Company be entitled to compensation for any loss of any right or benefit or prospective right or benefit under the Plan which the Participant might otherwise have enjoyed whether such compensation is claimed by way of damages for wrongful dismissal or other breach of contract or by way of compensation for loss of office or otherwise howsoever.

(b) Section 409A. The RSUs awarded pursuant to this Agreement are intended to be exempt from or comply with the requirements of Section 409A of the Internal Revenue Code and the Treasury Regulations issued thereunder ("**Section 409A**"). The delivery of Ordinary Shares on the vesting of the RSUs may not be accelerated or deferred unless permitted or required by Section 409A.

(c) Participant's Acknowledgements. The Participant acknowledges that he or she: (i) has read this Agreement; (ii) has been represented in the preparation, negotiation and execution of this Agreement by legal counsel of the Participant's own choice or has voluntarily declined to seek such counsel; (iii) understands the terms and consequences of this Agreement; and (iv) is fully aware of the legal and binding effect of this Agreement.

(d) Governing Law. This Agreement shall be governed by, except to the extent preempted by other applicable laws (1) with respect to the corporate law requirements applicable to the Company, the validity and authorization of the issuance of Ordinary Shares under the Plan and similar matters, the laws of Ireland (without reference to conflict of law principles thereof) and (2) with respect to all other matters relating to the Plan and Awards, the laws of the State of Delaware, excluding choice-of-law principles of the law of that state.

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Schedule 1

Vesting Schedule

Schedule 2

Additional terms to Restricted Share Unit Award Agreement

Terms and Conditions

This Schedule (the "Schedule") includes additional terms and conditions that govern the RSUs granted to you under the Plan if you reside in one of the countries listed below. Certain capitalized terms used but not defined in this Schedule have the meanings set forth in the Plan and/or the Agreement.

Notifications

This Schedule also includes country-specific information of which you should be aware with respect to your participation in the Plan. The information is based on the securities, exchange control and other laws in effect in the respective countries as of January 2018. Such laws are often complex and change frequently. As a result, the Company strongly recommends that you do not rely on the information noted herein as the only source of information relating to the consequences of your participation in the Plan because the information may be out of date at the time that you vest in the RSUs and Ordinary Shares are issued to you or the shares issued upon vesting of the RSUs are sold.

In addition, the information is general in nature and may not apply to your particular situation, and the Company is not in a position to assure you of any particular result. Accordingly, you are advised to seek appropriate professional advice as to how the relevant laws in your country may apply to your particular situation. Finally, please note that if you are a citizen or resident of a country other than the country in which you are currently working, or transfers employment after grant, the information contained in the Schedule may not be applicable.

Ireland

Notifications

Director Notification Obligation. If you are a director, shadow director or secretary of the Company or an Irish subsidiary or affiliate of the Company, and you acquire or dispose of an interest under this Agreement comprising more than 1% of the share capital in the Company, you must notify the entity in which you hold that office (whether the Company itself or an Irish subsidiary or affiliate of the Company) in writing within five business days of receiving or disposing of an interest in the Company, or within five business days of becoming aware of the event giving rise to the notification requirement or within five days of becoming a director or secretary if such an interest exists at the time. This notification requirement also applies with respect to the interests of a spouse or children under the age of 18 (whose interests will be attributed to the director, shadow director or secretary).

SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Amendment**"), dated as of January 8, 2020 (the "**Amendment Effective Date**"), is made among Nabriva Therapeutics Public Limited Company, a public limited company incorporated in Ireland under registration number 599588 and having its registered office at 25-28 North Wall Quay, Dublin 1, Ireland ("**Parent**"), Nabriva Therapeutics Ireland Designated Activity Company, a designated activity company incorporated in Ireland under registration number 612454 and having its registered office at Suite 510, Regus Dublin Airport, Skybridge House, Dublin Airport, Swords, County Dublin, Ireland ("**Nabriva Ireland**"; together with Parent, individually and collectively, jointly and severally, the "**Borrower**"), Nabriva Therapeutics GmbH, a limited liability company (Gesellschaft mit beschränkter Haftung) incorporated under the laws of the Republic of Austria, having its seat in Vienna and its registered address at Leberstraße 20, 1110 Vienna, and registered with the companies' register (Firmenbuch) of the commercial court of Vienna (Handelsgericht Wien) under registration number 269261 y ("**Nabriva Austria**"), Nabriva Therapeutics US, Inc., a Delaware corporation ("**Nabriva US**"), Zavante Therapeutics, Inc., a Delaware corporation ("**Zavante**"; together with Nabriva Austria and Nabriva US, collectively referred to as the "Guarantors" and each, a "**Guarantor**"), Hercules Capital, Inc. , a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and Lender (in such capacity, together with its successors and assigns in such capacity, "**Agent**").

The Loan Parties, the Lenders and Agent are parties to a Loan and Security Agreement dated as of December 20, 2018, as amended by the First Amendment to Loan and Security Agreement dated September 26, 2019 (and as further amended, restated or modified from time to time, the "**Loan and Security Agreement**"). Loan Parties have requested that the Lenders agree to certain consents and amendments to the Loan and Security Agreement. The Lenders have agreed to such request, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION 1 Definitions; Interpretation.

(a) **Terms Defined in Loan and Security Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) **Interpretation**. The rules of interpretation set forth in the last paragraph of Section 1.1 of the Loan and Security Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2 Amendments to the Loan and Security Agreement.

(a) The Loan and Security Agreement shall be amended as follows effective as of the Amendment Effective Date:

(i) New Definitions. The following definitions are added to Section 1.1 in their proper alphabetical order:

"**Second Amendment**" means that certain Second Amendment to Loan and Security Agreement, dated as of the Second Amendment Effective Date, by and among Borrower, the Guarantors, Agent and the lenders party thereto.

"**Second Amendment Effective Date**" means January 8, 2020.

(ii) Section 7.12(b). Section 7.12(b) is hereby amended and restated as follows:

(b) The Loan Parties shall be required to hold, in US Dollars, an amount of Unrestricted Cash in Deposit Accounts in the United States, Ireland and Luxembourg with respect to which Agent has an Account Control Agreement or a Foreign Account Pledge Agreement equal

to the lesser of (i) 120% of the outstanding Secured Obligations, and (ii) 75% of all Unrestricted Cash (excluding amounts held in Excluded Accounts) of Parent and its Subsidiaries.

(iii) Section 7.21(a). Section 7.21(a) is hereby amended and restated as follows:

(a) Minimum Cash. At all times, the Loan Parties shall be required to maintain Unrestricted Cash in Deposit Accounts held in the United States and Ireland in an amount greater than or equal to Ten Million US Dollars ($10,000,000) *plus* the amount of the Loan Parties' accounts payable under GAAP not paid after the 90th day following the invoice date for such accounts payable.

(b) **Compliance Certificate.** Exhibit F of the Loan and Security Agreement, the Compliance Certificate, is hereby amended and restated in its entirety as set forth in Annex A attached hereto.

(c) **References Within Loan and Security Agreement**. Each reference in the Loan and Security Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 3 Conditions of Effectiveness. The effectiveness of Section 2 of this Amendment shall be subject to the satisfaction of each of the following conditions precedent:

(a) **Fees and Expenses**. The Loan Parties shall have paid (i) all invoiced costs and expenses then due under the Loan Documents, and (ii) all other invoiced fees, costs and expenses, if any, due and payable as of the Amendment Effective Date under the Loan and Security Agreement.

(b) **This Amendment**. Agent shall have received this Amendment, executed by Agent, the Lenders and the Loan Parties.

(c) **Representations and Warranties; No Default**. On the Amendment Effective Date, after giving effect to the amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 4 shall be true and correct on and as of the Amendment Effective Date as though made on and as of such date; and

(ii) There exist no Events of Default or events that with the passage of time would result in an Event of Default.

SECTION 4 Representations and Warranties. To induce the Lenders to enter into this Amendment, Each Loan Party hereby confirm, as of the date hereof, (a) that the representations and warranties made by it in Section 6 of the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects, except to the extent such representations and warranties expressly relate to an earlier date; (b) that there has not been and there does not exist a Material Adverse Effect; (c) that the information included in the Perfection Certificate delivered to Agent on the Closing Date remains true and correct; (d) Lender has and shall continue to have valid, enforceable and perfected first-priority liens, on and security interests in the Collateral and all other collateral heretofore granted by such Loan Party to Lender, pursuant to the Loan Documents or otherwise granted to or held by Lender; (e) the agreements and obligations of such Loan Party contained in the Loan Documents and in this Amendment constitute the legal, valid and binding obligations of such Loan Party, enforceable against such Loan Party in accordance with their respective terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditors' rights or by the application of general principles of equity; and (f) the execution, delivery and performance of this Amendment by such Loan Party will not violate any law, rule, regulation, order, contractual obligation or organizational document of such Loan Party and will not result in, or require, the creation or imposition of any lien, claim or encumbrance of any kind on any of its properties or revenues. For the purposes of this Section 4, each reference in Section 6 of the Loan and Security Agreement to "this Agreement," and the words "hereof," "herein," "hereunder," or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 5 Miscellaneous.

(a) **Consent.** Agent hereby consents to the actual Net Product Revenue recognized by Parent during the month of September 2019 to apply to the month of October 2019 for purposes of Section 7.21(b)(i) of the Loan Agreement.

(b) **Loan Documents Otherwise Not Affected; Reaffirmation; No Novation**.

(i) Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. The Lenders' and Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future.

(ii) Each Loan Party hereby expressly (1) reaffirms, ratifies and confirms its Obligations under the Loan Agreement and the other Loan Documents, (2) reaffirms, ratifies and confirms the grant of security under Section 3.1 of the Loan and Security Agreement, (3) reaffirms that such grant of security in the Collateral secures all Obligations under the Loan and Security Agreement, and with effect from (and including) the Amendment Effective Date, such grant of security in the Collateral: (x) remains in full force and effect notwithstanding the amendments expressly referenced herein; and (y) secures all Obligations under the Loan and Security Agreement, as amended by this Amendment, and the other Loan Documents, (4) agrees that this Amendment shall be a "Loan Document" under the Loan Agreement and (5) agrees that the Loan Agreement and each other Loan Document shall remain in full force and effect following any action contemplated in connection herewith.

(iii) This Amendment is not a novation and the terms and conditions of this Amendment shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. Nothing in this Amendment is intended, or shall be construed, to constitute an accord and satisfaction of any Loan Party's Secured Obligations under or in connection with the Loan and Security Agreement and any other Loan Document or to modify, affect or impair the perfection or continuity of Agent's security interest in, (on behalf of itself and the Lenders) security titles to or other liens on any Collateral for the Secured Obligations.

(c) **Conditions**. For purposes of determining compliance with the conditions specified in Section 3, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Agent shall have received notice from such Lender prior to the Amendment Effective Date specifying its objection thereto.

(d) **Release**. In consideration of the agreements of Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each Loan Party, on behalf of itself and its successors, assigns, and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lenders and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually as a "**Releasee**"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment for or on account of, or in relation to, or in any way in connection with the Loan Agreement, or any of the other Loan Documents or transactions thereunder or related thereto. Borrower understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above.

