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

Form 10-K

☒ **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**

Commission file number: 001-36066

PARATEK PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0960223**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

75 Park Plaza
Boston, MA 02116
(617) 807-6600

(Address, including zip code, and telephone number, including area code, of registrant's principal executive office)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	PRTK	The Nasdaq Global Market

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T 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 Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the common stock of the registrant held by non-affiliates of the registrant on the last business day of the registrant's second fiscal quarter was: $127,549,862.

As of February 28, 2020, there were 42,219,278 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2020 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A within 120 days of the registrant's year ended December 31, 2019 are incorporated herein by reference into Part III of this Annual Report on Form 10-K.

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Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that are based upon current expectations within the meaning of the Private Securities Litigation Reform Act of 1995. Paratek Pharmaceuticals, Inc. intends that such statements be protected by the safe harbor created thereby. In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions intended to identify forward-looking statements. Examples of such forward-looking statements include, but are not limited to, statements about or relating to:

- our intention to market NUZYRA® as an empiric monotherapy that will be commercialized worldwide for the treatment of serious, community-acquired bacterial infections;
- our ability to successfully market, commercialize and achieve market acceptance for NUZYRA;
- the therapeutic and commercial potential of NUZYRA and SEYSARA®;
- proposed new products or developments, including additional indications for NUZYRA;
- our expectations regarding the potential benefits of the licensing, collaboration, partnership and other strategic arrangements and transactions we have entered into and may enter into in the future;
- our ability to establish and maintain potential new collaborative, partnering or other strategic arrangements for commercialization of our products and the development of our product candidates;
- our plans to pursue expansion of omadacycline to additional markets through collaboration or distribution arrangements;
- the timing, scope and anticipated initiation, enrollment and completion of our ongoing and planned clinical trials and any other future clinical trials that we or our development partners may conduct;
- the anticipated progress of our clinical programs, including whether our ongoing clinical trials will achieve clinically relevant results;
- the timing of regulatory discussions and submissions, and the anticipated timing, scope and outcome of related regulatory actions or guidance;
- our ability to obtain, maintain and expand United States, or U.S., Food and Drug Administration, or FDA, and non-U.S. regulatory approvals of our products and product candidates;
- our ability to timely secure supply and manufacture conforming products;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- availability of additional potential funding under our contract with the Biomedical Advanced Research and Development Authority, or BARDA, a division of the U.S. Department of Health and Human Services’ Office of the Assistant Secretary for Preparedness and Response;
- the plans, strategies and objectives of management for future operations;
- future economic conditions or performance;
- our expectations regarding the continued growth of our business operations due, in part, to the commercialization of NUZYRA;
- our estimates regarding the sufficiency of our cash resources, expenses, capital requirements and needs for additional financing, and our ability to obtain additional financing; and
- our projected financial performance.

Forward-looking statements are neither historical facts nor assurances of future performance. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, time frames or achievements to be materially different from the information set forth in these forward-looking statements. While we believe that we have a reasonable basis for each forward-looking statement, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. We discuss many of these risks in the "Risk Factors" section and elsewhere in this Annual Report on Form 10-K. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Any of the events anticipated by the forward-looking statements may not occur or, if any of them do, the impact they will have on our business, results of operations and financial condition is uncertain. We hereby qualify all of our forward-looking statements by these cautionary statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

PARATEK® and NUZYRA® are registered trademarks of Paratek Pharmaceuticals, Inc. SEYSARA® is a U.S. registered trademark of Almirall, LLC. and a trademark of Paratek in foreign jurisdictions. Other trademarks referred to in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, we only use the ® or ™ symbol the first time any trademark is mentioned.

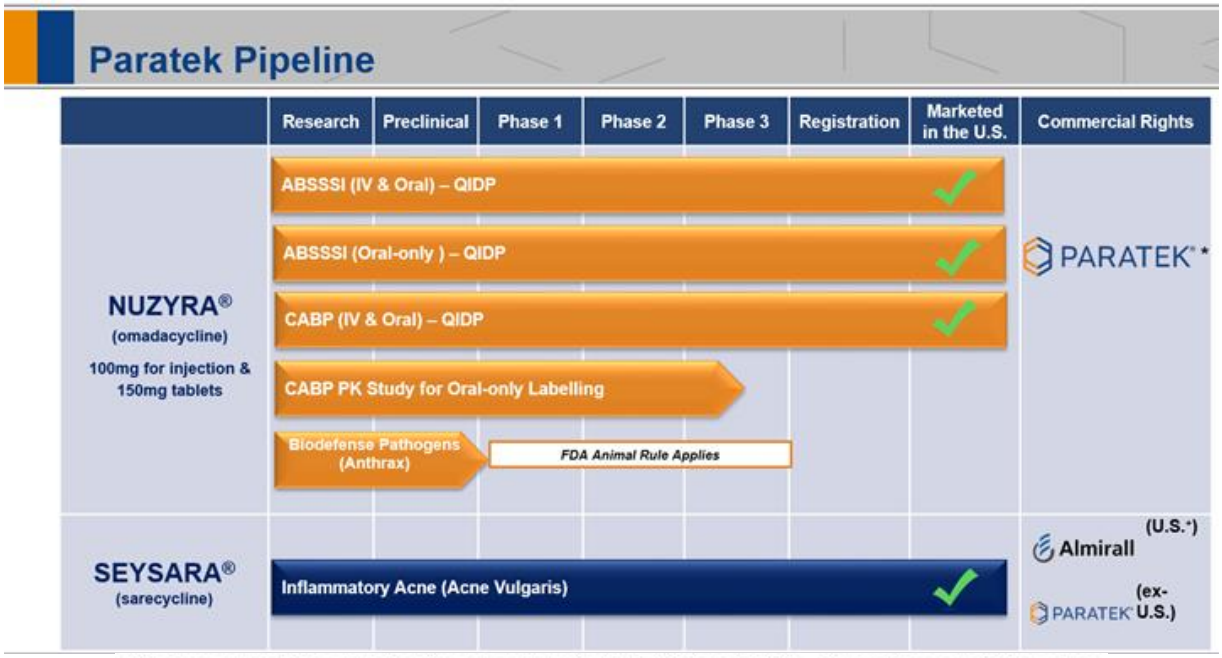
All references to "Paratek," "we," "us," "our" or the "Company" in this Annual Report on Form 10-K mean Paratek Pharmaceuticals, Inc. and its subsidiaries.

PART I

Item 1. Business

Overview

We are a commercial-stage biopharmaceutical company focused on the development and commercialization of novel life-saving therapies for life-threatening diseases or other public health threats for civilian, government and military use. We have used our expertise in biology and tetracycline chemistry to create chemically diverse and biologically distinct small molecules derived from the minocycline core structure. Our United States, or U.S., Food and Drug Administration, or FDA, approved commercial product, NUZYRA® (omadacycline) is a once-daily oral and intravenous antibiotic for the treatment of adult patients with community-acquired bacterial pneumonia, or CABP, and acute skin and skin structure infections, or ABSSSI, caused by susceptible pathogens. SEYSARA® (sarecycline) is an FDA-approved product with respect to which we have exclusively licensed in the U.S. and the People's Republic of China, Hong Kong and Macau, or the greater China region, certain rights to Almirall, LLC, or Almirall. SEYSARA is currently being marketed by Almirall in the U.S. as a new once-daily oral therapy for the treatment of moderate to severe acne vulgaris. With respect to our technology as it relates to sarecycline, we retain development and commercialization rights in all countries other than the U.S. and the greater China region, and in February 2020, we exclusively licensed from Almirall certain technology owned or in-licensed by Almirall or its affiliates that is necessary or useful to develop or commercialize sarecycline outside of the U.S.



*We have entered into a collaboration agreement with Zai Lab (Shanghai) Co., Ld., for the greater China region
+We have entered into a license agreement with Almirall for the greater China region

NUZYRA

We believe that NUZYRA has the potential to become the primary choice of physicians for use as a broad-spectrum monotherapy antibiotic for ABSSSI, CABP and other serious community-acquired bacterial infections where resistance is of concern. We believe NUZYRA will be used in the emergency room, hospital and community care settings. We have designed NUZYRA to provide potential advantages over existing antibiotics, including activity against resistant bacteria, broad-spectrum antibacterial activity, oral and IV formulations with once-daily dosing, no dosing adjustments for patients on concomitant medications and a generally safe and well-tolerated profile. NUZYRA also has the potential to be used as an oral and IV antibiotic for the treatment of pulmonary anthrax and may be suitable for prophylactic use as a priority medical countermeasure.

To date, we have conducted more than 30 Phase 1 studies of omadacycline to characterize the effects of the drug on humans, including how it is absorbed, metabolized, and excreted. These Phase 1 studies also included evaluation in special populations like hepatic and renal failure patients. We have also conducted three successful Phase 3 clinical studies. Our first two Phase 3 clinical studies were for the treatment of ABSSSI (OASIS-1) and CABP (OPTIC). Both studies utilized initiation of IV therapy with transitions to oral-based treatment on clinical response. Our third Phase 3 clinical study (OASIS-2) was an oral-only administration of omadacycline in ABSSSI compared to oral-only linezolid. All three Phase 3 clinical studies resulted in omadacycline demonstrating positive efficacy results and a generally safe and well tolerated profile. These data formed the basis of approval for NUZYRA in the U.S.

In October 2018, we submitted a Market Authorization Applications, or MAA, submission to the European Medicines Agency, or the EMA, for the treatment of adults with ABSSSI and CABP caused by susceptible bacteria. Based on the review of the data and the application, the EMA recommended approval for NUZYRA for the treatment of ABSSSI but not for CABP. The EMA stated that a second study is required for the CABP indication, which is consistent with EU guidance that typically requires two Phase 3 studies per indication for approval. In the EU, the ten-year market exclusivity for NUZYRA would begin with the first approval. As a result, in the fourth quarter of 2019, we withdrew our submission of the MMA to the EMA for NUZYRA to preserve exclusivity until such time as both the ABSSI and CABP indications can be approved concurrently in an effort to maximize the value of NUZYRA in the EU. The EU represents only a modest market opportunity compared to the U.S. Our goal to partner in the EU once both indications are approved remains unchanged.

In December 2019, we entered into a five-year contract with an option to extend to ten years with the Biomedical Advanced Research and Development Authority, or BARDA, a division of the U.S. Department of Health and Human Services, or HHS, Office of the Assistant Secretary for Preparedness and Response, or ASPR, herein referred to as the BARDA contract. The BARDA contract supports the development of NUZYRA for the treatment of pulmonary anthrax, FDA post-marketing requirements, or PMRs, associated with the initial NUZYRA approval, and an option for BARDA to procure up to 10,000 treatment courses of NUZYRA for the Strategic National Stockpile, or SNS, for use against potential biothreats. Under the terms of the BARDA contract, we have been awarded initial funding of approximately $59.4 million for the development of NUZYRA for the treatment of pulmonary anthrax and the purchase of an initial 2,500 treatment courses of NUZYRA to add to the current SNS. The BARDA contract provides for additional potential staged funding including approximately $76.8 million for existing FDA PMRs scheduled to begin in April 2020 and approximately $20.4 million for manufacturing-related requirements scheduled to begin in June 2020. The remaining staged, milestone-based funding includes the potential for approximately $12.7 million to support the development of NUZYRA for the prophylaxis of anthrax and a maximum of approximately $115.3 million to provide for three additional purchases of NUZYRA for the SNS, each of which will be triggered upon us demonstrating continued progress in the anthrax development program.

We have initiated discussions with the FDA to explore potential regulatory registration paths to determine the efficacy and safety of omadacycline in patients afflicted with non-tuberculous mycobacteria, or NTM, which are environmental organisms that can be found in soil, dust, and water, including natural and municipal water sources. Infection occurs when a person is exposed to NTM organisms. NTM can form difficult-to-eliminate biofilms, which are collections of microorganisms that stick to each other, and adhere to surfaces in moist environments. Although severe infection can affect the lymph nodes, skin, soft tissues, bones, and joints, the vast majority of NTM infection cases are pulmonary. The diagnosis of NTM infection is often delayed due to non-specific symptoms and a lack of disease state awareness by clinicians.

Mycobacterium abscessus, or M. abscessus, complex comprises a group of rapidly growing, multidrug-resistant, nontuberculous mycobacteria that are responsible for a wide spectrum of skin and soft tissue diseases, central nervous system infections, bacteremia, and ocular and other infections. Infections caused by the M. abscessus complex are notoriously difficult to treat due to intrinsic resistance to many classes of antibiotics. Few oral antibiotics demonstrate in vitro activity against the M. abscessus complex, making long-term treatment of this infection extremely complicated. The M. abscessus complex is frequently resistant to antibiotics that are used in the treatment of other NTM species such as rifamycins, ethambutol, and fluoroquinolones. There is currently only one FDA-approved antibiotic for the treatment of NTM species; Arikayce, an inhaled liposomal amikacin, has been approved for treatment of refractory pulmonary disease caused by Mycobacterium avium complex. There are no FDA-approved treatments for pulmonary disease caused by M. abscessus complex.

One of the key components of M. abscessus complex treatment is the use of three or more antimicrobials in most treatment regimens to increase drug efficacy and decrease the development of antibiotic resistance. Currently available treatment options for M. abscessus complex pulmonary infection are lengthy and require complex, multi-antibiotic regimens and are generally not tolerated and have significant safety challenges. General treatment principles that should be followed include:

- Prolonged therapy (treat for at least 12 months of culture negativity);
- An induction phase of therapy with a three- to four-drug regimen including one to two different active intravenous agents;

- A suppressive phase, which should involve at least two oral or inhaled antibiotics considered active based on drug susceptibilities since most patients cannot tolerate months of intravenous therapy; and
- The inclusion of a macrolide in the treatment regimen improves treatment outcomes and regimen tolerability against isolates without a functional erm gene.

Omadacycline has several key characteristics that may prove beneficial to patients with M. abscessus complex pulmonary infection. These include:

- Favorable pharmacokinetics with both intravenous and oral formulations including high lung penetration concentrations and high intracellular pulmonary macrophage levels;
- Established safety profile in pre-clinical studies and Phase 3 clinical trials, including a class that is currently used for the treatment of NTM and chronically in many difference disease states; and
- Potent in vitro activity versus M. abscessus complex.

Omadacycline has demonstrated potent activity against M. abscessus complex species in three separate studies. In two published reports (Kaushik 2019 and Shoen 2019), the MIC50 and MIC90 values obtained were 1 and 2 µg/mL, respectively. In a third ongoing study, the preliminary MIC50 and MIC90 values were 0.12 and 0.5 µg/mL, respectively (Brown-Elliot; preliminary data on file at Paratek). Differences in the results of these studies are likely due to experimental methodology or isolate selection; nonetheless, in all cases omadacycline and tigecycline had similar, if not identical, minimum inhibitory concentration, or MIC, values.

Initial discussions have occurred with the FDA on a program to support registration on NUZYRA for M. abscessus complex. Additional discussions are planned during the second quarter of 2020 to further refine this program.

Sarecycline

Sarecycline, also known as SEYSARA in the U.S., is a novel, next generation, narrow spectrum tetracycline designed specifically for dermatological use. In July 2007, we exclusively licensed the right to develop and commercialize sarecycline for the treatment of acne to Warner Chilcott Company, Inc. (which was acquired by Actavis PLC in October 2013 and became Allergan in October 2015) and, September 2018, Allergan assigned such rights to Almirall. In February 2020, we exclusively licensed to Almirall certain technology owned or in-licensed by us or our affiliates in order to research, develop and commercialize sarecycline for the treatment of acne in the greater China region. Almirall is responsible for all costs associated with developing and commercializing sarecycline for the treatment of acne in the U.S. and the greater China region. In exchange for such license rights, we have the right to receive (i) milestone payments upon the achievement of certain development- and regulatory-based events in the U.S. and (ii) a royalty on U.S.-based and greater China region-based net sales. With respect to our technology as it relates to sarecycline, we retain development and commercialization rights outside of the U.S. and the greater China region and, with respect to certain technology owned or in-licensed by Almirall or its affiliates necessary or useful to develop or commercialize sarecycline outside of the U.S. and the greater China region, we exclusively licensed such technology from Almirall in February 2020, all of which is available for licensing to other partners in key international markets, such as the EU, Japan, the rest of Asia (excluding the greater China region), Canada and Latin America. In the event we directly commercialize or sublicense a third party to commercialize sarecycline outside of the U.S. and the greater China region, we owe Almirall (i) a royalty on our or our affiliates' net sales and (ii) a percentage of the consideration (e.g., milestones, royalties) we receive from our sublicensees in connection with their development and commercialization of sarecycline.

Almirall currently holds a nonexclusive license to develop and commercialize sarecycline for the treatment of rosacea in the U.S., and in the U.S., Paratek cannot grant rights on back-up compounds, lead candidate(s), or products licensed to Almirall for rosacea.

Corporate History

Merger of Transcept Pharmaceuticals, Inc. and Paratek Pharmaceuticals, Inc.

We are incorporated under the laws of the State of Delaware. On October 30, 2014, Transcept Pharmaceuticals, Inc., or Transcept, completed a business combination with privately-held Paratek Pharmaceuticals, Inc., or Old Paratek, in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of June 30, 2014, by and among Transcept, Tigris Merger Sub, Inc., or Merger Sub, Tigris Acquisition Sub, LLC, or Merger LLC, and Old Paratek, or the Merger Agreement, pursuant to which Merger Sub merged with and into Old Paratek, with Old Paratek surviving as a wholly-owned subsidiary of Transcept, followed by the merger of Old Paratek with and into Merger LLC, with Merger LLC surviving as a wholly-owned subsidiary of Transcept (we refer to these mergers together as the Merger). Immediately following the Merger, Transcept changed its name to "Paratek Pharmaceuticals, Inc.", and Merger LLC changed its name to "Paratek Pharma, LLC." In connection with the closing of the Merger, our common stock began trading on The Nasdaq Global Market under the ticker symbol "PRTK" on October 31, 2014.

The Antibiotics Market and Limitations of Current Therapies

Physicians commonly prescribe antibiotics to treat patients with acute and chronic infectious diseases that are either known, or presumed, to be caused by bacteria. The World Health Organization has identified the development of worldwide resistance to currently available antibacterial agents as being one of the three greatest threats to human health in this decade. In a press release announcing the release of a study titled "Hospital and Societal Costs of Antimicrobial Resistant Infections in a Chicago Teaching Hospital: Implications for Antibiotic Stewardship," it was estimated that antibiotic-resistant infections cost the U.S. healthcare system in excess of $20 billion annually. In addition, these infections result in more than $35 billion in societal costs and more than 8 million additional days spent in the hospital. Historically, the majority of life-threatening infections resulting from antibiotic-resistant bacteria were acquired in the hospital setting. According to AMR data from 2015 projected to 2028, approximately 6.7 million antibiotic treated events occur annually in the two combined indications of ABSSSI and CABP in U.S. hospitals. Furthermore, research conducted by Paratek suggests that in these same indications of ABSSSI and CABP there are approximately 890 thousand patients treated in U.S hospitals who fail to respond or are intolerant to the existing generic options. In the U.S. community setting, IMS NDTI data (2014-2015) projected to 2028 suggests there are approximately 23.7 million prescriptions for ABSSSI and CABP. Additionally, research conducted by Paratek suggests that approximately 2.1 million patients fail to respond or are intolerant to the existing oral generics in the U.S. community setting. The emergence of multi-drug resistant pathogens, coupled with limitations in terms of intolerance to existing generic options, emphasizes the need for novel agents capable of overcoming antibiotic resistance.

Bacteria are often broadly classified as gram-positive bacteria, including antibiotic-resistant bacteria such as methicillin-resistant Staphylococcus aureus, or MRSA, and multi-drug resistant Streptococcus pneumoniae, or MDR-SP; gram-negative bacteria, including antibiotic-resistant bacteria such as extended-spectrum beta-lactamases, or ESBL, producing *Enterobacteriaceae*; atypical bacteria, including *Chlamydophila pneumoniae* and *Legionella pneumophila*; and anaerobic bacteria, including *Bacteroides* and *Clostridia*. Antibiotics that are active against both gram-positive and gram-negative bacteria are referred to as "broad-spectrum", while antibiotics that are active only against a select subset of gram-positive or gram-negative bacteria are referred to as "narrow spectrum". Today, because many of the currently prescribed antibiotics that have activity against resistant organisms typically are "narrow spectrum," they cannot be used as an empiric monotherapy treatment of serious infections where gram-negative, atypical or anaerobic bacteria may also be involved. Empiric monotherapy refers to the use of a single, antibacterial agent to begin treatment of an infection before the specific pathogen causing the infection has been identified. We believe omadacycline will be used in the emergency room, hospital and community care settings. Based on studies published by the Cleveland Clinic Foundation, the National Institutes of Health, or NIH, and American Academy of Family Physicians, rates of infections involving organisms other than gram-positive bacteria have been found to be as much as 15% in ABSSSI and up to 40% in CABP.

When a patient goes to the emergency room or hospital for treatment of a serious infection, the physician's selection of which IV antibiotic to use is often based on the severity of infection, the pathogen(s) believed most likely to be involved and the probability of a resistant pathogen(s) being present. After initial IV therapy and once the infection begins to respond to treatment, hospitals and physicians face strong pressures to discharge patients from the hospital to reduce costs, limit hospital-acquired infections and improve the patient's quality of life. In order to transition patients out of the hospital and home to complete the course of therapy, physicians typically prefer to have the option to prescribe a bioequivalent oral formulation of the same antibiotic.

Antibiotics used to treat ABSSSI, CABP and other serious, community-acquired bacterial infections must satisfy a wide range of criteria on a cost-effective basis. For example, we believe that existing treatment options for ABSSSI, including vancomycin, linezolid, daptomycin, piperacillin tazobactam, oritavancin, dalbavancin, tigecycline and delafloxacin; and for CABP, including levofloxacin, moxifloxacin, azithromycin, ceftriaxone, clarithromycin, ceftaroline, delfaloxacin, lefamulin and tigecycline; have one or more of the following significant limitations:

- *Limited spectrum of antibacterial activity*. Since it may take as long as 48 to 72 hours to identify the pathogen(s) causing an infection and most of the currently available options that cover resistant pathogens are narrow-spectrum treatments, physicians frequently prescribe two or more antibiotics to treat a broad-spectrum of potential pathogens. For example, vancomycin, linezolid and daptomycin, the most frequently prescribed treatments for certain serious bacterial skin infections, are narrow-spectrum treatments active only against gram-positive bacteria. The currently available treatment with a more appropriate spectrum for use as a monotherapy against serious and antibiotic-resistant bacterial infections is tigecycline, but it has other significant limitations, most notably dose limiting tolerability of nausea and vomiting.
- *Lack of both oral and IV formulations*. The most common treatments for serious bacterial infections, vancomycin, daptomycin, ceftriaxone, piperacillin tazobactam, and tigecycline are only available as injectable or IV formulations. The lack of an effective bioequivalent oral formulation of these and many other commonly prescribed antibiotics requires continued IV therapy, which is inconvenient for the patient and may result in longer hospital stays and greater cost. Alternatively, because of the absence of the same antibiotic in an oral, well-tolerated formulation, physicians may switch the patient to a different orally available antibiotic at the time of hospital discharge. This carries the risk of new side effects and possible treatment failure if the oral antibiotic does not cover the same bacteria that were being effectively treated by the IV antibiotic therapy. While linezolid is a twice-daily IV and oral therapy, it is a narrow-spectrum treatment that is associated with increasing bacterial resistance, side effects from interactions with other therapies and other serious safety concerns.

- *Safety/tolerability concerns and side effects*. Concerns about antibiotic safety and tolerability are among the leading reasons why patients stop treatment and fail therapy. The most commonly used antibiotics, such as vancomycin, linezolid, daptomycin, levofloxacin, moxifloxacin, azithromycin, piperacillin/tazobactam and tigecycline, are associated with safety and tolerability concerns. For example, vancomycin, which requires frequent therapeutic monitoring of blood levels and corresponding dose adjustments, is associated with allergic reactions and can cause kidney damage, loss of balance, loss of hearing, vomiting and nausea in certain patients. Linezolid is associated with bone marrow suppression and loss of vision and should not be taken by patients who are also on many commonly prescribed anti-depressants, such as monoamine oxidase inhibitors and serotonin reuptake inhibitors. Daptomycin has been associated with a reduction of efficacy in patients with moderate renal insufficiency and has a side effect profile that includes muscle damage. Piperacillin/tazobactam is not used in patients with beta-lactam (penicillin) allergy while tigecycline is associated with tolerability concerns because of nausea and vomiting. Levofloxacin and moxifloxacin are associated with tendon rupture and peripheral neuropathy. In July 2016, the FDA approved changes to the labels of fluoroquinolone antibacterial drugs for systemic use (i.e., taken by mouth or by injection), stating "These medicines are associated with disabling and potentially permanent side effects of the tendons, muscles, joints, nerves, and central nervous system that can occur together in the same patient." As a result, the FDA revised the Boxed Warning, FDA's strongest warning, to address these serious safety issues. They also added a new warning and updated other parts of the drug label, including the patient Medication Guide. Additionally, a May 2012 article in the New England Journal of Medicine indicated that a small number of patients treated with azithromycin and quinolones, such as levofloxacin or moxifloxacin, may experience sudden death due to cardiac arrhythmia, which is often predicted by a prolongation of the corrected QT interval, or QTc. The FDA issued a Drug Safety Communication on March 12, 2013 titled "Azithromycin (Zithromax or Zmax) and the risk of potentially fatal heart rhythms," and the azithromycin drug label warnings were strengthened to address this concern.
- *Increasing bacterial resistance*. Bacterial resistance to the most frequently prescribed antibiotics (branded or generic) has limited their potential to treat infections, which often prevents their use as an empiric monotherapy. We believe that MRSA and MDR-SP, in the community have posed treatment challenges because of resistance to penicillins (resistance rate up to 100% for both), cephalosporins (100% and 11%, respectively, for ceftriaxone), macrolides (83% and 86%, respectively, for erythromycin/azithromycin) and quinolones (73% and 2%, respectively, for levofloxacin), particularly in ABSSSI and CABP. There have also been recent reports of resistance developing during treatment with daptomycin and concerns about an increasing frequency of strains of *Staphylococcus aureus* with reduced susceptibility to vancomycin. Additionally, linezolid use has been associated with drug resistance, including reports of outbreaks of resistance among *Staphylococcus aureus* and *Enterococcus strains*.

These limitations can ultimately lead to longer hospital stays, greater healthcare costs and increased morbidity and mortality due to lower cure rates and additional side effects. While certain antibiotics address some of these outcomes, we do not believe there is one superior treatment option that satisfies all outcomes. We believe that it is essential for the treatment of patients with serious, community-acquired bacterial infections that physicians prescribe the right antibiotic the first time, as ineffective antibiotics can quickly lead to progressively more severe and invasive infections or even death.

Attributes of NUZYRA

- *Equivalent Once-daily oral and IV formulations to support transition therapy*. We have studied once-daily IV and oral formulations of omadacycline in more than 30 studies and approximately 2,500 subjects to-date across multiple Phase 1, Phase 2 and Phase 3 clinical trials. The equivalent exposures of the oral and IV formulations permit transition therapy, which could allow patients to start treatment on the IV formulation in the hospital setting then "transition" to the oral formulation of the same bioequivalent antibacterial agent once the infection is responding enabling the patient to be released from the hospital to complete the full course of therapy at home. We believe that transition therapy has the potential to avoid the concerns that can accompany switching from an IV agent to a different class of oral antibiotic and to facilitate the continuance of curative therapy at home.
- *Broad-spectrum of antibacterial activity*. Omadacycline has demonstrated *in vitro* activity against all common pathogens found in ABSSSI, such as *Staphylococcus aureus*, including MRSA, *Streptococci* (including Group A *Streptococci*), anaerobic pathogens and many gram-negative organisms. Omadacycline is also active *in vitro* against the key pathogens found in CABP, such as Streptococcus pneumoniae, including MDR-SP, *Staphylococcus aureus*, *Haemophilus influenzae* and atypical bacteria, including *Legionella pneumophila*. On the basis of the *in vitro* spectrum of activity demonstrated by omadacycline against a range of pathogens in our pre-clinical testing, we believe omadacycline has the in vitro spectrum of coverage needed to potentially become the primary antibiotic choice of physicians and serve as an empiric monotherapy option for ABSSSI and CABP where resistance is of concern.

- *Generally safe and well tolerated profile*. To date, we have observed omadacycline to be generally well tolerated in studies involving approximately 2,500 subjects. We have conducted a thorough QTc study, as defined by FDA guidance to assess prolongation of QTc, an indicator of cardiac arrhythmia. This study suggests no prolongation of QTc by omadacycline at three times the therapeutic exposure. In addition, phase 3 clinical studies support that lack of cardiovascular effects associated with omadacycline. There have been no Adverse Events, or AEs, of ventricular arrhythmia, QT prolongation, seizures, syncope, or sudden death in the completed studies. Further, in clinical studies, omadacycline does not appear to adversely affect blood cell production, nor does it appear to metabolize in the liver or anywhere else in the body, thus reducing the likelihood of causing drug-to-drug interactions. Additionally, omadacycline has resulted in low rates of diarrhea, and we have not observed confirmed cases of *Clostridium difficile* infection, which can frequently occur from the use of other classes of broad-spectrum antibiotics such as beta-lactams and quinolones.
- *Designed to overcome bacterial resistance*. We designed omadacycline to overcome the two major mechanisms of tetracycline resistance, known as pump efflux and ribosome protection. This approach was via structure-activity relationship chemistry-based modifications of the seven and nine positions of minocycline. Our attempts to generate resistance to omadacycline in the laboratory suggest a low potential for developing resistance. In addition, our testing of thousands of bacterial samples in the laboratory suggests that omadacycline has not been affected to date by clinically relevant mechanisms of resistance to tetracyclines or to any other class of antibiotics.
- *Tissue penetration.* Omadacycline appears to penetrate tissues broadly, including lung, muscle, and kidney, thereby achieving high concentrations at the sites of infection. Because omadacycline is eliminated from the body (as unchanged parent compound) via the kidneys and intestine in an expected manner, based on the results of our Phase 1 studies, we believe it may potentially be used in patients with diminished kidney and liver function, without dose adjustment, and may potentially have benefit in patients receiving poly-pharmacy, where drug-drug interactions are of concern. We have completed pre-clinical work evaluating omadacycline for the potential treatment of sinusitis, also known as an acute sinus infection or rhinosinusitis.

Omadacycline Post-Approval Requirements in the U.S.

Under the Pediatric Research Equity Act (21 U.S.C. 355c), or PREA, all applications for new active ingredients are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable. As part of the approval for NUZYRA, the FDA has waived the pediatric study requirement for ages 0 to < 8 years and deferred submission of pediatric studies for ages 8 to < 18 years. Specifically, the FDA has requested that we develop an age appropriate formulation, and complete three pediatric studies, including a pediatric PK study followed by safety and efficacy studies in pediatric patients with both CABP and ABSSSI. In addition to pediatric requirements, as with all antibiotic approvals, the FDA has also required a U.S. surveillance study for five years from the date of marketing to monitor for the development of resistance to NUZYRA (omadacycline) in those organisms specific to the indications in the label. Lastly, FDA has required a second study be conducted in patients with CABP.

NUZYRA Commercialization Strategy

We currently market NUZYRA in the U.S. as an empiric monotherapy and plan for NUZYRA to be commercialized worldwide for the treatment of serious, community-acquired bacterial infections. We retain worldwide commercial rights to omadacycline, with the exception of the People's Republic of China, Hong Kong, Macau and Taiwan, where we have entered into a collaboration agreement with Zai Lab (Shanghai) Co., Ltd., or Zai. In the U.S. and Europe, we continue to reserve the right to either commercialize omadacycline alone, through one or more pharmaceutical companies that have established commercial capabilities, or some combination thereof.

In 2018 we entered into an arrangement with a third party to provide a contract field sales force of up to 80-85 sales representatives with associated training and other services. In February 2019, we launched NUZYRA with 40 sales representatives through a third party provider calling on approximately 400 hospitals across the U.S. By the end of 2019 we were at approximately 50 representatives. By the first quarter of 2020 we anticipate a full complement of between 50-60 representatives calling on approximately 850 hospitals.

We believe that there is a similar rapidly growing need in other markets throughout the world, including Europe, established Asian markets such as Japan and Korea, and emerging markets, such as Russia, South America and India. We plan to pursue expansion of omadacycline to these markets through collaboration or distribution arrangements.

Competition

NUZYRA 100 mg for injection and 150 mg tablets are distributed in the U.S. exclusively through a limited network of specialty pharmacy providers and distributors. This distribution process is designed to provide the best possible provider and patient experience and improve patient adherence to the indicated dosing.

We have contracted with the Lash Group, a third-party organization with extensive experience in delivering patient support services to help healthcare providers and patients access our network of specialty pharmacies and navigate the insurance process.

Paratek also employees Market Access Account Managers who educate payors and hospital formulary committee members about NUZYRA and a Trade Team that works with our network of specialty pharmacies and distributors to assist in the execution of our distribution plan.

Three of the nation's largest Pharmacy Benefit Managers, CVS Caremark, Express Scripts and OptumRx, have listed NUZYRA 150 mg tablets on their commercial formulary. Approximately 85% of insured commercial lives in the U.S. have no or limited prior authorizations for NUZYRA 150 mg tablets. We define limited prior authorizations as those where prescribing NUZYRA is based on the package insert, which is consistent with the label indication for use approved by the FDA. The majority of state Medicaid programs cover NUZYRA 150 mg tablets.

On October 1, 2019, NUZYRA 100 mg for injection was issued a permanent J-code under the Healthcare Common Procedure Coding System, which is a standardized code system necessary for medical providers to submit healthcare claims to Medicare and other health insurances in a consistent and orderly manner. NUZYRA 100 mg for injection, has also received transitional pass-through status from the Centers for Medicare and Medicaid Services, or the CMS, which is intended to encourage the use of newly FDA-approved medical devices, drugs, and biologics to increase Medicare patients' access to these innovative therapies by paying hospital outpatient departments more than the established facility fees. Pass-through status is temporary lasting at least two but not more than three years.

Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical companies and generic drug companies. We believe that our product candidates offer key potential advantages over competitive products that could enable our product candidates to capture meaningful market share from our competitors.

NUZYRA competes with other antibiotics in the serious bacterial skin infection market. These include, but are not limited to, vancomycin, marketed as a generic by Abbott Laboratories and others; linezolid, marketed as Zyvox by Pfizer Inc. and available as a generic; daptomycin, marketed as Cubicin by Merck Pharmaceuticals, Inc. and available as a generic; dalbavancin, marketed as Dalvance by Allergan; tedizolid, marketed as Sivextro by Merck Pharmaceuticals, Inc.; oritavancin, marketed as Orbactiv and delafloxacin marketed as Baxdela by Melinta Therapeutics, Inc.; quinupristin/dalfopristin, marketed as Synercid by Pfizer, Inc.; tigecycline, marketed as Tygacil by Pfizer Inc. and available as a generic; telavancin, marketed as Vibativ by Cumberland Therapeutics Inc.; ceftaroline, marketed as Teflaro by Allergan; lefamulin marketed as Xenleta by Nabriva Therapeutics and generic trimethoprim/sulfamethoxazole and clindamycin.

Further, we expect that product candidates currently in review with the FDA, in Phase 3 clinical development, or that could enter Phase 3 clinical development in the near future, may represent significant competition if approved. These include, but are not limited to, CG-400549, under development by Crystal Genomics; GSK2140944, under development by GSK; nemonoxacin, under development by TaiGen Biotechnology; brilacidin, under development by Cellceutix; and radezolid, under development by Melinta Therapeutics Inc.

NUZYRA also competes with other antibiotics in the community-acquired pneumonia market. These include azithromycin, marketed as Zithromax and Z-PAK by Pfizer Inc. and available as a generic; clarithromycin, marketed as Biaxin by Abbott Laboratories and available as a generic; moxifloxacin, marketed as Avelox by Bayer AG and available as a generic; levofloxacin, marketed as Levaquin by Johnson & Johnson and available as a generic; tigecycline, marketed as Tygacil by Pfizer Inc. and available as a generic; linezolid, marketed as Zyvox by Pfizer Inc. and available as a generic; ceftriaxone, marketed as Rocephin by F. Hoffman-La Roche Ltd and available as a generic; and ceftaroline, marketed as Teflaro by Allergan, delafloxacin marketed as Baxdela by Melinta Therapeutics Inc; lefamulin marketed as Xenleta by Nabriva Therapeutics. We are also aware of various drugs that are or may eventually be under development for the treatment of CABP, radezolid, under development by Melinta Therapeutics; GSK2140944, under development by GSK and nemanoxacin, under development by TaiGen Biotechnology.

Many of our potential competitors have substantially greater financial, technical and human resources than we do, as well as greater experience in marketing products, discovering and developing product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Our competitors' drugs may be more effective, or more effectively marketed and sold, than our products or any other product candidate we may commercialize and may render our products or product candidates obsolete or non-competitive before we can recover the expenses of our development and commercialization. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Finally, the development of new treatment methods for the diseases we are targeting could render our products or product candidates non-competitive or obsolete.

Manufacturing

We do not own or operate current Good Manufacturing Practices, or cGMP, manufacturing facilities for the production of any of our products, nor do we have plans to develop our own manufacturing facilities in the foreseeable future. Our products are manufactured in synthetic processes from starting materials that have to date been generally available.

The manufacturing process of omadacycline tosylate has been validated at commercial scale. The active pharmaceutical ingredient manufacturing process is a three-step synthesis followed by purification and salt formation. The starting material is minocycline, which is well characterized and readily available. In 2018, we completed three process validation batches each for the IV and oral formulations of omadacycline, which have subsequently been put on stability. We have entered into commercial supply agreements with commercial manufacturing organizations as described below, to manufacture and supply the drug substance, drug product and finished packaged product.

CIPAN

In November 2016, we entered into a manufacturing and services agreement with CIPAN – Companhia Industrial Produtora de Antibióticos, or CIPAN. The agreement, as subsequently amended, provides the terms and conditions under which CIPAN will manufacture and supply to us increased quantities of minocycline starting material and crude omadacycline, or the CIPAN Products, for purification into omadacycline and, subsequently, for use in our products that contain omadacycline tosylate as the active pharmaceutical ingredient. Under this agreement, we are obligated to pay a CIPAN Product price in the four-digit U.S. dollar range per kilogram for minocycline starting material and in the four-digit or five-digit U.S. dollar range per kilogram for crude omadacycline, based on the annual volume of crude omadacycline that we order, subject to adjustments as set forth in the agreement. CIPAN will also perform certain services related to development, technology transfer and manufacturing of the CIPAN Products as provided in one or more statements of work, which shall set forth the fees payable by us to CIPAN for such services.

Our agreement with CIPAN will remain in effect for a fixed initial term, after which the agreement will continue, with respect to each CIPAN Product, for successive renewal terms unless either we or CIPAN have given written notice of termination within a certain period prior to the expiration of either the initial or then-current renewal term. The agreement may also be terminated under certain other circumstances, including by either party due to a material uncured breach by the other party or the other party's insolvency.

Carbogen

In December 2016, we entered into a manufacturing and services agreement with CARBOGEN AMCIS AG, or Carbogen. The agreement, as subsequently amended, provides for the terms and conditions under which Carbogen will manufacture and supply to us the active pharmaceutical ingredient for our omadacycline drug products in bulk quantities, or the Carbogen Product. Under this agreement, we are responsible for the cost and supply of crude omadacycline that Carbogen requires to manufacture the Carbogen Products and perform related services. We are obligated to pay Carbogen an amount in the seven-digit U.S. dollar range per batch of Carbogen Product that we order, depending on the size of the campaign, and the price may be adjusted in accordance with the terms of the agreement. We may also request that Carbogen perform certain services related to the Carbogen Product, for which we will pay reasonable compensation to Carbogen.

Our agreement with Carbogen will remain in effect for a fixed initial term and subsequent renewal terms. Both parties, however, are required to use diligent efforts to replace the existing agreement with a subsequent long-term agreement. We may terminate this agreement by delivering notice of termination to Carbogen. The agreement may also be terminated under certain other circumstances, including by either party due to a material uncured breach by the other party or the other party's insolvency.

Almac

In December 2016, we entered into a manufacturing and services agreement with Almac Pharma Services Limited, or Almac. The manufacturing agreement provides for the terms and conditions under which Almac will manufacture, package and supply to us omadacycline oral solid dosage tablets in bulk form, or the Almac Products. Under this manufacturing agreement, we are required to use commercially reasonable efforts to timely provide Almac with the active pharmaceutical ingredient needed to manufacture the Almac Products and perform related services. We are obligated to pay a supply price in the five-digit range in Great Britain Pounds, or GBP, per batch of the Almac Products, subject to adjustments as provided in the manufacturing agreement. Beginning in February 2020, we are also subject to an annual minimum revenue commitment in the six-digit GBP range. We will also negotiate with Almac, as part of each individual scope of work, the reasonable costs for the services to be performed for us by Almac.

In July 2019, we entered into a separate packaging and supply agreement with Almac to expand the packaging services performed by Almac. This packaging agreement provides for the terms and conditions under which Almac will deliver primary packaging, labelling, storage and related services for the Almac Products and secondary packaging, labelling, storage and related services for injectable omadacycline in vials, which are manufactured and supplied by a third party to Almac. Under this packaging agreement, we are required to provide certain intermediate materials necessary for Almac to perform these packaging services. We are obligated to pay a supply price in the five to six-digit U.S. dollar range per batch of packaged products, subject to adjustments as provided in the packaging agreement. We will also negotiate with Almac the reasonable costs for any additional services to be performed for us by Almac as set forth in individual scopes of work; such services are governed by the packaging agreement.

Each of our agreements with Almac will remain in effect for a fixed initial term, after which each agreement will continue for successive renewal terms unless either us or Almac have given written notice of termination within a certain period prior to the expiration of the initial or then-current renewal term. The manufacturing agreement or packaging agreement may also be terminated under certain other circumstances, including by either party due to a material uncured breach of the other party or the other party's insolvency.

Patheon

In July 2017, we entered into a master manufacturing services agreement and corresponding product agreement with Patheon UK Limited, or Patheon. The product agreement was amended in January 2019 to reflect exchange rate and pricing updates. The agreements provide for the terms and conditions under which Patheon will manufacture, package and supply to us, omadacycline in injectable form, or the Patheon Products. Under these agreements, we are required to deliver to Patheon the active pharmaceutical ingredient needed to manufacture the Patheon Products. We are obligated to pay a supply price in the six-digit dollar range per batch of the Patheon Products, subject to adjustments as provided in the agreements. Now that our omadacycline product has been approved, we are also subject to an annual minimum purchase requirement in the six-digit U.S. dollar range. If we desire for Patheon to conduct additional services other than those expressly set forth in the agreements, those would be subject to additional fees.

Our agreements with Patheon will remain in effect for a fixed initial term, after which they will continue for successive renewal terms unless either we or Patheon have given written notice of termination within a certain period prior to the expiration of the applicable initial or then-current renewal term. The agreements may also be terminated under certain other circumstances, including by either party due to a material uncured breach of the other party or the other party's insolvency.

Research and Development

We have and will continue to make substantial investments in research and development. Our research and development expenses totaled $39.6 million and $57.5 million in 2019 and 2018, respectively.

In the ordinary course of business, we enter into agreements with third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories, to conduct our clinical studies and aspects of our research and preclinical testing. These third parties provide project management and monitoring services and regulatory consulting and investigative services.

Intellectual Property

The proprietary nature of, and protection for, our proprietary drug development platform, our product candidates and our discovery programs, processes and know-how are important to our business. We seek patent protection in the U.S. and internationally for areas such as composition of matter and the chemistries that allow for the synthesis of novel, substituted tetracycline compounds that exhibit significant antibacterial and/or anti-inflammatory activity, and any other technology to which we have rights, where available and when appropriate. Our policy is to pursue, maintain and defend patent rights, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets that may be important to the development of our business.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our proprietary technologies and compounds, our current product and future product candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to prevent third parties from making, using, selling, offering to sell or importing our products and technology depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology.

As of December 31, 2019, our patent portfolio of owned or exclusively licensed patents and applications includes 66 issued U.S. patents, 20 pending U.S. patent applications and corresponding foreign national or regional counterpart patents or applications. We expect that the patents and patent applications in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other government fees are paid, would expire between 2020 and 2039, excluding any additional terms from patent term adjustments or patent term extensions under the Hatch-Waxman Amendments.

NUZYRA (omadacycline)

The patent portfolio for omadacycline is directed to cover compositions of matter, formulations, salts and polymorphs, manufacturing methods, methods of use, dosing regimens, and modes of administration. The patents and patent applications covering omadacycline include patents and patent applications owned by us. In some corresponding foreign patents and patent applications, omadacycline is covered along with other compounds in patents and patent applications that are owned jointly by us and Tufts University, or Tufts, that are subject to a license agreement we have with Tufts. The issued composition of matter patent in the U.S. (U.S. Patent No. 7,553,828), if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, was expected to expire in 2023, however, we believe that additional term for certain omadacycline patents may result from the patent term extension provision of the Hatch-Waxman Amendments of 1984, including the composition of matter patent which is anticipated to be extended until May 2028 and a method of use patent (U.S. 9,265,740) is expected to be extended until October 2030. Filings for both patent term extensions have been made with the U.S. Patent & Trademark Office. Omadacycline has received Qualified Infectious Disease Product, or QIDP, designation under the Generating Antibiotic Incentives Now Act, or the GAIN Act. This may provide up to an additional five years of market exclusivity layered with protection provided by the Hatch-Waxman Amendments, which GAIN also enables exclusivity to 2028. We expect that the other patents and patent applications in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, would expire between 2021 and 2039, excluding any additional terms from patent term adjustments or patent term extensions under the Hatch-Waxman Amendments.

SEYSARA (sarecycline)

The patent portfolio for our acne and rosacea program is directed to cover compositions of matter, methods of use, methods of manufacturing, as well as salts and polymorphs of sarecycline. Amongst other patent filings and granted patents, our patent portfolio includes issued U.S. Patent No. 8,318,706, or the ‘706 Patent, which covers composition of matter of sarecycline and issued U.S. Patent No. 8,513,223, or the ‘223 Patent, which covers methods of use for sarecycline, and corresponding foreign national or regional counterpart applications. The ‘706 Patent is expected to expire in 2032 (this expiry taking into account the expected patent term extension as provided by the Hatch-Waxman Amendments) and the ‘223 Patent is expected to expire in 2029, if the appropriate maintenance, renewal, annuity or other governmental fees are paid. Filing for the patent term extension has been made with the U.S. Patent & Trademark Office. In February 2020, we finalized a license agreement with Almirall granting us exclusive rights to certain technology owned or in-licensed by Almirall or its affiliates that is necessary or useful to develop or commercialize sarecycline outside of the U.S., including exclusive rights in joint intellectual property and certain Almirall solely-owned intellectual property.

Intermezzo

As of December 31, 2019, our patent portfolio of owned or exclusively licensed patents and applications includes four issued U.S. patents directed to formulations and methods of use. The issued U.S. patents expire between 2025 and 2029.

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Trademarks

We have registered trademarks and service marks or pending trademark and services mark applications in a number of countries for PARATEK, PARATEK & HEXAGON DESIGN, NUZYRA and its design logo, and other marks which we presently use or may use in connection with our pharmaceutical research and development as well as with our product candidates. SEYSARA is a trademark for which Almirall has registered in the U.S. and for which Paratek has applied for in a number of foreign countries. Paratek has registered SEYSARA in China and, as part of the China License (as defined below) may assign such registration to Almirall in connection with Almirall's development and commercialization of sarecycline in the greater China region. In connection with the ongoing development and advancement of our products and services in the U.S. and in various international jurisdictions, we routinely seek to create protection for our marks and enhance their value by pursuing trademarks and service marks where available and when appropriate.

Collaborations and License Agreements

Our commercial strategy is to partner with established pharmaceutical companies to develop and market products for the larger community markets, while retaining certain rights to products aimed at concentrated markets, such as hospital-based products, where we may seek to participate in development and commercialization.

Biomedical Advanced Research and Development Authority

On December 18, 2019, we entered into a contract with BARDA, a division of the U.S Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, to support the development of NUZYRA for the treatment of pulmonary anthrax, FDA PMR associated with the initial NUZYRA approval, and with an option for BARDA to procure up to 10,000 treatment courses of NUZYRA for the SNS for use against potential biothreats.

The BARDA contract could result in payments to us of up to approximately $284.7 million and consists of a five-year base period-of-performance and a total contract period-of-performance (base period plus option exercises) of up to ten years. Under the base period-of-performance, we will conduct activities necessary to (i) allow the product to be used under an Emergency Use Authorization, (ii) obtain licensure of NUZYRA through a supplemental NDA submission for anthrax, and (iii) provide up to 2,500 treatment courses of the drug product to be stored as vendor managed inventory and subsequently delivered to the SNS. The contract options may be exercised to perform additional studies necessary for licensure, support post-licensure commitments as required by the FDA, additional security requirements, and procure additional treatment regimens.

Under the terms of the agreement, BARDA awarded initial funding of approximately $59.4 million for the development of NUZYRA for the treatment of pulmonary anthrax and the purchase of an initial 2,500 treatment courses of NUZYRA to add to the current SNS. The contract provides for potential additional staged funding including approximately $76.8 million for existing FDA PMR commitments scheduled to begin in April 2020 and approximately $20.4 million for manufacturing-related requirements scheduled to begin in June 2020. The remaining funding includes the potential for approximately $12.7 million to support the development of NUZYRA for the prophylaxis of anthrax and a maximum of approximately $115.4 million to provide for three additional purchases of NUZYRA, each of which will be triggered upon development milestones related to the anthrax treatment development program.

The BARDA contract contains a number of terms and conditions that are customary for government contracts of this nature, including provisions giving the government the right to terminate the contract at any time for its convenience.

Tetraphase Pharmaceuticals, Inc.

On March 18, 2019, Paratek and Tetraphase Pharmaceuticals, Inc., or Tetraphase, entered into a License Agreement, or the Tetraphase License Agreement. Under the terms of the Tetraphase License Agreement, we granted to Tetraphase a non-exclusive, worldwide, royalty-bearing license, with the right to grant sublicenses, under certain Paratek patents, to develop, make, have, use, import, offer for sale and sell the licensed product, or XERAVA™, which is a drug for the treatment of complicated, intra-abdominal infections caused by bacteria, which was approved by the FDA in August 2018.

The terms of the Tetraphase License Agreement provide for Tetraphase to pay royalties at a low single digit percent on net product revenues of the licensed product sold in the U.S. Tetraphase's obligation to pay royalties with respect to the licensed product shall be retroactive to the date of the first commercial sale of the licensed product in the U.S., which occurred in February 2019. Tetraphase is currently selling XERAVA™ (Eravacycline) in the U.S.

The Tetraphase License Agreement will continue until the expiration of and payment by Tetraphase of all Tetraphase's payment obligations, which is when there are no longer any valid claims of the licensed Paratek patents that would be infringed, in the absence of a license, by a manufacture, use, or sales of the licensed product. The principal licensed patent under the Tetraphase License Agreement is expected to expire in October 2023.

Zai Lab (Shanghai) Co., Ltd.

On April 21, 2017, Paratek Bermuda Ltd., a wholly owned subsidiary of Paratek Pharmaceuticals, Inc., and Zai entered into a License and Collaboration Agreement, or the Zai Collaboration Agreement. On December 18, 2019 Paratek Bermuda Ltd. assigned its rights under the Zai Collaboration Agreement to Paratek Pharmaceuticals, Inc. Under the terms of the Zai Collaboration Agreement, Paratek granted Zai an exclusive license to develop, manufacture and commercialize omadacycline, or the licensed product, in the People's Republic of China, Hong Kong, Macau and Taiwan, or the Zai territory, for all human therapeutic and preventative uses other than biodefense. Zai will be responsible for the development, manufacturing and commercialization of the licensed product in the Zai territory, at its sole cost with certain assistance from Paratek.

Under the terms of the Zai Collaboration Agreement, Paratek earned an upfront cash payment of $7.5 million in April 2017, $5.0 million upon approval by the FDA of a New Drug Application, or NDA, submission in the CABP indication, in October 2018 and $3.0 million upon submission of the first regulatory approval application for a licensed product in the People's Republic of China in December 2019. Paratek is eligible to receive up to $6.0 million in potential future regulatory milestone payments and $40.5 million in potential future commercial milestone payments, the next being $6.0 million upon regulatory approval for a licensed product in the People's Republic of China. The terms of the Zai Collaboration Agreement also provide for Zai to pay Paratek tiered royalties at a low double digit to mid-teen percent on net sales of the licensed product in the Zai territory.

The Zai Collaboration Agreement will continue, on a region-by-region basis, until the expiration of and payment by Zai of all Zai's payment obligations, which is until the later of: (i) the abandonment, expiry or final determination of invalidity of the last valid claim within the Paratek patents that covers the licensed product in the region in the Zai territory in the manner that Zai or its affiliates or sublicensees exploit the licensed product or intend for the licensed product to be exploited; or (ii) the eleventh anniversary of the first commercial sale of such licensed product in such region.

Almirall, LLC

In July 2007, we and Warner Chilcott Company, Inc. (which became a part of Allergan), entered into a collaborative research and license agreement, under which we granted Allergan an exclusive license to research, develop, manufacture and commercialize tetracycline products for use in the U.S. for the treatment of acne and rosacea. In September 2018, Allergan assigned to Almirall, its rights under the collaboration agreement, or the Almirall Collaboration Agreement. Since Allergan did not exercise its development option with respect to the treatment of rosacea prior to initiation of a Phase 3 trial for the product, the license grant to Allergan, which was assigned to Almirall, converted to a non-exclusive license for the treatment of rosacea as of December 2014. Under the terms of the Almirall Collaboration Agreement, we and Almirall are responsible for, and are obligated to use, commercially reasonable efforts to conduct specified development activities for the treatment of acne and, if requested by Almirall, we may conduct certain additional development activities to the extent we determine in good faith that we have the necessary resources available for such activities.

Under the terms of the Almirall Collaboration Agreement, Almirall is responsible for and is obligated to use commercially reasonable efforts to develop and commercialize tetracycline compounds that are specified in the agreement for the treatment of acne. We have agreed during the term of the Almirall Collaboration Agreement not to directly or indirectly develop or commercialize any tetracycline compounds in the U.S. for the treatment of acne, and Almirall has agreed during the term of the Almirall Collaboration Agreement not to directly or indirectly develop or commercialize any tetracycline compound included as part of the agreement for any use other than as provided in the Almirall Collaboration Agreement.

The Almirall Collaboration Agreement contains two performance obligations: (i) an exclusive license to research, develop and commercialize tetracycline products for use in the U.S. for the treatment of acne and rosacea and (ii) research and development services. The performance obligation to deliver the license was satisfied upon execution of the Almirall Collaboration Agreement in July 2007. All research and development services were completed by December 2010. The options provided to Almirall for additional development services do not provide Almirall with a material right as these services will not be provided at a significant or incremental discount. As such, the option services are not performance obligations.

We received an upfront fee in the amount of $4.0 million upon the execution of the Almirall Collaboration Agreement, $1.0 million upon filing of an Investigational NDA in 2010, $2.5 million upon initiation of Phase 2 trials in 2012 and $4.0 million upon initiation of Phase 3 trials associated with the Almirall Collaboration Agreement in December 2014.

In December 2017, the FDA's acceptance of the NDA for sarecycline was received, triggering a milestone payment of $5.0 million earned upon acceptance of an NDA for a product licensed under the Almirall Collaboration Agreement. As the performance obligation to deliver the license was satisfied in 2007 and research and development services completed by December 2010, all subsequent milestone payments are recognized as revenue when the risk of significant reversal is resolved, generally when the milestone event occurs. Therefore, the $5.0 million milestone payment was recognized in December 2017 and subsequently collected in the first quarter of 2018.

In October 2018, the FDA's regulatory approval of sarecycline, under the tradename SEYSARA, triggered the last milestone payment under the Almirall Collaboration Agreement of $12.0 million. Since FDA approval of SEYSARA was outside of the Company's control and not obtained until October 2, 2018, the achievement of the milestone was not deemed probable and the risk of significant reversal of revenue was not resolved until such time. Upon the FDA approval, the uncertainty related to this milestone was resolved and a significant reversal of revenue would not occur in future periods. As such, the $12.0 million milestone payment was recognized as revenue at the time of FDA approval. Almirall is also obligated to pay us tiered royalties, ranging from the mid-single digits to the low double digits, based on net sales of tetracycline compounds developed under the Almirall Collaboration Agreement, with a standard royalty reduction post patent expiration for such product for the remainder of the royalty term. Almirall's obligation to pay us royalties for each tetracycline compound it commercializes under the Almirall Collaboration Agreement expires on the later of the expiration of the last to expire patent that covers the tetracycline compound in the U.S. and the date on which generic drugs that compete with the tetracycline compound reach a certain threshold market share in the U.S.

Either we or Almirall may terminate the Almirall Collaboration Agreement for certain specified reasons at any time after Almirall has commenced development of any tetracycline compound, including if Almirall determines that it would not be commercially viable to continue to develop or commercialize the tetracycline compound and/or that it is unlikely to obtain regulatory approval of the tetracycline compound, and, in any case, no backup tetracycline compound is in development or ready to be developed and the parties are unable to agree on an extension of the development program or an alternative course of action. Either we or Almirall may terminate the Almirall Collaboration Agreement for the other party's uncured breach of a material term of the agreement on 60 days' notice (unless the breach relates to a payment term, which requires a 30-day notice) or upon the bankruptcy of the other party that is not discharged within 60 days. Upon the termination of the Almirall Collaboration Agreement by Almirall for our breach, Almirall's license will continue following the effective date of termination, subject to the payment by Almirall of the applicable milestone and royalty payments specified in the agreement unless our breach was with respect to certain specified obligations, in which event the obligation of Almirall to pay us any further royalty or milestone payments will terminate. Upon the termination of the Almirall Collaboration Agreement by us for Almirall's breach or the voluntary termination of the agreement by Almirall, Almirall's license under the agreement will terminate.

In February 2020, we entered into (i) the Ex-U.S. License, under which Almirall, or the Ex-U.S. License, granted to us an exclusive license in and to certain technology owned or in-licensed by Almirall or its affiliates in order to research, develop, manufacture and commercialize sarecycline in all countries other than the U.S. and (ii) a license agreement with Almirall that is specific to the greater China region, or the China License, under which we granted to Almirall an exclusive license in and to certain technology owned or in-licensed by us or our affiliates in order to research, develop and commercialize sarecycline for the treatment of acne in the greater China region.

Under the terms of the Ex-U.S. License, at our request, and subject to certain limitations, Almirall will provide us, our affiliates and our sublicensees with reasonable assistance in connection with our efforts to (i) source commercial supplies of sarecycline products, (ii) implement the then-current process for manufacturing sarecycline products at our facilities or at the facilities of our contract manufacturers, including any updates to such manufacturing process, and (iii) qualify commercial suppliers of sarecycline products.

Under the terms of the China License, Almirall is responsible for and is obligated to use commercially reasonable efforts to develop and commercialize sarecycline for the treatment of acne and has certain time-based diligence requirements.

We and Almirall have each agreed during the term of the Ex-U.S. License and the term of the China License to use commercially reasonable efforts to not, directly or indirectly, make sarecycline products commercialized by us, our respective affiliates or our respective sublicensees available for resale in the other's respective territory or territories.

No upfront fees or milestones are owed in connection with either the Ex-U.S. License or the China License.

In connection with the Ex-U.S. License, we pay Almirall, on a country-by-country and product-by-product basis, (i) for fifteen years following the first commercial sale of a sarecycline product in a country, a percentage of the consideration (e.g., milestones, royalties) we receive from third party sublicensees in connection with developing and commercializing sarecycline outside of the U.S., which ranges from one-half of such consideration for sarecycline products for the treatment of acne to one-fifth of such consideration for sarecycline products for the treatment of other indications, in each case subject to a 50% reduction for any sarecycline product not in a solid oral tablet formulation for which Paratek or its affiliates have incurred significant development costs and (ii) for eight years following the first commercial sale of a sarecycline product in a country, a royalty in the middle-single digits on our or our affiliates' net sales of sarecycline products outside of the U.S., subject to certain standard reductions. In connection with the China License, for fifteen years following the first commercial sale of a sarecycline product in China, Almirall pays us a royalty in the high-single digits on their, their affiliates' or their sublicensees' net sales of sarecycline products in the greater China region, subject to certain standard reductions.

Both the Ex-U.S. License and the China License terminate upon full satisfaction and expiration of a party's payment obligations under the relevant agreement. We may terminate the Ex-U.S. License for convenience upon sixty days' notice. Almirall may terminate the China License for convenience upon sixty days' notice. Either we or Almirall may terminate the Ex-U.S. License or the China License for the other party's uncured breach of a material term of the agreement on sixty days' notice (unless the breach relates to a payment term, which requires thirty days' notice) or upon the bankruptcy of the other party that is not discharged within sixty days. Upon the termination of the Ex-U.S. License by us for Almirall's breach or insolvency, our license will continue following the effective date of termination, subject to the payment by us of the applicable royalty payments specified in the Ex-U.S. License (unless Almirall's breach relates to a certain specific obligation, in which case, our license survives royalty-free). Upon the termination of the Ex-U.S. License by Almirall for our breach or insolvency or upon our voluntary termination of the Ex-U.S. License, our license under the Ex-U.S. License will terminate. Upon the termination of the China License by Almirall for our breach or insolvency, Almirall's license will continue following the effective date of termination, subject to the payment by Almirall of the applicable royalty payments specified in the China License (unless our breach relates to a certain specific obligation, in which case, Almirall's license survives royalty-free). Upon the termination of the China License by us for Almirall's breach or insolvency or upon Almirall's voluntary termination of the China License, Almirall's license under the China License will terminate.

Tufts University

In February 1997, we and Tufts entered into a license agreement under which we acquired an exclusive license to certain patent applications and other intellectual property of Tufts related to the drug resistance field to develop and commercialize products for the treatment or prevention of bacterial or microbial diseases or medical conditions in humans or animals or for agriculture. We subsequently entered into eleven amendments to that agreement, or collectively the Tufts License Agreement, to include patent applications filed after the effective date of the original license agreement, to exclusively license additional technology from Tufts, to expand the field of the agreement to include disinfectant applications, and to change the royalty rate and percentage of sublicense income paid by us to Tufts under sublicense agreements with specified sublicensees. We are obligated under the Tufts License Agreement to provide Tufts with annual diligence reports and a business plan and to meet certain other diligence milestones. We have the right to grant sublicenses of the licensed rights to third parties, which will be subject to the prior approval of Tufts unless the proposed sublicensee meets a certain net worth or market capitalization threshold. We are primarily responsible for the preparation, filing, prosecution and maintenance of all patent applications and patents covering the intellectual property licensed under the Tufts License Agreement at our sole expense. We have the first right, but not the obligation, to enforce the licensed intellectual property against infringement by third parties.

We issued Tufts 1,024 shares of our common stock on the date of execution of the original license agreement, and we may be required to make certain payments of up to $0.3 million to Tufts upon the achievement by products developed under the agreement of specified development and regulatory approval milestones. We have already made a payment of $50,000 to Tufts for achieving the first milestone following commencement of the Phase 3 clinical trial for omadacycline and a payment of $100,000 to Tufts for achieving the second milestone following our first marketing application (NDA) submitted in the U.S. We are also obligated to pay Tufts a minimum royalty payment in the amount of $25,000 per year. In addition, we are obligated to pay Tufts royalties based on gross sales of products, as defined in the agreement, ranging in the low single digits depending on the applicable field of use for such product sale. If we enter into a sublicense under the Tufts License Agreement, based on the applicable field of use for such product, we will be obligated to pay Tufts (i) a percentage, ranging from 10% to 14% (ten percent to fourteen percent) for compounds other than omadacycline, and a percentage in the single digits for the compound omadacycline, of that portion of any sublicense issue fees or maintenance fees received by us that are reasonably attributable to the sublicense of the rights granted to us under the Tufts License Agreement and (ii) the lesser of (a) a percentage, ranging from the low tens to the high twenties based on the applicable field of use for such product, of the royalty payments made to us by the sublicensee or (b) the amount of royalty payments that would have been paid by us to Tufts if we had sold the products.

Unless terminated earlier, the Tufts License Agreement will expire at the same time as the last-to-expire patent in the patent rights licensed to us under the agreement and after any such expiration we will continue to have an exclusive, fully-paid-up license to such intellectual property licensed from Tufts. Tufts has the right to terminate the agreement upon 30 days' notice should we fail to make a material payment under the Tufts License Agreement or commit a material breach of the agreement and not cure such failure or breach within such 30-day period, or if, after we have started to commercialize a product under the Tufts License Agreement, we cease to carry on its business for a period of 90 consecutive days. We have the right to terminate the Tufts License Agreement at any time upon 180 days' notice. Tufts has the right to convert our exclusive license to a non-exclusive license if we do not commercialize a product licensed under the agreement within a specified time period.

U.S. Army Medical Research Institute of Infectious Diseases

In October 2016, we announced that we entered into a Cooperative Research and Development Agreement with the U.S. Army Medical Research Institute of Infectious Diseases to study omadacycline against pathogenic agents causing infectious diseases of public health and biodefense importance. These studies were designed to confirm humanized dosing regimens of omadacycline in order to study the efficacy of omadacycline against biodefense pathogens, including Yersinia pestis, or plague, and Bacillus anthracis, or anthrax. The Cooperative Research and Development agreement expired on February 24, 2020. All future biothreat work will be completed under the BARDA contract.

Past Collaborations

Novartis International Pharmaceutical Ltd.

In September 2009, we and Novartis International Pharmaceutical Ltd., or Novartis, entered into a Collaborative Development, Manufacture and Commercialization License Agreement, or the Novartis Agreement, which provided Novartis with a global, exclusive patent and technology license for the development, manufacturing and marketing of omadacycline. The Novartis Agreement was terminated by Novartis without cause in June 2011 and the termination was effective 60 days later. We and Novartis subsequently entered into a letter agreement in January 2012, or the Novartis Letter Agreement, as amended, pursuant to which we reconciled shared development costs and expenses and granted Novartis a right of first negotiation with respect to commercialization rights of omadacycline following approval of omadacycline from the FDA, EMA, or any regulatory agency, but only to the extent we had not previously granted such commercialization rights related to omadacycline to another third party as of any such approval. We also agreed to pay Novartis a 0.25% royalty, to be paid from net sales received by us in any country following the launch of omadacycline in that country and continuing until the later of expiration of the last active valid patent claim covering such product in the country of sale and 10 years from the date of first commercial sale in such country. The amended Novartis Letter Agreement resulted in a long-term liability in the amount of $3.4 million as of December 31, 2019 and $3.6 million as of December 31, 2018 included within "Other Long-Term Liabilities" on our consolidated balance sheet. In addition, a short-term liability of $0.1 million included within "Other current liabilities" on our consolidated balance sheet as of December 31, 2019 represents the portion of royalty payments due to Novartis within twelve months. No short-term portion existed as of December 31, 2018. There are no other payment obligations to Novartis under the Novartis Agreement or the amended Novartis Letter Agreement.

Purdue Pharma L.P.

In July 2009, we and Purdue Pharma L.P., or Purdue Pharma, entered into a collaboration agreement, or the Purdue Collaboration Agreement, which granted an exclusive license to Purdue Pharma to commercialize Intermezzo in the U.S. in exchange for a non-refundable license fee, certain milestone payments and tiered royalties on net sales of Intermezzo.