(e) **No Reliance**. Borrower hereby acknowledges and confirms to Agent and the Lenders that Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(f) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(g) **Governing Law**. **THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAWS OTHER THAN THE LAWS OF THE STATE OF NEW YORK), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL.**

(h) **Complete Agreement; Amendments**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(i) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(j) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(k) **Loan Documents**. This Amendment and the documents related thereto shall constitute Loan Documents.

[Balance of Page Intentionally Left Blank; Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

Nabriva Therapeutics Public Limited Company

GIVEN under the **COMMON SEAL** of

NABRIVA THERAPEUTICS PUBLIC LIMITED COMPANY

and **DELIVERED** as a **DEED**:

/s/ Gary Sender
Gary Sender
Authorised Signatory

Nabriva Therapeutics Ireland Designated Activity Company

SIGNED AND DELIVERED as a Deed

for and on behalf of

NABRIVA THERAPEUTICS IRELAND DESIGNATED ACTIVITY COMPANY

by its lawfully appointed attorney

GARY SENDER

/s/ Gary Sender
Signature of Attorney

in the presence of:

/s/ Chris Naftzger
Signature of Witness

Attorney
Occupation of Witness

1305 Homestead Lane, Lancaster PA 17663
Address of Witness

GUARANTORS:

NABRIVA THERAPEUTICS GMBH

By: /s/ Gary Sender
Name: Gary Sender
Title: CFO

NABRIVA THERAPEUTICS US, INC.

By: /s/ Gary Sender
Name: Gary Sender
Title: CFO

ZAVANTE THERAPEUTICS, INC.

By: /s/ Gary Sender
Name: Gary Sender
Title: CFO

AGENT:

HERCULES CAPITAL, INC.,
as Agent

By: /s/ Jennifer Choe
Name: Jennifer Choe
Title: Assistant General Counsel

LENDER:

HERCULES CAPITAL, INC.,
as Lender

By: /s/ Jennifer Choe
Name: Jennifer Choe
Title: Assistant General Counsel

EXHIBIT F

COMPLIANCE CERTIFICATE

[_____ __, 20__]

Hercules Capital, Inc. (as "Agent")
400 Hamilton Avenue, Suite 310
Palo Alto, CA 94301

Reference is made to that certain Loan and Security Agreement dated December 20, 2018 and the Loan Documents (as defined therein) entered into in connection with such Loan and Security Agreement all as may be amended from time to time (hereinafter referred to collectively as the "Loan Agreement") by and among the lenders from time to time party thereto (collectively, the "Lender"), Hercules Capital, Inc., as agent for the Lender (the "Agent"), Nabriva Therapeutics Public Limited Company, a public limited company incorporated in Ireland under registration number 599588 and having its registered office at 25-28 North Wall Quay, Dublin 1, Ireland ("Parent"), Nabriva Therapeutics Ireland Designated Activity Company, a designated activity company incorporated in Ireland under registration number 612454 and having its registered office at Suite 510, Regus Dublin Airport, Skybridge House, Dublin Airport, Swords, County Dublin, Ireland ("Nabriva Ireland"; together with Parent, individually and collectively, jointly and severally, the "Borrower"), Nabriva Therapeutics GmbH, a limited liability company (*Gesellschaft mit beschränkter Haftung*) incorporated under the laws of the Republic of Austria, having its seat in Vienna and its registered address at Leberstraße 20, 1110 Vienna, and registered with the companies' register (*Firmenbuch*) of the commercial court of Vienna (*Handelsgericht Wien*) under registration number 269261 y ("Nabriva Austria"), Nabriva Therapeutics US, Inc., a Delaware corporation ("Nabriva US"), and Zavante Therapeutics, Inc., a Delaware corporation ("Zavante"), and each of their Subsidiaries from time to time party thereto (together with Nabriva Austria, and Nabriva US, collectively referred to as the "Guarantors" and each, a "Guarantor"). All capitalized terms not defined herein shall have the same meaning as defined in the Loan Agreement.

The undersigned is an Officer of the Parent, knowledgeable of all Loan Party financial matters, and is authorized to provide certification of information regarding the Loan Parties; hereby certifies, in such capacity, that in accordance with the terms and conditions of the Loan Agreement, the Loan Parties are in compliance for the period ending _____ of all covenants, conditions and terms therein and hereby reaffirms that all representations and warranties contained therein are true and correct in all material respects, other than as disclosed in this Compliance Certificate, on and as of the date of this Compliance Certificate with the same effect as though made on and as of such date, except to the extent such representations and warranties expressly relate to an earlier date, after giving effect in all cases to any standard(s) of materiality contained in the Loan Agreement as to such representations and warranties. Attached are the required documents supporting the above certification. The undersigned further certifies that these are prepared in accordance with GAAP (except for the absence of footnotes with respect to unaudited financial statement and subject to normal year-end adjustments) and are consistent from one period to the next except as explained below.

REPORTING REQUIREMENT	REQUIRED	CHECK IF ATTACHED
Interim Financial Statements	Monthly within 30 days, as applicable	
Interim Financial Statements	Quarterly within 45 or 60 days, as applicable	
Audited Financial Statements	FYE within 90 days	
Accounts Receivable and Accounts Payable (7.1(e))	Monthly within 30 days	
Projections (7.1(g))	FYE within 75 days	

Note: Section 7.12(b), 7.21(a), and 7.21(b) below can be completed through the use of an attached Excel-based spreadsheet (which is deemed part of this Compliance Certificate). Check if a supporting spreadsheet is attached: __ Yes; __ No

7.12(b) – Cash Management

(a) The amount of Unrestricted Cash in the United States, Ireland and Luxembourg as of the date hereof: $_____

(b) outstanding Secured Obligations: $_____ multiplied by 1.20 = $_____

(c) all Cash (excluding amounts held in Excluded Accounts) of Parent and its consolidated Subsidiaries: $_____ multiplied by 0.75 = $_____

(d) Is the amount reported in clause (a) greater than or equal to the lesser of (b) and (c)? __ Yes; __ No

If No: not in compliance

7.21(a) – Minimum Cash

(a) The amount of Unrestricted Cash in the United States and Ireland as of the date hereof: $_____

(b) The amount of the Loan Parties' accounts payable under GAAP not paid after the 90th day following the invoice date for such accounts payable $_____

(c) Clause (b) *plus* $10,000,000 is $_____

(d) Is the amount in clause (a) equal to or greater than the amount in clause (c)? __ Yes; __ No

If No: not in compliance.

7.21(b) – Performance Covenant

(a) Has the Performance Covenant Trigger Date passed? __ Yes; __ No

If Yes:

(i) Trailing six month Net Product Revenue: $_____

(ii) 80% of forecasted trailing six month Net Product Revenue in the Forecast: $_____

(iii) Is clause (i) greater than or equal to clause (ii)? __ Yes; __ No

If Yes: in compliance.

If No:

(iv) The amount of Unrestricted Cash as of the date of this Compliance Certificate: $_____

(v) 80% of Eligible Accounts as of the date of this Compliance Certificate: $_____

(vi) Clause (iv) *plus* clause (v) is: $_____

(vii) The amount of outstanding Advances plus the amount of accounts payable under GAAP not paid after the 90th day following the invoice date for such accounts payable as of the date of this Compliance Certificate is: $_____

(viii) Are both of the following true: **(a)** clause is (vi) greater than or equal to clause (vii), and **(b)** the amount in clause (iv) is greater than or equal to $40,000,000? __ Yes; __ No

If No: not in compliance.

If Yes: in compliance.

Section 7.19 – Intellectual Property

(a) Has any Loan Party filed or obtained any new Patent, registered Trademark, or registered Copyright since the last reported period? __ Yes; __ No

If yes: Borrower shall supplement such intellectual property security agreements and or other documents as needed to maintain a first priority perfected security interest in favor of Agent within 90 days of the date hereof.

(b) Is any utilized Intellectual Property not registered in the current legal name of Nabriva Austria as the owner of such Intellectual Property in the registry in the United States, Ireland and Austria? __ Yes (not in compliance); __ No (in compliance)

(c) Has Nabriva Austria filed corrective filings in the United States, Ireland or Austria to updated its name from Nabriva Therapeutics AG to Nabriva Therapeutics GmbH since the last reported period? __ Yes; __ No

If yes: Borrower shall supplement such intellectual property security agreements and or other documents as needed to maintain a first priority perfected security interest in favor of Agent within 90 days of the date hereof.

If yes: the IP Security Agreement, Debenture, and/or IP Security Agreement in relation to Nabriva Austria, as applicable, shall be supplemented within 90 days of the date hereof.

The undersigned hereby also confirms the below disclosed accounts represent all depository accounts and securities accounts presently open in the name of each Loan Party or and their Subsidiaries, as applicable.

		Depository AC #	Financial Institution	Account Type (Depository / Securities)	Last Month Ending Account Balance	Purpose of Account	New Account Since Last Reporting Period?
BORROWER Name/Address:							
	1						
	2						
	3						
	4						
	5						
	6						
	7						

BORROWER SUBSIDIARY Name/Address							
	1						
	2						
	3						
	4						
	5						
	6						
	7						

Very Truly Yours,

[ ],
on behalf of itself and its Subsidiaries

By: _____

Name: _____

Its: _____

Date Submitted: _____

Exhibit 10.41

Execution Version

THIRD AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **THIRD AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Amendment**"), dated as of March 11, 2020 (the "**Third Amendment Signing Date**"), is made among Nabriva Therapeutics Public Limited Company, a public limited company incorporated in Ireland under registration number 599588 and having its registered office at 25-28 North Wall Quay, IFSC, Dublin 1, Ireland ("**Parent**"), Nabriva Therapeutics Ireland Designated Activity Company, a designated activity company incorporated in Ireland under registration number 612454 and having its registered office at Alexandra House, Office 225/227, The Sweepstakes, Ballsbridge, Dublin 4, D04 C7H2, Republic of Ireland ("**Nabriva Ireland**"; together with Parent, individually and collectively, jointly and severally, the "**Borrower**"), Nabriva Therapeutics GmbH, a limited liability company (Gesellschaft mit beschränkter Haftung) incorporated under the laws of the Republic of Austria, having its seat in Vienna and its registered address at Leberstraße 20, 1110 Vienna, Austria and registered with the companies' register (Firmenbuch) of the commercial court of Vienna (Handelsgericht Wien) under registration number FN262261 Y ("**Nabriva Austria**"), Nabriva Therapeutics US, Inc., a Delaware corporation ("**Nabriva US**"), Zavante Therapeutics, Inc., a Delaware corporation ("**Zavante**"; together with Nabriva Austria and Nabriva US, collectively referred to as the "Guarantors" and each, a "**Guarantor**"), Hercules Capital, Inc., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and Lender (in such capacity, together with its successors and assigns in such capacity, "**Agent**").

The Loan Parties, the Lenders and Agent are parties to a Loan and Security Agreement dated as of December 20, 2018, as amended by the First Amendment to Loan and Security Agreement dated September 26, 2019, as amended by the Second Amendment to Loan and Security Agreement dated January 21, 2020 (and as further amended, restated or modified from time to time, the "**Loan and Security Agreement**"). Loan Parties have requested that the Lenders agree to certain consents and amendments to the Loan and Security Agreement. The Lenders have agreed to such request, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION 1 Definitions; Interpretation.