In December 2013, Purdue Pharma notified us that it intended to discontinue use of the Purdue Pharma sales force to actively market Intermezzo to healthcare professionals during the first quarter of 2014.

In October 2014, we announced that our Board of Directors had approved a special dividend of, among other things, the right to receive, on a pro rata basis, 100% of any royalty income received by us pursuant to the Purdue Collaboration Agreement and 90% of any cash proceeds from a sale or disposition of Intermezzo, less fees and expenses incurred in connection with such activity, to the extent that either occurred prior to the second anniversary of the closing date of the Merger. On October 28, 2016, in satisfaction of our payment obligation of the proceeds of sale or disposition of the Intermezzo assets to the former Transcept stockholders under the Merger Agreement, we executed a royalty sharing agreement, or the Royalty Sharing Agreement, with the Special Committee of the Company's Board of Directors, or the Special Committee, a committee established in connection with the Merger. Under the Royalty Sharing Agreement, we agreed to pay to the former Transcept stockholders 50% of all royalty income received by us pursuant to the Purdue Collaboration Agreement, net of all costs, fees and expenses incurred by us in connection with the Purdue Collaboration Agreement, related agreements, the Intermezzo product and the administration of the royalty income to the Transcept stockholders. The NDA for Intermezzo was then withdrawn from the FDA by Purdue Pharma as of December 31, 2018 and further sales of the drug are not planned. Neither us nor the former shareholders of Transcept will receive future cash payments pursuant to the Royalty Sharing Agreement. As such, we wrote off the remaining balance of the Intermezzo product rights during the fourth quarter of 2018.

Government Regulation

Government authorities in the U.S., at the federal, state and local level, as well as those of other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, packaging, advertising, promotion, storage, distribution, and export and import of our products. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulation require the expenditure of substantial time and financial resources.

U.S. Government Regulation

NDA Approval Processes

In the U.S., the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, or the FDCA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulation require the expenditure of substantial time and financial resources. Failure to comply with the FDCA and other applicable U.S. requirements at any time during the product development process, approval process or after approval may subject us to a variety of administrative or judicial sanctions, any of which could have a material adverse effect on us. These sanctions could include:

- refusal to approve pending applications;
- withdrawal of an approval;
- imposition of a clinical hold;
- warning letters, untitled letters and similar communications;
- product seizures or recalls;
- total or partial suspension of production or distribution; or
- injunctions, fines, restitution, disgorgement of profits or civil or criminal investigations and penalties brought by the FDA and the Department of Justice, or DOJ, or other governmental entities.

The process required by the FDA before a drug may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practices or other applicable regulations;
- submission to the FDA of an Investigational New Drug, or IND, application, which must become effective 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 to establish the safety and efficacy of the proposed drug for its intended use, conducted in accordance with current Good Clinical Practices, or cGCP, which are ethical and scientific quality standards and FDA requirements for conducting, recording and reporting clinical trials to assure that the rights, safety and well-being of trial participants are protected;
- preparation and submission to the FDA of an NDA;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug's safety, identity, strength, quality and purity; and
- FDA review and approval of the NDA.

Once a pharmaceutical candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. Some preclinical or nonclinical testing may continue even after the IND is submitted. In addition to including the results of the preclinical studies, the IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase lends itself to an efficacy determination. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the IND on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. A clinical hold may occur at any time during the life of an IND and may affect one or more specific studies or all studies conducted under the IND.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with cGCP. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol and any amendments must be submitted to the FDA as part of the IND, and progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently in other situations, including the occurrence of serious adverse events. An IRB at each institution participating in the clinical trial must review and approve the protocol and any amendments before a clinical trial commences or continues at that institution, approve the information regarding the clinical trial and the informed consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations. Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and elimination. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be inherently too toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the target disease or condition.
- *Phase 2.* Clinical trials are initiated in a limited patient population intended 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.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide an adequate basis for regulatory approval and product labeling.

Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time for a variety of reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution 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.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points, including prior to submission of an IND, at the end of Phase 2 and before an NDA is submitted. Meetings at other times may also be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the End-of-Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial or trials that they believe will support approval of the new drug. If this type of discussion occurred, a sponsor may be able to request a special protocol assessment, or SPA, agreement, a voluntary process the purpose of which is to reach agreement with the FDA on the design of a Phase 3 clinical trial protocol and analysis that will form the primary basis of an efficacy claim.

According to FDA guidance for industry on the SPA agreement process, a sponsor that meets the prerequisites may make a specific request for a SPA and must provide information necessary for discussion and agreement on the design and size of the proposed clinical trial. The FDA has a goal of evaluating the protocol within 45 days of the request to assess whether the proposed trial is adequate, and that evaluation may result in discussions and/or requests for additional information. A SPA agreement request must be made before the proposed clinical trial begins. If an agreement is reached, it will be documented in writing and made part of the record. The agreement may not be changed by the sponsor or the FDA after the trial begins, except with the written agreement of the sponsor and the FDA or if the FDA determines that a substantial scientific issue essential to determining the safety or efficacy of the drug was identified after the testing began. Also, if the sponsor makes any unilateral changes to the approved protocol, the agreement will be invalidated. A SPA agreement is intended to provide greater assurance that if the agreed upon clinical trial protocols are followed, the clinical trial endpoints are achieved, and there is a favorable risk-benefit profile, the data may serve as the primary basis for an efficacy claim in support of NDA approval. However, SPA agreements are not a guarantee of an approval of a product candidate or any permissible claims about the product candidate, and final determinations of approvability will not be made until the FDA completes its review of the entire NDA.

The Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric studies for certain drugs and biologics. Specifically, PREA requires original NDAs, biologic license applications, or BLAs, and supplements thereto for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to contain a pediatric assessment unless the sponsor has received a deferral or waiver. The FDA has waived the pediatric study requirement for ages 0 to < 8 years because there is nonclinical evidence strongly suggesting that omadacycline would be unsafe in this pediatric group due to the risk of tetracycline-associated tooth discoloration and enamel hypoplasia, and the risk of tetracycline-associated inhibition of bone growth. The FDA has deferred submission of pediatric studies for ages 8 to < 18 (ABSSSI until 2024 and CABP until 2026) years because the product was ready for approval for use in adults.

Concurrent with clinical trials, companies usually complete additional animal safety studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and the manufacturer must develop methods for testing the quality, purity and potency of the final drugs. 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.

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of a NDA requesting approval to market the product for one or more indications. The submission of a NDA is subject to the payment of user fees, but a waiver of such fees may be obtained under specified circumstances. The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may request additional information rather than accept a NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in-depth review. NDAs receive either standard or priority review. A drug representing a significant improvement in the safety or effectiveness of the treatment, prevention or diagnosis of a serious disease or condition may receive priority review. The FDA has agreed to specified performance goals in the review process of NDAs. Under that agreement, 90% of applications seeking approval of New Molecular Entities, or NMEs, are meant to be reviewed within ten months from the date on which FDA accepts the NDA for filing, and 90% of applications for NMEs that have been designated for “priority review” are meant to be reviewed within six months of the filing date. For applications seeking approval of drugs that are not NMEs, the ten-month and six-month review periods run from the date that FDA receives the application. The review process may be extended by the FDA for three additional months to consider a major amendment to the application following the original submission.

The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing complies with cGMP requirements to assure and preserve the product’s safety, identity, strength, quality and purity. The FDA may refer the NDA to an advisory committee for review and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendation.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured and tested. These pre-approval inspections may cover all facilities associated with NDA submission, including drug component manufacturing (such as active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP. In addition, the FDA may require, as a condition of approval, Risk Evaluation and Mitigation Strategies, or REMS, restricted distribution and use, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials, restrictions on direct-to-consumer advertising or commitments to conduct additional research post-approval.

On the basis of the FDA’s evaluation of the NDA and accompanying information, 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. If the FDA ultimately decides that the NDA does not satisfy the criteria for approval, the FDA will issue a complete response letter to indicate that the agency will not approve the NDA in its present form. The complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application.

Expedited Review and Approval

The FDA has various programs, including Fast Track and priority review, which are intended to expedite or simplify the process for reviewing drugs. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. Generally, drugs that may be eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious diseases with the potential, based on nonclinical or clinical data, to fill an unmet medical need. Priority review is designed to give drugs that offer a significant improvement in safety or effectiveness of treatment for a serious condition an expedited review within eight months from the completed submission (six months from filing) as compared to a standard review time of twelve months from the completed submission (10 months from filing) for a standard new molecular entity NDA. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track-designated drug and expedite review of the application for a drug designated for priority review.

The GAIN Act is intended to provide incentives for the development of new QIDPs. A new drug that is designated as a QIDP after a request by the sponsor that is made before an NDA is submitted will be eligible, if approved, for an additional five years of exclusivity beyond any period of exclusivity to which it would have previously been eligible. In addition, a QIDP will receive priority review and qualify for a Fast Track designation. QIDPs are defined as antibacterial or antifungal drugs intended to treat serious or life-threatening infections, including those caused by an antibacterial or antifungal resistant pathogen or qualifying pathogens identified by the FDA. Examples of pathogens that may be designated as a qualifying pathogen include MRSA, vancomycin-resistant *Enterococcus* and multi-drug resistant gram-negative bacteria. Omadacycline (both IV and oral formulations) has been designated as a QIDP for complicated UTI, ABSSSI and CABP.

Beyond GAIN Act

In addition to the GAIN Act, the 21st Century Cures Act, signed into law in December 2016, established a new FDA limited population pathway for antimicrobial drugs that treat serious or life-threatening infections for which there are unmet medical needs. The U.S. Congress has initiated a significant number of other legislative proposals in recent years to provide further incentives in anti-infective development. For example, in December 2018, the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms Act of 2018, or DISARM Act, was introduced in the Senate to incentivize the research and development of advanced antibiotics through certain reimbursement-related incentives. It is possible that these or other proposals related to anti-infective development may be enacted into law in the future. We cannot predict whether or what legislative changes will be enacted or how they may impact our business and our products.

Patent Term Restoration and Data Exclusivity

Depending upon the timing, duration and specifics of FDA approval of the use of our drugs, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years for a single patent for an approved product as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. We have applied for restoration of patent term for NUZYRA and SEYSARA, as detailed in the Intellectual Property Section.

Data exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent data exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an Abbreviated New Drug Application, or ANDA, or a 505(b)(2) NDA submitted by another company using the drug entitled to data exclusivity as the reference listed drug, or RLD. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of data exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the use or conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent for other uses or conditions of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

In addition, as described above, under the GAIN Act a new drug that is designated as a QIDP is eligible for an additional five years of exclusivity to be added to certain other exclusivity periods that the application may qualify for upon approval, specifically five-year exclusivity, three-year exclusivity, and orphan exclusivity.

Pediatric Exclusivity

The Best Pharmaceuticals for Children Act provides for an additional six months of exclusivity, which is added on to patent and exclusivity periods in effect at the time the pediatric exclusivity award is granted, if a sponsor conducts clinical trials in children in response to a written request from the FDA, or a Written Request. The FDA may request studies on approved indications in separate Written Requests. The issuance of a Written Request does not require the sponsor to undertake the described studies. To date, we have not received any Written Requests.

Post-approval Requirements

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, including safety issues, with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. The FDA and other authorities also strictly regulate the promotional claims that may be made about prescription products. Under the FDCA the sponsor of an approved drug in the U.S. may not promote that drug for unapproved, or off-label, uses, although a physician may prescribe a drug for an off-label use in accordance with the practice of medicine. If we are found to have promoted off-label uses, we may be subject to significant liability, including sanctions, civil and criminal fines, and injunctions prohibiting us from engaging in specified promotional conduct.

Moreover, any drug products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things:

- record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
- drug sampling and distribution requirements;
- notifying the FDA and gaining its approval of specified manufacturing or labeling changes;
- complying with certain electronic records and signature requirements; and
- complying with FDA promotion and advertising requirements.

Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with cGMP requirements and other laws.

Failure to comply with the FDCA and other applicable U.S. requirements at any time during the product development process, approval process or after approval may subject us to a variety of administrative or judicial sanctions, any of which could have a material adverse effect on us. These sanctions could include:

- refusal to approve pending applications;
- withdrawal of an approval;
- imposition of a clinical hold;
- warning letters, untitled letters and similar communications;
- product seizures or recalls;
- total or partial suspension of production or distribution; or
- injunctions, fines, restitution, disgorgement of profits or civil or criminal investigations and penalties brought by the FDA and the Department of Justice, or DOJ, or other governmental entities.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Other Healthcare Laws

We may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Within the U.S., we are subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. Although the specific provisions of these laws vary, their scope is generally broad and there may not be regulations, guidance or court decisions that apply the laws to particular industry practices. There is therefore a possibility that our practices might be challenged under such laws. Anti-kickback laws generally prohibit a prescription drug manufacturer from soliciting, offering, receiving, or paying any remuneration to generate business, including the purchase or prescription of a particular drug. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, any claims for payment for reimbursed drugs or services to third party payors (including Medicare and Medicaid) that are false or fraudulent. Violations of "fraud and abuse" laws may be punishable by criminal or civil sanctions, including fines and civil monetary penalties, and/or exclusion from federal health care programs (including Medicare and Medicaid).

Laws and regulations have also been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and health care providers; require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government; and/or require disclosure to the government and/or public of financial interactions (so-called "sunshine laws"). State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures. Manufacturers must also submit information to the FDA on the identity and quantity of drug samples requested and distributed by a manufacturer during each year. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, our activities could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

Federal and state laws also protect the privacy and security of health information specifically or other personally identifiable information generally. The laws may apply to us or to healthcare providers and other third parties with which we interact.

Foreign Regulation

In addition to regulations in the U.S., we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the EU, before we may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under EU regulatory systems, a company may submit marketing authorization applications under the centralized, decentralized or mutual recognition procedures, or under the purely national route of approval. The centralized procedure is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases, and designated orphan medicines, and is optional for other medicines that are highly innovative. Under the centralized procedure, a marketing application is submitted to the EMA, where it will be evaluated by the relevant scientific committee, in most cases the Committee for Medicinal Products for Human Use, and a favorable opinion typically results in the grant by the European Commission of a single marketing authorization that is valid for all EU member states and, by extension (after national implementing measures), in Norway, Iceland and Liechtenstein. In general, an initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period. The decentralized procedure allows marketing authorization applications to be submitted simultaneously in two or more EU member states, whereas the mutual recognition procedure must be used if the product has already been authorized in at least one other EU member state. Both the decentralized and mutual recognition procedures provide for approval by one or more "concerned" member states based on an assessment of an application performed by one-member state, known as the "reference" member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must approve the assessment report and related materials, unless they identify a serious risk to public health. Under the mutual recognition procedure, the concerned member states have the same 90-day period to recognize the marketing authorization in the reference member state. In either case, concerns about serious risks to public health escalate through the relevant EMA scientific committees, and the disputed points may eventually result in a consensus opinion from the Committee for Medicinal Products for Human Use that is referred to the European Commission, whose decision is binding on all member states. The purely national procedure results in a marketing authorization in a single EU member state.

In light of the United Kingdom's vote in 2016 to leave the EU, the so-called Brexit vote, there may be changes forthcoming in the scope of the EU marketing authorization approval procedure, as well as changes to the United Kingdom's national medicines laws, as the terms of that exit are negotiated between the United Kingdom and the EU. Since the regulatory framework for pharmaceutical products in the United Kingdom relating to 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 will materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom. In the first instance, a separate United Kingdom authorization from any centralized authorization for the EU would need to be applied for in advance of a hard Brexit or before the end of any agreed transitional period. In the immediately foreseeable future, the process is likely to remain very similar to that applicable in the EU, albeit that the processes for applications will be separate. Longer term, the United Kingdom is likely to develop its own legislation that diverges from that in the EU.

Reimbursement

Significant uncertainty exists regarding the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of our products will depend, in part, on the availability of coverage and the adequacy of reimbursement from third-party payors. Third-party payors include government authorities or government healthcare programs, such as Medicare and Medicaid, and private entities, such as managed care organizations, private health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Some third-party payors may manage utilization of a particular product by requiring pre-approval (known as "prior authorization") for coverage of particular prescriptions (to allow the payor to assess medical necessity). If the prior authorization (medical necessity) is denied by the payor, the patient may not be able to afford the full cost of the medication without the coverage from the third party payor. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain net price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for drug products can differ significantly from payor to payor. One third-party payor's decision to cover a particular drug product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate.

Third-party payors are increasingly challenging the price and examining the cost-effectiveness of new products and services in addition to their safety and efficacy. To obtain or maintain coverage and reimbursement for any current or future product, we may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our product. These studies will be in addition to the studies required to obtain or maintain regulatory approvals. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. Thus, obtaining and maintaining reimbursement status is complex and costly.

Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign 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 new price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our or our partners' products or a decision by a third-party payor to not cover our or our partners' products could reduce physician usage of the product and have a material adverse effect on our sales, results of operations and financial condition. We expect that the pharmaceutical industry will experience pricing pressures due to the increasing influence of managed care (and related implementation of managed care strategies to control utilization), additional federal and state legislative and regulatory proposals to regulate pricing of drugs, limit coverage of drugs or reduce reimbursement for drugs, public scrutiny and the Trump administration's expressed desire to address the perceived high cost of pharmaceuticals in the U.S. While we cannot predict what executive, legislative and regulatory proposals will be adopted or other actions will occur, such events could have a material adverse effect on our business, financial condition and profitability.

Within the U.S., we may be required to provide discounts or rebates under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal healthcare programs such as Medicaid. Participation in such programs may require us to track and report certain drug prices. We may be subject to fines and other penalties if we fail to report such prices accurately.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. 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 of our products. Historically, products launched in the EU do not follow price structures of the U.S. and generally tend to be significantly lower.

Health Care and Other Reform

In the U.S., there have been and continue to be a number of significant legislative initiatives to contain healthcare costs. Federal and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, health care, which include initiatives to reduce the cost of healthcare. For example, in March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, or the Healthcare Reform Act, which expanded health care coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included changes to the coverage and reimbursement of drug products under government healthcare programs. Under the Trump administration, there have been ongoing efforts to modify or repeal all or certain provisions of the Healthcare Reform Act. For example, tax reform legislation was enacted at the end of 2017 that eliminated the tax penalty established under Healthcare Reform Act for individuals who do not maintain mandated health insurance coverage beginning in 2019. The Healthcare Reform Act has also been subject to judicial challenge. In December 2018, a federal district court, in a challenge brought by a number of state attorneys general, found the Healthcare Reform Act unconstitutional in its entirety because, once Congress repealed the individual mandate provision, there was no longer a basis to rely on Congressional taxing authority to support enactment of the law. In December 2019, a federal appeals court agreed that the individual mandate provision was unconstitutional but remanded the case back to the district court to assess more carefully whether any provisions of the Healthcare Reform Act were severable and could survive. Pending action by the district court and resolution of any appeals, which could take some time, the Healthcare Reform Act is still operational in all respects.

There have also been other reform initiatives under the Trump Administration, including initiatives focused on drug pricing. For example, legislation enacted in 2018 increased the discount that manufacturers of Medicare Part D brand name drugs must provide to Medicare Part D beneficiaries during the coverage gap from 50% to 70% starting in 2019. As another example, in May of 2018, President Trump and the Secretary of the Department of Health and Human Services released a “blueprint” to lower prescription drug prices and out-of-pocket costs. Certain proposals in the blueprint, and related drug pricing measures proposed since the blueprint, could cause significant operational and reimbursement changes for the pharmaceutical industry. As another example, in 2019, the CMS revised Medicare Part D regulations to support health plans’ negotiation of lower drug prices with manufacturers and reduce health plan members’ out-of-pocket costs. As another example, legislation enacted in 2019 revised how certain prices reported by manufacturers under the Medicaid drug rebate program are calculated, a revision that the Congressional Budget office had estimated would save the Medicaid program approximately $3 billion over the next ten years.

There have also been efforts by federal and state government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation. Recently, there has been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There have also been recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices.

General legislative cost control measures may also affect reimbursement for our product candidates. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2029 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Adoption of new legislation at the federal or state level could affect demand for, or pricing of, our current or future products if approved for sale. We cannot, however, predict the ultimate content, timing or effect of any changes to the Healthcare Reform Act or other federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

Government Contracts and Regulation

We currently contract with the federal government. The BARDA contract could result in payments to us of up to approximately $284.7 million, and consists of a five-year base period-of-performance and a total contract period-of-performance (base period plus option exercises) of up to ten years for us to complete the studies and manufacturing activities necessary for the FDA to consider emergency use authorization NUZYRA to treat people exposed to anthrax. As a government contractor, we are subject to complex and wide-ranging federal and agency-specific regulations and contractual requirements that not only govern how we perform under the contract but also impose other requirements that affect our operations, including socio-economic obligations such as obligations related to affirmative action or maintaining a drug-free workplace. While many of our employees have been involved in government contracts previously, many of these government contracting requirements are new to Paratek as a company. Failure to comply with government contracting requirements could result in termination of our contract and the imposition of penalties.

Employees

As of February 28, 2020, we had 102 total employees, 101 of whom are full-time employees and 40 of whom were primarily engaged in research and development activities. A total of 12 employees have an M.D., Pharm.D, or Ph.D. degree. None of our employees are represented by a labor union, and we consider our employee relations to be good.

Financial and Segment Information

We operate our business as a single segment, as defined by generally accepted accounting principles. Our financial information is included in the consolidated financial statements and the related notes.

Available Information

We are a reporting company under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and file reports, proxy statements and other information with the Securities and Exchange Commission, or the SEC. You may access this information at the SEC's Internet site: www.sec.gov. This site contains reports, proxies and information statements and other information regarding issuers that file electronically with the SEC.

Our internet web site address is *www.paratekpharma.com*. We make available, free of charge at the "Investors" portion of our web site, annual reports 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 Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Reports of beneficial ownership filed pursuant to Section 16(a) of the Exchange Act are also available on our web site. Information in, or that can be accessed through, this web site is not part of this Annual Report on Form 10-K.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below and all information contained in this report before you decide to purchase our common stock. If any of the possible adverse events described below actually occurs, we may be unable to conduct our business as currently planned and our financial condition and operating results could be harmed. In addition, the trading price of our common stock could decline due to the occurrence of any of the events described below, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business.

Risk Related to Financial Condition

We have incurred significant losses since inception and anticipate that we will incur losses for the foreseeable future. To date we have not generated sufficient revenue from product sales to cover corresponding expenses and we may never achieve or sustain profitability.

We received FDA approval for NUZYRA in October 2018 and launched NUZYRA in the U.S. in February 2019. Additionally, FDA approval was granted in October 2018 for SEYSARA, which Almirall has rights to commercialize and with respect to which we will be entitled to tiered royalties, on net sales in the U.S. and a flat royalty on net sales in the greater China region. SEYSARA was launched in the U.S. in January 2019. Although NUZYRA and SEYSARA are now being sold by us and Almirall, respectively, it will take some time to attain profitability and we may never do so. Our net loss for the year ended December 31, 2019 was $128.8 million. As of December 31, 2019, our accumulated deficit was $711.3 million. We expect to continue to incur losses for the foreseeable future as we seek to maintain and expand regulatory approvals for our products, continue to commercialize NUZYRA, establish our sales, marketing and distribution infrastructure to commercialize products for which we obtain marketing approval, including NUZYRA, and add personnel to support our product development and commercialization efforts and operations. The net losses and negative operating cash flows incurred to date, together with expected future losses, have had, and likely will continue to have, an adverse effect on our stockholders' equity (deficit) and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate future revenue.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate any sufficient product revenues to achieve profitability. For example, our expenses could increase if we are required by regulatory agencies outside of the U.S. to perform studies in addition to those that we have already performed or currently expect to perform.

To become and remain profitable, we must succeed in developing and commercializing products with significant market potential. This will require us to be successful in a range of challenging activities, including manufacturing, marketing and commercializing approved products, such as NUZYRA, developing product candidates and obtaining regulatory approval for them. We may never succeed in these activities and may never generate revenue from product sales that is significant enough to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress the market value of our common stock, could impair our ability to raise capital, expand our business, develop other product candidates or continue our operations and could cause investors to lose all or part of their investments.

We may continue to require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back or cease our product development programs or commercialization efforts for NUZYRA.

As of December 31, 2019, our cash, cash equivalents and marketable securities were $215.4 million. We will require substantial additional funding to meet FDA post-marketing approval requirements for NUZYRA, which we expect to be funded through the BARDA contract. Additional funding may also be needed to support and accelerate the commercialization of NUZYRA, to fund the development of omadacycline in other indications, including NTM, and to advance the development of potential other product candidates, and such funding may not be available on favorable terms or at all. Although it is difficult to predict our liquidity requirements, based upon our current operating plan, we anticipate that our cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months from the filing date of this Annual Report on Form 10-K. Because the profitability of NUZYRA and SEYSARA, and the successful development of any other future product candidates, is uncertain, we are unable to estimate the actual funds we will require to fund our continuing operations, including for our clinical development programs and commercialization efforts for NUZYRA.

Our future funding requirements will depend on many factors, including but not limited to:

- the progress of clinical development of omadacycline in additional indications, including NTM;
- the costs and timing of commercialization activities for NUZYRA;
- product revenue received from commercial sales of NUZYRA;
- royalty revenue received from commercial sales of SEYSARA by Almirall;
- timing and amount of actual reimbursements and NUZYRA purchases under the BARDA contract;
- the ability of Zai to develop, manufacture and commercialize omadacycline in the Zai territory;
- the scope, progress, timing, cost and results of research, preclinical development and clinical trials;
- the costs, timing and outcome of seeking, obtaining, maintaining and expanding FDA and non-U.S. regulatory approvals;
- the costs associated with manufacturing and establishing sales, marketing and distribution capabilities;
- the number and characteristics of other product candidates that we may pursue;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management, scientific, commercial, operations and medical personnel;
- the effect of competing products that may limit market penetration of our products;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems
- resources required to develop and implement policies and processes to promote ongoing compliance with applicable healthcare laws and regulations;
- costs required to ensure that our and our partners' business arrangements with third parties comply with applicable healthcare laws and regulations; and
- the economic and other terms, timing and success of our existing collaboration and licensing arrangements and any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under such arrangements.

Until we generate a sufficient amount of product and royalty revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through a combination of public or private equity offerings, debt or other structured financings, strategic collaborations and grant funding. There can be no assurance that we would be successful in securing additional funds on acceptable terms. If additional funds are not available, we may be forced to cease operations, significantly reduce operating expenses or delay, curtail or eliminate one or more of our development programs or our business operations.

Raising additional capital or entering into certain other arrangements may cause dilution to our stockholders, restrict our operations or require us to relinquish rights.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs primarily through the sale of additional equity or convertible debt securities, which would dilute shareholder ownership interest. The terms of these new securities may include liquidation or other preferences that adversely affect shareholders' rights as common stockholders. Future debt financing, if available at all, 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 licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, NUZYRA, sarecycline, any future product candidates or future revenue streams, or grant licenses on terms that are not favorable to us. We cannot assure you that we will be able to obtain additional funding if and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to grant rights to develop and market NUZYRA, sarecycline or any future product candidates that we may otherwise prefer to develop and market ourselves.

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

On June 27, 2019, we entered into an Amended and Restated Loan and Security Agreement, or the Amended Hercules Loan Agreement, with Hercules Technology III, L.P., certain other lenders, together, the Lenders, and Hercules Capital, Inc. (as agent), under which the Company may borrow up to $100.0 million in multiple tranches, each, a Term Loan Tranche. The Amended Hercules Loan Agreement amends and restates in its entirety our prior Loan and Security Agreement dated as of September 30, 2015, as amended. As of December 31, 2019, we have drawn down on $70.0 million. The Amended Hercules Loan Agreement provides for an extension of the scheduled maturity date of the $60.0 million Term Loan Tranche, or the First Tranche, from September 1, 2021 to September 1, 2023, upon certain events set forth in the Amended Hercules Loan Agreement, and an extension of the scheduled maturity date of the $10.0 million Term Loan Tranche, or the Second Tranche, and additional Term Loan Tranches (if any), from August 1, 2022 to August 1, 2024, upon certain events set forth in the Amended Hercules Loan Agreement. The Amended Hercules Loan Agreement also provides for an additional $10.0 million of additional Term Loan Tranches (up to a total of $30.0 million of additional Term Loan Tranches), or the Additional Tranches, that may be available to the Company, subject to approval by Hercules, in its sole discretion, whether to provide such tranches. As such there can be no assurance as to whether or not the Additional Tranches shall be funded.

All obligations under the Amended Hercules Loan Agreement are secured by substantially all of our existing property and assets, excluding our intellectual property. 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:

- we will need to repay our indebtedness by making payments of interest and principal, which will reduce the amount of money available to finance our operations, our research and development efforts and other general corporate activities; and
- our failure to comply with the affirmative, restrictive or financial covenants in the Amended Hercules Loan Agreement could result in an event of default that, if not cured or waived, could result in the acceleration of our obligation to repay this indebtedness, and Hercules could seek to enforce its security interest in the assets securing such indebtedness.

In April 2018, we issued $165.0 million aggregate principal amount of 4.75% Convertible Senior Subordinated Notes due 2024, or the Notes. The Notes bear cash interest at the annual rate of 4.75%, payable on November 1 and May 1 of each year, beginning on November 1, 2018, and mature on May 1, 2024 unless earlier repurchased, redeemed or converted.

In addition, on February 25, 2019, we, through our wholly-owned subsidiary Paratek Royalty Corporation, or the Subsidiary, entered into a royalty-backed loan agreement, or the Royalty-Backed Loan Agreement, with Healthcare Royalty Partners III, L.P., or HCRP. Pursuant to the terms of the Royalty-Backed Loan Agreement, the Subsidiary borrowed a $32.5 million loan, which was secured by, and is being repaid based upon, royalties from the Almirall Collaboration Agreement. The Royalty-Backed Loan Agreement matures on May 1, 2029, at which time, if not earlier repaid in full, the outstanding principal amount of the loan, together with any accrued and unpaid interest, and all other obligations then outstanding, shall be due and payable in cash by the Subsidiary.

The Royalty-Backed Loan Agreement contains customary defined events of default, upon which any outstanding principal and unpaid interest shall be immediately due and payable. These include: failure to pay any principal or interest when due; any uncured breach of a representation, warranty or covenant; any uncured failure to perform or observe covenants; any uncured cross default under a material contract; any uncured breach of our representations, warranties or covenants under its Contribution and Servicing Agreement with the Subsidiary; any termination of the Almirall Collaboration Agreement; and certain bankruptcy or insolvency events.

To the extent additional debt (including without limitation the Additional Tranches) is added to our current debt levels, the risks described above could increase.

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

Failure to satisfy our current and future debt obligations under the Amended Hercules Loan Agreement could result in an event of default and, as a result, Hercules could accelerate all of the amounts due. In the event of an acceleration of amounts due under the Amended Hercules 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, Hercules could seek to enforce its 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 Hercules 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:

- dispose of certain assets;
- change our lines of business;
- engage in mergers or consolidations;
- incur additional indebtedness;
- create liens on assets;
- pay dividends and make distributions or repurchase our capital stock; and
- engage in certain transactions with affiliates.

Risks Related to Maintaining and Expanding Regulatory Approval and Other Legal Compliance Matters

If clinical trials for omadacycline are prolonged, delayed or stopped, we may be unable to obtain regulatory approval and commercialize omadacycline for the treatment of additional indications on a timely basis.

In October 2018, the FDA approved NUZYRA in the U.S. for the treatment of adults with CABP and ABSSSI that are proven or strongly suspected to be caused by susceptible bacteria. The completion of any future clinical trials, including FDA PMRs, could be substantially delayed or prevented by several factors, including:

- delay or failure to obtain sufficient supplies of the product candidate for our clinical trials;
- delay or failure to obtain sufficient supplies of the comparator antibiotic for our clinical trials;
- the limited number of, and competition for, suitable sites to conduct our clinical trials, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;
- any delay or failure to obtain regulatory approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;
- clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or clinical research organizations, or CROs, or local regulatory authorities, the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs; and
- delay or failure to obtain Institutional Review Board/ethics committee approval to conduct a clinical trial at a prospective site or within a specific region or country.

The completion of our clinical trials could also be substantially delayed or prevented by several factors, including:

- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial;
- unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by patients;
- lack of omadacycline efficacy evidenced during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols;
- inability to monitor patients adequately during or after treatment by us and/or our CROs;
- delay or failure to obtain sufficient supplies of omadacycline or of the relevant comparator product; and
- the need to repeat or terminate clinical trials as a result of inconclusive or negative results or unforeseen complications during clinical trial testing.

In particular, our ability to enroll patients in our clinical trials in sufficient numbers and on a timely basis will be subject to a number of factors, including the size of the patient population needed, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant indication and the eligibility criteria for the clinical trial.

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit clinical trial protocols to regulatory agencies/ Institutional Review Boards/ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the Institutional Review Board overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site or us due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;
- lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions; and
- upon a breach or pursuant to the terms of any agreement with, or for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates.

In addition, clinical practices vary globally, and there is a lack of harmonization among the guidance provided by various regulatory bodies of different regions and countries with respect to the data that is required to receive marketing approval, which makes designing global trials increasingly complex. Differing regulatory approval requirements in different countries also make it more difficult for us to conduct unified global trials, which can lead to increased development costs and marketing delays or non-viability of our clinical trials. The approval procedure and the time required to obtain approval also varies among countries. Furthermore, regulatory agencies may have varying interpretations of the same data, and approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions.

The results of previous clinical trials may not be predictive of future results, and the results of any ongoing or future clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities.

Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or our partners may decide, or regulators may require us, to conduct additional clinical or preclinical testing which could delay submission of a supplemental NDA and regulatory approval. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. Success in early stage clinical trials does not mean that future larger registration clinical trials will be successful, because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through early stage clinical trials. Product candidates that have shown promising results in early-stage (pre-Phase 3) clinical trials may still suffer significant setbacks in subsequent registration clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and/or new indications, and flaws in the design of a clinical trial may not become apparent until the clinical trial is underway, well advanced or completed. Further, if future product candidates are found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for them and our business would be harmed. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier stage clinical trials.

Positive results in our randomized Phase 2 and Phase 3 clinical studies of omadacycline in complicated skin and skin structure infections, ABSSSI and CABP, may not be predictive of the results in any other indications, such as omadacycline for the treatment of NTM. In some instances, there can be significant variability in safety and/or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial protocols, differences in size, type and geographic distribution of the patient populations, adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. We do not know whether any Phase 2, Phase 3 or other clinical trials we or any of our collaborators may conduct, or have conducted in the past, will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our future product candidates.

Further, our and our partners' product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials or registration trials. The FDA or other non-U.S. regulatory authorities may disagree with our clinical trial design and our interpretation of data from preclinical studies and clinical trials even when we have Special Protocol Assessment agreements. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 clinical trial that has the potential to result in FDA or other agencies' approval. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. In addition, the FDA or other non-U.S. regulatory authorities may not approve the labeling claims that we believe would be supported by the clinical data, or be necessary or desirable for the successful commercialization of our products. If an unforeseen safety issue arises, the FDA always has the option to initiate a REMS or add additional warnings to a product label upon approval.

The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our partners from obtaining approvals for the commercialization of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and other U.S. and non-U.S. regulatory authorities. Regulations differ from country to country, which will require us to expend additional resources in each market for which a separate regulatory approval is required. We are not permitted to market our product candidates outside of the U.S. until we receive marketing approval from applicable regulatory authorities outside of the U.S. Although omadacycline and sarecycline received FDA approval, approval of other indications, including treatment of NTM with omadacycline, is subject to the risks of failure inherent in drug development.

Failure to comply with FDA and non-U.S. regulatory requirements may, either before or after product approval, if any, subject us to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing process;
- warning letters or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- suspension of any ongoing clinical trials;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending NDAs or supplements to approved NDAs.

The FDA and foreign regulatory authorities also have substantial discretion in the drug approval process. The number of preclinical studies and clinical trials that will be required for regulatory approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular drug candidate. Regulatory agencies can delay, limit or deny approval of a product candidate for many reasons, including:

- a product candidate may not be deemed safe or effective;
- the results may not confirm the positive results from earlier preclinical studies or earlier stage clinical trials;
- regulatory agencies may not find the data from preclinical studies and clinical trials sufficient;
- regulatory agencies may not approve our third-party manufacturer’s processes or facilities;
- regulatory agencies may require significant warning or restrictions on use to the product label; or
- regulatory agencies may change their approval policies or adopt new regulations.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from omadacycline or any other particular product candidate, which likely would result in significant harm to our financial position. Furthermore, any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product. These limitations may limit the size of the market opportunity for the product.

Even though NUZYRA and SEYSARA have been approved by the FDA in the U.S., they face post-approval development and regulatory requirements, which may limit how they are manufactured and marketed, and could materially impair our ability to generate revenue.

In October 2018, the FDA approved NUZYRA in the U.S. for the treatment of adults with CABP and ABSSSI that are proven or strongly suspected to be caused by susceptible bacteria, as well as SEYSARA for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients nine years of age and older. NUZYRA and SEYSARA are subject to, among other things, ongoing FDA requirements governing the manufacturing, labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety, efficacy and other post-market information. As part of the FDA approval for NUZYRA, we are required to conduct post-marketing pediatric studies, including a single dose pharmacokinetic and safety study in children ages eight to seventeen who are receiving antibacterial drug therapy for an infectious disease, an active-controlled safety study in children ages eight to seventeen who have acute bacterial skin and skin structure infections, and an active-controlled safety study in children ages eight to seventeen who have CABP. In addition, we are also required to conduct an active-controlled safety and efficacy study in adults with CABP and a U.S. surveillance study for five years from the date of marketing to determine if resistance to NUZYRA has developed in those organisms specific to the indications in the label. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA and other regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to current GMP regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. As such, we and our partners and any of our and their respective contract manufacturers are subject to ongoing review and periodic inspections to assess compliance with cGMPs. Additionally, to the extent we want to make certain changes to the approved products, product labeling, or manufacturing processes or manufacturing sites, we will need to submit new applications or supplements to FDA and obtain the agency's approval.

Accordingly, we and others with whom we work will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We and our partners are also required to report adverse reactions and production problems, if any, to the FDA and to comply with requirements concerning, among other things, advertising and promotion for our products. 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 label. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from pharmaceutical companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. Accordingly, we and our partners will not be able to promote our products for indications or uses for which they are not approved. A company that is found to have promoted off-label use of its product may be subject to significant liability, including civil and criminal sanctions. We intend to comply with the requirements and restrictions of the FDA and other regulatory agencies with respect to off-label promotion, but we cannot be sure that the FDA or other regulatory agencies will agree that we have not violated their restrictions. As a result, we may be subject to criminal and civil liability. If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Even if it is later determined that we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products. We intend to engage in medical education activities and communicate with healthcare providers in compliance with all applicable laws, regulatory guidance and industry best practices. Although we believe we have put in place a compliance program, which is designed to ensure that all such activities are performed in a legal and compliant manner, we cannot be certain that our program will address all areas of potential exposure and the risks in this area cannot be entirely eliminated.

Additionally, if a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product, us or our partners, including requiring withdrawal of the product from the market. If we or our partners fail to comply with the regulatory requirements of the FDA and other U.S. and non-U.S. regulatory authorities, or if previously unknown problems with our products, manufacturers or manufacturing processes are discovered, the FDA or other regulatory authorities could impose significant penalties, such as:

- issuance of warning letters or untitled letters;
- imposition of injunctions or civil or criminal penalties;
- imposition of fines, restitution or disgorgement of profits or revenue;

- suspension or withdrawal of regulatory approval;
- restrictions on product distribution or use;
- imposition of total or partial suspension of production;
- suspension of any ongoing clinical trials;
- requirements to conduct post-marketing clinical trials;
- refusal to approve pending applications or supplements to applications;
- restrictions on the labeling or marketing of a product;
- imposition of restrictions on operations, including costly new manufacturing requirements; or
- seizure or detainment of products or requirements for us or our partners to initiate a product recall.

If we and our partners are not able to maintain regulatory compliance, we may not achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Our products may have undesirable side effects that may require them to be taken off the market or otherwise limit their sales.

Although NUZYRA and SEYSARA have undergone safety testing in humans and in laboratory animals, not all adverse effects of drugs can be predicted or anticipated from these clinical studies and preclinical safety and toxicology studies. Unforeseen side effects from either NUZYRA or SEYSARA could arise after the approved product has been marketed. Many of the most widely used antibiotics are associated with treatment-limiting adverse events, including in some instances, kidney damage, allergic reactions or sudden cardiovascular death due to cardiac arrhythmia. The results of future clinical trials or from marketing experience may show that NUZYRA or SEYSARA, or any other current or future product candidate, cause undesirable or unacceptable side effects. Furthermore, even though both NUZYRA and SEYSARA have received marketing approval, if we or others later identify undesirable or unacceptable side effects caused by NUZYRA or SEYSARA:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we or our partners may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we or our partners may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may withdraw approvals of an approved product, or otherwise require us or our partners to take our approved product off the market, or impose restrictions on its distribution;
- we or our partners may be subject to litigation or product liability claims and be held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us, our current partners or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our products. Furthermore, NUZYRA and SEYSARA are commercially available and each may be used in a wider population and in a less rigorously controlled environment than in clinical studies. As a result, regulatory authorities, healthcare practitioners, third-party payors or patients may perceive or conclude that the use of the product is associated with previously unknown serious adverse effects, undermining commercialization efforts.

Coverage and reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient coverage and reimbursement for our products, it is less likely that our products will be widely used.

Market acceptance and sales of NUZYRA, SEYSARA and any of our or our partners' other products will depend on coverage and reimbursement policies. Government authorities and third-party payors, such as private health plans, decide which drugs they will cover and establish reimbursement levels. Coverage and reimbursement may vary among third-party payors. Coverage may not be available, and reimbursement may not be adequate, for NUZYRA, SEYSARA or any other products that we or our partners develop and commercialize. Also, coverage and reimbursement policies may reduce the demand for, or the price paid for, our or our partners' products. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our or our partners' products unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of such products. Therefore, if coverage is not available or reimbursement is limited, we and our partners may not be able to successfully commercialize NUZYRA, SEYSARA or any future approved products, if any.

Third-party payors may limit coverage or impose conditions on coverage. For example, third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. As another example, third-party payors may require use of alternative therapies or a demonstration that a product is medically necessary for a particular patient before use of a product will be covered. A decision by a third-party payor not to cover our products could reduce utilization of those products.

A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will apply, or patient copayment will be at an acceptable level for physicians to choose to prescribe our drug. In addition, pharmaceutical companies often need to offer third party payors rebates and administration fees on the cost of drugs dispensed to the payors' members in order to increase the possibility of favorable coverage and adequate cost sharing thresholds for patients. We may be required to provide such rebates to some third-party payors in relation to our product(s). Adequate third-party reimbursement, taking into account such rebates as applicable, may not be available and we may not be able to maintain price levels sufficient to realize an appropriate profit, including a return on our investment in product development.

Outside of the U.S., in some countries, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take a significant amount of time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. In some countries, we or our partners may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available products in order to obtain or maintain reimbursement or pricing approval. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, there could be a material adverse effect on our business.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The U.S. and several foreign jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our or our partners' ability to sell approved products profitably. Among policymakers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The U.S. government and individual states have aggressively pursued healthcare reform, as evidenced by the passage of the Healthcare Reform Act and the ongoing efforts to modify or repeal that legislation. The Healthcare Reform Act substantially changed the way healthcare is financed by both governmental and private insurers and contains a number of provisions that affect coverage and reimbursement of drug products and/or that could potentially reduce the demand for pharmaceutical products such as increasing drug rebates under state Medicaid programs for brand name prescription drugs and extending those rebates to Medicaid managed care and assessing a fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid. Modifications have been implemented under the Trump Administration and additional modifications or repeal may occur. For instance, tax reform legislation was enacted at the end of 2017 that eliminated the individual health insurance mandate which is expected to increase the number of Americans without comprehensive health insurance. In December of 2018, a federal district court also found the Healthcare Reform Act unconstitutional in its entirety. In December 2019, a federal appeals court agreed that the individual mandate provision was unconstitutional but remanded the case back to the district court to assess more carefully whether any provisions of the Healthcare Reform Act were severable and could survive. Pending action by the district court and resolution of any appeals, which could take some time, the Healthcare Reform Act is still operational in all respects. Other aspects of healthcare reform, such as expanded government enforcement authority could also affect our business and are ongoing. See "*Government Regulation - Health Care and Other Reform*". We cannot predict the ultimate content, timing or effect of any changes to the Healthcare Reform Act or other federal and state reform efforts.

Additional legislative actions to control U.S. healthcare or other costs have passed. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare, but not Medicaid, payments to providers in 2013 and will remain in effect through 2029 unless additional Congressional action is taken.

There is no assurance that federal or state healthcare reform or other legislative and regulatory initiatives will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative, judicial or administrative changes relating to healthcare reform will affect our business.

In the U.S. there is increasing scrutiny of drug prices and federal or state reforms could impact our ability to establish what we believe is a fair price for our products, and ultimately diminish our revenue prospects.

Recently, there has been considerable public and government scrutiny in the U.S. of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There have also been several recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices or price increases. Adoption of new legislation at the federal or state level could affect demand for, or pricing of, our product candidates, if approved for sale and could diminish our ability to establish what we believe is a fair price for our products, ultimately diminishing our revenue for our products.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the U.S., 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 U.S. in order to obtain coverage for NUZYRA 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.

If we or our partners market products in a manner that violates fraud and abuse and other healthcare laws, or if we or our partners violate government price reporting laws, we or our partners may be subject to administrative civil and/or criminal penalties.

Within the U.S., various state and federal healthcare laws restrict certain marketing practices in the pharmaceutical industry. When we or any of our partners market approved products, such as NUZYRA or SEYSARA, some of our or our partners' business activities could possibly be subject to challenge under one or more of these laws. The laws and regulations that may affect our ability to operate include:

- federal false claims, false statements and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
- federal healthcare program anti-kickback law, which prohibit, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- federal anti-kickback prohibition known as Eliminating Kickbacks in Recovery Act or EKRA, enacted in 2018, which prohibits certain payments related to referrals of patients to certain providers (recovery homes, clinical treatment facilities and laboratories) and applies to services reimbursed by private health plans as well as government health care programs;
- the federal law known as HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the so-called "federal sunshine" law, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to the federal government for re-disclosure to the public (the scope of which reportable interactions will increase for interactions occurring during or after 2021); and
- state law equivalents of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state laws regulating interactions between pharmaceutical manufactures and healthcare providers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

Efforts to ensure that our and our partners' business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. With the approval of NUZYRA and SEYSARA, we have become subject to an expanded number of these laws and have, and will need to continue, to expend resources to develop and implement policies and processes to promote ongoing compliance. Although we believe we currently maintain an appropriate compliance program, we cannot be certain that the program will adequately detect or prevent violations.

Many of these laws and their implementing regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, our activities could be subject to challenge. It is possible that governmental authorities will conclude that our or our partners' business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our or our partners' operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we or our partners may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could significantly harm our business.

Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Drug Rebate Program to reduce liability for Medicaid rebates.

Outside of the U.S., foreign laws may also regulate our activities, or those of our collaboration partners.

We may be subject to significant fines if we fail to comply with data privacy and securities laws.

We may be subject to privacy and security laws in the various jurisdictions in which we operate, obtain or store personally identifiable information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business.

Within the U.S., our operations may be affected by the Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, collectively, HIPAA, which impose obligations on certain "covered entities," such as healthcare providers, health plans and healthcare clearinghouses, and certain of their "business associate" contractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Although we believe that we currently are neither a "covered entity" nor a "business associate" under the legislation, a business associate relationship may be imputed from facts and circumstances even in the absence of an actual business associate agreement. In addition, HIPAA may affect our interactions with customers who are covered entities or their business associates because HIPAA affects the ability of these entities to disclose patient health information to us. Various states also have laws that regulate the privacy and security of patient information and so may affect our business operations. For example, we are subject to the California Consumer Privacy Act, or CCPA, that became effective on January 1, 2020. The CCPA gives California consumers, defined to include all California residents, certain rights, including the right to ask companies to disclose the types of personal information collected, specific pieces of information collected by a company, the categories of sources from which such information was collected, the business purpose for collecting or selling the consumer's personal information, and the categories of third parties with whom a company shares personal information. The CCPA also imposes several obligations on companies to provide notice to California consumers regarding a company's data processing activities. Additionally, the CCPA gives California consumers the right to ask companies to delete a consumer's personal information and it places limitations on a company's ability to sell personal information, including providing consumers a right to opt out of sales of their personal information.

Outside the U.S., other data privacy and security regulations may apply. For example, the processing of personal data in the European Economic Area, or the EEA, is subject to the General Data Protection Regulation, or the GDPR, which took effect in May 2018. The GDPR increases obligations with respect to clinical trials conducted in the EEA, such as in relation to the provision of fair processing notices, exercising data subject rights and reporting certain data breaches to regulators and affected individuals, as well as how we document our relationships with third parties that process GDPR-covered personal data on our behalf. The GDPR also increases the scrutiny applied to transfers of personal data from the EEA, including from clinical trial sites in the EEA, to countries that are considered by the European Commission to lack an adequate level of data protection, such as the U.S. Compliance with data privacy and security regulation can require allocation of resources as well as changes in operations and non-compliance can result in substantial fines. In addition, the GDPR and the CCPA impose substantial fines and other regulatory penalties for breaches of data protection requirements and they confer a private right of action on data subjects, in the case of the GDPR, and consumers, in the case of the CCPA, and their representatives for breaches of certain data protection requirements.

Risks Related to Our Business

We are highly dependent on the commercial success of NUZYRA in the U.S. and, to a lesser extent, SEYSARA.

Our success is currently dependent on the successful commercialization of NUZYRA in the U.S., which is also being developed by Zai in the Zai territory, and, to a lesser extent, SEYSARA, which Almirall has the rights to commercialize in the U.S. and the greater China region. We are not currently developing, and have no such plans to develop, any other product candidates, other than omadacycline for the treatment of NTM, anthrax, and other relevant preclinical or clinical investigations. We may need additional financing or grants to fund development of any current or future product candidates.

The majority of our time, resources and effort are focused on the commercialization of NUZYRA and our ability to generate product revenues will depend heavily on the successful commercialization of NUZYRA, which will depend on, among other things, our ability to:

- secure sufficient starting materials and maintain commercial manufacturing arrangements with third-party manufacturers;
- produce, through a validated process, sufficient quantities and inventory of NUZYRA to meet demand;
- build and maintain internal sales, distribution and marketing capabilities sufficient to generate commercial sales of NUZYRA;
- secure widespread acceptance of our product from physicians, healthcare payors, patients and the medical community;
- properly price and obtain coverage and adequate reimbursement of NUZYRA by governmental authorities, private health insurers, managed care organizations and other third-party payors;
- maintain compliance with ongoing FDA labeling, packaging, storage, advertising, promotion, recordkeeping, safety and other PMRs;
- manage our costs and expenses commensurate with NUZYRA's projected growth; and
- establish and maintain collaborations with third parties for the commercialization of NUZYRA in countries outside of the U.S., such as our existing collaboration with Zai to develop, manufacture and commercialize omadacycline in the Zai territory, and such collaborators' ability to obtain regulatory and reimbursement approvals in such countries.

There are no guarantees that we will be successful in completing these tasks. In addition, we have begun, and will need to continue investing substantial financial and management resources to build out our commercial infrastructure and to recruit and train sufficient additional qualified marketing, sales and other personnel in support of our sales of NUZYRA.

If a pandemic, epidemic or outbreak of an infectious disease occurs, our business may be adversely affected. In December 2019, a novel strain of coronavirus was identified in Wuhan, China. This virus continues to spread globally and, as of March 2020, has spread to over 50 countries, including the U.S. Such events may result in a period of business and manufacturing disruption, and in reduced sales and operations, any of which could materially affect our business, financial condition and results of operations. For example, the spread of the coronavirus in the U.S. may result in travel restrictions impacting our sales professionals. In addition, hospitals may reduce staffing, divert resources to patients suffering from the infectious disease or limit access for non-patients, including our sales professionals, which could negatively impact the ability of our sales professionals to effectively access physicians. Any of the foregoing could adversely affect our sales of NUZYRA.

Sales of NUZYRA and SEYSARA may be slow or limited for a variety of reasons including competing therapies or safety issues. If NUZYRA and SEYSARA are not successful in gaining broad commercial acceptance, our business would be harmed.

Sales of NUZYRA and SEYSARA are dependent on several factors including our and our partners' ability to educate and increase physician awareness of the benefits, safety and cost-effectiveness of NUZYRA and SEYSARA relative to competing therapies. The degree of market acceptance of NUZYRA and SEYSARA among physicians, patients, healthcare payors and the medical community depends on a number of factors, including:

- acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- prevalence and severity of any adverse side effects;
- availability of alternative treatments;
- pricing, cost effectiveness and value propositions;

- effectiveness of our sales and marketing capability and strategies;
- complications or barriers that inhibit our commercial team from reaching the appropriate audience to promote our product(s) because of the spread of the coronavirus or any outbreak of other contagious diseases, especially during the early phase of our commercial launch of NUZYRA;
- ability to obtain sufficient third-party coverage and reimbursement;
- the clinical indications for which NUZYRA and SEYSARA are approved, as well as changes in the standard of care for their targeted indications;
- the continuing effectiveness of manufacturing and supply chain;
- warnings and limitations contained in the approved labeling for NUZYRA;
- warnings and limitations contained in the approved labeling for SEYSARA, including that efficacy of SEYSARA beyond 12 weeks and safety beyond 12 months have not been established;
- safety concerns with similar products marketed by others;
- the prevalence and severity of any side effects as a result of treatment with NUZYRA and SEYSARA;
- our ability to comply with FDA PMRs associated with the FDA approval of NUZYRA, including conducting and completing post-marketing studies; and
- the actual market-size for NUZYRA and SEYSARA, which may be larger or smaller than expected.

In addition, since NUZYRA and SEYSARA are subject to continual review by the FDA, there can be no assurance that newly discovered or developed safety issues will not arise. With the use of any newly marketed drug by a wider patient population, serious adverse events may occur from time to time that initially do not appear to relate to the drug itself. For example, any safety issues could cause us to suspend or cease marketing NUZYRA, cause us to modify how we market NUZYRA, and may subject us to substantial liabilities and adversely affect our revenues and financial condition. In the event of a withdrawal of NUZYRA from the market, our revenues would decline significantly, and our business would be seriously harmed and could fail. We and our partners additionally may experience significant fluctuations in sales of NUZYRA and SEYSARA from period to period and, ultimately, we may never generate sufficient revenues from NUZYRA and SEYSARA to reach or maintain profitability or sustain our anticipated operations.

We face significant competition and if our competitors develop and market products that are more effective, safer or less expensive than our products, our commercial opportunities will be negatively impacted.

The life sciences industry is highly competitive and subject to rapid and significant technological change, including but not limited to with respect to innovations related to diagnostic devices. NUZYRA and SEYSARA do or will compete with other drugs and therapies that currently exist or are being developed. Products that we may develop in the future are also likely to face competition from other drugs and therapies, some of which we may not currently be aware. We have competitors both in the U.S. and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research, development and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds to in-license novel compounds or develop technologies, that could make the product candidates that we develop obsolete or less competitive. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or regulatory approvals or discovering, developing and commercializing competing technologies before we do so for any of our product candidates.

The GAIN Act is intended to provide incentives for the development of new Qualified Infectious Disease Products. These incentives may result in more competition in the market for new antibiotics and may cause pharmaceutical and biotechnology companies with more resources than we have to shift their efforts toward the development of products that could be competitive with our product candidates.

NUZYRA competes with other antibiotics in the serious bacterial skin infection market. These include, but are not limited to, vancomycin, marketed as a generic by Abbott Laboratories and others; linezolid, marketed as Zyvox by Pfizer Inc. and available as a generic; daptomycin, marketed as Cubicin by Merck Pharmaceuticals, Inc. and available as a generic; dalbavancin, approved in May 2014 and marketed as Dalvance by Allergan; tedizolid, marketed as Sivextro by Merck Pharmaceuticals, Inc.; delafloxacin marketed as Baxdela by Melinta Therapuetics, Inc.; oritavancin, approved in August 2014 and marketed as Orbactiv by Melinta Therapeutics,

Inc.; quinupristin/dalfopristin, marketed as Synercid by Pfizer, Inc.; tigecycline, marketed as Tygacil by Pfizer Inc. and available as a generic; telavancin, marketed as Vibativ by Cumberland Therpeutics Inc.; ceftaroline, marketed as Teflaro by Allergan; and the following generics: trimethoprim/sulfamethoxazole, clindamycin minocycline, doxycycline, and tetracycline. We are also aware of various drugs that are or may eventually be under development for the treatment of serious skin infections, and these include but are not limited to: Iclaprim by Motif Bio and Lefamulin by Nabriva.

NUZYRA competes with other antibiotics in the community-acquired pneumonia market. These include, but are not limited to, azithromycin, marketed as Zithromax and Z-PAK by Pfizer Inc. and available as a generic; clarithromycin, marketed as Biaxin by Abbott Laboratories and available as a generic; moxifloxacin, marketed as Avelox by Bayer AG and available as a generic; levofloxacin, marketed as Levaquin by Johnson & Johnson and available as a generic; tigecycline, marketed as Tygacil by Pfizer Inc. and available as a generic; linezolid, marketed as Zyvox by Pfizer Inc. and available as a generic; ceftriaxone, marketed as Rocephin by F. Hoffman-La Roche Ltd and available as a generic; delafloxacin marketed as Baxdela by Melinta Therapeutics Inc; lefamulin marketed as Xenleta by Nabriva Therapeutics Inc. and ceftaroline, marketed as Teflaro by Allergan. We are also aware of various drugs that are or may eventually be under development for the treatment of CABP, including, but not limited to, radezolid, under development by Melinta Therapeutics; and GSK2140944, under development by GSK.

Finally, SEYSARA faces competition in the acne markets where generic tetracyclines such as doxycycline and minocycline are available in every market around the world. Branded generic versions of tetracycline derivatives are sold by several companies.

Many of our competitors have substantially greater financial, technical and human resources than we do, as well as greater experience in the marketing of products, discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Our competitors' drugs may be more effective, or more effectively marketed and sold, than NUZYRA, SEYSARA or any future product candidate we may commercialize and may render NUZYRA, SEYSARA or our other product candidates obsolete or non-competitive before we can recover the expenses of our development and commercialization. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Finally, the development of new treatment methods for the diseases we are targeting could render NUZYRA, SEYSARA or any future product candidates non-competitive or obsolete.

In addition, many universities and private and public research institutes may become active in our target indications. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy, safety and reliability of NUZYRA, SEYSARA and our and our partners' other product candidates, including as relative to marketed products and product candidates in development by third parties;
- our and our partners' ability to reliably secure starting materials and manufacture any of our formulations;
- the speed at which we and our partners develop future product candidates;
- our and our partners' ability to commercialize and market, or find partners to help or exclusively commercialize and market, NUZYRA, SEYSARA or any future product candidates that receive regulatory approval;
- our and our partners' ability to design and successfully execute appropriate clinical trials, as well as the results of such clinical trials, including our two Phase 2 registration clinical trials for omadacycline-one in cystitis, a common uncomplicated UTI, and one in acute pyelonephritis, a common complicated UTI;
- our and our partners' ability to recruit and enroll patients for our and our partners' clinical trials;
- our and our partners' ability to maintain a productive relationship with regulatory authorities;
- the timing and scope of regulatory approvals;
- the effectiveness of our, our current partners' or any future partners' marketing and sales capabilities;
- the price of our products, including in comparison to branded or generic competitors;
- coverage and adequate levels of reimbursement under private and governmental health insurance plans, including Medicare;
- our and our partners' ability to protect and maintain intellectual property rights related to NUZYRA, SEYSARA and any of our or their other product candidates;
- our and our partners' ability to manage costs and expenses commensurate with NUZYRA and SEYSARA's projected growth;

- our and our partners' ability to maintain compliance with ongoing FDA labeling, packaging, storage, advertising, promotion, recordkeeping, safety and other PMRs, including required post-marketing studies;
- our and our partners' ability to manufacture and sell commercial quantities at a reasonable cost of NUZYRA and SEYSARA; and
- acceptance of NUZYRA and SEYSARA by physicians and other healthcare providers.

In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

Furthermore, price competition may inhibit the acceptance of our products, physicians may be reluctant to switch from existing products to our products, physicians may switch to other newly approved drug products, or physicians may choose to reserve our products for use in limited circumstances.

If BARDA were to eliminate, reduce, or delay funding for our contract, we would experience a negative impact on our programs associated with such funding.

On December 18, 2019, we entered into a five-year contract, with an option to extend to ten years, with BARDA, a division of HHS. The objectives of our BARDA contract are to support the development of NUZYRA for the treatment of pulmonary anthrax and the fulfillment of FDA PMR associated with NUZRYA's initial approval. The BARDA contract also includes an option for BARDA to procure up to 10,000 treatment courses of NUZYRA for the SNS for use against potential biothreats. If BARDA were to eliminate, reduce, or delay funding for these programs or prohibit reimbursement of some of our incurred costs, we would have to seek additional funding to continue development of NUZYRA for the treatment of anthrax or significantly decrease or cease the product's development for that indication. Moreover, a loss of BARDA funding could jeopardize our ability to fulfill NUZYRA's FDA post-marketing requirements or to fulfill them in a timely manner, and FDA could take enforcement action against us, including by issuing a Warning Letter or by imposing civil monetary penalties.

The BARDA contract includes special requirements, which subject us to the risk of a reduction or loss of funding.

Our BARDA contract subjects us to various U.S. government contract requirements, including general clauses for a cost-reimbursement research and development contract, which may limit our reimbursement. In addition, if we are found to be in violation of the BARDA contract, it could result in termination. If BARDA terminates our contract with us for its convenience, or if we default by failing to perform in accordance with the contract schedule and terms, a significant negative impact on our cash flows and operations could result.

U.S. government contracts, such as our BARDA contract, generally contain unfavorable termination provisions, which may subject us to additional risks as compared to our competitors that have not entered into such contracts. These risks include the ability of the U.S. government to unilaterally:

- terminate or reduce the scope of our contract with or without cause;
- interpret relevant regulations (federal acquisition regulation clauses);
- require performance under circumstances which may not be favorable to us;
- require an in-process review where the U.S. government will review the project and its options under the contract;
- control the timing and amount of funding, which impacts the development progress of our programs; and
- audit and object to our contract-related costs and fees, including allocated indirect costs.

Termination and audit provisions in our BARDA contract could create additional risks for our business.

The U.S. government may terminate our BARDA contract for its convenience or if we default by failing to perform in accordance with the contract schedule and terms. Termination for convenience provisions generally enable us to recover only our incurred or committed costs, and settlement expenses and profit on the work completed prior to termination. Termination does not permit these recoveries under default provisions. If our contract expires or is terminated, the U.S. government could dispute wind-down and termination costs and may question prior expenses under the contract and deny payment of those expenses. If we decide to challenge the U.S. government for denying certain payments under a contract, such a challenge could subject us to substantial additional expenses which we may or may not recover. Further, should the U.S. government terminate our BARDA contract for its convenience, or if we default by failing to perform in accordance with the contract schedule and terms, our cash flows and business operations could be negatively impacted.

We rely and will continue to rely on outsourcing arrangements for manufacturing of NUZYRA and any future product candidates. Reliance on third- party manufacturers could impair the commercialization of NUZYRA or delay approval of any future product candidates.

We do not currently own or operate manufacturing facilities for the production of NUZYRA or any other product candidate, nor do we currently intend to manufacture NUZYRA or any other pharmaceutical products that we may plan to sell in the future. We currently depend on third-party contract manufacturers for the supply of the active pharmaceutical ingredients for NUZYRA. We have entered into certain long-term manufacturing and supply agreements. These include (i) a manufacturing and services agreement with CIPAN for the supply of starting materials for our supply of omadacycline and crude omadacycline, (ii) an outsourcing agreement with Carbogen for the supply of active pharmaceutical ingredient for our omadacycline products, (iii) a manufacturing and services agreement with Almac for the supply of omadacycline oral solid dosage tablets, (iv) a packaging and supply agreement with Almac for the primary packing, labelling, storage and related services for omadacycline oral solid dosage tablets and the secondary packaging, labelling, storage and related services for injectable omadacycline in vials, (v) a manufacturing and services agreement with Patheon under which Patheon will manufacture, package and supply to us, omadacycline in injectable form and (vi) a third party logistics provider agreement with ICS (Amerisource Bergan Co.) under which ICS will perform distribution and logistics services. We are currently in discussions with other third-party manufacturers and may enter into additional long-term supply agreements with them. We may not be able to reach agreement with some of these contract manufacturers, or to identify and reach arrangement on satisfactory terms with other contract manufacturers, to manufacture NUZYRA or any future product candidates. Additionally, we anticipate that the facilities used by any contract manufacturer to manufacture NUZYRA or any future product candidates will be the subject of inspections by regulatory agencies before the FDA and other regulatory authorities that approve an NDA or marketing authorization for the product candidate manufactured at that facility. We will depend on these third-party manufacturing partners for compliance with the FDA's manufacturing requirements for finished products. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA and other regulatory authorities' cGMP requirements, any future product candidates may not be approved or, in the case of NUZYRA, may be subject to delays in release and/or product recalls. While third-party manufacturers of NUZYRA have previously passed FDA and other regulatory agency inspections, we cannot provide assurance that they will pass such inspections in the future.

Furthermore, any interruption of the development or operation of the manufacturing facilities due to, among other reasons, events such as order delays for equipment or materials, equipment malfunction, quality control and quality assurance issues, regulatory delays and possible negative effects of such delays on supply chains and expected timelines for product availability, production yield issues, shortages of qualified personnel, discontinuation of a facility or business or failure or damage to a facility by natural disasters or pandemics, could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available NUZYRA, other product candidates or materials. For example, in December 2019, a strain of coronavirus was reported to have surfaced in Wuhan, China, which has and is continuing to spread throughout China and other parts of the world. We maintain a supply chain structure that presently allows us to avoid the business effects of the current coronavirus outbreak. However, the future impact of this outbreak is highly uncertain and cannot be predicted. If the coronavirus effects the producers of certain materials, or spreads broadly to other regions as is predicted, including to Portugal, Italy, Switzerland, Northern Ireland, or the U.S. or to the countries where Almirall contracts for the production of SEYSARA, or if the duration of the disruption is longer than anticipated, our business and financial performance could be adversely affected.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products and product candidates ourselves, including:

- the possibility of a breach of the manufacturing agreements by the third parties because of factors beyond our control;
- the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer;
- the possibility that third parties are unable to manufacture NUZYRA consistently in commercial quantities, at acceptable costs on expected timelines;
- the possibility that we may not be able to maintain or secure manufacturers or manufacturing capacity in a timely manner and on satisfactory terms in order to meet our manufacturing needs; and
- the possibility that the third parties may not be able to respond adequately to unexpected changes in demand forecasts that may result in either lost revenue or excessive inventory with decreasing shelf-life.

Any of these factors could cause the delay of further commercialization of NUZYRA, delay the development and approval of any future product candidates, or cause us to incur higher costs or prevent us from commercializing any future product candidates successfully. Furthermore, if contract manufacturers fail to continuously meet FDA compliance standards or fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take one or more years to establish an alternative source of supply and to have any such new source approved by the FDA or any other relevant regulatory authorities.