(a) **Terms Defined in Loan and Security Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) **Interpretation**. The rules of interpretation set forth in the last paragraph of Section 1.1 of the Loan and Security Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2 Amendments to the Loan and Security Agreement.

(a) The Loan and Security Agreement shall be amended as follows effective as of the Third Amendment Effective Date:

(i) New Definitions. The following definitions are added to Section 1.1 in their proper alphabetical order:

"**Applicable Amount**" means Ten Million US Dollars ($10,000,000); provided however, upon the occurrence of the Third Amendment Prepayment, the Applicable Amount shall be Three Million US Dollars ($3,000,000).

"**Closing End of Term Charge**" has the meaning given to it in Section 2.6.

"**Disclosed Matters**" means (i) the Loan Parties' failure to obtain FDA approval for CONTEPO pursuant to that certain Complete Response Letter dated

April 30, 2019 issued by the FDA, and (ii) the Parent's failure to satisfy Section 7.21(b)(i)(A) prior to the date of the Third Amendment Prepayment.

"**Performance Covenant Trigger II Date**" means the date that is the later of the dates described in clauses (a) and (b) (both of which must occur in order for the Performance Covenant Trigger II Date to occur): (a) the date Borrower pays the Third Amendment Prepayment and (b) May 1, 2020.

"**Third Amendment**" means that certain Third Amendment to Loan and Security Agreement, dated as of the Third Amendment Signing Date, and effective as of the Third Amendment Effective Date, by and among Borrower, the Guarantors, Agent and the lenders party thereto.

"**Third Amendment Effective Date**" has the meaning given to it in the Third Amendment.

"**Third Amendment End of Term Charge I**" has the meaning given to it in Section 2.6.

"**Third Amendment End of Term Charge II**" has the meaning given to it in Section 2.6.

"**Third Amendment Prepayment**" has the meaning given to it in the Third Amendment.

"**Third Amendment Prepayment Amount**" has the meaning given to it in the Third Amendment.

"**Third Amendment Signing Date**" means March 11, 2020.

(ii) Amended and Restated Definitions. The definition of Performance Covenant Trigger Date is hereby amended and restated as follows:

"**Performance Covenant Trigger I Date**" means the date that is the later of the dates described in clauses (a) and (b) (both of which must occur in order for the Performance Covenant Trigger I Date to occur): (a) the earliest Advance Date of a Tranche 2 Advance, a Tranche 3 Advance, a Tranche 4 Advance, Tranche 5 Advance, or a Tranche 6 Advance and (b) the date that is six (6) months following the earliest of the (i) achievement of Performance Milestone 1 and (ii) achievement of Performance Milestone 2. The Loan Parties acknowledge and agree that the Performance Covenant Trigger I Date occurred on February 20, 2020.

(iii) Section 2.2. Section 2.2(d) is hereby amended by inserting the following sentence as the third sentence thereof:

As of the Third Amendment Effective Date, and upon the occurrence of the Third Amendment Prepayment, the amortization schedule of principal and interest for payment of the remaining Advances is set forth on Annex A.

(iv) Section 2.5. Section 2.5 is hereby amended and restated as follows:

2.5 Prepayment. At its option upon at least five (5) Business Days prior written notice to Agent, Borrower may prepay all or any portion greater than or equal to Five Million Dollars ($5,000,000) of the outstanding Advances by

paying the entire principal balance (or portion thereof), and all accrued and unpaid interest with respect to the principal balance being prepaid, together with a prepayment charge equal to the following percentage of the Advance amount being prepaid: other than with respect to the Third Amendment Prepayment Amount, if such Advance amounts are prepaid in any of the first twelve (12) months following the Closing Date, 3.0%; after twelve (12) months but prior to twenty four (24) months following the Closing Date, 2.0%; and thereafter, 1.0% (each, a "Prepayment Charge"). Borrower agrees that the Prepayment Charge is a reasonable calculation of Lender's lost profits in view of the difficulties and impracticality of determining actual damages resulting from an early repayment of the Advances. Borrower shall prepay the outstanding amount of all principal and accrued interest through the prepayment date and the Prepayment Charge upon the occurrence of a Change in Control. Notwithstanding the foregoing, (a) Agent and Lender agree to waive the Prepayment Charge if Agent, Lender or any of their respective Affiliates (in its sole discretion) agree in writing to refinance the Advances on or prior to the Term Loan Maturity Date and (b) any applicable Prepayment Charge with respect to the Third Amendment Prepayment shall be due and payable in accordance with Section 2.6 of this Agreement.

(v) Section 2.6. Section 2.6 is hereby amended and restated as follows:

2.6 End of Term Charges. On the earliest to occur of (i) the Term Loan Maturity Date, (ii) the date that Borrower prepays all of the outstanding Secured Obligations (other than any inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement), or (iii) the date that all of the Secured Obligations become due and payable, Borrower shall pay Lender a charge equal to (x) $2,432,500 (the "Closing End of Term Charge"), plus (y) $300,000 (the "Third Amendment End of Term Charge I"), plus (z) 6.95% of the aggregate principal amount of all Advances (if any) funded by a Lender to the Borrower after the Third Amendment Signing Date (the "Third Amendment End of Term Charge II"). Notwithstanding the required payment date of such charges, the Closing End of Term Charge shall be deemed earned by Lender as of the Closing Date, the Third Amendment End of Term Charge I shall be deemed earned by Lender as of the Third Amendment Signing Date and the Third Amendment End of Term Charge II shall be deemed earned by Lender on the date a Term Loan Advance is made after the Third Amendment Signing Date.

(vi) Section 7.21. Section 7.21 is hereby amended and restated as follows:

7.21 Financial Covenants.

(a) Minimum Cash. At all times, the Loan Parties shall be required to maintain Unrestricted Cash in Deposit Accounts and Securities Accounts held in the United States and Ireland in an amount greater than or equal to the Applicable Amount *plus* the amount of the Loan Parties' accounts payable under GAAP not paid after the 90th day following the invoice date for such accounts payable; provided that this Section 7.21(a) shall cease to apply after approval from the FDA of the NDA for CONTEPO with a label generally consistent with the target label included in Borrower's NDA filing.

(b) Performance Covenant.

(i) At all times following the Performance Covenant Trigger I Date up to the date the Borrower pays the Third Amendment Prepayment, Parent shall either (A) as determined as of the last day of

each month achieve trailing six month Net Product Revenue of an amount greater than or equal to 80% of forecasted trailing six month Net Product Revenue as set forth in the Forecast, or (B) maintain Liquidity (on a consolidated basis) in an amount greater than or equal to the principal balance of then-outstanding Advances plus the amount of the Loan Parties' accounts payable under GAAP not paid after the 90th day following the invoice date for such accounts payable; provided that for purposes of this covenant "Liquidity" must include a minimum of $40,000,000 in Unrestricted Cash (i.e. not Eligible Accounts).

(ii) At all times on and after the Performance Covenant Trigger II Date, Parent shall either (A) as determined as of the last day of each month, achieve 70% of forecasted trailing six month Net Product Revenue as set forth in the Forecast, or (B) maintain Unrestricted Cash in the United States and Ireland in an amount greater than or equal to $3,000,000.

Borrower shall provide Agent evidence of compliance with the financial covenants under this Section 7.21 upon request in form and substance reasonably requested by Agent.

(vii) Section 9.3. Section 9.3 is hereby amended and restated as follows:

9.3 Material Adverse Effect. A circumstance has occurred that has had a Material Adverse Effect; provided that solely for purposes of this Section 9.3, the failure to achieve Performance Milestone 1, Performance Milestone 2, Performance Milestone 3, Performance Milestone 4, Performance Milestone 5, Performance Milestone 6 or the occurrence of the Disclosed Matters, in each case, in and of itself, shall not constitute a Material Adverse Effect; or

(viii) Section 9. Section 9 shall be amended by adding new Section 9.9 as follows:

9.9 Third Amendment Prepayment. Failure by Borrower to pay the Third Amendment Prepayment no earlier than April 1, 2020, but no later than April 3, 2020.

(b) **Compliance Certificate.** Exhibit F of the Loan and Security Agreement, the Compliance Certificate, is hereby amended and restated in its entirety as set forth in Annex B attached hereto.

(c) **References Within Loan and Security Agreement**. Each reference in the Loan and Security Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 3 Conditions of Effectiveness. This Amendment shall become effective (the "**Third Amendment Effective Date**") as of the date on which each of the following conditions precedent has been satisfied:

(a) **Fees and Expenses**. The Loan Parties shall have paid (i) all invoiced out-of-pocket costs and expenses of Agent and Lenders including the legal fees and disbursements of counsel to Agent and Lenders (provided that such legal fees and disbursements of outside counsel to the Agent and the Lenders shall not exceed $50,000), in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith.

(b) **This Amendment**. Agent shall have received this Amendment, executed by Agent, the Lenders and the Loan Parties.

(c) **Consents**. Agent shall have received certified copies of consents from each Loan Party's respective board of directors (or applicable governing body) evidencing approval of this Amendment.

(d) **Perfection Certificate**. Agent shall have received a Perfection Certificate of Parent in form and substance satisfactory to Agent.

(e) **Power of Attorney**. Agent shall have received a Power of Attorney for Nabriva Ireland in form and substance satisfactory to Agent.

(f) **Representations and Warranties; No Default**. On the Third Amendment Signing Date, the Third Amendment Effective Date, and after giving effect to the amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 4 of this Amendment shall be true and correct on and as of the Third Amendment Signing Date and Third Amendment Effective Date as though made on and as of each such date; and

(ii) There exist no Events of Default or events that with the passage of time would result in an Event of Default.

SECTION 4 Representations and Warranties. To induce the Lenders to enter into this Amendment, each Loan Party hereby confirms, as of the Third Amendment Signing Date and Third Amendment Effective Date, (a) that the representations and warranties made by it in Section 5 of the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects, except to the extent such representations and warranties expressly relate to an earlier date and except that (i) Sections 5.4 shall be qualified by the Disclosed Matters and (ii) such representations and warranties are deemed updated by the information provided in the Perfection Certificate that was delivered to Agent in connection with this Amendment; (b) that, except for the Disclosed Matters, there has not been and there does not exist a Material Adverse Effect; (c) [reserved]; (d) Lender has and shall continue to have valid, enforceable and perfected first-priority liens, on and security interests in the Collateral and all other collateral heretofore granted by such Loan Party to Lender, pursuant to the Loan Documents or otherwise granted to or held by Lender; (e) the agreements and obligations of such Loan Party contained in the Loan Documents and in this Amendment constitute the legal, valid and binding obligations of such Loan Party, enforceable against such Loan Party in accordance with their respective terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditors' rights or by the application of general principles of equity; and (f) the execution, delivery and performance of this Amendment by such Loan Party will not violate any law, rule, regulation, order, contractual obligation or organizational document of such Loan Party and will not result in, or require, the creation or imposition of any lien, claim or encumbrance of any kind on any of its properties or revenues. For the purposes of this Section 4, each reference in Section 6 of the Loan and Security Agreement to "this Agreement," and the words "hereof," "herein," "hereunder," or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 5 Miscellaneous.