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

If the FDA or other applicable regulatory authorities approve generic products that compete with NUZYRA, SEYSARA or any of our or our partners' product candidates, or if existing generic antibiotics are viewed as being equally effective to NUZYRA, SEYSARA or any of our or our partners' product candidates, the sales of NUZYRA, SEYSARA or, if approved, such product candidates would be adversely affected.

Once an NDA or marketing authorization application outside of the U.S. is approved, the product covered thereby becomes a "listed drug" that can, in turn, be cited by potential competitors in support of approval of an ANDA in the U.S. Agency regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non- infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes in the U.S. and in nearly every pharmaceutical market around the world. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use, or labeling, as our product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our product candidate. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market, and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product is typically lost to the generic product. Accordingly, competition from generic equivalents to ours or any of our partners' future products, if any, would materially adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in our or any of our partners' products, including NUZYRA and SEYSARA. For example, vancomycin has been available in generic form for many years, and Zyvox (linezolid) is now available in generic form. We cannot yet ascertain what impact these generic products and any future approved generic products will have on sales of NUZYRA, SEYSARA or, if approved, any of our or our partners' product candidates.

The success of our business may be dependent on the actions of our collaborative partners.

An element of our business and funding strategy is to enter into collaborative arrangements with established pharmaceutical and biotechnology companies who will finance or otherwise assist in the development, manufacture and marketing of products incorporating our technology, and who also provide us with funding in the form of milestone payments for progress in clinical development or regulatory approval. For example, we exclusively licensed rights to sarecycline for the treatment of acne in the U.S. to Allergan, who assigned such rights to Almirall, and Almirall is responsible for all clinical development, registration and commercialization in the U.S. of sarecycline for the treatment of acne. In addition, Almirall has an exclusive license to develop and commercialize sarecycline (i) for the treatment of acne in the greater China region and (ii) for the treatment of rosacea in the U.S., which converted to a non-exclusive license in December 2014 after Allergan did not exercise its development option with respect to rosacea. In April 2017, Paratek Bermuda Ltd., a wholly owned subsidiary of Paratek Pharmaceuticals, Inc., entered into the Zai Collaboration Agreement, pursuant to which we granted Zai an exclusive license to develop, manufacture and commercialize omadacycline in the Zai territory for all human therapeutic and preventative uses other than biodefense. Zai is responsible for the development, manufacturing and commercialization of the licensed product in the Zai territory, at its sole cost with certain assistance from Paratek. On December 18, 2019 Paratek Bermuda Ltd. assigned its rights under the Agreement to Paratek Pharmaceuticals, Inc.

Accordingly, our prospects will depend in part upon our ability to attract and retain collaborative partners and to develop technologies and products that achieve the criteria for milestone payments. When we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party in the respective territory. In addition, our collaborative partners may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms. We may not be successful in establishing or maintaining collaborative arrangements on acceptable terms or at all, collaborative partners may terminate funding before completion of projects, our product candidates may not achieve the criteria for milestone payments, our collaborative arrangements may not result in successful product commercialization, and we may not

derive any revenue from such arrangements. For example, we previously entered into a license and collaboration agreement with Novartis for the development of omadacycline, which was terminated. To the extent that we are not able to develop and maintain collaborative arrangements, we would need substantial additional capital to undertake research, development and commercialization activities on our own, we may be forced to limit the number of our product candidates we can commercially develop or the territories in which we commercialize them, and we might fail to commercialize products or programs for which a suitable collaborator cannot be found.

Reliance on collaborative relationships poses a number of risks, including the following:

- our collaborators may not perform their obligations as expected or in compliance with applicable laws;
- the prioritization, amount and timing of resources dedicated by our collaborators to their respective collaborations with us is not under our control;
- some product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products;
- our collaborators may elect not to proceed with the development of product candidates that we believe to be promising;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- some of our collaborators might develop independently, or with others, products that could compete with our products;
- a delay in the development timeline for omadacycline in the Zai territory would result in a potential loss of milestone payments and future royalties (if any) from the partnership under the Zai Collaboration Agreement;
- if the exclusive rights to sarecycline in the U.S. or the greater China region are returned to us by Almirall, or the rights to omadacycline in the Zai territory returned to us by Zai, we will need to establish a new development and commercialization partnership to further sarecycline in the U.S. and China (including Hong Kong and Macau) or omadacycline in the Zai territory. There can be no assurance that we would be able to find such a partner; and
- development, manufacture and commercialization efforts by Zai of omadacycline in the Zai territory and by Almirall of sarecycline in the greater China region could be adversely impacted by the effects of the coronavirus or any outbreak of contagious diseases.

If we are not able to establish and sustain additional partnerships, we may have to alter our commercialization and development plans, which could harm our business.

We may require additional funding to support and accelerate commercialization of NUZYRA and to continue the development of any other product candidates. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates, as we have done with Allergan (who assigned its rights to Almirall) for sarecycline in connection with the treatment of acne and rosacea in the U.S., with Almirall for sarecycline in connection with the treatment of acne in in the greater China region and with Zai for omadacycline in connection with all human therapeutic and preventative uses other than biodefense in the Zai territory.

We face significant competition in seeking appropriate collaborators. Whether or not we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside of the U.S., the potential market for the product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the patent position protecting the product candidate, the potential of competing products, the need to seek licenses or sub-licenses to third-party intellectual property and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies and whether collaboration on an alternative product could be more attractive than a collaboration with us. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms or at all. If we are unable to do so, it may delay completion of development and potential commercialization of our products. If we elect to increase our expenditures to fund development, registration or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Further, even if we are able to enter into collaborations, we must be able to sustain a mutually beneficial working relationship with our collaborators in order to achieve the intended benefits of those collaborations. In the past, certain of our collaborators, including Novartis, have terminated their partnering relationships with us due to delays and uncertainties in connection with the FDA regulatory pathway for approval of omadacycline for the ABSSSI and CABP indications. This past history may affect our ability to attract and enter into collaboration arrangements with future partners or collaborators.

We are continuing to build our sales and distribution infrastructure. If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing NUZYRA or any future product candidates to their full potential.

While we have entered into an arrangement with a third party to provide a contract field sales force, we currently are building the sales force and distribution capabilities within our organization. We are in the process of establishing a sales and marketing organization with technical expertise and supporting distribution capabilities to successfully commercialize NUZYRA, or to outsource this function to a third party. Both of these options can be expensive and time consuming. In addition, we may not be able to hire a sales force in the U.S. that is large enough or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our sales, marketing and distribution capabilities would adversely impact the commercialization of NUZYRA.

With respect to our existing products and any future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or as an alternative to our own sales force and distribution systems. To the extent that we enter into co-promotion or other licensing arrangements, our product revenue and profitability may be lower than if we directly marketed or sold any approved products. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

We have limited experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties.

We will need to commit significant time and financial and managerial resources to maintain and further develop our marketing and sales force to ensure they have the technical expertise required to address any challenges we may face with the commercialization of NUZYRA.

Factors that may inhibit our efforts to maintain and develop our commercialization capabilities include:

- an inability to retain an adequate number of effective commercial personnel in the medical markets we intend to target;
- an inability to train sales personnel, who may have limited experience with our company or NUZYRA, to deliver a consistent message regarding NUZYRA and be effective in convincing physicians to prescribe NUZYRA;
- a lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- an inability to equip sales personnel with effective materials, including medical and sales literature to help them educate physicians and our healthcare providers regarding NUZYRA and its proper administration;
- unforeseen costs and expenses associated with maintaining and further developing an independent sales and marketing organization; and
- complications or barriers that inhibit our commercial team from reaching the appropriate audience to promote our product(s) because of the spread of the coronavirus or any outbreak of other contagious diseases, especially during the early phase of our commercial launch of NUZYRA.

If we are not successful in establishing and maintaining an effective sales and marketing infrastructure, we will have difficulty commercializing NUZYRA and our future product revenue will suffer, which would adversely affect our business and financial condition.

If we enter into arrangements with third parties to perform sales, marketing 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 and sell any products that we develop ourselves. In addition, we likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing NUZYRA.

If we are unable to establish and maintain our agreements with third parties to distribute NUZYRA to patients, our results of operations and business could be adversely affected.

We rely on third parties to commercially distribute NUZYRA to patients. We have contracted with a third-party logistics company to warehouse NUZYRA and to process and ship customer orders and have negotiated contracts with specialty pharmacies and specialty distributors to sell and distribute NUZYRA. The specialty pharmacies sell NUZYRA directly to patients and provide patient education and ongoing management. The specialty distributors sell NUZYRA to hospitals and other large buying institutions. We have also contracted with a third-party patient services hub to help us with some or all of the following: benefits investigation and reimbursement adjudication support, patient assistance programs and ongoing compliance support. This distribution network will require significant coordination with our sales and marketing and finance organizations. In addition, failure to coordinate financial systems could negatively impact our ability to accurately report product revenue from NUZYRA. If we are unable to effectively manage the distribution process, the commercial launch and sales of NUZYRA, as well as any future products we may commercialize, sales could be delayed or severely compromised and our results of operations may be harmed.

In addition, the use of specialty pharmacies, specialty distributors and a third-party patient services hub involves certain risks, including, but not limited to, risks that these organizations will:

- not provide us with accurate or timely information regarding their inventories, the number of patients who are using NUZYRA or serious adverse reactions, events and/or product complaints regarding NUZYRA;
- not effectively sell or support NUZYRA, or communicate publicly concerning NUZYRA in a manner that is contrary to FDA rules and regulations;
- reduce or discontinue their efforts to sell or support NUZYRA;
- not devote the resources necessary to sell NUZYRA in the volumes and within the time frame we expect;
- be unable to satisfy financial obligations to us or others; or
- cease operations.

Any such events may result in decreased product sales and lower product revenue, which would harm our results of operations and business. Additionally, the provision of patient support services, although fairly typical in the pharmaceutical industry, can be subject to challenge under fraud and abuse or FDA laws if not structured appropriately.

Independent clinical investigators and CROs that we engage to conduct our clinical trials may not devote sufficient time or attention to our and our partners' clinical trials or be able to repeat their past success.

We expect to depend on independent clinical investigators and CROs to participate in and conduct our clinical trials, including our ongoing PK studies for omadacycline in oral only CABP, and any PMRs with the FDA. There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our or our partners' development programs. These investigators and CROs will not be our employees, and we will not be able to control, other than by contract, the amount of resources, including time, that they devote to our product candidates and clinical trials. If independent investigators fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we and our partners develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. Further, the FDA requires that we and our partners comply with standards, commonly referred to as current Good Clinical Practices, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, safety, integrity and confidentiality of clinical trial subjects are protected. Failure of clinical investigators or CROs to meet their obligations to us or comply with current Good Clinical Practices could adversely affect the clinical development of our product candidates and harm our business.

If NUZYRA or SEYSARA do not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, our revenue generated from their sales will be limited.

The commercial success of NUZYRA and SEYSARA will depend upon their level of market acceptance among physicians, patients and the medical community. The degree of market acceptance of NUZYRA and SEYSARA will depend on a number of factors, including:

- limitations or warnings contained in the product's FDA or foreign regulatory approved labeling;
- changes in the standard of care for the targeted indications for any of our products;
- limitations in the approved clinical indications for our products;
- demonstrated clinical safety and efficacy compared to other products;
- lack of significant adverse side effects;
- sales, marketing, reimbursement and distribution support;
- availability of coverage and adequate reimbursement from governmental or private third-party payors, such as Medicare or managed care plans;
- the extent to which government or third-party payors implement utilization management techniques, such as unreasonably high copayment formulary tiers, prior authorization or quantity limits for our product(s), or even refuse to provide coverage or adequate reimbursement for the products;
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness and value of our products;
- availability of alternative therapies at similar or lower cost, including generics and over-the-counter products;
- the extent to which the product is approved for inclusion on formularies of hospitals, and third-party payors, including managed care organizations;
- whether the product is designated under physician treatment guidelines as a therapy for particular infections;
- whether the product is designated under national treatment or formulary guidelines;
- adverse publicity about our products or favorable publicity about competitive products;
- convenience and ease of administration of our products; and
- potential product liability claims.

Although we believe our clinical studies demonstrate that NUZYRA and SEYSARA represent clinically meaningful and efficacious options for patients and physicians, it is possible that as we receive data from additional clinical trials or in a post-market setting from physician and patient experiences with the commercial products that do not continue to support such interpretations. It is also possible that the FDA, physicians and third-party payors will not agree with our interpretation of our existing and future clinical trial data. If we are unable to demonstrate the value of NUZYRA and SEYSARA based on our data, our opportunity for these products to maintain premium pricing and be commercialized successfully would be adversely affected. If NUZYRA or SEYSARA do not achieve an adequate level of acceptance by physicians, patients and the medical community, we and our partners may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of NUZYRA, SEYSARA or any future product candidates may require significant resources and may never be successful.

Even though NUZYRA and SEYSARA have been approved for marketing in the U.S., we or our partners may never obtain approval of or commercialize NUZYRA or SEYSARA outside of the U.S., which would limit our ability to realize their full market potential.

In October 2018, the FDA approved NUZYRA in the U.S. for the treatment of adults with CABP and ABSSSI that are proven or strongly suspected to be caused by susceptible bacteria. We have global commercial rights to omadacycline, except that we have entered into a collaboration with Zai to develop, manufacture and commercialize omadacycline in the Zai territory. In October 2018, the FDA also approved SEYSARA for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients nine years of age and older. In the U.S. and the greater China region, Almirall has the exclusive rights to commercialize SEYSARA for the treatment of acne, whereas we retain all rights to sarecycline all other countries. In the future, we, or our partners, may seek to commercialize omadacycline or sarecycline in countries outside of the U.S. and the greater China region.

In order to market products outside of the U.S., we and our partners must comply with numerous and varying regulatory requirements of other jurisdictions regarding safety and efficacy. Approval procedures vary among jurisdictions and can involve product testing and administrative review periods different from, and greater than, those in the U.S.

Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries.

Regulatory approval in one jurisdiction does not ensure regulatory approval in another, but failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory process in others. Failure to obtain regulatory approvals in other jurisdictions or any delay or setback in obtaining such approvals could adversely affect our business and financial condition.

Bacteria might develop resistance to NUZYRA, which would decrease the efficacy and commercial viability of NUZYRA.

Antibiotic resistance is primarily caused by the genetic mutation of bacteria resulting from suboptimal exposure to antibiotics where the drug does not eradicate all of the bacteria. While antibiotics have been developed to treat many of the most common infections, the extent and duration of their use worldwide has resulted in new mutated strains of bacteria resistant to current treatments. NUZYRA has been developed to treat patients infected with drug-resistant bacteria. If physicians, rightly or wrongly, associate the resistance issues of older generations of tetracyclines with NUZYRA, physicians might not prescribe NUZYRA for treating a broad range of infections. In addition, bacteria might develop resistance to NUZYRA if such bacteria are improperly dosed or treated repeatedly with NUZYRA over multiple years, causing the efficacy of NUZYRA to decline, which would negatively affect our potential to generate revenue from NUZYRA.

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

Despite the implementation of security measures, our internal computer systems, and those of our CROs, our partners and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. In addition, our systems safeguard important confidential personal data regarding our subjects. If a computer failure were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further commercialization of NUZYRA and development of any future product candidates could be delayed.

If any product liability lawsuits are successfully brought against us or any of our collaborative partners, we may incur substantial liabilities and may be required to limit commercialization of our products, including NUZYRA and SEYSARA.

We face an inherent risk of product liability lawsuits related to the testing of our products in seriously ill patients and will face an even greater risk from sales of NUZYRA and SEYSARA. Product liability claims may be brought against us or our partners by participants enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling any of our products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for NUZYRA or SEYSARA;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire clinical trial programs;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients or other claimants;

- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability of us or our partners to successfully commercialize our products.

With the approval of NUZYRA and SEYSARA for commercial sale, we are highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Also, because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our results of operations.

We currently hold $10.0 million in product liability insurance coverage in the aggregate annually, with a per incident limit of $10.0 million, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is becoming increasingly expensive. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on its business. These liabilities could prevent or interfere with our product development and commercialization efforts. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash resources and adversely affect our business, financial condition and results of operation.

If we fail to attract and retain key management and scientific personnel, we may be unable to successfully commercialize NUZYRA or any future product candidates.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are to a certain extent dependent on the members of our senior management team for our business success. The employment agreements with our senior management team can be terminated by us or them at any time, with notice. The departure of any of our executive officers could result in a significant loss in the knowledge and experience that we, as an organization, possesses and could cause significant delays, or outright failure, in the execution of our strategies, the successful commercialization of NUZYRA, and the development of any future product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, development and clinical personnel. We may not be able to attract or retain such qualified personnel due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly our development objectives and timelines, the success of our commercialization efforts, our ability to raise additional capital and our ability to implement our business strategy.

On March 15, 2019, Douglas Pagán resigned from his position as our Chief Financial Officer. We have initiated a search to identify and recruit a new candidate for the role of Chief Financial Officer. However, we cannot guarantee that the transition to a new Chief Financial Officer will be successful or will not result in a negative impact to the Company. Leadership transitions can be inherently difficult to manage, may cause uncertainty or a disruption to a business or may increase the likelihood of turnover in other key management and employees.

We depend on various consultants and advisors for the success and continuation of our development efforts.

We work extensively with various consultants and advisors, who provide advice and/or services in various business and development functions, including clinical development, operations and strategy, regulatory matters, legal and finance. The potential success of our drug development programs depends, in part, on continued successful collaborations with certain of these consultants and advisors. Our consultants and advisors are not our employees and may have commitments and obligations to other entities that may limit their availability to us. Typically, these advisors will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. We do not know if we will be able to maintain such relationships or that such consultants and advisors will not enter into other arrangements with competitors, any of which could have a detrimental impact on our development objectives and our business.

We will need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of February 28, 2020, we had 101 full-time employees. We expect to expand our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations that may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to successfully commercialize NUZYRA, develop any future product candidates and compete effectively with others in our industry will depend, in part, on our ability to effectively manage any future growth.

Our and our partners' business may become subject to economic, political, regulatory and other risks associated with international operations.

Our business is subject to risks associated with conducting business internationally, in part due to a number of our suppliers and collaborative and clinical trial relationships being located outside of the U.S. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation or political instability, in particular foreign economies and markets;
- differing regulatory requirements for drug approvals in foreign countries;
- differing regulatory requirements for drug product pricing and reimbursement;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the U.S;
- difficulties associated with staffing and managing foreign operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, typhoons, floods and fires and pandemics such as the coronavirus.

These risks may materially adversely affect our ability to attain or sustain profitable operations.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research and development involves the use of potentially hazardous materials and chemicals. Our operations may have produced hazardous waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by local, state and federal laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. We are also subject to numerous environmental, health and workplace safety laws and regulations and fire and building codes, including those governing laboratory procedures, exposure to blood-borne pathogens, use and storage of flammable agents and the handling of biohazardous materials. Although we have always maintained workers' compensation insurance as prescribed by the Commonwealths of Massachusetts and Pennsylvania to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Our employees, contractors, partners, principal investigators, CROs, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, contractors, partners, principal investigators, CROs, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, federal and state healthcare fraud and abuse laws and regulations, laws that require the reporting of financial information or data timely, completely or accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, 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. Third-party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us resulting from this misconduct, 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 civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could significantly harm our business.

We enter into various contracts in the normal course of our business in which we 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 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 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 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, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or does not have assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of former employers.

Certain of our former employees were previously employed at universities or other biotechnology or pharmaceutical companies, including competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we ourselves inadvertently or otherwise used or disclosed trade secrets or other proprietary information. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent us or a collaboration partner's ability to develop or commercialize certain potential products, which could severely harm the business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Intellectual Property

If we are unable to obtain and enforce patent protection for products, our product candidates and related technology, our business could be materially harmed.

Issued patents may be challenged, invalidated or circumvented. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by pharmaceutical companies. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not allow us to protect our inventions with patents to the same extent as do the laws of the U.S. Because patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, or may not be the first to make the inventions claimed in issued patents or pending patent applications, or

may not be the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. If such inventions or related inventions are successfully patented by others, we may be required to obtain licenses under third-party patents to market our product candidates, as described in greater detail below. Therefore, enforceability and scope of our patents in the U.S. and in foreign countries cannot be predicted with certainty, and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives or may not survive legal or administrative challenges by competitors.

Our strategy depends on our ability to identify and seek and obtain patent protection for our discoveries. This process is expensive and time consuming, and we may not be able to file and prosecute successfully all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. The issuance of a patent does not ensure that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology. Third parties may also seek to market generic versions of any approved products by submitting ANDAs to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable and/or not infringed. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid and/or unenforceable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the U.S. Patent and Trademark Office, or USPTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. The laws of some foreign countries do not protect proprietary information to the same extent as do the laws of the U.S., and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries. Outside of the U.S., patent protection must be sought in individual jurisdictions, further adding to the cost and uncertainty of obtaining adequate patent protection outside of the U.S. Accordingly, additional patents protecting our technology may not issue in the U.S. or in foreign jurisdictions, and any patents that do issue may not have claims of adequate scope to provide competitive advantage. Moreover, third parties may be able to successfully obtain claims and such claims may be broad. The allowance of broader claims may increase the incidence and cost of patent interference proceedings, opposition proceedings and/or reexamination proceedings, the risk of infringement litigation and the vulnerability of the claims to challenge. On the other hand, the allowance of narrower claims does not eliminate the potential for adversarial proceedings and may fail to provide a competitive advantage. Our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products or provide us with any competitive advantage. Moreover, even after they have issued, our patents and any patent for which we have licensed or may license rights may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited or expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with our products which could adversely affect our competitive business position, business prospects and financial condition. The following are examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

- we or our partners may initiate litigation or other proceedings against third parties to enforce our patent rights;
- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;
- third parties may initiate opposition or reexamination proceedings challenging the validity or scope of our patent rights, requiring us or our partners to participate in such proceedings to defend the validity and scope of our patents;
- there may be a challenge or dispute regarding inventorship or ownership of patents currently identified as being owned by or licensed to us;
- the USPTO may initiate an interference between patents or patent applications owned by or licensed to us and those of our competitors, requiring us or our collaborators to participate in an interference proceeding to determine the priority of invention, which could jeopardize our patent rights; or
- third parties may submit ANDAs to the FDA seeking approval to market generic versions of our approved or future approved products prior to expiration of relevant patents owned by or licensed to us, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

These lawsuits and proceedings would be costly and could adversely affect our results of operations and divert the attention of our managerial and scientific personnel. A court or administrative body may decide that our patents are invalid or not infringed by a third party's product or activity or that the scope of certain issued claims must be further limited. An adverse outcome in a litigation or proceeding involving our own patents could limit our ability to assert our patents against these or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. An adverse outcome in a dispute involving inventorship or ownership of our patents could, for example, subject us to additional royalty obligations and expand the number of product candidates that are subject to the royalty and other obligations of our license agreement with Tufts.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;
- others may be able to make compounds that are similar to our products or product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- we may be unable to effectively protect our trade secrets;
- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

Our and our partners' success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to manufacture, use, sell, offer for sale or import our products or impair our competitive position. Patent applications that we believe we do not infringe, but that we may ultimately be found to infringe, could be issued to third parties. In addition, to the extent that a third party develops new technology that covers our products or product candidates, we and our partners may be required to obtain licenses to that technology, which licenses may not be available or may not be available on commercially reasonable terms. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations. Moreover, our or our partners' failure to maintain a license to any technology that we require may also materially harm our business, financial condition and results of operations. Furthermore, we would be exposed to a threat of litigation.

In the pharmaceutical industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace. The types of situations in which we may become a party to such litigation or proceedings include:

- we or our partners may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or processes do not infringe those third parties' patents;
- if our competitors file patent applications that claim technology also claimed by us, we or our collaborators may be required to participate in interference or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;
- if third parties initiate litigation claiming that our processes, products or use of products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings;
- if third parties initiate litigation claiming that our brand names infringe their trademarks, we and our collaborators will need to defend against such proceedings; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

These lawsuits would be costly and could affect our results of operations and divert the attention of our managerial and scientific personnel. There is a risk that a court would decide that we or our partners are infringing the third party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our partners may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product or product candidate. In addition, there is a risk that a court will order us or our partners to pay the other party damages. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties and require us to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. Any of these outcomes could have a material adverse effect on our business.

The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, do not develop or obtain non-infringing technology, fail to defend an infringement action successfully or has infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our products.

The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater 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. Patent litigation and other proceedings may also absorb significant management time and financial resources. There are inherent risks and uncertainties associated with any litigation, including those involving intellectual property, which litigation and risks can be costly in of itself or create an environment making it challenging to raise additional capital.

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

We are currently party to an intellectual property license agreement with Tufts. The license agreement imposes, and we expect that future license agreements may impose, various diligence, milestone payment, royalty, insurance and other obligations on us. For example, we are required to use our best efforts to effect introduction of licensed products under the agreement into the U.S. commercial market. If we fail to comply with our obligations under the license, Tufts may have the right to terminate the license agreement, in which event we might not be able to market any product that is covered by the agreement, such as NUZYRA. Termination of the license agreement or reduction or elimination of our licensed rights may result in us having to negotiate a new or reinstated license with less favorable terms. If Tufts were to terminate its license agreement with us for any reason, our business could be materially harmed. In the event that we are unable to maintain the Tufts license, we may lose the ability to exclude third parties from offering substantially identical products for sale and may even risk the threat of a patent infringement lawsuit from our former licensor based on our continued use of its intellectual property. Either of these events could adversely affect our competitive business position and harm our business.

Under our license agreement with Tufts, we are responsible for prosecution and maintenance of the licensed patents and patent applications, including payment of necessary government fees. In the event that any of the licensed patents or patent applications unintentionally lapse or are otherwise materially diminished in value, our relationship with Tufts could be harmed. This could result in termination of the license, loss of the rights to control prosecution of the licensed patents and patent applications and/or liability to Tufts for any loss.

If we or our partners are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, our policy is to enter into confidentiality agreements with our employees, consultants, collaborators and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual. Such assignment or license may not be available on commercially reasonable terms or at all.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously or concurrently employed at research institutions and/or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on our outside counsel to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business. In addition, we are responsible for the payment of patent fees for patent rights that we have licensed from other parties. If any licensor of these patents does not itself elect to make these payments, and we fail to do so, we may be liable to the licensor for any costs and consequences of any resulting loss of patent rights.

If we do not obtain protection under the Hatch-Waxman Amendments and similar foreign legislation by extending the term of patents covering each of our product candidates, our business may be materially harmed.

Based on the FDA marketing approval of our products, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process, with the condition that this five year extension does not extend the patent for more than fourteen years from the approval date. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than our request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product may not extend beyond the current patent expiration dates and our competitors may obtain approval to market competing products sooner. As a result, our revenue could be reduced, possibly materially.

Our contract with BARDA may affect our intellectual property rights.

Our contract with BARDA includes provisions that implement the Bayh-Dole Act of 1980 and grant the U.S. government certain rights in inventions that may be conceived or first actually reduced to practice under the contract. In particular, the U.S. government is granted a nonexclusive, nontransferable, irrevocable, paid-up, worldwide license to practice such inventions or have such inventions practiced for or on the U.S. government's behalf. The U.S. government also has "march-in" rights with respect to such inventions, which allow the U.S. government to directly or require us, our assignee, or our exclusive licensee to license such inventions to a third party on an exclusive, partially exclusive, or non-exclusive basis if the U.S. government determines that such an action is necessary (i) because adequate steps have not been taken to achieve practical application of such an invention, (ii) to alleviate health or safety needs, (iii) to meet requirements for public use specified by federal regulations, or (iv) due to a violation of an agreement to manufacture substantially in the U.S. a product embodying such an invention or produced through the use of such an invention. Unless waived by the U.S. government, we are required to obtain such an agreement to manufacture substantially in the U.S. from another party to which we exclusively license such an invention. The U.S. government also has the right to take title to such inventions if we fail to disclose, elect title to, or pursue or maintain patent protection for such inventions within specified periods of time.

Risks Related to the Notes

Servicing our debt, including the Notes, requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Notes, depends on our future performance, which is subject to regulatory, economic, financial, competitive and other factors beyond our control. We are a biopharmaceutical company that has not yet generated profit from product sales. We expect to continue to incur losses as we add infrastructure and personnel to support our commercialization and product development efforts and operations. Accordingly, our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

The Notes are subordinated to our senior indebtedness, effectively subordinated to our secured indebtedness and structurally junior to any liabilities of our subsidiaries.

The Notes are our general, unsecured, senior subordinated obligations and rank equally in right of payment with all of our future unsecured, senior subordinated indebtedness; senior to all of our future subordinated indebtedness; junior to all of our existing and future senior indebtedness, whether or not secured; effectively subordinated to all of our secured indebtedness, including secured indebtedness under the Hercules Loan Agreement to the extent of the value of the assets securing such indebtedness; and structurally junior to the liabilities, including trade payables, of our subsidiaries. In the event of our bankruptcy, liquidation, reorganization or other winding up, our assets that secure debt ranking senior in right of payment to the Notes will be available to pay obligations on the Notes only after the secured debt has been repaid in full from these assets, and the assets of our subsidiaries will be available to pay obligations on the Notes only after all claims senior to the Notes have been repaid in full. There may not be sufficient assets remaining to pay amounts due on any or all of the Notes then outstanding. The indenture governing the Notes does not prohibit us from incurring additional senior debt or secured debt, nor does it prohibit any of our subsidiaries from incurring additional liabilities.

Despite our current debt levels, we may still incur substantially more debt or take other actions which would intensify the risks discussed above.

Despite our current consolidated debt levels, we and our subsidiaries may be able to incur substantial additional debt in the future, subject to the restrictions contained in our debt instruments, some of which may be secured debt. We are not restricted under the terms of the indenture governing the Notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing the Notes that could have the effect of diminishing our ability to make payments on the Notes when due. While the Hercules Loan Agreement restricts our ability and the ability of our subsidiaries to issue or incur additional indebtedness, including secured indebtedness, if our loans under the Hercules Loan Agreement mature or are repaid, we may not be subject to such restrictions under the terms of any subsequent indebtedness.

We may not have the ability to raise the funds necessary to repurchase the Notes upon a fundamental change, and our existing or future debt may contain limitations on our ability to repurchase the Notes.

Holders of the Notes have the right to require us to repurchase their Notes upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the Notes to be repurchased, *plus* accrued and unpaid interest, if any. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Notes surrendered therefor. In addition, our ability to repurchase the Notes may be limited by law, by regulatory authority or by agreements governing our indebtedness that exist at the time of the repurchase. The Hercules Loan Agreement currently limits our ability to repurchase the Notes. Our failure to repurchase Notes at a time when the repurchase is required by the indenture governing the Notes would constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under the Hercules Loan Agreement and/or agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes.

In addition, our borrowings under the Hercules Loan Agreement are, and are expected to continue to be, at variable rates of interest and expose us to interest rate risk. If interest rates increase, our debt service obligations on the variable rate indebtedness would increase even though the amount borrowed remained the same, and our net income would decrease.

The Hercules Loan Agreement limits our ability to pay any cash amount upon repurchase of the Notes.

The Hercules Loan Agreement prohibits us from making any cash payments to repurchase the Notes upon a fundamental change. Any new credit facility that we may enter into may have similar restrictions.

Our failure to repurchase the Notes as required under the terms of the Notes would constitute a default under the indenture governing the Notes and permit holders of the Notes to accelerate our obligations under the Notes. A default under the indenture or the fundamental change itself could also lead to a default under the Hercules Loan Agreement or agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes.

Future sales of our common stock or equity-linked securities in the public market could lower the market price for our common stock.

In the future, we may sell additional shares of our common stock or equity-linked securities to raise capital. In addition, a substantial number of shares of our common stock are reserved for issuance upon the exercise of stock options and upon conversion of the Notes. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock. The issuance and sale of substantial amounts of common stock or equity-linked securities, or the perception that such issuances and sales may occur, could adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity or equity-linked securities.

Risks Related to Our Common Stock

The trading price of our common stock is volatile.

The trading price of our common stock could be subject to significant fluctuations. Market prices for securities of pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the trading price of our common stock to fluctuate include:

- the commercial performance of NUZYRA and SEYSARA;
- our ability to maintain and expand regulatory approval for NUZYRA;
- issues in manufacturing NUZYRA;
- the results of our current and any future clinical trials of NUZYRA or any future product candidates;
- the entry into, or termination of, key agreements, including key commercial partner agreements;
- the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;

- adverse publicity relating to the antibiotics market, including with respect to other products and potential products in such market;
- the introduction of technological innovations or new therapies that compete with our products;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- changes in the structure of healthcare payment systems; and
- period-to-period fluctuations in our financial results, including, in particular, our use of cash in operations.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

We expect that we will retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in our certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders and the ability of the board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, or DGCL, which prohibits stockholders owning in excess of 15% of our voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Future sales of shares by existing stockholders could cause the trading price of our common stock to decline.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of December 31, 2019, approximately 0.9 million shares of common stock are held by our directors, executive officers and other affiliates and are subject to volume limitations under Rule 144 under the Securities Act. In addition, approximately 2.9 million shares of common stock that are subject to outstanding options and restricted stock units as of December 31, 2019 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rule 144 under the Securities Act. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Because our merger resulted in an ownership change under Section 382 of the Internal Revenue Code for Transcept, Transcept's pre-merger net operating loss carryforwards and certain other tax attributes are subject to limitations. The net operating loss carryforwards and other tax attributes of the former Paratek entity and us may also be subject to limitations as a result of ownership changes.

If a corporation undergoes an "ownership change" within the meaning of Section 382 of the Internal Revenue Code of 1986, as amended, or Section 382, the corporation's net operating loss carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. The Merger resulted in an ownership change for Transcept and, accordingly, Transcept's net operating loss carryforwards and certain other tax attributes are subject to limitations on their use after the Merger. Old Paratek's net operating loss carryforwards may also be subject to limitation as a result of prior shifts in equity ownership and/or the Merger. Additional ownership changes in the future could result in additional limitations on Transcept's, Old Paratek's and our net operating loss carryforwards. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of Transcept's, Old Paratek's or our net operating loss carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations.

If securities or industry analysts do not publish research or reports or publish inaccurate or unfavorable research about us, the trading price and trading volume of our common stock could decline.

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us, our business and our common stock. As of December 31, 2019, we had research coverage by seven securities analysts. If the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research regarding us or our business model, technology or stock performance, the trading price of our common stock would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause the trading price or trading volume of our common stock to decline. Moreover, the unpredictability of our financial results likely reduces the certainty, and therefore reliability, of the forecasts by securities or industry analysts of our future financial results, adding to the potential volatility of the trading price of our common stock.

Maintaining and improving our financial controls and the requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified board members.

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and The Nasdaq Global Market rules. The requirements of these rules and regulations have increased and will continue to significantly increase our legal and financial compliance costs, including costs associated with the hiring of additional personnel, making some activities more difficult, time-consuming or costly, and may also place undue strain on our personnel, systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition.

The Sarbanes-Oxley Act requires, among other things, that we maintain disclosure controls and procedures and internal control over financial reporting. Ensuring that we have adequate internal financial and accounting controls and procedures in place, as well as maintaining these controls and procedures, is a costly and time-consuming effort that needs to be re-evaluated frequently. Section 404 of the Sarbanes-Oxley Act, or Section 404, requires that we annually evaluate our internal control over financial reporting to enable management to report on, and our independent auditors to audit as of the end of each fiscal year, the effectiveness of those controls. In connection with the Section 404 requirements, both we and our independent registered public accounting firm test our internal controls and could, as part of that documentation and testing, identify material weaknesses, significant deficiencies or other areas for further attention or improvement.

Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, require the hiring of additional finance, accounting and other personnel, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. Moreover, adequate internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. As a result, our failure to satisfy the requirements of Section 404 on a timely basis could result in the loss of investor confidence in the reliability of our financial statements, which in turn could cause the market value of our common stock to decline.

Various rules and regulations applicable to public companies make it more difficult and more expensive for us to maintain directors' and officers' liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to maintain coverage. If we are unable to maintain adequate directors' and officers' liability insurance, our ability to recruit and retain qualified officers and directors, especially those directors who may be deemed independent for purposes of The Nasdaq Global Market rules, will be significantly curtailed.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our headquarters are located in Boston, Massachusetts, where we occupy approximately 12,000 square feet of office space under a lease that expires in 2021. We also rent approximately 19,000 square feet of office space in King of Prussia, Pennsylvania on a monthly basis under a lease that expires in 2024.

Item 3. Legal Proceedings

From time to time the Company is involved in legal proceedings arising in the ordinary course of business. The Company believes there is no litigation pending that could have, individually, or in the aggregate, a material adverse effect on its results of operations or financial condition.

Item 4. Mine Safety Disclosures

None.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on The Nasdaq Global Market under the symbol "PRTK." As of February 28, 2020, there were 82 holders of record of our common stock.

Recent Sales of Unregistered Securities

Set forth below is information regarding securities sold by us during 2018 that were not registered under the Securities Act. Also included is the consideration, if any, received by us for the securities and information relating to the section of the Securities Act, or rule of the SEC under which exemption from registration was claimed.

On August 1, 2018, we entered into the fifth amendment to the Hercules Loan Agreement with Hercules. In connection with the amendment, we issued to Hercules Capital, Inc. a warrant to purchase our common stock, or the Fifth Amendment Warrant. The Fifth Amendment Warrant is exercisable for a minimum of up to 19,627 shares of our common stock (and additional shares if certain additional tranches are funded) at an exercise price of $10.19 per share. The Fifth Amendment Warrant's total relative fair value of $0.1 million was determined using a Black-Scholes option-pricing model, as described in Note 12, *Common Stock*, in the accompanying notes to the consolidated financial statements, and was included as a discount to the Term Loan, as defined in Note 16, *Long-Term Debt*. The exercise price and the number of shares are subject to adjustment upon a merger event, reclassification of the shares of common stock, subdivision or combination of the shares of common stock or certain dividends payments. The Fifth Amendment Warrant is exercisable at any time until the earlier of seven years from issuance and the consummation of a Public Acquisition, as defined in the Fifth Warrant agreement, and will be exercised automatically on a net issuance basis if not exercised prior to the termination date and if the then-current fair market value of one share of common stock is greater than the exercise price then in effect.

No underwriters were involved in the foregoing sale of securities. The Fifth Amendment Warrant was issued to Hercules Capital, Inc. in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2), relative to transactions by an issuer not involving any public offering. Hercules Capital, Inc. represented to us in connection with its purchase that it was an "accredited investor" as defined in Rule 501 of Regulation D promulgated under the Securities Act and was acquiring the securities for its own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof. Hercules Capital, Inc. received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

Securities authorized for issuance under equity compensation plans

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2019:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights		Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights		Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans(1)	
Equity compensation plans approved by stockholders (1)	4,945,451	(2)	$ 8.78	(3)	1,331,743	(4)
Equity compensation plans not approved by stockholders	700,485	(5)	12.10	(6)	709,515	(7)
Total	5,645,936		$ 9.19		2,041,258	

(1) The number of authorized shares under the 2015 Equity Incentive Plan, or the 2015 Plan, will automatically increase on January 1 of each year, for the period commencing on (and including) January 1, 2016 and ending on (and including) January 1, 2025, in an amount equal to 5% of the total number of shares of common stock outstanding on December 31st of the preceding calendar year. Notwithstanding the foregoing, the Board of Directors of the Company may act prior to January 1st of a given year to provide that there will be no January 1st increase in the Share Reserve for such year or that the increase in the Share Reserve for such year will be a lesser number of shares of common stock than would otherwise occur.

(2) Includes 2,688,888 shares relating to outstanding options, 2,152,108 shares relating to restricted stock units and 104,455 warrants outstanding.

(3) Represents the weighted-average exercise price of outstanding options, warrants and rights.

(4) Includes 798,187 shares available under the 2009 and 2018 Employee Stock Purchase Plans. All shares cancelled or forfeited during the years ended December 31, 2019 and 2018 under the 2006 and 2014 Plans became available for grant under the 2015 Plan.

(5) Includes 547,185 shares relating to outstanding options and 153,300 shares relating to restricted stock units under the 2015 Inducement Plan and the 2017 Inducement Plan.

(6) Represents the weighted-average exercise price of outstanding options and rights.

(7) Includes 306,500 shares that remain available for grant under the 2015 Inducement Plan that the Company does not currently anticipate issuing.

Issuer Purchases of Equity Securities

There were no repurchases of our common stock during the fourth quarter of 2019.

Item 6. Selected Financial Data

The following selected financial data has been derived from our audited consolidated financial statements. The information below is not necessarily indicative of the results of future operations and should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," and Item 1A, "Risk Factors," of this Annual Report on Form 10-K, and the consolidated financial statements and related notes thereto included in Item 8, "Financial Statements and Supplementary Data", of this Annual Report on Form 10-K, in order to fully understand factors that may affect the comparability of the information presented below.

	Year Ended December 31,				
	2019	2018	2017	2016	2015
	(in thousands, except per share and data)				
Consolidated Statements of Operations Data:					
Revenue	$ 16,544	$ 17,117	$ 12,616	$ 29	$ —
Operating expenses:					
Cost of product revenue	3,484	—	—	—	—
Research and development	39,554	57,508	60,072	83,460	50,765
General and administrative	89,135	63,658	36,965	26,400	19,988
Impairment of intangible assets	—	107	743	—	2,860
Change in fair value of contingent consideration	—	(71)	(584)	(345)	(3,560)
Total operating expenses	132,173	121,202	97,196	109,515	70,053
Loss from operations	(115,629)	(104,085)	(84,580)	(109,486)	(70,053)
Non-operating other expense, net	(12,860)	(7,769)	(3,736)	(2,150)	(807)
Net loss before provision for income taxes	(128,489)	(111,854)	(88,316)	(111,636)	(70,860)
Provision for income taxes	301	502	753	—	—
Net loss attributable to common stockholders	$ (128,790)	$ (112,356)	$ (89,069)	$ (111,636)	$ (70,860)
Net loss per share, basic and diluted	$ (3.93)	$ (3.57)	$ (3.32)	$ (5.51)	$ (4.29)
Weighted average common shares outstanding, basic and diluted	32,791,934	31,513,454	26,827,253	20,253,082	16,501,912

	As of December 31,	
	2019	2018
Selected Consolidated Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 215,379	$ 292,838
Total assets	251,079	300,192
Working capital	219,154	237,534
Current liabilities	24,200	17,709
Long-term debt	260,728	228,959
Common stock and additional paid-in capital	671,537	630,174
Accumulated deficit	(711,258)	(582,468)
Total stockholders' equity (deficit)	(39,647)	47,578

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains certain statements that are not strictly historical and are "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995 and involve a high degree of risk and uncertainty. Actual results may differ materially from those projected in the forward-looking statements due to other risks and uncertainties. All forward-looking statements included in this section are based on information available to us as of the date hereof, and we assume no obligation to update any such forward-looking statement, except as required by law.

Company Overview

We are a commercial-stage biopharmaceutical company focused on the development and commercialization of novel life-saving therapies for life-threatening diseases or other public health threats for civilian, government and military use. We have used our expertise in biology and tetracycline chemistry to create chemically diverse and biologically distinct small molecules derived from the minocycline core structure. Our United States, or U.S., Food and Drug Administration, or FDA, approved commercial product, NUZYRA® (omadacycline) is a once-daily oral and intravenous antibiotic for the treatment of adult patients with community-acquired bacterial pneumonia, or CABP, and acute skin and skin structure infections, or ABSSSI, caused by susceptible pathogens. SEYSARA® (sarecycline) is an FDA-approved product with respect to which we have exclusively licensed in the U.S. and greater China region, which includes the People's Republic of China, Hong Kong and Macau, certain rights to Almirall, LLC, or Almirall. SEYSARA is currently being marketed by Almirall in the U.S. as a new once-daily oral therapy for the treatment of moderate to severe acne vulgaris. With respect to our technology as it relates to sarecycline, we retain development and commercialization rights in all countries other than the U.S. the greater China region.

To date, we have devoted a substantial amount of our resources to research and development efforts, including conducting clinical trials for omadacycline, protecting our intellectual property and providing selling, general and administrative support for these operations. We began generating revenue from product sales in February 2019; as such, we have financed our operations primarily through sales of our common stock, debt financings, strategic collaborations, and grant funding.

We have incurred significant losses since our inception in 1996. Our accumulated deficit at December 31, 2019 was $711.3 million and our net loss for the year ended December 31, 2019 was $128.8 million. A substantial amount of our net losses resulted from costs incurred in connection with our research and development programs and selling, general and administrative costs associated with our operations. The net losses and negative operating cash flows incurred to date, together with expected future losses, have had, and likely will continue to have, an adverse effect on our stockholders' equity (deficit) and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate offsetting revenue, if any. We expect to continue to incur significant expenses and operating losses for the next several years.

While the BARDA contract is expected to significantly strengthen our cash position, unless we can generate a sufficient amount of revenue from our commercial products, we may need to raise additional capital in order to support and accelerate the commercialization of omadacycline and to advance the development of our other indications for omadacycline, such as NTM, or other product candidates. If we cannot generate a sufficient amount of product or royalty revenue to finance our cash requirements, we expect to finance our future cash needs primarily through a combination of public or private equity offerings, debt or other structured financings, strategic collaborations and grant funding. We may be unable to raise capital when needed or on attractive terms, which would force us to delay, limit, reduce or terminate our development programs or commercialization efforts. We will need to generate significant revenue to achieve and sustain profitability, and we may never be able to do so.

Financial Operations Overview

Revenue

Revenue earned during the year ended December 31, 2019 was attributable to U.S. NUZYRA product sales in the U.S. of $11.5 million, net, and royalty and collaboration revenue of $5.0 million, consisting primarily of a $3.0 million milestone payment earned upon submission by Zai of the first regulatory approval application for a licensed product in the People's Republic of China in December 2019 and royalties earned from SEYSARA sales in the U.S.

Cost of Product Revenue

Cost of product revenue during the year ended December 31, 2019 consisted of the cost of the product itself, labor and overhead, as well as stability studies, inventory scrap and royalty expense.

Research and Development Expense

Research and development expenses consisted primarily of costs directly incurred by us for the development of our product candidates, which include:

- expenses incurred under agreements with clinical research organizations, or CROs, and investigative sites that conduct our clinical trials;
- the cost of acquiring and manufacturing preclinical and clinical study materials and developing manufacturing processes;
- direct employee-related expenses, including salaries, benefits, travel and stock-based compensation expense of our research and development personnel;
- allocated facilities, depreciation, and other expenses, which include rent and maintenance of facilities, insurance and other supplies; and
- costs associated with preclinical activities and regulatory compliance.

Research and development costs are expensed as incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites.

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our products or product candidates for which we or any partner obtain regulatory approval, such as NUZYRA and SEYSARA. Aside from the FDA approval of NUZYRA and SEYSARA in the U.S., we or our partners may never succeed in achieving regulatory approval for NUZYRA or SEYSARA outside of the U.S., or other product candidates. The duration, costs and timing of clinical trials and development of our product candidates depend on a variety of factors, including:

- the scope, rate of progress, and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- future clinical trial results;
- potential changes in government regulation; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that therapeutic candidate. For example, if the FDA, or another regulatory authority, were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of the clinical development of product candidates or if we experience significant delays in the enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

We manage certain activities, such as clinical trial operations, manufacture of clinical trial material, and preclinical animal toxicology studies, through third-party contract organizations. The only costs we track by each product candidate are external costs such as services provided to us by CROs, manufacturing of preclinical and clinical drug product, and other outsourced research and development expenses. We do not assign or allocate to individual development programs internal costs such as salaries and benefits, facilities costs, lab supplies and the costs of preclinical research and studies. Our external research and development expenses for omadacycline and other projects during the years ended December 31, 2019 and 2018 are as follows:

	Year Ended December 31,	
(in thousands)	**2019**	**2018**
Omadacycline	$ 24,397	$ 32,316
Other research and development costs	15,157	25,192
Total	$ 39,554	$ 57,508

Selling, General and Administrative Expense

Selling, general and administrative expenses consist principally of costs associated with our contract sales force, commercial support personnel, and medical affairs professionals, as well as personnel in executive and other administrative functions. Other selling, general and administrative expenses include marketing, trade, and other commercial costs and distribution fees necessary to support the launch of NUZYRA and professional fees for legal, consulting and accounting services.

Interest Expense

Interest expense represents interest incurred on the Hercules Loan Agreement (as defined below), the Notes (as defined below), and the Royalty-Backed Loan Agreement (as defined below), as well as the adjustment of our marketable securities to amortized cost.

Interest Income

Interest income represents interest earned on our money market funds and marketable securities.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018

	Year Ended December 31,	
	2019	2018
Product revenue, net	$ 11,517	$ —
Collaboration and royalty revenue	5,027	17,117
Net revenue	16,544	17,117
Expenses:		
Cost of product revenue	3,484	—
Research and development	39,554	57,508
Selling, general and administrative	89,135	63,658
Impairment of intangible assets	—	107
Changes in fair value of contingent consideration	—	(71)
Total operating expenses	132,173	121,202
Loss from operations	(115,629)	(104,085)
Other income and expenses:		
Interest income	3,574	3,260
Interest expense	(16,403)	(10,985)
Other losses, net	(31)	(44)
Net loss before provision for income taxes	(128,489)	(111,854)
Provision for income taxes	301	502
Net loss	$ (128,790)	$ (112,356)

Revenue

Net product revenue recognized on sales of NUZYRA in the U.S. was $11.5 million for the year ended December 31, 2019. No product revenue was recorded for the year ended December 31, 2018.

Collaboration and Royalty Revenue

Collaboration and royalty revenue for the year ended December 31, 2019 was primarily the result of a $3.0 million milestone payment earned under the license and collaboration agreement with Zai Lab (Shanghai) Co., Ltd. or the Zai Collaboration Agreement (as defined below), upon submission of the first regulatory approval application for a licensed product in the People's Republic of China in December 2019, $1.9 million of royalty revenues earned on sales of SEYSARA in the U.S. by Almirall under the Almirall Collaboration Agreement (as defined below), and $0.1 million of royalty revenues earned on sales of XERAVA in the U.S. by Tetraphase under the Tetraphase License Agreement (as defined below). Fourth quarter royalty revenue recognized for sales of SEYSARA in the U.S. was estimated using third party data and an approximation of discounts and allowances to calculate net product sales, to which we then applied the applicable royalty percentage specified in the Almirall Collaboration Agreement. Differences between actual and estimated royalty revenue will be adjusted for in the period in which they become known, which is expected to be the following quarter.

Collaboration and royalty revenue for the year ended December 31, 2018 was primarily the result of a $12.0 million milestone payment earned under the Almirall Collaboration Agreement, a $5.0 million milestone payment earned under the Zai Collaboration Agreement, and $0.1 million of revenue earned under a royalty sharing agreement entered into with former Transcept stockholders or the Royalty Sharing Agreement. The Zai Collaboration Agreement and Almirall Collaboration Agreement milestone payments were earned upon FDA approval of NUZYRA and SEYSARA, respectively, in October 2018.

Cost of Product Revenue

Cost of product revenue of $3.5 million for the year ended December 31, 2019 consisted primarily of costs associated with the manufacturing of NUZYRA as well as costs of product provided under our sampling and other commercial programs, royalties on net sales of NUZYRA owed to Tufts, and certain period costs. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, certain of the costs of NUZYRA units recognized as revenue during the year ended December 31, 2019 were expensed prior to FDA approval in October 2018, and therefore are not included in cost of sales during the period. We expect cost of sales to increase in relation to net product revenues as we deplete these inventories, which we anticipate will occur in the second quarter of 2020. No cost of product revenue was recorded for the year ended December 31, 2018.

Research and Development Expense

Research and development expenses were $39.6 million for the year ended December 31, 2019, compared to $57.5 million for the year ended December 31, 2018. The $17.9 million decrease is primarily the result of the capitalization of NUZYRA commercial supply costs, which were classified as research and development expense until FDA approval of NUZYRA on October 2, 2018, partially offset by higher clinical study costs associated with our Phase 2 UTI program.

We anticipate that research and development expenses will remain relatively consistent in future periods as a result of winding down of our Phase 2 program evaluating omadacycline for the treatment of UTI and beginning our FDA post-marketing commitments and work for exploring pathways for NTM indications.

Selling, General and Administrative Expense

Selling, general and administrative expenses were $89.1 million for the year ended December 31, 2019, compared to $63.7 million for the year ended December 31, 2018. The $25.4 million increase is primarily the result of the cost of our contract sales force, higher marketing, trade and distribution fees, and increased salaries, benefits and other personnel-related costs in support of the commercialization of NUZYRA.

Impairment of Intangible Assets

During 2018, we recorded a $0.1 million impairment charge in connection with an expected decline in Intermezzo sales and the withdrawal of the NDA for Intermezzo from the FDA by Purdue Pharma as of December 31, 2018. As a result of this withdrawal, further sales of the drug are not planned and neither Paratek nor the former shareholders of Transcept will receive future cash payments pursuant to the Royalty Sharing Agreement. As such, we impaired the remaining balance of the Intermezzo product rights during 2018.

Changes in Fair Value of Contingent Obligations

During the year ended December 31, 2018, we recorded a $0.1 million decrease in the fair value of our contingent obligation to former Transcept shareholders. The decrease in the fair value of our contingent obligation is the result of Purdue no longer selling Intermezzo, as described in the "*Impairment of Intangible Assets*" section above.

Other Income and Expenses

Interest expense for the year ended December 31, 2019 represents interest incurred on the Notes (as defined below) of $8.7 million, the Hercules Loan Agreement of $6.8 million, and the Royalty-Backed Loan Agreement of $2.7 million, partially offset by the net accretion of our marketable securities of $1.8 million. Interest income for the year ended December 31, 2019 represents interest earned on our money market funds and marketable securities of $3.6 million. Interest expense for the year ended December 31, 2018 represents interest incurred on the Hercules Loan Agreement of $6.7 million and the Notes of $6.0 million, partially offset by the net accretion of our marketable securities of $1.7 million. Interest income for the year ended December 31, 2018 represents interest earned on our money market funds and marketable securities of $3.3 million.

Liquidity and Capital Resources

On July 2, 2019, we entered into an At the Market Sales Agreement, or the 2019 Sales Agreement, with Jefferies LLC, or Jefferies, and BTIG, LLC, or BTIG, under which we may offer and sell our common stock having aggregate sales proceeds of up to $50.0 million from time to time through Jefferies and BTIG as our sales agents. Sales of our common stock through Jefferies and BTIG, if any, will be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act. For the year ended December 31, 2019, we sold 6,524,194 shares of our common stock pursuant to the 2019 Sales Agreement for $26.6 million in proceeds, after deducting commissions of $0.8 million. As of February 28, 2020, $13.2 million remains available for sale under the 2019 Sales Agreement.

On February 25, 2019, we, through our wholly-owned subsidiary Paratek Royalty Corporation, entered into the Royalty-Backed Loan Agreement with Healthcare Royalty Partners III, L.P. Pursuant to the terms of the Royalty-Backed Loan Agreement, upon the satisfaction of the conditions precedent set forth therein, we borrowed a $32.5 million loan, which was secured by, and will be repaid based upon, royalties from the Almirall Collaboration Agreement. On May 1, 2019, we received $27.8 million, net of $0.5 million lender discount, $0.2 million in lender expenses incurred, and $4.0 million that was deposited into an interest reserve account. We also paid $1.2 million in other lender fees related to the Royalty-Backed Loan Agreement.

On April 18, 2018, we entered into a Purchase Agreement, or the Purchase Agreement, with several initial purchasers, or the Initial Purchasers for whom Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Partners LLC acted as representatives, relating to the sale of $135.0 million aggregate principal amount of 4.75% Convertible Senior Subordinated Notes due 2024, or the Notes. We also granted the Initial Purchasers an option to purchase up to an additional $25.0 million aggregate principal amount of Notes, which was exercised in full on April 20, 2018. In addition, J. Wood Capital Advisors LLC, the Company's financial advisor, purchased $5.0 million aggregate principal amount of Notes in a separate, concurrent private placement on the same terms as other investors. After deducting costs incurred of $6.0 million, we received proceeds from the sale of the Notes of $159.0 million in April 2018.

On January 22, 2018, we completed an underwritten public offering of 3,205,128 shares of our common stock, resulting in total proceeds of $50.0 million. Offering expenses incurred were $0.2 million.

On December 1, 2017, we filed a registration statement on Form S-3 with the SEC, which was declared effective on December 8, 2017, to sell certain of our securities in an aggregate amount of up to $250.0 million. As of December 31, 2019, $222.6 million remains available on this shelf registration statement, with $22.6 million reserved for potential sales under the 2019 Sales Agreement.

In February 2017, we entered into the Controlled Equity Offering^{SM} Sales Agreement, or the 2017 Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, under which we were permitted, at our discretion, from time to time sell shares of our common stock, with a sales value of up to $50.0 million through Cantor. We provided Cantor with customary indemnification rights, and Cantor was entitled to a commission at a fixed rate of 3% of the gross proceeds per share sold. Sales of the shares under the 2017 Sales Agreement were to be made in transactions deemed to be "at the market offerings", as defined in Rule 415 under the Securities Act. We sold 2,102,315 shares of common stock pursuant to the 2017 Sales Agreement for $47.7 million in proceeds, after deducting commissions of $1.5 million. The 2017 Sales Agreement was terminated effective on June 22, 2019.

We have used and we intend to continue to use the net proceeds from the above offerings of our common stock and the Notes, as well as from the Hercules Loan Agreement and the Royalty-Backed Loan Agreement, together with our existing capital resources and future NUZYRA product sales, to fund our ongoing company operations, including clinical studies of omadacycline, NUZYRA commercial operations, and for working capital and other general corporate purposes. Refer to Note 16, *Long-Term Debt*, for further details on the Royalty-Backed Loan Agreement and the Hercules Loan Agreement.

As of December 31, 2019, we had cash, cash equivalents and marketable securities of $215.4 million.

The following table summarizes our cash provided by and (used in) operating, investing and financing activities (in thousands):

	Year Ended December 31,	
	2019	2018
Net cash used in operating activities	$ (134,045)	$ (81,179)
Net cash provided by (used in) investing activities	134,554	(127,874)
Net cash provided by financing activities	57,622	220,727

Cash used in operating activities for the year ended December 31, 2019 of $134.0 million was primarily the result of our $128.8 million net loss, a $10.9 million increase in inventory purchases and a $11.2 million increase in accounts receivable and other current assets. This was offset by $14.3 million in stock-based compensation expense, primarily due to the vesting of several performance based stock unit, or PRSU, awards, and $3.5 million of non-cash interest expense related to the Hercules Loan Agreement, the Notes and the Royalty-Backed Loan Agreement. Cash used in operating activities for the year ended December 31, 2018 of $81.2 million is primarily the result of our $112.4 million net loss. This is offset by $27.3 million in non-cash items, including, $25.5 million in stock-based compensation expense primarily due to the vesting of several PRSU awards, $2.8 million of non-cash interest expense related to the Hercules Loan Agreement, as amended, the Notes, and $1.1 million in net depreciation, amortization and accretion, as well as a $5.0 million decrease in accounts receivable.

Investing Activities

Net cash provided by investing activities during the year ended December 31, 2019 of $134.6 million consists of $102.2 million investments in marketable securities (U.S. treasury securities) offset by proceeds from maturities of marketable securities of $237.0 million.

Net cash used in investing activities during the year ended December 31, 2018 of $127.9 million consists of $292.9 million investments in marketable securities (U.S. treasury securities) offset by proceeds from maturities of marketable securities of $165.0 million.

Financing Activities

Net cash provided by financing activities for 2019 includes the following:

- $0.5 million in net proceeds raised through the 2018 ESPP (as defined below);
- $30.6 million in net proceeds received from the Royalty-Backed Loan Agreement; and
- $26.6 million in net proceeds raised through the sale of shares of our common stock through the 2019 Sales Agreement.

Net cash provided by financing activities for 2018 includes the following:

- $159.0 million in net proceeds raised through the sale of the Notes;
- $49.8 million in net proceeds raised through the January 2018 offering of common stock;
- $10.0 million in net proceeds received from the Hercules Loan Agreement; and
- $1.7 million in net proceeds raised through the sale of shares of our common stock through the 2017 Sales Agreement.

Future Funding Requirements

We began generating revenue from product sales in February 2019 when we launched NUZYRA in the U.S. and from Almirall's launch of SEYSARA in the U.S. in January 2019. Our future funding requirements will depend on our ability to generate revenue from sales of NUZYRA, and our partner, Almirall's, ability to generate revenues from sales of SEYSARA, with respect to which we are entitled to tiered royalties in the U.S. and flat royalties in the greater China region. We do not expect to generate any other revenue unless and until our partner, Zai, obtains regulatory approval of and commercializes one or more of our product candidates in the Zai territory. Zai submitted the first regulatory approval application for a licensed product in the People's Republic of China in December 2019, which was accepted by the China National Medical Products Administration in February 2020. We will require substantial additional funding to meet FDA PMRs for NUZYRA, which we expect to be funded through the BARDA contract. Additional resources will also be needed to support and accelerate the commercialization of NUZYRA, fund the development of omadacycline in other indications, including NTM, and to advance the development of potential other product candidates, and such funding may not be available on favorable terms or at all.

We expect to continue to incur significant expenditures and operating losses for the next several years. These expenses include:

- conduct additional clinical trials of omadacycline;
- seek regulatory approvals for additional indications for omadacycline, such as omadacycline for the treatment of NTM;
- continue to establish a sales, marketing and distribution infrastructure to commercialize NUZYRA and increase our manufacturing capacity and capabilities to satisfy demand;
- add personnel to support our planned commercialization efforts;
- build product inventory; and
- service and pay down our debt.

Based upon our current operating plan, which includes estimated NUZYRA product sales and expense reimbursement of activities related to the BARDA contract, we anticipate that our existing cash, cash equivalents and marketable securities of $215.4 million as of December 31, 2019, will extend our cash runway through the end of 2023 with a pathway to cash flow break even. This anticipated pathway assumes we will be able to fund all company operating expenses, anticipated capital expenditures, and debt service, including repayment in full of the Hercules Loan and Security Agreement under its existing terms.

We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our pharmaceutical products, and the unknown extent to which we will maintain existing or enter into new collaborations with third parties to participate in the development and commercialization of our product and product candidates, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures that we will require to fund our continuing operations, including for our clinical development programs and commercialization efforts for NUZYRA. Our future capital requirements will depend on many factors, including:

- the progress of clinical development of omadacycline in additional indications, including NTM;
- the costs and timing of commercialization activities for NUZYRA;
- product revenue received from commercial sales of NUZYRA;
- royalty revenue received from commercial sales of SEYSARA by Almirall;
- timing and amount of actual reimbursements and NUZYRA purchases under the BARDA contract;
- the ability of Zai to develop, manufacture and commercialize omadacycline in the Zai territory;
- the scope, progress, timing, cost and results of research, preclinical development and clinical trials;
- the costs, timing and outcome of seeking, obtaining, maintaining and expanding FDA and non-U.S. regulatory approvals;
- the costs associated with manufacturing and establishing sales, marketing and distribution capabilities;
- the number and characteristics of other product candidates that we may pursue;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management, scientific, commercial, operations and medical personnel;
- the effect of competing products that may limit market penetration of our products;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- resources required to develop and implement policies and processes to promote ongoing compliance with applicable healthcare laws and regulations;
- costs required to ensure that our and our partners' business arrangements with third parties comply with applicable healthcare laws and regulations; and
- the economic and other terms, timing and success of our existing collaboration and licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under such arrangements.

Until we can generate a sufficient amount of product and royalty revenue to finance our cash requirements, if ever, we expect to finance our future cash needs primarily through a combination of public or private equity offerings, debt or other structured financings, strategic collaborations and grant funding. We do not have any committed external sources of funds other than the rights under the BARDA contract and the rights to contingent milestone payments and/or royalties under the Almirall Collaboration Agreement, the Almirall China License Agreement, the Tetraphase License Agreement and the Zai Collaboration Agreement, which are terminable by Almirall, Tetraphase and Zai, respectively, upon prior written notice. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect stockholders' rights. Future 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 marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, NUZYRA, sarecycline, future revenue streams, research programs or product candidates or 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 NUZYRA, sarecycline or any future product candidates that we may otherwise prefer to develop and market ourselves.

Off-Balance Sheet Arrangements

As of December 31, 2019, we do not have any off-balance sheet arrangements.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles of the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to, among other items, accounts receivable and related reserves, inventory, goodwill, net product revenue, royalty revenue, stock-based compensation arrangements, manufacturing and clinical accruals, useful lives for depreciation and amortization of long-lived assets and valuation allowances on deferred tax assets. Actual results could differ from those estimates. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2, *Summary of Significant Accounting Policies*, to the consolidated financial statements included in Item 8, "Financial Statements and Supplementary Data," of this Annual Report on Form 10-K, we believe that the following accounting policies are the most critical to assist stockholders and investors reading the consolidated financial statements in fully understanding and evaluating our financial condition and results of operations.

Revenue Recognition

Effective January 1, 2018, we adopted Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*, or ASC 606, using the full retrospective transition method. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, and financial instruments. Under 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. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied as services are rendered.

We enter into collaboration agreements for research, development, manufacturing and commercial services that are within the scope of ASC 606, under which it licenses certain rights to its product candidates to third parties. The terms of these arrangements typically include payment to us of one or more of the following: non-refundable, upfront license fees; reimbursement of certain costs; customer option exercise fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products. The amount of variable consideration is constrained until it is probable that the revenue is not at a significant risk of reversal in a future period. The contracts into which we enter generally do not include significant financing components.

As part of the accounting for these arrangements, we must use significant judgment to determine: (a) the transaction price under step (iii) above and (b) the timing of revenue recognition, including the appropriate measure of progress, in step (v) above. We use judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price, as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. If a milestone or other variable consideration relates specifically to our efforts to satisfy a single performance obligation or to a specific outcome from satisfying the performance obligation, we generally allocate the milestone amount entirely to that performance obligation once it is probable that a significant revenue reversal would not occur.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Licenses of intellectual property

In assessing whether a license is distinct from the other promises, we consider factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, we consider whether the collaboration partner can benefit from a license for its intended purpose without the receipt of the remaining promise(s), whether the value of the license is dependent on the unsatisfied promise(s), whether there are other vendors that could provide the remaining promise(s), and whether it is separately identifiable from the remaining promise(s). For licenses that are combined with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. We evaluate the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Customer options

If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. We evaluate the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent or include a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. We allocate the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that the customer will exercise. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised.

Milestone payments

At the inception of each arrangement that includes milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant reversal of cumulative revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of us or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. We evaluate factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant reversal of cumulative revenue would not occur. At the end of each subsequent reporting period, we reevaluate the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Contract costs

We recognize as an asset the incremental costs of obtaining a contract with a customer if the costs are expected to be recovered. As a practical expedient, we recognize the incremental costs of obtaining a contract as an expense when incurred if the amortization period of the asset that we otherwise would have recognized is one year or less. To date, we have not incurred any incremental costs of obtaining a contract with a customer.

The Company sells its product principally to a limited number of specialty distributors and specialty pharmacy providers in the U.S. These customers subsequently resell the Company's product to health care providers or dispense the product to patients. 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 our product.

Revenues from product sales are recognized when the customer obtains control of the Company's product, which typically occurs once the Company has transferred physical possession of the good to the customer. 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. Variable consideration is only included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. 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 based on the Company's estimates of channel mix. The types of variable consideration in our product revenue are as follows:

- Trade discounts and allowances
- Product returns
- Chargebacks and rebates
- Government rebates
- Commercial payer and other rebates
- 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. 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.