(a) **Forecast.** Agent shall have received updated projections in form and substance satisfactory to Agent in its sole discretion, which projections shall constitute "Forecast" as defined in the Loan and Security Agreement. Such projections were delivered by to and accepted by the Agent on March 10, 2020.

(b) **Third Amendment Prepayment**. Notwithstanding anything to the contrary in the Agreement and the Loan Documents, the Borrower shall prepay a portion of the principal balance of the outstanding Advances equal to Thirty Million Dollars ($30,000,000.00), and all accrued and unpaid interest with respect to such principal balance being prepaid, (the "**Third Amendment Prepayment Amount**") no earlier than April 1, 2020, but no later than April 3, 2020 (the "**Third Amendment Prepayment**").

(c) **IP Security Agreement**. Within 5 Business Days of the Third Amendment Effective Date, Agent shall have received a supplement to the IP Security Agreement, dated as of December 20, 2018, among the Loan Parties and Agent in form and substance satisfactory to Agent.

(d) **Irish Security Deliverables**. Within 5 Business Days of the Third Amendment Effective Date, Agent shall have received the Irish share security deliverables, required pursuant to Clause 6.2 of the Irish law Debenture dated 18 December 2018 in form and substance satisfactory to Agent.

(e) **Loan Documents Otherwise Not Affected; Reaffirmation; No Novation**.

(i) Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. The Lenders' and Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future.

(ii) Each Loan Party hereby expressly (1) reaffirms, ratifies and confirms its Obligations under the Loan and Security Agreement and the other Loan Documents, (2) reaffirms, ratifies and confirms the grant of security under Section 3.1 of the Loan and Security Agreement, (3) reaffirms that such grant of security in the Collateral secures all Obligations under the Loan and Security Agreement, and with effect from (and including) the Third Amendment Signing Date and Third Amendment Effective Date, such grant of security in the Collateral: (x) remains in full force and effect notwithstanding the amendments expressly referenced herein; and (y) secures all Obligations under the Loan and Security Agreement, as amended by this Amendment, and the other Loan Documents, (4) agrees that this Amendment shall be a "Loan Document" under the Loan and Security Agreement and (5) agrees that the Loan and Security Agreement and each other Loan Document shall remain in full force and effect following any action contemplated in connection herewith.

(iii) This Amendment is not a novation and the terms and conditions of this Amendment shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. Nothing in this Amendment is intended, or shall be construed, to constitute an accord and satisfaction of any Loan Party's Secured Obligations under or in connection with the Loan and Security Agreement and any other Loan Document or to modify, affect or impair the perfection or continuity of Agent's security interest in, (on behalf of itself and the Lenders) security titles to or other liens on any Collateral for the Secured Obligations.

(f) **Conditions**. For purposes of determining compliance with the conditions specified in Section 3, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Agent shall have received notice from such Lender prior to the Third Amendment Effective Date specifying its objection thereto.

(g) **Release**. In consideration of the agreements of Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each Loan Party, on behalf of itself and its successors, assigns, and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lenders and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually as a "**Releasee**"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment for or on account of, or in relation to, or in any way in connection with the Loan and Security Agreement, or any of the other Loan Documents or transactions thereunder or related thereto. Borrower understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other

proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above.

(h) **No Reliance**. Borrower hereby acknowledges and confirms to Agent and the Lenders that Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(i) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(j) **Governing Law**. **THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAWS OTHER THAN THE LAWS OF THE STATE OF NEW YORK), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL.**

(k) **Complete Agreement; Amendments**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(l) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(m) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(n) **Loan Documents**. This Amendment and the documents related thereto shall constitute Loan Documents.

[Balance of Page Intentionally Left Blank; Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

Nabriva Therapeutics Public Limited Company

GIVEN under the **COMMON SEAL** of

NABRIVA THERAPEUTICS PUBLIC LIMITED COMPANY

and **DELIVERED** as a **DEED**:

/s/ Gary Sender
Gary Sender
Authorized Signatory

Nabriva Therapeutics Ireland Designated Activity Company

SIGNED AND DELIVERED as a Deed

for and on behalf of

NABRIVA THERAPEUTICS IRELAND DESIGNATED ACTIVITY COMPANY

by its lawfully appointed attorney

GARY SENDER

/s/ Gary Sender
Signature of Attorney

in the presence of:

/s/ Robert Crotty
Signature of Witness

Attorney
Occupation of Witness

1000 Continental Drive, King of Prussia, PA
Address of Witness

GUARANTORS:

NABRIVA THERAPEUTICS GMBH

By: /s/ Mihovil Spoljaric
Name: Mihovil Spoljaric
Title: Managing Director

NABRIVA THERAPEUTICS US, INC.

By: /s/ Gary Sender
Name: Gary Sender
Title: Treasurer

ZAVANTE THERAPEUTICS, INC.

By: /s/ Gary Sender
Name: Gary Sender
Title: Treasurer

AGENT:

HERCULES CAPITAL, INC.,
as Agent

By: /s/ Jennifer Choe
Name: Jennifer Choe
Title: Associate General Counsel

LENDER:

HERCULES CAPITAL, INC.,
as Lender

By: /s/ Jennifer Choe
Name: Jennifer Choe
Title: Associate General Counsel

NABRIVA THERAPEUTICS plc

2020 SHARE INCENTIVE PLAN

1. Purpose

The purpose of this 2020 Share Incentive Plan (the "***Plan***") of Nabriva Therapeutics plc, a public limited company organized under the laws of the Republic of Ireland (the "***Company***"), is to advance the interests of the Company's shareholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to the Company and by providing such persons with equity ownership opportunities and performance-based incentives that are intended to better align the interests of such persons with those of the Company's shareholders. Except where the context otherwise requires, the term "***Company***" shall include any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the United States Internal Revenue Code of 1986, as amended, and any regulations thereunder (the "***Code***") and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a controlling interest, as determined by the Board of Directors of the Company (the "***Board***").

2. Eligibility

All of the Company's employees, as well as any non-employee service providers solely to the extent approved by the Board and set forth in a sub-plan established pursuant to Section 12(e) hereof, are eligible to be granted Awards (as defined below) under the Plan. Each person who is granted an Award under the Plan, including any sub-plan of the Plan, is deemed a "***Participant***." The Plan provides for the following types of awards, each of which is referred to as an "***Award***": Options (as defined in Section 5), SARs (as defined in Section 6), Restricted Shares (as defined in Section 7), RSUs (as defined in Section 7) and Other Share-Based and Other Cash-Based Awards (as defined in Section 8). Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.

3. Administration and Delegation

(a) Administration by Board of Directors. The Plan will be administered by the Board. The Board shall have authority to grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may construe and interpret the terms of the Plan and any Award agreements entered into under the Plan. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award. All actions and decisions by the Board with respect to the Plan and any Awards shall be made in the Board's discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Award.

(b) Appointment of Committees. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a "***Committee***"). All references in the Plan to the "***Board***" shall mean the Board or a Committee of the Board or the officers referred to in Section 3(c) to the extent that the Board's powers or authority under the Plan have been delegated to such Committee or officers.

(c) Delegation to Officers. Subject to any requirements of applicable law, the Board may delegate to one or more officers of the Company the power to grant Awards (subject to any limitations under the Plan) to employees or officers of the Company and to exercise such other powers under the Plan as the Board may determine, provided that the Board shall fix the terms of Awards to be granted by such officers, the maximum number of shares subject to Awards that the officers may grant, and the time period in which such Awards may be granted; and provided further, that no officer shall be authorized to grant Awards to any "executive officer" of the Company (as defined by Rule 3b-7 under the Securities Exchange Act of 1934, as amended (the "***Exchange Act***")) or to any "officer" of the Company (as defined by Rule 16a-1(f) under the Exchange Act).

4. Shares Available for Awards

(a) Number of Shares; Share Counting.

(1) Authorized Number of Shares. Subject to adjustment under Section 10, Awards may be made under the Plan (any or all of which Awards may be in the form of Incentive Share Options (as defined in Section 5(b)) for up to 1,837,500 ordinary shares of the Company (the "Ordinary Shares"). Ordinary Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares.

(2) Share Counting. For purposes of counting the number of shares available for the grant of Awards under the Plan under this Section 4(a):

(A) all Ordinary Shares covered by SARs shall be counted against the number of shares available for the grant of Awards under the Plan; *provided, however*, that (i) SARs that may be settled only in cash shall not be so counted and (ii) if the Company grants a SAR in tandem with an Option for the same number of Ordinary Shares and provides that only one such Award may be exercised (a "***Tandem SAR***"), only the shares covered by the Option, and not the shares covered by the Tandem SAR, shall be so counted, and the expiration of one in connection with the other's exercise will not restore shares to the Plan;

(B) if any Award (i) expires or is terminated, surrendered or cancelled without having been fully exercised or is forfeited in whole or in part (including as the result of Ordinary Shares subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or (ii) results in any Ordinary Shares not being issued (including as a result of a SAR that was settleable either in cash or in shares actually being settled in cash), the unused Ordinary Shares covered by such Award shall again be available for the grant of Awards; *provided, however*, that (1) in the case of Incentive Share Options, the foregoing shall be subject to any limitations under the Code, (2) in the case of the exercise of a SAR, the number of shares counted against the shares available under the Plan shall be the full number of shares subject to the SAR multiplied by the percentage of the SAR actually exercised, regardless of the number of shares actually used to settle such SAR upon exercise and (3) the shares covered by a Tandem SAR shall not again become available for grant upon the expiration or termination of such Tandem SAR;

(C) Ordinary Shares delivered (either by actual delivery, attestation, or net exercise) to the Company by a Participant to (i) purchase Ordinary Shares upon the exercise of an Award or (ii) satisfy tax withholding obligations with respect to Awards (including shares retained from the Award creating the tax obligation) shall not be added back to the number of shares available for the future grant of Awards; and

(D) Ordinary Shares repurchased by the Company on the open market using the proceeds from the exercise of an Award shall not increase the number of shares available for future grant of Awards.

(b) Substitute Awards. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or shares of an entity, the Board may grant Awards in substitution for any options or other shares or share-based awards granted by such entity or an affiliate thereof. Substitute Awards may be granted on such terms as the Board deems appropriate in the circumstances, notwithstanding any limitations

on Awards contained in the Plan. Substitute Awards shall not count against the overall share limit set forth in Section 4(a)(1), except as may be required by reason of Section 422 and related provisions of the Code.

5. Share Options

(a) General. The Board may grant options to purchase Ordinary Shares (each, an "***Option***") and determine the number of Ordinary Shares to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to applicable federal or state securities laws, as the Board considers necessary or advisable.

(b) Incentive Share Options. An Option that the Board intends to be an "incentive share option" as defined in Section 422 of the Code (an "***Incentive Share Option***") shall only be granted to employees of Nabriva Therapeutics plc, any of Nabriva Therapeutics plc's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Code, and any other entities the employees of which are eligible to receive Incentive Share Options under the Code, and shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code. An Option that is not intended to be an Incentive Share Option shall be designated a "***Nonstatutory Share Option***." The Company shall have no liability to a Participant, or any other person, if an Option (or any part thereof) that is intended to be an Incentive Share Option is not an Incentive Share Option or if the Company converts an Incentive Share Option to a Nonstatutory Share Option.