The amount of variable consideration is estimated by using either of the following methods, depending on which method better predicts the amount of consideration to which the Company is entitled:

a) The "expected value" is the sum of probability-weighted amounts in a range of possible consideration amounts. Under ASC 606, an expected value may be an appropriate estimate of the amount of variable consideration if the Company has many contracts with similar characteristics.

b) The "most likely amount" is the single most likely amount in a range of possible consideration amounts (i.e., the single most likely outcome of the contract). Under ASC 606, the most likely amount may be an appropriate estimate of the amount of variable consideration if the contract has only two possible outcomes (i.e., either achieve or do not achieve a threshold specified in a contract).

The method selected is applied consistently throughout the contract when estimating the effect of an uncertainty on an amount of variable consideration. In addition, the Company considers all the information (historical, current, and forecasted) that is reasonably available to the Company and shall identify a reasonable number of possible consideration amounts. The relevant factors used in this determination include, but are not limited to, current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns.

In assessing whether a constraint is necessary, 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:

Trade Discounts and Allowances - The Company generally provides customers with discounts that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, the Company receives sales order management, data and distribution services from certain customers. To the extent the services received are distinct from the Company's sale of products to the customer, these payments are classified in selling, general and administrative expenses in the consolidated statements of operation and comprehensive loss of the Company.

Product Returns – Generally, the Company's customers have the right to return any unopened/unused product supply during the 18-month period beginning six months prior to the labeled expiration date and ending 12 months after the labeled expiration date. Since the Company currently does not have history of NUZYRA returns, the Company estimated returns based on industry data for comparable products in the market. As the Company distributes its product and establish historical sales over a longer period of time (i.e., two 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.

At the end of each reporting period for any of our 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 – Although the Company primarily sells products to specialty distributors in the U.S., the Company also enters into agreements with hospitals and outpatient infusion centers, either directly or through group purchasing organizations acting on behalf of their members, in connection with the purchase of product. Based on these agreements, some of the Company's customers have the right to receive a discounted price on product purchases. In the case of discounted pricing, 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.

Government Rebates –The Company is subject to discount obligations under state Medicaid programs and Medicare. The Company estimates our 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 estimate the number of patients in the prescription drug coverage gap for whom it will owe an additional liability under the Medicare Part D program. The Company's liability for these rebates consists of an estimate of claims for the current quarter and estimated future claims that will be made for product sales that have been recognized as revenue but remain in distribution channel inventory at period end.

Commercial Payer and Other Rebates – The Company plans to continue to contract with certain private payer organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of NUZYRA 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. As the Company distributes its product and establishes historical sales over a longer period of time (i.e., two years), the Company will be able to place more reliance on historical data related to commercial payer rebates (i.e., actual utilization units) while continuing to rely on third party data related to payer prescriptions and utilization.

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 sale that has been recognized as revenue but remains in the distribution and pharmacy channel inventories at the end of each reporting period.

At the end of each reporting period, the Company adjusts its allowances for cash discounts, product returns, chargebacks, and other rebates and discounts when the Company believes actual experience may differ from current estimates.

Marketable Securities

We consider all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include cash held in banks and amounts held primarily in interest-bearing money market accounts. Cash equivalents are carried at cost, which approximates their fair market value.

We determine the appropriate classification of marketable securities at the time of purchase and reevaluate such designation at each balance sheet date. We classified all of our marketable securities at December 31, 2019 as "available-for-sale" pursuant to ASC 320, *Investments – Debt and Equity Securities.* Investments not classified as cash equivalents are presented as either short-term or long-term investments based on both their maturities as well as the time period we intend to hold such securities. Available-for-sale securities are maintained by an investment manager and consist of U.S. treasury securities. Available-for-sale securities are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders' equity (deficit) until realized. Any premium or discount arising at purchase is amortized or accreted to interest expense or income over the life of the instrument. Realized gains and losses are determined using the specific identification method and are included in other income or expense. There were no material realized gains or losses on marketable securities recognized for the years ended December 31, 2019 and 2018.

We review marketable securities for other-than-temporary impairment whenever the fair value of a marketable security is less than the amortized cost and evidence indicates that a marketable security's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of investments are recognized in the consolidated statements of operations and comprehensive loss if we have experienced a credit loss, has the intent to sell the marketable security, or if it is more likely than not that we will be required to sell the marketable security before recovery of the amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with our investment policy, the severity and duration of the impairment and changes in value subsequent to the end of the period. There were no other-than-temporary impairments of investments recognized for the years ended December 31, 2019 and 2018.

Inventory

Inventories are stated at the lower of cost or estimated net realizable value, on a first-in, first-out basis. Prior to the regulatory approval of our product candidates, we incurred expenses for the manufacture of drug product that could potentially be available to support the commercial launch of our products. Until the first reporting period when regulatory approval has been received or is otherwise considered probable, we record all such costs as research and development expense. Inventory used in clinical trials is also expensed as research and development expense when selected for such use. We perform an assessment of the recoverability of capitalized inventory during each reporting period and writes down any excess and obsolete inventory to its net realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded as a component of cost of product sales in the consolidated statements of operations and comprehensive loss. The determination of whether inventory costs will be realizable requires the use of estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required.

Accrued Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed for us and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us periodically in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated expenses include fees paid to:

- CROs, in connection with clinical trials;
- contract manufacturing organizations with respect to clinical material supply and commercial product;
- vendors in connection with preclinical development and operational activities; and
- legal and other professional service providers.

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

Research and Development Expenses

We charge costs of our research and development to expense as incurred. Research and development expenses consist of the costs incurred in performing research and development activities, including personnel-related costs, stock-based compensation, facilities, research-related overhead, clinical trial costs, contracted services, manufacturing, license fees and other external costs. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received rather than when the payment is made.

Stock-Based Compensation

We account for our stock-based awards in accordance with ASC 718, *Compensation—Stock Compensation*, or ASC 718, which requires all stock-based payments to employees, including grants of employee stock options, modifications to existing stock options, and restricted stock unit awards, to be recognized as expense based on their fair values. We recognize the compensation cost of awards subject to performance-based vesting conditions over the requisite service period, to the extent achievement of the performance condition is deemed probable relative to targeted performance. If achievement of the performance condition is not probable, but the award will vest based on the service condition, we recognize the expense over the requisite service period.

We estimate the fair value of our stock-based awards to employees and non-employees using the Black-Scholes option pricing model, which requires the input of highly subjective assumptions, including (1) the expected volatility of our stock, (2) the expected term of the award, (3) the risk-free interest rate and (4) expected dividends. Due to the lack of a public market for our common stock prior to the completion of the Merger on October 30, 2014, and resulting lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, we have selected companies with characteristics that we believe are comparable to ours, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. We compute the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period as the calculated expected term of our stock-based awards. During 2015, we began to blend our stock price history, for the length of time we have market data for our stock, with the historical volatility of the group of similar public companies for the expected term of each grant to estimate volatility. We have estimated the expected life of our employee stock options as the average of the midpoints between vesting exercise date for each vesting-trance and the contractual term of the options as the last available exercise date of the option. The risk-free interest rates for periods within the expected life of the option are based on the U.S. Treasury yield curve in effect during the period the options were granted. We recognize the effect of forfeitures in compensation cost when they occur.

Recent Accounting Standards

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842). The amendment requires a lessee to recognize assets and liabilities for leases with a term of more than 12 months. A lessee would recognize a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the leased asset (the underlying asset) for the lease term. The guidance is required to be adopted using a modified retrospective approach applied to leases existing at the date of initial application. The new standard was effective for the Company on January 1, 2019. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. The Company adopted the new standard on January 1, 2019 and used the effective date as its date of initial application. Consequently, financial information will not be restated, and the disclosures required under the new standard will not be provided for dates and periods prior to January 1, 2019.

The new standard provides a number of optional practical expedients in transition. The Company elected to utilize the available package of practical expedients permitted under the transition guidance within the new standard, which did not require the reassessment of the following: (i) whether existing or expired arrangements are or contain a lease, (ii) the lease classification of existing or expired leases, and (iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. Further, the Company utilized the short-term lease exemption for all leases with a lease term of 12 months or less for purposes of applying the recognition and measurements requirements in the new standard. The Company's analysis included, but is not limited to, assessing its existing lease and service contracts, determining the appropriate discount rates to apply to its leases in order to determine the impact that the new leasing. Further, the Company has established policies and procedures in order to adhere to the requirements of the new standard, which includes enhanced disclosure requirements.

The adoption of this standard resulted in the recognition of operating lease liabilities and right-of-use assets of $3.7 million and $3.2 million, respectively, on the Company's consolidated balance sheet relating to its leases for its corporate headquarters in Boston, Massachusetts and for office space in King of Prussia, Pennsylvania. The adoption of the standard did not have a material effect on the Company's consolidated statements of operation and comprehensive loss, consolidated statements of cash flows, or consolidated statements of stockholders' equity (deficit).

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, or ASU 2018-07. These amendments expand the scope of Topic 718, *Compensation—Stock Compensation* (which previously only included share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. ASU No. 2018-07 supersedes Subtopic 505-50, *Equity—Equity-Based Payments to Non-Employees*. ASU No. 2018-07 is effective for public companies for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. The Company adopted this guidance effective January 1, 2019. The adoption of ASU No. 2018-07 did not have a material impact on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, *Simplifying the Test for Goodwill Impairment*, or ASU 2017-04. The amendments in ASU 2017-04 eliminate the current two-step approach used to test goodwill for impairment and require an entity to apply a one-step quantitative test and record the amount of goodwill impairment as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. ASU 2017-04 is effective for fiscal years and interim periods beginning after December 15, 2019 (upon the first goodwill impairment test performed during that fiscal year). Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. A reporting entity must apply the amendments in ASU 2017-04 using a prospective approach. We adopted this standard on January 1, 2020. The adoption of ASU 2017-04 is not expected to have a material impact on our consolidated financial position or results of operations.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. This standard modifies certain disclosure requirements on fair value measurements. This standard became effective for us on January 1, 2020. We adopted the standard on January 1, 2020. The adoption of this standard is not expected to have a material impact on our disclosures.

In June 2016 the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, or ASU 2016-13. The FASB subsequently issued amendments to ASU 2016-13, which have the same effective date and transition date of January 1, 2023. These standards require that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, these standards now require allowances to be recorded instead of reducing the amortized cost of the investment. These standards limit the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases. Based on the composition of our investment portfolio, accounts receivable and other financial assets, current market conditions and historical credit loss activity, we do not expect the adoption of these standards to have a material effect on the Company's consolidated balance sheet, consolidated statements of operation and comprehensive loss and related disclosures.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2019 and the effect such obligations are expected to have on our liquidity and cash flow in future years (in thousands):

	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Lease obligations	$ 3,564	$ 1,178	$ 1,472	$ 914	$ —
Licenses	225	25	50	50	100
Long-term debt	70,000	—	70,000	—	—
Convertible senior subordinated notes (a)	165,000	—	165,000	—	—
Commercial supply agreements	2,862	531	2,331	—	—
Total contractual cash obligations	$ 241,651	$ 1,734	$ 238,853	$ 964	$ 100

(a) See Note 16, *Long-term Debt*, for additional information.

Leases

We lease our Boston, Massachusetts and King of Prussia, Pennsylvania office spaces under non-cancelable operating leases expiring in 2021 and 2024, respectively.

We entered into the original King of Prussia and Boston leases in January 2015 and April 2015, respectively. The lease terms under the original agreements were for six and four years, respectively. Each agreement had one renewal option for an extended term. The King of Prussia and Boston lease terms under the original agreements began in June 2015 and July 2015, respectively.

We executed an amended lease agreement on our Boston office space in July 2016. The amended lease agreement added 4,153 rentable square feet of office space and extended the original lease term by two years. In accordance with the amended lease agreement, we paid a security deposit of $0.1 million. Subsequent to the amended lease agreement, we record monthly lease expense of approximately $49,000 for the Boston office space.

We executed an amended lease agreement on our King of Prussia office space in October 2016. The amended lease agreement is for 19,708 rentable square feet of office space and we took control of such office space during the first quarter of 2017. The total lease commitment is over a seven-year and seven-month lease term. The amended lease agreement contains rent escalation and a partial rent abatement period, which is accounted for as rent expense under the straight-line method. We are required to make additional payments under the facility operating leases for taxes, insurance, and other operating expenses incurred during the operating lease period.

Licenses

Under a license agreement with Tufts University, or Tufts, we were required to make aggregate regulatory milestone payments of up to $300,000 associated with the first Phase 3 clinical trials, filing of an NDA, and approval of its first product candidate, all of which have been paid. We are also obligated to pay Tufts a minimum royalty payment in the amount of $25,000 per year. We also agreed to pay Tufts royalties based on gross sales of products, as defined in the agreement, ranging in the low single digits depending on the applicable field of use for such product sale. Also, if we enter into a sublicense under the agreement, based on the applicable field of use for such product, we agreed to pay Tufts a percentage, ranging from 10% to 14 % for compounds other than omadacycline, and a percentage in the single digits for the compound omadacycline, of that portion of any sublicense issue fees or maintenance fees received by us that are reasonably attributable to the sublicense of the rights granted to us under the Tufts License Agreement and the lesser of a percentage, ranging from the low tens to the high twenties based on the applicable field of use for such product, of the royalty payments made to us by the sublicensee or the amount of royalty payments that would have been paid by us to Tufts if we had sold the products.

In September 2009, we and Novartis International Pharmaceutical Ltd., or Novartis, entered into a Collaborative Development, Manufacture and Commercialization License Agreement, or the Novartis Agreement, which provided Novartis with a global, exclusive patent and technology license for the development, manufacturing and marketing of omadacycline. The Novartis Agreement was terminated by Novartis without cause in June 2011 and the termination was effective 60 days later. We and Novartis subsequently entered in a letter agreement in January 2012, or the Novartis Letter Agreement, as amended, pursuant to which we reconciled shared development costs and expenses and granted Novartis a right of first negotiation with respect to commercialization rights of omadacycline following approval of omadacycline from the FDA, EMA, or any regulatory agency, but only to the extent we had not previously granted such commercialization rights related to omadacycline to another third party as of any such approval. We also agreed to pay Novartis a 0.25% royalty based on annual net sales of our omadacycline products. The amended Novartis Letter Agreement resulted in a long-term liability in the amount of $3.4 million and $3.6 million for the year ended December 31, 2019 and 2018, respectively, included within "Other Long-Term Liabilities" on our consolidated balance sheet. In addition, a short-term liability of $0.1 million included within "Other current liabilities" on our consolidated balance sheet as of December 31, 2019 represents the portion of royalty payments due to Novartis within twelve months. No short-term portion existed as of December 31, 2018. There are no other payment obligations to Novartis under either the Novartis Agreement or the amended Novartis Letter Agreement.

In February 2020, we entered into an ex-U.S. license agreement with Almirall, the Ex-U.S. License, under which Almirall granted to us an exclusive license in and to certain technology owned or in-licensed by Almirall or its affiliates in order to research, develop, manufacture and commercialize sarecycline in all countries other than the U.S. In connection with the Ex-U.S. License, we pay Almirall, on a country-by-country and product-by-product basis (i) for eight (8) years following the first commercial sale of a sarecycline product in a country, a royalty in the middle-single digits on our or our affiliates' nets sales of sarecycline products outside of the U.S. (other than China (including Hong Kong and Macau), the development and commercialization rights to which for sarecycline in connection with the treatment of acne we exclusively licensed to Almirall), subject to certain standard reductions, and (ii) for fifteen years following the first commercial sale of a sarecycline product in a country, a percentage of the consideration (e.g., milestones, royalties) we receive from third party sublicensees in connection with developing and commercializing sarecycline outside of the U.S., which ranges from one-half of such consideration for sarecycline products for the treatment of acne to one-fifth of such consideration for sarecycline products for the treatment of other indications, in each case subject to a 50% reduction for any sarecycline product not in a solid oral tablet formulation for which Paratek or its affiliates have incurred significant development costs and (ii) for eight years following the first commercial sale of a sarecycline product in a country, a royalty in the middle-single digits on our or our affiliates' net sales of sarecycline products outside of the U.S., subject to certain standard reductions.

Long-Term Debt

As of December 31, 2019 and 2018, we had recorded long-term debt obligations of $260.7 million, net of debt discount of $6.8 million and $229.0 million, net of debt discount of $6.0 million, respectively. Debt issuance costs are presented on the consolidated balance sheet as a direct deduction from the related debt liability rather than capitalized as an asset in accordance with ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*.

Hercules Loan Agreement

On June 27, 2019, the Company entered into an Amended and Restated Loan and Security Agreement, or the Amended Hercules Loan Agreement, with Hercules Technology III, L.P., certain other lenders, together, the Lenders, and Hercules Capital, Inc. (as agent), under which the Company may borrow up to $100.0 million in multiple tranches, each, a Term Loan Tranche. The Amended Hercules Loan Agreement amends and restates in its entirety the Company's prior Loan and Security Agreement with the Lenders dated as of September 30, 2015 to, among other things, provide for an extension of the scheduled maturity date of the $60.0 million Term Loan Tranche, or the First Tranche, from September 1, 2021 to September 1, 2023, upon certain events set forth in the Amended Hercules Loan Agreement, and an extension of the scheduled maturity date of the $10.0 million Term Loan Tranche, or the Second Tranche, and additional Term Loan Tranches (if any), from August 1, 2022 to August 1, 2024, upon certain events set forth in the Amended Hercules Loan Agreement. The Amended Hercules Loan Agreement also provides for an additional $10.0 million of additional Term Loan Tranches (up to a total of $30.0 million of additional Term Loan Tranches) that may be available to the Company, subject to approval by Hercules, in its sole discretion, whether to provide such tranches. As such there can be no assurance as to whether or not the additional Term Loan Tranches shall be funded.

To date, we have issued to each of Hercules Technology II, L.P. and Hercules Technology III, L.P., a warrant to purchase 16,346 shares of our common stock (32,692 shares of common stock in total) at an exercise price of $24.47 per share and a warrant to purchase 18,574 shares of our common stock (37,148 shares of common stock in total) at an exercise price of $13.46 per share. We issued a warrant to Hercules Capital, Inc. that is exercisable for an aggregate of 5,374 shares of our common stock at an exercise price of $23.26 per share. We have also issued to Hercules Capital, Inc. a warrant to purchase up to 19,627 shares of its common stock at an exercise price of $10.19 per share.

Convertible Senior Subordinated Notes

On April 18, 2018, we entered into the Purchase Agreement with the Initial Purchasers for whom Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Partners LLC acted as representatives, relating to the sale of the Notes to the Initial Purchasers. We also granted the Initial Purchasers an option to purchase up to an additional $25.0 million aggregate principal amount of Notes, which was exercised in full on April 20, 2018.

The Purchase Agreement includes customary representations, warranties and covenants. Under the terms of the Purchase Agreement, we agreed to indemnify the Initial Purchasers against certain liabilities.

In addition, J. Wood Capital Advisors LLC, our financial advisor, purchased $5.0 million aggregate principal amount of Notes in a separate, concurrent private placement on the same terms as other investors.

The Notes were issued by us on April 23, 2018, pursuant to an Indenture, dated as of such date, or the Indenture, between us and U.S. Bank National Association, as trustee, or the Trustee. The Notes bear cash interest at the annual rate of 4.75%, payable on November 1 and May 1 of each year, beginning on November 1, 2018, and mature on May 1, 2024 unless earlier repurchased, redeemed or converted. We will settle conversions of the Notes through delivery of shares of our common stock in accordance with the terms of the Indenture. The initial conversion rate for the Notes is 62.8931 shares of common stock (subject to adjustment as provided for in the Indenture) per $1,000 principal amount of the Notes, which is equal to an initial conversion price of approximately $15.90 per share, representing a conversion premium of approximately 20% above the closing price of the common stock of $13.25 per share on April 18, 2018.

Holders of the Notes may convert all or any portion of their Notes, in multiples of $1,000 principal amount, at their option at any time prior to the close of business on the second scheduled trading day immediately preceding the stated maturity date.

We may not redeem the Notes prior to May 6, 2021. We may redeem for cash all or part of the Notes, at its option, on or after May 6, 2021 if the last reported sale price of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provides notice of redemption at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

If we experience a fundamental change, as described in the Indenture, prior to the maturity date of the Notes, holders of the Notes will, subject to specified conditions, have the right, at their option, to require us to repurchase for cash all or a portion of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any, to, but not including, the fundamental change repurchase date. In addition, following certain corporate events that occur prior to the maturity date of the Notes and following a notice of redemption of the Notes, we will increase the conversion rate for a holder who elects to convert its Notes in connection with such corporate event or redemption.

The Indenture provides for customary events of default. In the case of an event of default with respect to the Notes arising from specified events of bankruptcy or insolvency, all outstanding Notes will become due and payable immediately without further action or notice. If any other event of default with respect to the Notes under the Indenture occurs or is continuing, the Trustee or holders of at least 25% in aggregate principal amount of the then outstanding Notes may declare the principal amount of the Notes to be immediately due and payable.

In certain circumstances if, at any time during the six-month period beginning on, and including, the date that is six months after the last date of original issuance of the Notes, we fail to timely file certain documents or reports required under the Securities Exchange Act of 1934, as amended, or the Notes are not otherwise freely tradable by holders of the Notes other than our affiliates or holders that were our affiliates at any time during the three months immediately preceding, additional interest will accrue on the Notes during the first 90-day period in which its failure to file has occurred and is continuing or such Notes are not otherwise freely tradable by holders other than the our affiliates (or holders that were our affiliates at any time during the three months immediately preceding).

After deducting costs incurred of $6.0 million, we raised net proceeds from the issuance of long-term convertible debt of $159.0 million in April 2018. All costs were deferred and are being amortized over the life of the Notes at an effective interest rate of 5.47% and recorded as additional interest expense.

Royalty-Backed Loan Agreement

On February 25, 2019, we, through our wholly-owned subsidiary Paratek Royalty Corporation, or the Subsidiary, entered into a royalty-backed loan agreement, or the Royalty-Backed Loan Agreement, with Healthcare Royalty Partners III, L.P., or HCRP. Pursuant to the terms of the Royalty-Backed Loan Agreement, upon the satisfaction of the conditions precedent set forth therein, the Subsidiary borrowed a $32.5 million loan, which was secured by, and will be repaid based upon, royalties from the Almirall Collaboration Agreement. On May 1, 2019, we received $27.8 million, net of $0.5 million lender discount, $0.2 million in lender expenses incurred, and $4.0 million that was deposited into an interest reserve account. We also paid $1.2 million in other lender fees related to the Royalty-Backed Loan Agreement.

Under the Royalty-Backed Loan Agreement, the outstanding principal balance will bear interest at an annual rate of 12.0%. Payments of interest under the Royalty-Backed Loan Agreement are made quarterly out of the Almirall Collaboration Agreement royalty payments received since the immediately preceding payment date. On each interest payment date, any royalty payments in excess of accrued interest on the loan will be used to repay the principal of the loan until the balance is fully repaid. In addition, the Subsidiary made up-front payments to HCRP of (i) a 1.5% fee and (ii) up to $300,000 for HCRP's expenses. The Royalty-Backed Loan Agreement matures on May 1, 2029, at which time, if not earlier repaid in full, the outstanding principal amount of the loan, together with any accrued and unpaid interest, and all other obligations then outstanding, shall be due and payable in cash. We entered into a Pledge and Security Agreement in favor of HCRP, pursuant to which the Subsidiary's obligations under the Loan Agreement are secured by a pledge of all of our holdings of the Subsidiary's capital stock.

The Royalty-Backed Loan Agreement contains certain customary affirmative covenants, including those relating to: use of proceeds; maintenance of books and records; financial reporting and notification; compliance with laws; and protection of our intellectual property. The Royalty-Backed Loan Agreement also contains certain customary negative covenants, barring the Subsidiary from: certain fundamental transactions; issuing dividends and distributions; incurring additional indebtedness outside of the ordinary course of business; engaging in any business activity other than related to the Almirall Collaboration Agreement; and permitting any additional liens on the collateral provided to HCRP under the Royalty-Backed Loan Agreement.

The Royalty-Backed Loan Agreement contains customary defined events of default, upon which any outstanding principal and unpaid interest shall be immediately due and payable. These include: failure to pay any principal or interest when due; any uncured breach of a representation, warranty or covenant; any uncured failure to perform or observe covenants; any uncured cross default under a material contract; any uncured breach of our representations, warranties or covenants under its Contribution and Servicing Agreement with the Subsidiary; any termination of the Almirall Collaboration Agreement; and certain bankruptcy or insolvency events.

Contract Service Providers

In the course of normal business operations, we also have agreements with contract service providers to assist in the performance of research and development, clinical trials, manufacturing and other activities for operating purposes which are cancelable at any time by us, generally upon 30 days' prior written notice. These payments are not included in this table of contractual obligations.

We could also enter into additional collaborative research, contract research, manufacturing, supplier and contractor agreements in the future, which may require upfront payments and/or long-term commitments of cash.

Commercial Supply Agreements

We have entered into multiple commercial supply agreements. Please refer to Item 1, *Business*, for further details on our agreements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We do not enter into financial instruments for trading or speculative purposes. Our cash, cash equivalents and investments balance as of December 31, 2019 consisted of cash and cash equivalents and U.S. treasury securities. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates, particularly because our investments are in short-term marketable securities. Due to the short-term duration of our investment portfolio and the low-risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability and intention to hold our investments until maturity and, therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio.

We engage CROs and contract manufacturers on a global scale. We may be subject to fluctuations in foreign currency rates in connection with certain of these agreements. We currently do not hedge any such foreign currency exchange rate risk. Transactions denominated in currencies other than U.S. dollars are recorded based on exchange rates at the time such transactions arise and were less than 3.0% of total liabilities as of December 31, 2019.

Item 8. Financial Statements and Supplementary Data

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Paratek Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Paratek Pharmaceuticals, Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated March 10, 2020 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.

Boston, Massachusetts
March 10, 2020

Paratek Pharmaceuticals, Inc.
Consolidated Balance Sheets
(in thousands, except for share and par value amounts)

	December 31,	
	2019	2018
Assets		
Current assets		
Cash and cash equivalents	$ 102,302	$ 46,987
Marketable securities	113,077	203,364
Restricted cash	324	266
Accounts receivable, net	8,475	41
Inventories, net	11,579	598
Other receivables	1,108	208
Prepaid and other current assets	6,489	3,779
Total current assets	243,354	255,243
Long-term restricted cash	3,007	249
Long-term marketable securities	—	42,487
Fixed assets, net	1,227	1,173
Goodwill	829	829
Right-of-use asset	2,514	—
Other long-term assets	148	211
Total assets	$ 251,079	$ 300,192
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 4,116	$ 2,090
Accrued expenses	16,696	15,619
Other current liabilities	3,388	—
Total current liabilities	24,200	17,709
Long-term debt	260,728	228,959
Long-term lease liabilities	2,095	—
Other liabilities	3,703	5,946
Total liabilities	290,726	252,614
Commitments and contingencies (Note 18)		
Stockholders' equity (deficit)		
Preferred stock:		
Undesignated preferred stock: $0.001 par value; 5,000,000 authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 39,827,749 and 32,259,363 issued and outstanding at December 31, 2019 and 2018, respectively	40	32
Additional paid-in capital	671,497	630,142
Accumulated other comprehensive income (loss)	74	(128)
Accumulated deficit	(711,258)	(582,468)
Total stockholders' equity (deficit)	(39,647)	47,578
Total liabilities and stockholders' equity (deficit)	$ 251,079	$ 300,192

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

Paratek Pharmaceuticals, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2019	2018
Product revenue, net	$ 11,517	$ —
Collaboration and royalty revenue	5,027	17,117
Net revenue	16,544	17,117
Expenses:		
Cost of product revenue	3,484	—
Research and development	39,554	57,508
Selling, general and administrative	89,135	63,658
Impairment of intangible assets	—	107
Changes in fair value of contingent consideration	—	(71)
Total operating expenses	132,173	121,202
Loss from operations	(115,629)	(104,085)
Other income and expenses:		
Interest income	3,574	3,260
Interest expense	(16,403)	(10,985)
Other losses, net	(31)	(44)
Net loss before provision for income taxes	(128,489)	(111,854)
Provision for income taxes	301	502
Net loss	$ (128,790)	$ (112,356)
Other comprehensive loss		
Unrealized gain on available-for-sale securities, net of tax	202	30
Other comprehensive gain	202	30
Comprehensive loss	$ (128,588)	$ (112,326)
Net loss per share:		
Basic and diluted net loss per common share	$ (3.93)	$ (3.57)
Weighted average common shares outstanding		
Basic and diluted	32,791,934	31,513,454

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

Paratek Pharmaceuticals, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)
(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balances at December 31, 2017	27,941,015	$ 28	$ 552,720	$ (158)	$ (470,112)	$ 82,478
Exercise of stock options	53,938	—	286	—	—	286
Issuance of common stock, net of expenses	3,301,436	3	51,514	—	—	51,517
Vesting of restricted stock unit awards	962,974	1	(1)	—	—	—
Issuance of warrants for common stock	—	—	130	—	—	130
Employee stock purchase plan expense			7	—	—	7
Unrealized gain on available-for-sale securities, net of tax	—	—	—	30	—	30
Stock-based compensation expense	—	—	25,486	—	—	25,486
Net loss	—	—	—	—	(112,356)	(112,356)
Balances at December 31, 2018	32,259,363	$ 32	$ 630,142	$ (128)	$ (582,468)	$ 47,578
Issuance of common stock, net of expenses	6,524,194	7	26,552	—	—	26,559
Vesting of restricted stock unit awards	862,546	1	(1)	—	—	—
Issuance of stock under the employee stock purchase plan	181,646	—	509	—	—	509
Employee stock purchase plan expense	—	—	101	—	—	101
Unrealized gain on available-for-sale securities, net of tax	—	—	—	202	—	202
Stock-based compensation expense	—	—	14,194	—	—	14,194
Net loss	—	—	—	—	(128,790)	(128,790)
Balances at December 31, 2019	39,827,749	$ 40	$ 671,497	$ 74	$ (711,258)	$ (39,647)

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

Paratek Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2019	2018
Net loss	$ (128,790)	$ (112,356)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and accretion	(1,292)	(1,066)
Stock-based compensation expense	14,295	25,492
Non-cash interest expense	3,480	2,792
Impairment of intangible assets	—	107
Change in fair value of contingent consideration	—	(71)
Changes in operating assets and liabilities		
Accounts receivable, prepaid, and other current assets	(11,228)	4,440
Purchase of prepaid interest - marketable securities	(239)	(715)
Inventories	(10,856)	—
Operating lease right-of-use asset	721	—
Accounts payable and accrued expenses	374	(641)
Operating lease liability	(1,718)	—
Other liabilities and other assets	1,208	839
Net cash used in operating activities	(134,045)	(81,179)
Investing activities		
Purchase of fixed assets	(239)	(60)
Purchase of marketable securities	(102,207)	(292,864)
Proceeds from maturities of marketable securities	237,000	165,050
Net cash provided by (used in) investing activities	134,554	(127,874)
Financing activities		
Proceeds from issuance of long-term convertible debt, net of costs	—	158,974
Proceeds from issuance of long-term debt, net of costs	—	9,950
Proceeds from issuance of long-term royalty-backed loan agreement, net of costs	30,554	—
Proceeds from employee stock purchase plan	509	—
Proceeds from exercise of stock options	—	286
Proceeds from issuance of common stock, net	26,559	51,517
Net cash provided by financing activities	57,622	220,727
Net increase in cash, cash equivalents and restricted cash	58,131	11,674
Cash, cash equivalents and restricted cash at the beginning of period	47,502	35,828
Cash, cash equivalents and restricted cash at end of period	$ 105,633	$ 47,502
Supplemental disclosure of noncash financing activities		
Fair value of warrants issued	$ —	$ 130
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 15,960	$ 9,310
Purchases of equipment included in accrued expenses	$ 339	$ —

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

1. Organization

Paratek Pharmaceuticals, Inc., or the Company or Paratek, is a Delaware corporation with its corporate office in Boston, Massachusetts and an office in King of Prussia, Pennsylvania.

We are a commercial-stage biopharmaceutical company focused on the development and commercialization of novel life-saving therapies for life-threatening diseases or other public health threats for civilian, government and military use. We have used our expertise in biology and tetracycline chemistry to create chemically diverse and biologically distinct small molecules derived from the minocycline core structure. The Company's United States, or U.S., Food and Drug Administration, or FDA, approved commercial product, NUZYRA® (omadacycline) is a once-daily oral and intravenous broad-spectrum antibiotic for the treatment of adult patients with community-acquired bacterial pneumonia, or CABP, and acute bacterial skin and skin structure infections, or ABSSSI, caused by susceptible pathogens. The Company launched NUZYRA in the U.S. in February 2019. SEYSARA® (sarecycline) is an FDA-approved product, with respect to which the Company has exclusively licensed development and commercialization rights for the treatment of acne in the U.S. and the Peoples Republic of China, Hong Kong, and Macau, or the greater China region, to Almirall, LLC, or Almirall. SEYSARA was launched by Almirall in the U.S. in January 2019 as a new once-daily oral therapy for the treatment of moderate to severe acne vulgaris. The Company retains development and commercialization rights with respect to sarecycline in all other countries other than the U.S. and the greater China region.