(c) Exercise Price. The Board shall establish the exercise price of each Option or the formula by which such exercise price will be determined provided that in all cases it will not be less than the nominal value of an Ordinary Share. The exercise price shall be specified in the applicable Option agreement which may be electronic. The exercise price shall be not less than 100% of the Grant Date Fair Market Value (as defined below) of the Ordinary Shares on the date the Option is granted; *provided* that if the Board approves the grant of an Option with an exercise price to be determined on a future date, the exercise price shall be not less than 100% of the Grant Date Fair Market Value on such future date. "***Grant Date Fair Market Value***" of an Ordinary Share for purposes of the Plan will be determined as follows:

(1) if the Ordinary Shares trade on a national securities exchange, the closing sale price (for the primary trading session) on the date of grant; or

(2) if the Ordinary Shares do not trade on any such exchange, the average of the closing bid and asked prices on the date of grant as reported by an over-the-counter marketplace designated by the Board; or

(3) if the Ordinary Shares are not publicly traded, the Board will determine the Grant Date Fair Market Value for purposes of the Plan using any measure of value it determines to be appropriate (including, as it considers appropriate, relying on appraisals) in a manner consistent with the valuation principles under Code Section 409A, except as the Board may expressly determine otherwise.

For any date that is not a trading day, the Grant Date Fair Market Value of an Ordinary Share for such date will be determined by using the closing sale price or average of the bid and asked prices, as appropriate, for the immediately preceding trading day and with the timing in the formulas above adjusted accordingly. The Board can substitute a particular time of day or other measure of "closing sale price" or "bid and asked prices" if appropriate because of exchange or market procedures or can, in its sole discretion, use weighted averages either on a daily basis or such longer period as complies with Code Section 409A.

The Board has sole discretion to determine the Grant Date Fair Market Value for purposes of the Plan, and all Awards are conditioned on the participants' agreement that the Administrator's determination is conclusive and binding even though others might make a different determination.

(d) Duration of Options. Each Option shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable Option agreement; *provided, however*, that no Option will be granted with a term in excess of 10 years.

(e) Exercise of Options. Options may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic) approved by the Company, together with payment in full (in the manner specified in Section 5(f)) of the exercise price for the number of shares for which the Option is exercised. Ordinary Shares subject to the Option will be delivered by the Company as soon as practicable following exercise.

(f) Payment Upon Exercise. Ordinary Shares purchased upon the exercise of an Option granted under the Plan shall be paid for as follows:

(1) in cash or by check, payable to the order of the Company;

(2) except as may otherwise be provided in the applicable Option agreement or approved by the Board, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;

(3) to the extent provided for in the applicable Option agreement or approved by the Board, and subject to compliance with applicable law, by delivery (either by actual delivery or attestation) of Ordinary Shares owned by the Participant valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Board), provided (i) such method of payment is then permitted under applicable law, (ii) such Ordinary Shares, if acquired directly from the Company, were owned by the Participant for such minimum period of time, if any, as may be established by the Board and (iii) such Ordinary Shares are not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;

(4) to the extent provided for in the applicable Nonstatutory Share Option agreement or approved by the Board, and subject to compliance with applicable law, by delivery of a notice of "net exercise" to the Company, as a result of which the Participant would receive (i) the number of shares underlying the portion of the Option being exercised, less (ii) such number of shares as is equal to (A) the aggregate exercise price for the portion of the Option being exercised divided by (B) the fair market value of an Ordinary Share (valued in the manner determined by (or in a manner approved by) the Board) on the date of exercise;

(5) to the extent permitted by applicable law and provided for in the applicable Option agreement or approved by the Board, by payment of such other lawful consideration as the Board may determine; or

(6) by any combination of the above permitted forms of payment.

(g) Limitation on Repricing. Unless such action is approved by the Company's shareholders, the Company may not (except as provided for under Section 10): (1) amend any outstanding Option granted under the Plan to provide an exercise price per share that is lower than the then-current exercise price per share of such outstanding Option, (2) cancel any outstanding option (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan (other than Awards granted pursuant to Section 4(c)) covering the same or a different number of Ordinary Shares and having an exercise price per share lower than the then-current exercise price per share of the cancelled option, (3) cancel in exchange for a cash payment any outstanding Option with an exercise price per share above the then-current fair market value of an Ordinary Share (valued in the manner determined by (or in a manner approved by) the Board), or (4) take any other action under the Plan that constitutes a "repricing" within the meaning of the rules of the Nasdaq Stock Market ("***NASDAQ***").

(h) No Reload Options. No Option granted under the Plan shall contain any provision entitling the Participant to the automatic grant of additional Options in connection with any exercise of the original Option.

(i) No Dividend Equivalents. No Option shall provide for the payment or accrual of dividend equivalents.

6. Share Appreciation Rights

(a) General. The Board may grant Awards consisting of share appreciation rights ("***SARs***") entitling the holder, upon exercise, to receive a number of Ordinary Shares or cash or a combination thereof (such form to be determined by the Board) determined by reference to appreciation, from and after the date of grant, in the fair market value of an Ordinary Share (valued in the manner determined by (or in a manner approved by) the Board) over the measurement price established pursuant to Section 6(b). The date as of which such appreciation is determined shall be the exercise date. The SAR agreement may be in written or electronic form.

(b) Measurement Price. The Board shall establish the measurement price of each SAR and specify it in the applicable SAR agreement. The measurement price shall not be less than 100% of the Grant Date Fair Market Value of an Ordinary Share on the date the SAR is granted; *provided* that if the Board approves the grant of a SAR effective as of a future date, the measurement price shall be not less than 100% of the Grant Date Fair Market Value on such future date.

(c) Duration of SARs. Each SAR shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable SAR agreement; *provided*, *however*, that no SAR will be granted with a term in excess of 10 years.

(d) Exercise of SARs. SARs may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic) approved by the Company, together with any other documents required by the Board.

(e) Limitation on Repricing. Unless such action is approved by the Company's shareholders, the Company may not (except as provided for under Section 10): (1) amend any outstanding SAR granted under the Plan to provide a measurement price per share that is lower than the then-current measurement price per share of such outstanding SAR, (2) cancel any outstanding SAR (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan (other than Awards granted pursuant to Section 4(c)) covering the same or a different number of Ordinary Shares and having a measurement price per share lower than the then-current measurement price per share of the cancelled SAR, (3) cancel in exchange for a cash payment any outstanding SAR with a measurement price per share above the then-current fair market value of the Ordinary Shares (valued in the manner determined by (or in a manner approved by) the Board), or (4) take any other action under the Plan that constitutes a "repricing" within the meaning of the rules of the NASDAQ.

(f) No Reload SARs. No SAR granted under the Plan shall contain any provision entitling the Participant to the automatic grant of additional SARs in connection with any exercise of the original SAR.

(g) No Dividend Equivalents. No SAR shall provide for the payment or accrual of dividend equivalents.

7. Restricted Shares; RSUs

(a) General. The Board may grant Awards entitling recipients to acquire Ordinary Shares ("***Restricted Shares***"), subject to the right of the Company to repurchase (in accordance with applicable law and the award agreement) all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) from the recipient in the event that conditions specified by the Board in the applicable Award are not satisfied prior to the end of the applicable restriction period or periods established by the Board for such Award. The Board may also grant Awards entitling the recipient to receive Ordinary Shares or cash to be delivered at the time such Award vests ("***RSUs***").

(b) Terms and Conditions for Restricted Shares and RSUs. The Board shall determine the terms and conditions of Restricted Shares and RSUs, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any. The award agreement with respect to Restricted Shares or RSUs, as applicable, may be in written or electronic form.

(c) Additional Provisions Relating to Restricted Shares.

(1) Dividends. Unless otherwise provided in the applicable Award agreement, any dividends (whether paid in cash, shares or property) declared and paid by the Company with respect to Restricted Shares ("***Unvested Dividends***") shall be paid to the Participant only if and when such shares become free from the restrictions on transferability and forfeitability that apply to such shares. Each payment of Unvested Dividends will be made no later than the end of the calendar year in which the dividends are paid to shareholders of that class of shares or, if later, the 15th day of the third month following the lapsing of the restrictions on transferability and the forfeitability provisions applicable to the underlying Restricted Shares. No interest will be paid on Unvested Dividends.

(2) Share Certificates. The Company may require that any share certificates issued in respect of Restricted Shares, as well as dividends or distributions paid on such Restricted Shares, shall be deposited in escrow by the Participant, together with a share power endorsed in blank, with the Company (or its designee). At the expiration of the applicable restriction periods, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to his or her Designated Beneficiary. "***Designated Beneficiary***" means (i) the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death or (ii) in the absence of an effective designation by a Participant, the Participant's estate.

(d) Additional Provisions Relating to RSUs.

(1) Settlement. Upon the vesting of and/or lapsing of any other restrictions (i.e., settlement) with respect to each RSU, the Participant shall be entitled to receive from the Company the number of Ordinary Shares specified in the Award agreement or (if so provided in the applicable Award agreement or otherwise determined by the Board) an amount of cash equal to the fair market value (valued in the manner determined by (or in a manner approved by) the Board) of such number of shares or a combination thereof. The Board may provide that settlement of RSUs shall be deferred, on a mandatory basis or at the election of the Participant, in a manner that complies with Section 409A of the Code or any successor provision thereto, and the regulations thereunder ("***Section 409A***").

(2) Voting Rights. A Participant shall have no voting rights with respect to any RSUs.

(3) Dividend Equivalents. The Award agreement for RSUs may provide Participants with the right to receive an amount equal to any dividends or other distributions declared and paid on an equal number of outstanding Ordinary Shares ("***Dividend Equivalents***"). Dividend Equivalents may be paid currently or credited to an account for the Participant, may be settled in cash and/or Ordinary Shares and shall be subject to the same restrictions on transfer and forfeitability as the RSUs with respect to which paid, in each case to the extent provided in the Award agreement. No interest will be paid on Dividend Equivalents.

8. Other Share-Based and Other Cash-Based Awards

(a) General. The Board may grant other Awards of Ordinary Shares, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, Ordinary Shares or other property ("***Other Share-Based Awards***"). Such Other Share-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Share-Based Awards may be paid in Ordinary Shares or cash, as the Board shall determine. The Board may also grant Awards under the Plan that are denominated in, or settled in, cash rather than in Ordinary Shares ("***Other Cash-Based Awards***")

(b) Terms and Conditions. Subject to the provisions of the Plan, the Board shall determine the terms and conditions of each Other Share-Based Award or other Cash-Based Award, including any purchase price applicable thereto.

(c) Dividend Equivalents. The Award agreement for an Other Share-Based Award or an Other Cash-Based Award may provide Participants with the right to receive Dividend Equivalents. Dividend Equivalents may

be paid currently or credited to an account for the Participant, may be settled in cash and/or Ordinary Shares and shall be subject to the same restrictions on transfer and forfeitability as the Other Share-Based Award or Other Cash-Based Award with respect to which paid, in each case to the extent provided in the Award agreement. No interest will be paid on Dividend Equivalents.

9. Performance Awards.

(a) Grants. Awards under the Plan may be made subject to the achievement of performance goals pursuant to this Section 9 ("***Performance Awards***").

(b) Performance Measures. The Board may specify that the degree of granting, vesting and/or payout of an Award shall be subject to the achievement of one or more objective performance measures, which shall be based on the relative or absolute attainment of specified levels of one or any combination of the following, which may be determined pursuant to generally accepted accounting principles ("***GAAP***") or on a non-GAAP basis, as determined by the Board: net income, earnings before or after discontinued operations, interest, taxes, depreciation and/or amortization, operating profit before or after discontinued operations and/or taxes, sales, sales growth, earnings growth, cash flow or cash position, gross margins, share price, market share, return on sales, assets, equity or investment, improvement of financial ratings, achievement of balance sheet or income statement objectives, total shareholder return or any other performance measure selected by the Board. Such goals may reflect absolute entity or business unit performance or a relative comparison to the performance of a peer group of entities or other external measure of the selected performance criteria and may be absolute in their terms or measured against or in relationship to other companies comparably, similarly or otherwise situated. The Board may specify that such performance measures shall be adjusted to exclude any one or more of (i) non-recurring or unusual gains or losses, (ii) gains or losses on the dispositions of discontinued operations, (iii) the cumulative effects of changes in accounting principles, (iv) the writedown of any asset, (v) fluctuation in foreign currency exchange rates, (vi) charges for restructuring and rationalization programs or (vii) any other adjustment determined by the Board. Such performance measures: (x) may vary by Participant and may be different for different Awards; (y) may be particular to a Participant or the department, branch, line of business, subsidiary or other unit in which the Participant works and may cover such period as may be specified by the Board; and (z) shall be set by the Board at such time as it determines in its discretion.

(c) Adjustments. Notwithstanding any provision of the Plan, the Board may adjust, upwards or downwards, the number of shares or cash payable pursuant to such Award, and the Board may waive the achievement of the applicable performance measures in any circumstance, including in the case of the death or disability of the Participant or a change in control of the Company.

(d) Other. The Board shall have the power to impose such other restrictions on Performance Awards as it may deem necessary or appropriate.

10. Adjustments for Changes in Ordinary Shares and Certain Other Events

(a) Changes in Capitalization. In the event of any alteration or reorganization whatsoever taking place in the capital structure of the Company whether by way of share split, reverse share split, share dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of Ordinary Shares other than an ordinary cash dividend, (i) the number and class of securities available under the Plan, (ii) the share counting rules set forth in Section 4(a), (iii) the number and class of securities and exercise price per share of each outstanding Option, (iv) the share and per-share provisions and the measurement price of each outstanding SAR, (v) the number of shares subject to and the repurchase price per share subject to each outstanding award of Restricted Shares and (vi) the share and per-share-related provisions and the purchase price, if any, of each outstanding RSU and each Other Share-Based Award, shall be equitably adjusted by the Company (or substituted Awards may be made, if applicable) in the manner determined by the Board. Without limiting the generality of the foregoing, in the event the Company effects a split of the Ordinary Shares by means of a share dividend and the exercise price of and the number of shares subject to an outstanding Option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then an optionee who exercises an Option between the record date and the distribution date for such share dividend shall be entitled to receive, on the distribution date, the share dividend with respect to the Ordinary

Shares acquired upon such Option exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such share dividend.

(b) Reorganization Events.

(1) Definition. A "***Reorganization Event***" shall mean: (a) any merger or consolidation of the Company with or into another entity as a result of which all of the Ordinary Shares of the Company are converted into or exchanged for the right to receive cash, securities or other property or is canceled, (b) any transfer or disposition of all of the Ordinary Shares of the Company for cash, securities or other property pursuant to a share exchange or other transaction or (c) any liquidation or dissolution of the Company. For the avoidance of doubt, any one or more of the above events may be effected pursuant to (A) a compromise or arrangement sanctioned by the court under Chapter 1 of Part 9 of the Companies Act 2014 of the Republic of Ireland or (B) otherwise under Part 9 of the Companies Act 2014 of the Republic of Ireland or (C) otherwise under the Companies Act 2014 of the Republic of Ireland.

(2) Consequences of a Reorganization Event on Awards Other than Restricted Shares.

(A) In connection with a Reorganization Event, the Board may take any one or more of the following actions as to all or any (or any portion of) outstanding Awards other than Restricted Shares on such terms as the Board determines (except to the extent specifically provided otherwise in an applicable Award agreement or another agreement between the Company and the Participant): (i) provide that such Awards shall be assumed, or substantially equivalent Awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to a Participant, provide that all of the Participant's unvested Awards will be forfeited immediately prior to the consummation of such Reorganization Event and/ or that all of the Participant's unexercised Awards will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the Participant (to the extent then exercisable) within a specified period following the date of such notice, (iii) provide that outstanding Awards shall become exercisable, realizable or deliverable, or restrictions applicable to an Award shall lapse, in whole or in part prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event under the terms of which holders of Ordinary Shares will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the "***Acquisition Price***"), make or provide for a cash payment to Participants with respect to each Award held by a Participant equal to (A) the number of Ordinary Shares subject to the vested portion of the Award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such Reorganization Event) multiplied by (B) the excess, if any, of (I) the Acquisition Price over (II) the exercise, measurement or purchase price of such Award and any applicable tax withholdings, in exchange for the termination of such Award, (v) provide that, in connection with a liquidation or dissolution of the Company, Awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings) and (vi) any combination of the foregoing. In taking any of the actions permitted under this Section 10(b)(2)(A), the Board shall not be obligated by the Plan to treat all Awards, all Awards held by a Participant, or all Awards of the same type, identically.

(B) Notwithstanding the terms of Section 10(b)(2)(A)(i), in the case of outstanding RSUs that are subject to Section 409A: (i) if the applicable RSU agreement provides that the RSUs shall be settled upon a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i), and the Reorganization Event constitutes such a "change in control event", then no assumption or substitution shall be permitted pursuant to Section 10(b)(2)(A)(i) and the RSUs shall instead be settled in accordance with the terms of the applicable RSU agreement; and (ii) the Board may only undertake the actions set forth in clauses (iii), (iv) or (v) of Section 10(b)(2)(A) if the Reorganization Event constitutes a "change in control event" as defined under Treasury Regulation Section 1.409A-3(i)(5)(i) and such action is permitted or required by Section 409A; if the Reorganization Event is not a "change in control event" as so defined or such action is not permitted or required by Section 409A, and the acquiring or succeeding corporation does not assume or substitute the RSUs pursuant to clause (i) of Section 10(b)(2)(A), then the unvested RSUs shall terminate immediately prior to the consummation of the Reorganization Event without any payment in exchange therefor.

(C) For purposes of Section 10(b)(2)(A)(i), an Award (other than Restricted Shares) shall be considered assumed if, following consummation of the Reorganization Event, such Award confers the right

to purchase or receive pursuant to the terms of such Award, for each Ordinary Share subject to the Award immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Ordinary Shares for each Ordinary Share held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding Ordinary Shares); *provided*, *however*, that if the consideration received as a result of the Reorganization Event is not solely ordinary shares of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise or settlement of the Award to consist solely of such number of ordinary shares of the acquiring or succeeding corporation (or an affiliate thereof) that the Board determined to be equivalent in value (as of the date of such determination or another date specified by the Board) to the per share consideration received by holders of outstanding Ordinary Shares as a result of the Reorganization Event.

(3) Consequences of a Reorganization Event on Restricted Shares. Upon the occurrence of a Reorganization Event other than a liquidation or dissolution of the Company, the repurchase and other rights of the Company with respect to outstanding Restricted Shares shall inure to the benefit of the Company's successor and shall, unless the Board determines otherwise, apply to the cash, securities or other property which the Ordinary Shares were converted into or exchanged for pursuant to such Reorganization Event in the same manner and to the same extent as they applied to such Restricted Shares; *provided*, *however*, that the Board may either provide for termination or deemed satisfaction of such repurchase or other rights under the instrument evidencing any Restricted Shares or any other agreement between a Participant and the Company, either initially or by amendment, or provide for forfeiture of such Restricted Shares if issued at no cost. Upon the occurrence of a Reorganization Event involving the liquidation or dissolution of the Company, except to the extent specifically provided to the contrary in the instrument evidencing any Restricted Shares or any other agreement between a Participant and the Company, all restrictions and conditions on all Restricted Shares then outstanding shall automatically be deemed terminated or satisfied.

11. General Provisions Applicable to Awards

(a) Transferability of Awards. Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by a Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution or, other than in the case of an Incentive Share Option, pursuant to a qualified domestic relations order, and, during the life of the Participant, shall be exercisable only by the Participant; *provided*, *however*, that, except with respect to Awards subject to Section 409A, the Board may permit or provide in an Award for the gratuitous transfer of the Award by the Participant to or for the benefit of any immediate family member, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if the Company would be eligible to use a Form S-8 under the Securities Act of 1933, as amended for the registration of the sale of the Ordinary Shares subject to such Award to such proposed transferee; *provided further*, that the Company shall not be required to recognize any such permitted transfer until such time as such permitted transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of the Award. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees. For the avoidance of doubt, nothing contained in this Section 11(a) shall be deemed to restrict a transfer to the Company.

(b) Documentation. Each Award shall be evidenced in such form (written, electronic or otherwise) as the Board shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) Termination of Service. The Board shall determine the effect on an Award of the disability, death, termination or other cessation of employment, authorized leave of absence or other change in the employment of a Participant and the extent to which, and the period during which, the Participant, or the Participant's legal representative, conservator, guardian or Designated Beneficiary, may exercise rights, or receive any benefits, under an Award.

(d) Withholding. The Participant must satisfy all applicable federal, state, and local or other income and employment tax withholding obligations before the Company will deliver share certificates or otherwise recognize ownership of Ordinary Shares under an Award. The Company may elect to satisfy the withholding

obligations through additional withholding on salary or wages. If the Company elects not to or cannot withhold from other compensation, the Participant must pay the Company the full amount, if any, required for withholding or have a broker tender to the Company cash equal to the withholding obligations. Payment of withholding obligations is due before the Company will issue any shares on exercise, vesting or release from forfeiture of an Award or at the same time as payment of the exercise or purchase price, unless the Company determines otherwise. If provided for in an Award or approved by the Committee, a Participant may satisfy the tax obligations in whole or in part by delivery (either by actual delivery or attestation) of Ordinary Shares, including shares retained from the Award creating the tax obligation, valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Company); *provided, however*, except as otherwise provided by the Committee, that the total tax withholding where shares are being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal and state tax purposes, including payroll taxes, that are applicable to such supplemental taxable income), except that, to the extent that the Company is able to retain Ordinary Shares having a fair market value (determined by, or in a manner approved by, the Company) that exceeds the statutory minimum applicable withholding tax without financial accounting implications or the Company is withholding in a jurisdiction that does not have a statutory minimum withholding tax, the Company may retain such number of Ordinary Shares (up to the number of shares having a fair market value equal to the maximum individual statutory rate of tax (determined by, or in a manner approved by, the Company)) as the Company shall determine in its sole discretion to satisfy the tax liability associated with any Award. Shares used to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements.

(e) Amendment of Award. Except as otherwise provided in Section 5(g) or 6(e), the Board may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or realization, and converting an Incentive Share Option to a Nonstatutory Share Option. The Participant's consent to such action shall be required unless (i) the Board determines that the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Plan or (ii) the change is permitted under Section 10.

(f) Conditions on Delivery of Shares. Notwithstanding any other provision of this Plan, (a) the Company shall not be obliged to issue any Ordinary Shares pursuant to an Award unless at least the par value of such newly issued Ordinary Share has been fully paid in advance in accordance with all applicable law (which requirement may mean the holder of an Award is obliged to make such payment) and (b) the Company will not be obligated to deliver any Ordinary Shares pursuant to the Plan or to remove restrictions from shares previously issued or delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and regulations and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(g) Acceleration. The Board may at any time provide that any Award shall become immediately exercisable in whole or in part, free from some or all restrictions or conditions or otherwise realizable in whole or in part, as the case may be.

12. Miscellaneous

(a) No Right To Employment. No person shall have any claim or right to be granted an Award by virtue of the adoption of the Plan, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.

(b) No Rights As Shareholder; Clawback. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a shareholder with respect to any Ordinary Shares to be issued with respect to an Award until becoming the record holder of such shares. In accepting an Award under

the Plan, the Participant agrees to be bound by any clawback policy that the Company has in effect or may adopt in the future.

(c) Effective Date and Term of Plan. The Plan shall become effective on the date the Plan is approved by the Company's shareholders (the "***Effective Date***"); provided, however, that to the extent the shareholders do not approve the Plan, any Awards granted hereunder that are settlable in cash shall remain outstanding and may in the future be granted, with the Plan remaining effective to the extent necessary to govern the administration of such Awards; provided, further, for the avoidance of doubt that if shareholder approval is not obtained within 12 months from the date that the Board adopts the Plan, no Incentive Stock Options may be granted under the Plan. No Awards shall be granted under the Plan after the expiration of 10 years from the Effective Date, but Awards previously granted may extend beyond that date.

(d) Amendment of Plan. The Board may amend, suspend or terminate the Plan or any portion thereof at any time provided that (i) no amendment that would require shareholder approval under the rules of the national securities exchange on which the Company then maintains its primary listing may be made effective unless and until the Company's shareholders approve such amendment; and (ii) if the national securities exchange on which the Company then maintains its primary listing does not have rules regarding when shareholder approval of amendments to equity compensation plans is required (or if the Company's Ordinary Shares are not then listed on any national securities exchange), then no amendment to the Plan (A) materially increasing the number of shares authorized under the Plan (other than pursuant to Section 4(c) or 10), (B) expanding the types of Awards that may be granted under the Plan, or (C) materially expanding the class of participants eligible to participate in the Plan shall be effective unless and until the Company's shareholders approve such amendment. In addition, if at any time the approval of the Company's shareholders is required as to any other modification or amendment under Section 422 of the Code or any successor provision with respect to Incentive Share Options, the Board may not effect such modification or amendment without such approval. Unless otherwise specified in the amendment, any amendment to the Plan adopted in accordance with this Section 12(d) shall apply to, and be binding on the holders of, all Awards outstanding under the Plan at the time the amendment is adopted, provided the Board determines that such amendment, taking into account any related action, does not materially and adversely affect the rights of Participants under the Plan.

(e) Authorization of Sub-Plans. The Board may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable securities, tax or other laws of various jurisdictions. The Board shall establish such sub-plans by adopting supplements to the Plan containing (i) such limitations on the Board's discretion under the Plan as the Board deems necessary or desirable or (ii) such additional terms and conditions not otherwise inconsistent with the Plan as the Board shall deem necessary or desirable. All supplements adopted by the Board shall be deemed to be part of the Plan, but each supplement shall apply only to Participants within the affected jurisdiction and the Company shall not be required to provide copies of any supplement to Participants in any jurisdiction which is not the subject of such supplement.

(f) Compliance with Section 409A of the Code. If and to the extent (i) any portion of any payment, compensation or other benefit provided to a Participant pursuant to the Plan in connection with his or her employment termination constitutes "nonqualified deferred compensation" within the meaning of Section 409A and (ii) the Participant is a specified employee as defined in Section 409A(a)(2)(B)(i) of the Code, in each case as determined by the Company in accordance with its procedures, by which determinations the Participant (through accepting the Award) agrees that he or she is bound, such portion of the payment, compensation or other benefit shall not be paid before the day that is six months plus one day after the date of "separation from service" (as determined under Section 409A) (the "***New Payment Date***"), except as Section 409A may then permit. The aggregate of any payments that otherwise would have been paid to the Participant during the period between the date of separation from service and the New Payment Date shall be paid to the Participant in a lump sum on such New Payment Date, and any remaining payments will be paid on their original schedule.

The Company makes no representations or warranty and shall have no liability to the Participant or any other person if any provisions of or payments, compensation or other benefits under the Plan are determined to constitute nonqualified deferred compensation subject to Section 409A but do not to satisfy the conditions of that section.

(g) Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, employee or agent of the Company will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan, nor will such individual be personally liable with respect to the Plan because of any contract or other instrument he or she executes in his or her capacity as a director, officer, employee or agent of the Company. The Company will, subject to applicable law, and the terms of the Company's constitutional documents, indemnify and hold harmless each director, officer, employee or agent of the Company to whom any duty or power relating to the administration or interpretation of the Plan has been or will be delegated, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Board's approval) arising out of any act or omission to act concerning the Plan unless arising out of such person's own fraud or bad faith.

(h) Governing Law. The provisions of the Plan and all Awards made hereunder shall be governed by, except to the extent preempted by other applicable laws (1) with respect to the corporate law requirements applicable to the Company, the validity and authorization of the issuance of Shares under the Plan and similar matters, the laws of Ireland (without reference to conflict of law principles thereof) and (2) with respect to all other matters relating to the Plan and Awards, the laws of the State of Delaware, excluding choice-of-law principles of the law of that state.

NABRIVA THERAPEUTICS plc 2020 SHARE INCENTIVE PLAN

SUB-PLAN GOVERNING AWARDS TO NON-EMPLOYEES

1 GENERAL

1.1 In accordance with Rule 12(e) of the 2020 Share Incentive Plan ("the Plan") the Board has determined to establish this sub-plan ("the Non-Employee Sub-Plan") for the purposes of Awards to individuals who are not employees of the Company, including directors, consultants and advisors of the Company.

1.2 All terms that are not otherwise defined herein shall have the same meaning as set forth in the Plan and all provisions of the Plan shall apply to this Non-Employee Sub-Plan except as outlined below.

2 PURPOSE

2.1 The purpose of the Non-Employee Sub-Plan is to advance the Company's growth and success and to advance its interests by attracting and retaining well-qualified non-employee directors, consultants and advisors and by providing such individuals with incentives to put forth maximum efforts for the long-term success of the Company's business.

3 TERMS OF NON-EMPLOYEE SUB-PLAN

3.1 Eligibility

All of the Company's directors, as well as consultants and advisors to the Company (as the terms consultants and advisors are defined and interpreted for purposes of Form S-8 under the Securities Act 1933, as amended, or any successor form) are eligible to be granted Awards (as defined below) under the Non-Employee Sub-Plan.

3.2 Administration

Awards to non-employee directors will be granted and administered by a Committee, all of the members of which are independent directors as defined by 5605(a)(2) of the NASDAQ Marketplace Rules.

3.3 Limits

The maximum value (calculated based on grant date fair value for financial reporting purposes) of Ordinary Shares subject to Awards granted in any fiscal year to any individual non-employee director shall not exceed $500,000 in the case of an incumbent director or $1,000,000 in the case of a new director during his or her first year of service. The maximum amount of cash compensation paid in any fiscal year to any individual non-employee director shall not exceed $175,000 in the case of an incumbent director or $225,000 in the case of the Chairman of the Board. The Committee may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the Committee may determine in its discretion, provided that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation.

3.4 Payment upon Exercise

The provisions of clause 5(f) of the Plan shall apply to this Non-Employee Sub-Plan except that the Company will not provide for or permit the "net exercise" arrangement referred to in clause 5(f)(4) of the Plan.

3.5 Termination of Status

The Board shall determine the effect on an Award of the disability, death, termination or other cessation of office or services or other change in the status of a Participant and the extent to which, and the period during which, the Participant, or the Participant's legal representative, conservator, guardian or Designated Beneficiary, may exercise rights, or receive any benefits, under an Award.

3.6 No Right To Status.

No person shall have any claim or right to be granted an Award by virtue of the adoption of the Non-Employee Sub-Plan, and the grant of an Award shall not be construed as giving a Participant the right to a continued relationship with the Company. The Company expressly reserves the right at any time to terminate its relationship with a Participant free from any liability or claim under the Non-Employee Sub-Plan, except as expressly provided in the applicable Award.

NABRIVA THERAPEUTICS PLC

SHARE OPTION / CASH-SETTLED SHARE APPRECIATION RIGHT AGREEMENT
GRANTED UNDER 2020 SHARE INCENTIVE PLAN

This Share Option /Cash-Settled Share Appreciation Right Agreement (this "**Agreement**") is made between Nabriva Therapeutics plc, a public limited company organized under the laws of Ireland (the "**Company**"), and the Participant pursuant to the 2020 Share Incentive Plan (the "**Plan**").

NOTICE OF GRANT

I. Participant Information

Participant:
Participant Address:

II. Grant Information

Grant Date: 2/6/2020
Number of Shares:
Exercise /Measurement Price Per Share:
Vesting Commencement Date: 2/6/2020
Type of Option:
Nonstatutory

III. Vesting Table

Vesting Date	Shares that Vest
First anniversary of the Vesting Commencement Date	25%
End of each successive one-month period following the first anniversary of the Vesting Commencement Date until the fourth anniversary of the Vesting Commencement Date	2.0833%

(1) The number of shares is subject to adjustment for any changes in the Company's capitalization as set forth in Section 10 of the Plan.

IV. Final Exercise Date

5:00 pm Eastern time on Date:

This Agreement includes this Notice of Grant and the following Exhibits, which are expressly incorporated by reference in their entirety herein:

Exhibit A — General Terms and Conditions
Exhibit B — Notice of Award Exercise
Exhibit C — Nabriva Therapeutics plc 2020 Share Incentive Plan

IN WITNESS WHEREOF, the parties hereto have executed this Agreement.

NABRIVA THERAPEUTICS PLC	PARTICIPANT	SPOUSAL CONSENT (if applicable)
Name: Title:	Name:	Name:

EXHIBIT A

GENERAL TERMS AND CONDITIONS

For valuable consideration, receipt of which is acknowledged, the parties hereto agree as follows:

1. Grant of Award. This Agreement evidences the grant by the Company, on the grant date (the "**Grant Date**") set forth in the Notice of Grant that forms part of this Agreement (the "**Notice of Grant**"), to the Participant of an option (an "**Option**") to purchase, in whole or in part, on the terms provided herein and in the Company's 2020 Share Incentive Plan (the "**Plan**"), the number of ordinary shares of the Company (the "**Ordinary Shares**") set forth in the Notice of Grant (the "**Shares**") at the exercise price per Share set forth in the Notice of Grant (the "**Exercise Price**"); provided, however, that if the Company's shareholders do not approve the Plan at the Company's 2020 Annual General Meeting of Shareholders (the "**2020 AGM**"), then the Option shall immediately and automatically, as of the date of such Meeting, convert into a cash-settled share appreciation right with respect to the same number of Shares and with a Measurement Price equal to the Exercise Price (the "**SAR**"), with such SAR representing the right of the Participant to receive, with respect to each Share for which the SAR is exercised, cash in an amount equal to the excess of the fair market value of the Shares as of the date of exercise over the Measurement Price. In no event may both the Option and the SAR be exercised. The Option and SAR shall collectively be referred to as the "**Award**". For the avoidance of doubt, in the event that the Plan is not approved by Company shareholders at the 2020 AGM, no Shares shall be issued upon exercise of this Award and if the Plan is approved by Company shareholders at the 2020 AGM, then only Shares and not cash shall be issued upon exercise of this Award. Unless earlier terminated, this Award shall expire at the time and on the date set forth in the Notice of Grant (the "**Final Exercise Date**").

It is intended that the Option evidenced by this Agreement shall not be an incentive share option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "**Code**") and shall instead be a nonstatutory share option. Except as otherwise indicated by the context, the term "**Participant**", as used in this Award, shall be deemed to include any person who acquires the right to exercise this Award validly under its terms.

2. Vesting Schedule.

This Award will become exercisable ("**vest**") in accordance with the Vesting Table set forth in the Notice of Grant.

The right to exercise the Award shall be cumulative so that to the extent the Award is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this Award under Section 3 hereof or the Plan.

3. Exercise of Award.

(a) Form of Exercise. Each election to exercise this Award shall be accompanied by a completed Notice of Award Exercise in the form attached hereto as Exhibit B, signed by the Participant, and received by the Company at its principal office, accompanied by this Agreement, and, to the extent that the Award is exercised as the Option, payment in full of the Exercise Price in the manner provided in the Plan. The Participant may exercise the Award with respect to less than the full number of Shares covered hereby, provided that no partial exercise of this Award may be for any fractional share.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this Award may not be exercised unless the Participant, at the time he or she exercises this Award, is, and has been at all times since the Grant Date, an employee, officer or director of, or consultant or advisor to, the Company or any parent or subsidiary of the Company as defined in Section 424(e) or (f) of the Code or any other

entity the employees, officers, directors, consultants, or advisors of which are eligible to receive Awards under the Plan (an "**Eligible Participant**").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (d) and (e) below, the right to exercise this Award shall terminate three months after such cessation (but in no event after the Final Exercise Date), provided that this Award shall be exercisable only to the extent that the Participant was entitled to exercise this Award on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the non-competition or confidentiality provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company, the right to exercise this Award shall terminate immediately upon such violation.

(d) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Final Exercise Date while he or she is an Eligible Participant and the Company has not terminated such service relationship for "**cause**" as specified in paragraph (e) below, this Award shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee), provided that this Award shall be exercisable only to the extent that this Award was exercisable by the Participant on the date of his or her death or disability, and further provided that this Award shall not be exercisable after the Final Exercise Date.

(e) Termination for Cause. If, prior to the Final Exercise Date, the Participant's service relationship with the Company is terminated by the Company for Cause (as defined below), the right to exercise this Award shall terminate immediately upon the effective date of such termination. If, prior to the Final Exercise Date, the Participant is given notice by the Company of the termination of his or her service relationship by the Company for Cause, and the effective date of such termination is subsequent to the date of the delivery of such notice, the right to exercise this Award shall be suspended from the time of the delivery of such notice until the earlier of (i) such time as it is determined or otherwise agreed that the Participant's service relationship shall not be terminated for Cause as provided in such notice or (ii) the effective date of such termination (in which case the right to exercise this Award shall, pursuant to the preceding sentence, terminate immediately upon the effective date of such termination). If the Participant is party to an employment, consulting or severance agreement with the Company or subject to a severance plan maintained by the Company, in either case, that contains a definition of "cause" for termination of service, "Cause" shall have the meaning ascribed to such term in such agreement or plan. Otherwise, "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant's service relationship shall be considered to have been terminated for "Cause" if the Company determines, within 30 days after the Participant's termination of service, that termination for Cause was warranted.

4. Tax Matters.

No Shares will be issued or cash paid pursuant to the exercise of this Award unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes (or equivalent in jurisdictions outside the United States, as applicable) required by law to be withheld in respect of this Award.

5. Transfer Restrictions; Clawback.

(a) This Award may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this Award shall be exercisable only by the Participant.

(b) In accepting this Award, the Participant agrees to be bound by any clawback policy that the Company may adopt in the future.

6. Data Privacy.

Consent

The Participant hereby acknowledges and consents to the collection, use, processing and/or transfer by the Company of Personal Data as defined and described in this Section 6. The Participant is not obliged to consent, however a failure to provide consent, or the withdrawal of consent at any time, may impact the Participant's ability to participate in the Plan. The Participant accepts that the consent provided pursuant to this Section 6 includes consent to any transfer of Personal Data throughout the world.

Information Collected

The Company and/or the Participant's employer collects and maintains certain personal information about the Participant that may include name, home address and telephone number, date of birth, social security number or other government or employer-issued identification number, salary grade, hire data, salary, citizenship, job title, any ordinary shares of the Company, or details of all Awards granted, canceled, vested, or unvested (collectively "**Personal Data**").

Uses made of Data

The Company may use, process and/or transfer Personal Data among other group companies to implement, administer and/or manage the Participant's participation in the Plan. The Company may further use, process, analyze and/or transfer Personal Data for its overall administration, management and/or improvement of the Plan and/or to comply with any applicable laws and regulations. The Company maintains technical, administrative and physical safeguards designed to protect Personal Data.

Disclosure of Data

The Company may share and/or transfer Personal Data, in electronic or other format, to selected third parties including but not limited to the Plan's service provider.

Such third parties assist in the implementation, administration and/or management of the Plan or the Participant's participation in the Plan, for example to facilitate the holding of shares of stock on Participant's behalf or to process the Participant's election to deposit shares of stock acquired pursuant to the Plan with a broker or other third party. Third parties retained by the Company may use the Personal Data as authorized by the Company to provide the requested services in accordance with the requirements of data protection legislation. Third parties may be located throughout the world, including but not limited to the United States. Third parties often maintain their own published policies that describe their privacy and security practices. The Company is not responsible for the privacy or security practices of any third parties.

Participant Rights

The Participant may request access to, rectification, erasure, portability or restriction of their Personal Data, or object to the processing of their Personal Data at any time by contacting the Company and/or the Plan's service provider. Participant shall have the right to obtain and reuse their Personal Data as provided to the Company. The Company will respond to any such request in writing, or orally if requested, as soon as practicable and in any event not more than one month after receipt of such request. The Company may request proof of identification to verify such a request.

7. Provisions of the Plan.

This Award is subject to the provisions of the Plan (including the provisions relating to amendments to the Plan), a copy of which is attached hereto as Exhibit C.

8. Governing Law

This Agreement shall be governed by, except to the extent preempted by other applicable laws (1) with respect to the corporate law requirements applicable to the Company, the validity and authorization of the issuance of Ordinary Shares under the Plan and similar matters, the laws of Ireland (without reference to conflict of law principles thereof) and (2) with respect to all other matters relating to the Plan and Awards, the laws of the State of Delaware, excluding choice-of-law principles of the law of that state.

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EXHIBIT B

NOTICE OF AWARD EXERCISE

[DATE]

Nabriva Therapeutics plc
25 — 28 North Wall Quay
Dublin 1
Ireland

Dear Sir or Madam:

I am the holder of the Share Option /Cash-Settled Share Appreciation Right Award granted to me under the Nabriva Therapeutics plc (the "**Company**") 2020 Share Incentive Plan (the "**Plan**") on February 6, 2020 for the purchase of [ ] ordinary shares of the Company at a purchase / measurement price of $[ ] per share.

I hereby exercise my Award as:

- if shareholder approval of the Plan was not obtained at the 2020 Annual General Meeting of Shareholders, an SAR with respect to [_____] Shares

OR

- if shareholder approval of the Plan was obtained at the 2020 Annual General Meeting of Shareholders, an option to purchase [ ] ordinary shares (the "**Shares**"), for which I have enclosed payment in the amount of [ ], the aggregate purchase price for the Shares. Please register my share certificate as follows:

Name(s): _____
_____

Address: _____
_____

Very truly yours,

_____
[Name]

EXHIBIT C

NABRIVA THERAPEUTICS PLC 2020 SHARE INCENTIVE PLAN

Exhibit 21.1

SUBSIDIARIES OF NABRIVA THERAPEUTICS plc

Nabriva Therapeutics GmbH	**Austria**
Nabriva Therapeutics Ireland Designated Activity Company	**Ireland**
Zavante Therapeutics, Inc.	**United States**
Nabriva Therapeutics US, Inc.	**United States**

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Nabriva Therapeutics plc:

We consent to the incorporation by reference in the registration statements (Nos. 333-208097, 333-222003, 333-226330, 333-228094 and 333-230216) on Forms S-8 and the registration statements (Nos. 333-219567 and 333-223739) on Forms S-3 of Nabriva Therapeutics plc of our report dated March 12, 2020 with respect to the consolidated balance sheets of Nabriva Therapeutics plc and subsidiaries as of December 31, 2018 and 2019, and the related consolidated statements of operations and comprehensive income (loss), changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes (collectively, the "consolidated financial statements"), which report appears in the December 31, 2019 annual report on Form 10-K of Nabriva Therapeutics plc.

Our report dated March 12, 2020 contains an explanatory paragraph that states that Nabriva Therapeutics plc has incurred recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 12, 2020

EXHIBIT 31.1

CERTIFICATIONS

I, Theodore Schroeder, certify that:

1. I have reviewed this Annual Report on Form 10-K of Nabriva Therapeutics plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Theodore Schroeder

Theodore Schroeder
Chief Executive Officer
(Principal Executive Officer)

Dated: March 12, 2020

EXHIBIT 31.2

CERTIFICATIONS

I, Gary Sender, certify that:

1. I have reviewed this Annual Report on Form 10-K of Nabriva Therapeutics plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Gary Sender

Gary Sender
Chief Financial Officer
(Principal Financial Officer)

Dated: March 12, 2020

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 on Form 10-K of Nabriva Therapeutics plc (the "Company") for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Theodore Schroeder, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Theodore Schroeder

Theodore Schroeder
Chief Executive Officer
(Principal Executive Officer)

Dated: March 12, 2020

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 on Form 10-K of Nabriva Therapeutics plc (the "Company") for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Gary Sender, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Gary Sender

Gary Sender
Chief Financial Officer
(Principal Financial Officer)

Dated: March 12, 2020