The Company has incurred significant losses since inception in 1996. The Company has generated an accumulated deficit of $711.3 million through December 31, 2019 and may require substantial additional funding in connection with the Company's continuing operations to support clinical development and commercialization activities associated with NUZYRA. Based upon the Company's current operating plan, it anticipates that cash, cash equivalents and available for sale marketable securities of $215.4 million as of December 31, 2019 will enable the Company to fund operating expenses and capital expenditure requirements through at least the next twelve months from the filing date of this Annual Report on Form 10-K. The Company expects to finance future cash needs primarily through a combination of product sales, royalties, public or private equity offerings, debt or other structured financings, strategic collaborations and grant funding. The Company is subject to risks common to companies in the biopharmaceutical industry, including, but not limited to, risks of failure of preclinical studies and clinical trials, the need to obtain additional financing to fund the future development of the Company's product candidates, the need to obtain compliant product from third party manufacturers, the need to obtain marketing approval for the Company's product candidates, the need to successfully commercialize and gain market acceptance of product candidates, the risks of manufacturing product with an external supply chain, dependence on key personnel, and compliance with government regulations.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in accordance with U.S. GAAP as found in the Accounting Standards Codification, or ASC, and Accounting Standards Update, or ASU, of the Financial Accounting Standards Board, or FASB, and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission, or the SEC. Beginning on January 1, 2019, the Company presented "accrued interest" as a separate line item in Note 11, *Accrued Expenses*. The Company reclassified accrued interest of $1.8 million as of December 31, 2018, previously presented as part of "accrued professional fees" into "accrued interest" in Note 11, *Accrued Expenses*. On December 31, 2018, the Company presented "accrued contract manufacturing costs" as a separate line item on its consolidated balance sheet. Beginning on January 1, 2019, the Company reclassified the December 31, 2018 accrued contract manufacturing costs balance of $2.8 million, into "accrued expenses". Also, beginning on January 1, 2019, the Company reclassified inventories of $0.6 million as of December 31, 2018 previously presented as part of "prepaid and other current assets" into "inventories, net" on the consolidated balance sheet.

Principles of Consolidation

The accompanying audited consolidated financial statements include the results of operations of Paratek Pharmaceuticals, Inc. and its wholly-owned subsidiaries, Paratek Pharma, LLC, Paratek Securities Corporation, Transcept Pharma, Inc., Paratek UK, Ltd, Paratek Bermuda, Ltd., Paratek Ireland Limited and Paratek Royalty Corporation. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management of the Company to make certain estimates and assumptions that affect the reported amounts 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. These estimates are based on management's best knowledge of current events and actions the Company may undertake in the future. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements. Estimates are used in accounting for, among other items, accounts receivable and related reserves, inventory, goodwill, net product revenue, royalty revenue, leases, stock-based compensation arrangements, manufacturing and clinical accruals, useful lives for depreciation and amortization of long-lived assets and valuation allowances on deferred tax assets. Actual results could differ from those estimates. The Company evaluates its estimates on an ongoing basis. Changes in estimates are reflected in reported results in the period in which they become known by the Company's management.

Cash and Cash Equivalents and Marketable Securities

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include cash held in banks and amounts held primarily in interest-bearing money market accounts. Cash equivalents are carried at cost, which approximates their fair market value.

The Company determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. The Company classified all of its marketable securities at December 31, 2019 as "available-for-sale" pursuant to ASC 320, *Investments – Debt and Equity Securities.* Investments not classified as cash equivalents are presented as either short-term or long-term investments based on both their maturities as well as the time period the Company intends to hold such securities. Available-for-sale securities are maintained by an investment manager and consist of U.S. treasury securities. Available-for-sale securities are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders' equity (deficit) until realized. Any premium or discount arising at purchase is amortized or accreted to interest expense or income over the life of the instrument. Realized gains and losses are determined using the specific identification method and are included in other income or expense. There were no material realized gains or losses on marketable securities recognized for the years ended December 31, 2019 and 2018.

The Company reviews marketable securities for other-than-temporary impairment whenever the fair value of a marketable security is less than the amortized cost and evidence indicates that a marketable security's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of investments are recognized in the consolidated statements of operations and comprehensive loss if the Company has experienced a credit loss, has the intent to sell the marketable security, or if it is more likely than not that the Company will be required to sell the marketable security before recovery of the amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with the Company's investment policy, the severity and duration of the impairment and changes in value subsequent to the end of the period. There were no other-than-temporary impairments of investments recognized for the years ended December 31, 2019 and 2018.

Fair Value of Financial Instruments

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC 820, *Fair Value Measurements and Disclosures*, or ASC 820, establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are those that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly.

Level 3—Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Restricted Cash

Cash accounts with any type of restriction are classified as restricted cash. If restrictions are expected to be lifted or to be used to pay a third party in the next twelve months, the restricted cash account is classified as current.

Accounts Receivable, Net

Accounts receivable as of December 31, 2019 represents trade accounts receivable of $4.8 million consisting of payments to be received from customers for sales of NUZYRA, net of prompt payment discounts, chargebacks, rebates and certain fees. An additional $3.7 million in accounts receivable consists of royalty and milestone revenue earned, but not yet received, during the year ended December 31, 2019 in connection with SEYSARA sales under the Almirall Collaboration Agreement, XERAVA sales under the Tetraphase License Agreement and a milestone achieved under the Zai Collaboration Agreement (as defined below). Refer to Note 5, *License and Collaboration Agreements*, for further details.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk consist primarily of cash, restricted cash, and accounts receivable. The Company places its cash in an accredited financial institution and this balance is above federally insured amounts. The Company has no off-balance sheet concentrations of credit risk such as foreign currency exchange contracts, option contracts or other hedging arrangements. For the year ended December 31, 2019, revenue consisted of product revenue from the sales of NUZYRA, a milestone payment earned in connection with the Zai Collaboration Agreement, and royalty income pursuant to the Tetraphase License Agreement and the Almirall Collaboration Agreement, as defined below. For the year ended December 31, 2018, revenue consisted of upfront fees and milestone payments received in connection with the Company's collaboration agreements with Almirall and Zai and royalty income pursuant to a royalty sharing agreement entered into with former Transcept stockholders or the Royalty Sharing Agreement, entered into by the Company in October 2016 with the Special Committee of the Company's Board of Directors. For the year ended December 31, 2019, the Tetraphase License Agreement, the Zai Collaboration Agreement and the Almirall Collaboration Agreement represented approximately 2%, 60% and 38%, respectively, of collaboration and royalty revenue. For the year ended December 31, 2018, the Almirall Collaboration Agreement and the Zai Collaboration Agreement represented approximately 70% and 29%, respectively, of collaboration and royalty income.

Fixed Assets

Fixed assets, including leasehold improvements, are recorded at cost and depreciated when placed into service using the straight-line method, based on their estimated useful lives as follows:

	Estimated Useful Life In Years
Laboratory equipment	5
Office equipment	5
Machinery and equipment	5
Computer equipment	3
Computer software	3

In addition, leasehold improvements are depreciated over the shorter of their estimated useful lives or the term of the respective lease on a straight-line basis.

Costs for capital assets not yet placed into service have been capitalized as construction-in-progress and will be depreciated in accordance with the above guidelines once placed into service. The Company reviews its long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted cash flow to the recorded value of the asset. If impairment is indicated, the asset will be written down to its estimated fair value on a discounted cash flow basis. Upon sale or retirement, the asset cost and related accumulated depreciation are removed from the respective accounts, and any related gain or loss is reflected in results of operations. Repair and maintenance costs are expensed as incurred.

Inventory

Inventories are stated at the lower of cost or estimated net realizable value, on a first-in, first-out basis. Prior to the regulatory approval of its product candidates, the Company incurs expenses for the manufacture of drug product that could potentially be available to support the commercial launch of its products. Until the first reporting period when regulatory approval has been received or is otherwise considered probable, the Company records all such costs as research and development expense. Inventory used in clinical trials is also expensed as research and development expense, when selected for such use. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period and writes down any excess and obsolete inventory to its net realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded as a component of cost of product sales in the consolidated statements of operations and comprehensive loss. The determination of whether inventory costs will be realizable requires the use of estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required.

Valuation of Other Long-Lived Intangible Assets

The Company's finite-lived intangible assets are stated at cost less accumulated amortization. The Company calculates amortization expense by the straight-line method using estimated useful lives of the related assets. The Company reviews finite-lived assets for impairment whenever events or changes in circumstances occur that indicate that the carrying amount of an asset (or asset group) may not be recoverable. The Company's impairment review is based on an estimate of the undiscounted cash flows at the lowest level for which identifiable cash flows exist and impairment occurs when the book value of the asset exceeds the estimated future undiscounted cash flows generated by the asset. When an impairment is indicated, a charge is recorded for the difference between the book value of the asset and its fair value. Depending on the asset, estimated fair value may be determined either by use of a discounted cash flow model, or by reference to estimated selling values of assets in a similar condition.

Valuation of Goodwill

The Company tests for goodwill impairment annually, on October 1, unless there are indications during an interim period that these assets are more likely than not to have become impaired. The first step of the goodwill impairment test is to compare the fair value of a reporting unit to its carrying amount to determine if there is potential impairment. If the fair value of the reporting unit is less than its carrying value, the second step of the goodwill impairment test is performed to measure the amount of impairment loss.

The second step of the goodwill impairment test compares the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. If the carrying amount of a reporting unit's goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized in an amount equal to that excess. The implied fair value of goodwill is determined in the same manner as the amount of goodwill recognized in a business combination. That is, the fair value of the reporting unit is allocated to all of the assets and liabilities of that unit (including any unrecognized intangible assets) as if the reporting unit had been acquired in a business combination and the fair value was the purchase price paid to acquire the reporting unit.

Determining the fair value of a reporting unit under the first step of the goodwill impairment test and determining the fair value of individual assets and liabilities of a reporting unit (including unrecognized intangible assets) under the second step of the goodwill impairment test is inherently subjective in nature and often involves the use of significant estimates and assumptions based on known facts and circumstances at the time we perform the valuation. The use of different assumptions, inputs and judgments or changes in circumstances could materially affect the results of the valuation and could have a significant impact on whether or not an impairment charge is recognized and the magnitude of any such charge. The Company did not record an impairment charge relating to goodwill for the years ended December 31, 2019 and 2018.

Accrued Expenses

The Company's process of determining accrued expense for a financial period-end involves reviewing open contracts and purchase orders, communicating with personnel to identify services that have been performed for the Company and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of the actual cost. The majority of the Company's service providers invoice periodically in arrears for services performed or when contractual milestones are met. The Company estimates accrued expenses at a financial period-end based on facts and circumstances known at that time and may periodically confirm the accuracy of estimates with its service providers and make adjustments if necessary.

Contingent Consideration

Contingent consideration arising from a business combination is included as part of the purchase price and is recognized at fair value as of the acquisition date. Subsequent to the acquisition date, the Company measures contingent consideration arrangements at fair value for each period until the contingency is resolved. These changes in fair value are recognized in the consolidated statements of operations. Changes in fair values reflect new information about the likelihood of the payment of the contingent consideration and the passage of time.

Leases

Effective January 1, 2019, the Company adopted ASU No. 2016-02, *Leases*, or ASC 842, using the required modified retrospective approach and utilizing the effective date as its date of initial application. Results and disclosure requirements for reporting periods after January 1, 2019 are presented under ASC 842, while prior period amounts have not been adjusted and continue to be reported in accordance with our historical accounting under Topic 840. The adoption of ASC 842 resulted in changes to the Company's accounting policies for leases previously recognized under ASC 840, as detailed below.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement including the use of a distinct identified asset(s) and the Company's control over the use of that identified asset. Most leases are recognized on the balance sheet as right-of-use assets and lease liabilities, current and non-current, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. These lease costs will be expensed as incurred. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. The Company monitors its plans to renew its material leases on a quarterly basis.

Right-of-use assets and lease liabilities are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received or initial direct costs. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

In accordance with ASC 842, components of a lease should be split into three categories: lease components (e.g., land, building, etc.), non-lease components (e.g., common area maintenance, consumables, etc.), and non-components (e.g., property taxes, insurance, etc.). The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components.

Although separation of lease and non-lease components is otherwise required, certain expedients are available. Entities may elect to not separate lease and non-lease components by class of underlying asset and account for each lease component and the related non-lease component together as a single component. For new and amended leases beginning in 2019 and after, the Company has elected to account for each lease component and related non-lease component as a single lease component and allocate all of the contract consideration to the lease component only.

Revenue Recognition

Effective January 1, 2018, the Company adopted ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606, using the full retrospective transition method. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, and financial instruments. Under 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. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied as services are rendered.

The Company enters into collaboration agreements for research, development, manufacturing and commercial services that are within the scope of ASC 606, under which it licenses certain rights to its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, upfront license fees; reimbursement of certain costs; customer option exercise fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products. The amount of variable consideration is constrained until it is probable that the revenue is not at a significant risk of reversal in a future period. The contracts into which the Company enters generally do not include significant financing components.

As part of the accounting for these arrangements, the Company must use significant judgment to determine: (a) the transaction price under step (iii) above and (b) the timing of revenue recognition, including the appropriate measure of progress, in step (v) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price, as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. If a milestone or other variable consideration relates specifically to the Company's efforts to satisfy a single performance obligation or to a specific outcome from satisfying the performance obligation, the Company generally allocates the milestone amount entirely to that performance obligation once it is probable that a significant revenue reversal would not occur.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Licenses of intellectual property

In assessing whether a license is distinct from the other promises, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from a license for its intended purpose without the receipt of the remaining promise(s), whether the value of the license is dependent on the unsatisfied promise(s), whether there are other vendors that could provide the remaining promise(s), and whether it is separately identifiable from the remaining promise(s). For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Customer options

If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. The Company evaluates the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent or include a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that the customer will exercise. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised.

Milestone payments

At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant reversal of cumulative revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant reversal of cumulative revenue would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Contract costs

The Company recognizes as an asset the incremental costs of obtaining a contract with a customer if the costs are expected to be recovered. As a practical expedient, the Company recognizes the incremental costs of obtaining a contract as an expense when incurred if the amortization period of the asset that the Company otherwise would have recognized is one year or less. To date, the Company has not incurred any incremental costs of obtaining a contract with a customer.

The Company sells its product principally to a limited number of specialty distributors and specialty pharmacy providers in the U.S. These customers subsequently resell the Company's product to health care providers or dispense the product to patients. 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 our product.

Revenues from product sales are recognized when the customer obtains control of the Company's product, which typically occurs once the Company has transferred physical possession of the good to the customer. 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. Variable consideration is only included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. 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 based on the Company's estimates of channel mix. The types of variable consideration in our product revenue are as follows:

- Trade discounts and allowances
- Product returns
- Chargebacks and rebates
- Government rebates
- Commercial payer and other rebates
- 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. 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.

The amount of variable consideration is estimated by using either of the following methods, depending on which method better predicts the amount of consideration to which the Company is entitled:

a) The "expected value" is the sum of probability-weighted amounts in a range of possible consideration amounts. Under ASC 606, an expected value may be an appropriate estimate of the amount of variable consideration if the Company has many contracts with similar characteristics.

b) The "most likely amount" is the single most likely amount in a range of possible consideration amounts (i.e., the single most likely outcome of the contract). Under ASC 606, the most likely amount may be an appropriate estimate of the amount of variable consideration if the contract has only two possible outcomes (i.e., either achieve or do not achieve a threshold specified in a contract).

The method selected is applied consistently throughout the contract when estimating the effect of an uncertainty on an amount of variable consideration. In addition, the Company considers all the information (historical, current, and forecasted) that is reasonably available to the Company and shall identify a reasonable number of possible consideration amounts. The relevant factors used in this determination include, but are not limited to, current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns.

In assessing whether a constraint is necessary, 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:

Trade Discounts and Allowances - The Company generally provides customers with discounts that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, the Company receives sales order management, data and distribution services from certain customers. To the extent the services received are distinct from the Company's sale of products to the customer, these payments are classified in selling, general and administrative expenses in the consolidated statements of operation and comprehensive loss of the Company.

Product Returns – Generally, the Company's customers have the right to return any unopened/unused product supply during the 18-month period beginning six months prior to the labeled expiration date and ending 12 months after the labeled expiration date. Since the Company currently does not have history of NUZYRA returns, the Company estimated returns based on industry data for comparable products in the market. As the Company distributes its product and establish historical sales over a longer period of time (i.e., two 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.

At the end of each reporting period for any of our 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 – Although the Company primarily sells products to specialty distributors in the U.S., the Company also enters into agreements with hospitals and outpatient infusion centers, either directly or through group purchasing organizations acting on behalf of their members, in connection with the purchase of product. Based on these agreements, some of the Company's customers have the right to receive a discounted price on product purchases. In the case of discounted pricing, 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.

Government Rebates –The Company is subject to discount obligations under state Medicaid programs and Medicare. The Company estimates our 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 estimate the number of patients in the prescription drug coverage gap for whom it will owe an additional liability under the Medicare Part D program. The Company's liability for these rebates consists of an estimate of claims for the current quarter and estimated future claims that will be made for product sales that have been recognized as revenue but remain in distribution channel inventory at period end.

Commercial Payer and Other Rebates – The Company plans to continue to contract with certain private payer organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of NUZYRA 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. As the Company distributes its product and establishes historical sales over a longer period of time (i.e., two years), the Company will be able to place more reliance on historical data related to commercial payer rebates (i.e., actual utilization units) while continuing to rely on third party data related to payer prescriptions and utilization.

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 sale that has been recognized as revenue but remains in the distribution and pharmacy channel inventories at the end of each reporting period.

At the end of each reporting period, the Company adjusts its allowances for cash discounts, product returns, chargebacks, and other rebates and discounts when the Company believes actual experience may differ from current estimates.

Cost of Product Revenue

Cost of revenue consists primarily of the manufacturing costs for NUZYRA. All manufacturing costs incurred prior to NUZYRA's approval in the U.S. on October 2, 2018 were expensed in research and development and were not included in cost of revenue.

Research and Development Expenses

Research and development expenses are charged to expense as incurred. Research and development expenses consist of the costs incurred in performing research and development activities, including personnel-related costs, stock-based compensation, facilities, research-related overhead, clinical trial costs, contracted services, manufacturing, license fees and other external costs. The Company accounts for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received rather than when the payment is made.

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 the Company 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 the Company would be able to realize our 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.

The Company records uncertain tax positions in accordance with ASC 740, *Income Taxes*, or ASC 740, on the basis of a two-step process in which (1) 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 (2) 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 recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations. The Company has not recorded interest and penalties related to any unrecognized tax benefits in the years ended December 31, 2019 and 2018.

Stock-Based Compensation

The Company accounts for its stock-based awards in accordance with ASC 718, *Compensation—Stock Compensation*, or ASC 718, which requires all stock-based payments to employees, including grants of stock options, modifications to existing stock options, and restricted stock unit awards, to be recognized as expense based on their fair values. The Company recognizes the compensation cost of awards subject to performance-based vesting conditions over the requisite service period, to the extent achievement of the performance condition is deemed probable relative to targeted performance using the accelerated attribution method. If achievement of the performance condition is not probable, but the award will vest based on the service condition, the Company recognizes the expense over the requisite service period. A change in the requisite service period that does not change the estimate of the total compensation cost (i.e., it does not affect the grant-date fair value or quantity of awards to be recognized) is recognized prospectively over the remaining requisite service period. A change in the estimate of the quantity of the awards that are considered probable of vesting results in a cumulative catch-up of stock-based compensation expense in the period of the change in estimate. The Company expenses restricted stock unit awards to employees based on the fair value of the award on a straight-line basis over the associated service period of the award.

Prior to the adoption of ASU No. 2018-07, "*Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*", or ASU No. 2018-07, as discussed below in the *Recent Accounting Pronouncements* disclosure, the measurement date for non-employee awards was generally the date the services were completed, resulting in financial reporting period adjustments to stock-based compensation during the vesting terms for changes in the fair value of the awards. After the adoption of ASU No. 2018-07, the measurement date for non-employee awards is the later of the adoption date of ASU No. 2018-07 or the date of grant, without changes in the fair value of the award. Stock-based compensation costs for non-employees are recognized as expense over the vesting period on a straight-line basis.

The Company estimates the fair value of its stock-based awards to employees and non-employees using the Black-Scholes option pricing model, which requires the input of assumptions, including (1) the expected volatility of stock, (2) the expected term of the award, (3) the risk-free interest rate and (4) expected dividends. Due to the lack of a public market for the Company's common stock prior to completion of reverse merger on October 30, 2014, and resulting lack of company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, the Company has selected companies with characteristics that are comparable, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The Company computes the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period as the calculated expected term of its stock-based awards. During 2015, the Company began to blend its stock price history, for the length of time it has market data for its stock, with the historical volatility of similar public companies for the expected term of each grant. The Company has estimated the expected life of its employee stock options as the average of the midpoints between vesting exercise date for each vesting-tranche and the contractual term of the options as the last available exercise date of the option. The risk-free interest rates for periods within the expected life of the option are based on the U.S. Treasury yield curve in effect during the period the options were granted.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in non-owner sources of equity of a business enterprise during a period from transactions, other events and circumstances and currently consists of net loss and changes in unrealized gains and losses on available-for-sale securities.

Segment and Geographic Information

Operating segments are defined as components of an enterprise engaging in business activities for which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment, and the Company operates in only one geographic segment.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date, but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. Refer to the Notes below for further details on subsequent events.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842). The amendment requires a lessee to recognize assets and liabilities for leases with term of more than 12 months. A lessee would recognize a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the leased asset (the underlying asset) for the lease term. The guidance is required to be adopted using a modified retrospective approach applied to leases existing at the date of initial application. The new standard was effective for the Company on January 1, 2019. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. The Company adopted the new standard on January 1, 2019 and used the effective date as its date of initial application. Consequently, financial information will not be restated, and the disclosures required under the new standard will not be provided for dates and periods prior to January 1, 2019.

The new standard provides a number of optional practical expedients in transition. The Company elected to utilize the available package of practical expedients permitted under the transition guidance within the new standard, which did not require the reassessment of the following: (i) whether existing or expired arrangements are or contain a lease, (ii) the lease classification of existing or expired leases, and (iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. Further, the Company utilized the short-term lease exemption for all leases with a lease term of 12 months or less for purposes of applying the recognition and measurements requirements in the new standard. The Company's analysis included, but is not limited to, assessing its existing lease and service contracts, determining the appropriate discount rates to apply to its leases in order to determine the impact that the new leasing. Further, the Company has established policies and procedures in order to adhere to the requirements of the new standard, which includes enhanced disclosure requirements.

The adoption of this standard resulted in the recognition of operating lease liabilities and right-of-use assets of $3.7 million and $3.2 million, respectively, on the Company's balance sheet relating to its leases for its corporate headquarters in Boston, Massachusetts and for office space in King of Prussia, Pennsylvania. The adoption of the standard did not have a material effect on the Company's consolidated statements of operation and comprehensive loss, consolidated statements of cash flows, or consolidated statements of stockholders' equity (deficit).

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, or ASU 2018-07. These amendments expand the scope of Topic 718, *Compensation—Stock Compensation* (which previously only included share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. ASU No. 2018-07 supersedes Subtopic 505-50, *Equity—Equity-Based Payments to Non-Employees*. ASU No. 2018-07 is effective for public companies for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. The Company adopted this guidance effective January 1, 2019. The adoption of ASU No. 2018-07 did not have a material impact on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, *Simplifying the Test for Goodwill Impairment*, or ASU 2017-04. The amendments in ASU 2017-04 eliminate the current two-step approach used to test goodwill for impairment and require an entity to apply a one-step quantitative test and record the amount of goodwill impairment as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. ASU 2017-04 is effective for fiscal years and interim periods beginning after December 15, 2019 (upon the first goodwill impairment test performed during that fiscal year). Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. A reporting entity must apply the amendments in ASU 2017-04 using a prospective approach. The Company adopted this standard on January 1, 2020. The adoption of ASU 2017-04 is not expected to have a material impact on our consolidated financial position or results of operations.

In August 2018 the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. This standard modifies certain disclosure requirements on fair value measurements. This standard became effective for us on January 1, 2020. The Company adopted this standard on January 1, 2020. The adoption of this standard is not expected to have a material impact on our disclosures.

In June 2016 the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The FASB subsequently issued amendments to ASU 2016-13, which have the same effective date and transition date of January 1, 2023. These standards require that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, these standards now require allowances to be recorded instead of reducing the amortized cost of the investment. These standards limit the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases. Based on the composition of our investment portfolio, accounts receivable and other financial assets, current market conditions and historical credit loss activity, the adoption of these standards is not expected to have a material effect on the Company's consolidated balance sheet, consolidated statements of operation and comprehensive loss and related disclosures.

3. Product Revenue

To date, our only source of product revenue has been from the sales of NUZYRA, which we began shipping to our customers in February 2019. The following table summarizes balances and activity in each of the product revenue allowance and reserve categories:

	Chargebacks, discounts and fees	Government and other rebates	Returns	Patient assistance	Total
Balance at December 31, 2018	$ —	$ —	$ —	$ —	$ —
Provision related to current period sales	926	1,424	369	174	2,893
Adjustment related to prior period sales	—	—	—	—	—
Credit or payments made during the period	(627)	(729)	—	(45)	(1,401)
Balance at December 31, 2019	$ 299	$ 695	$ 369	$ 129	$ 1,492

4. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method or the if-converted method, as applicable. For purposes of this calculation, shares of common stock issuable upon conversion of convertible debt, stock options, restricted stock units, warrants to purchase common stock, and shares issuable under the employee stock purchase plan are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following table presents the computation of basic and diluted net loss per share.

	Year Ended December 31,	
	2019	2018
Numerator		
Net loss	$ (128,790)	$ (112,356)
Denominator		
Weighted-average common shares outstanding—basic and diluted	32,791,934	31,513,454
Net loss per share—basic and diluted	$ (3.93)	$ (3.57)

The following outstanding shares subject to stock options and restricted stock units, warrants to purchase shares of common stock, common stock issuable upon conversion of convertible debt and shares issuable under the employee stock purchase plan were antidilutive due to a net loss in the periods presented and, therefore, were excluded from the dilutive securities computation for the years ended December 31, 2019 and 2018 as indicated below:

	Year Ended December 31,	
	2019	2018
Excluded potentially dilutive securities (1):		
Common stock issuable under outstanding convertible notes	10,377,361	10,377,361
Shares subject to outstanding options to purchase common stock	3,236,073	3,777,162
Unvested restricted stock units	2,305,408	1,470,237
Shares subject to warrants to purchase common stock	104,455	104,455
Shares issuable under employee stock purchase plan	798,187	979,833
Totals	16,821,484	16,709,048

(1) The number of shares is based on the maximum number of shares issuable on exercise or conversion of the related securities as of the year end. Such amounts have not been adjusted for the treasury-stock method or weighted-average outstanding calculations as required if the securities were dilutive.

5. License and Collaboration Agreements

Biomedical Advanced Research and Development Authority

On December 18, 2019, the Company entered into a five-year contract with BARDA, a division of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, with an option to extend up to ten years, to support the development of NUZYRA for the treatment of pulmonary anthrax, FDA post-marketing requirements, or PMRs, associated with the initial NUZYRA approval, and with an option for BARDA to procure up to 10,000 treatment courses of NUZYRA for the Strategic National Stockpile, or SNS, for use against potential biothreats.

The BARDA contract could result in payments to the Company of up to approximately $284.7 million and consists of a five-year base period-of-performance and a total contract period-of-performance (base period plus option exercises) of up to ten years. Under the base period-of-performance, the Company will conduct activities necessary to (i) allow the product to be used under an Emergency Use Authorization (ii) obtain licensure of NUZYRA through a supplemental New Drug Application, or NDA, submission for anthrax, and (iii) provide up to 2,500 treatment courses of the drug product to be stored as vendor managed inventory and subsequently delivered to the SNS. The contract options may be exercised to perform additional studies necessary for licensure, support post-licensure commitments as required by the FDA, additional security requirements, and procure additional treatment regimens.

Under the terms of the agreement, BARDA will award initial funding of approximately $59.4 million for the development of NUZYRA for the treatment of pulmonary anthrax and the purchase of an initial 2,500 treatment courses of NUZYRA to add to the current SNS. The contract provides for potential additional staged funding including approximately $76.8 million for existing FDA PMR commitments scheduled to begin in April 2020 and approximately $20.4 million for manufacturing-related requirements scheduled to begin in June 2020. The remaining funding includes the potential for approximately $12.7 million to support the development of NUZYRA for the prophylaxis of anthrax and a maximum of approximately $115.4 million to provide for three additional purchases of NUZYRA, each of which will be triggered upon development milestones related to the anthrax treatment development program.

The BARDA contract contains a number of terms and conditions that are customary for government contracts of this nature, including provisions giving the government the right to terminate the contract at any time for its convenience.

No revenue was recognized under the BARDA contract during the year ended December 31, 2019.

Tetraphase Pharmaceuticals, Inc.

On March 18, 2019, Paratek and Tetraphase Pharmaceuticals, Inc., or Tetraphase, entered into a License Agreement, or the Tetraphase License Agreement. Under the terms of the Tetraphase License Agreement, Paratek granted to Tetraphase a non-exclusive, worldwide, royalty-bearing license, with the right to grant sublicenses, under certain Paratek patents, to develop, make, have, use, import, offer for sale and sell the licensed product, or XERAVA™ (Eravacycline), which is a drug for the treatment of complicated, intra-abdominal infections caused by bacteria, which was approved by the FDA in August 2018.

The terms of the Tetraphase License Agreement provide for Tetraphase to pay Paratek royalties at a low single digit percent on net product revenues of the licensed product sold in the U.S. Tetraphase's obligation to pay royalties with respect to the licensed product shall be retroactive to the date of the first commercial sale of the licensed product in the U.S., which occurred in February 2019. Tetraphase is currently selling XERAVA™ (Eravacycline) in the U.S.

The Tetraphase License Agreement will continue until the expiration of and payment by Tetraphase of all Tetraphase's payment obligations, which is when there are no longer any valid claims of the licensed Paratek patents that would be infringed, in the absence of a license, by a manufacture, use, or sales of the licensed product. The principal licensed patent under the Tetraphase License Agreement is expected to expire in October 2023.

The Company recognized $0.1 million of royalty revenue for the year ended December 31, 2019 under the Tetraphase License Agreement.

Zai Lab (Shanghai) Co., Ltd.

On April 21, 2017, Paratek Bermuda Ltd., a wholly-owned subsidiary of Paratek Pharmaceuticals, Inc., and Zai Lab (Shanghai) Co., Ltd., or Zai, entered into a License and Collaboration Agreement, or the Zai Collaboration Agreement. On December 18, 2019 Paratek Bermuda Ltd. assigned its rights under the Agreement to Paratek Pharmaceuticals, Inc. Under the terms of the Zai Collaboration Agreement, Paratek granted Zai an exclusive license to develop, manufacture and commercialize omadacycline, or the licensed product, in the People's Republic of China, Hong Kong, Macau and Taiwan, or the Zai territory, for all human therapeutic and preventative uses other than biodefense. Zai is responsible for the development, manufacturing and commercialization of the licensed product in the Zai territory, at its sole cost with certain assistance from Paratek.

Under the terms of the Zai Collaboration Agreement, Paratek earned an upfront cash payment of $7.5 million in April 2017, $5.0 million upon approval by the FDA of a NDA submission in the CABP indication, in October 2018 and $3.0 million upon submission of the first regulatory approval application for a licensed product in the People's Republic of China in December 2019. Paratek is eligible to receive up to $6.0 million in potential future regulatory milestone payments and $40.5 million in potential future commercial milestone payments, the next being $6.0 million upon regulatory approval for a licensed product in the People's Republic of China. The terms of the Zai Collaboration Agreement also provide for Zai to pay Paratek tiered royalties at a low double digit to mid-teen percent on net sales of the licensed product in the Zai territory.

The Zai Collaboration Agreement will continue, on a region-by-region basis, until the expiration of and payment by Zai of all Zai's payment obligations, which is until the later of: (i) the abandonment, expiry or final determination of invalidity of the last valid claim within the Paratek patents that covers the licensed product in the region in the Zai territory in the manner that Zai or its affiliates or sublicensees exploit the licensed product or intend for the licensed product to be exploited; or (ii) the eleventh anniversary of the first commercial sale of such licensed product in such region.

The Company evaluated the Zai Collaboration Agreement under ASC 606. The Company determined that there were six material promises under the Zai Collaboration Agreement: (i) an exclusive license to develop, manufacture and commercialize omadacycline in the Zai territory, (ii) the initial technology transfer (iii) a transfer of certain materials and materials know-how, (iv) optional manufacturing services, (v) optional regulatory support and (vi) optional commercialization support. The Company determined that the exclusive license and initial technology transfer were not distinct from one another, as the license has limited value without the transfer of the Company's technology, which will allow Zai to develop the manufacturing process and commercialize omadacycline in the Zai territory in the timeline anticipated under the agreement. Without the technology transfer, Zai would incur additional costs to recreate the Company's know-how. Therefore, the license and initial technology transfer are combined as a single performance obligation. The transfer of materials is a single distinct performance obligation. The Company evaluated the option rights for manufacturing services, regulatory support and commercialization support to determine whether they represent or include material rights to Zai and concluded that the options were not issued at a discount, and therefore do not represent material rights. As such, they are not considered performance obligations at the outset of the arrangement.

Based on these assessments, the Company determined that two performance obligations existed at the outset of the Zai Collaboration Agreement: (i) the exclusive license combined with the initial technology transfer and (ii) the transfer of certain materials.

The Company determined that the upfront payment of $7.5 million constituted the entirety of the consideration to be included in the transaction price as of the outset of the Zai Collaboration Agreement. Future potential milestone payments were excluded from the transaction price as they are fully constrained as the risk of significant reversal has not yet been resolved. The achievement of the future potential milestones is not within the Company's control and is subject to certain research and development success or regulatory approvals and therefore carry significant uncertainty. The Company will reevaluate the likelihood of achieving future milestones at the end of each reporting period. As all performance obligations have been satisfied, if the risk of significant reversal is resolved, any future milestone revenue from the arrangement will be recognized as revenue in the period the risk is relieved.

As FDA approval was not within the control of the Company and was not obtained until October 2, 2018, the achievement of the milestone was not deemed probable and the risk of significant reversal of revenue was not resolved until that time. Upon the FDA approval, the uncertainty related to this milestone was resolved and a significant reversal of revenue would not occur in future periods. As such, the $5.0 million milestone payment was recognized as revenue at the time of FDA approval in the fourth quarter of 2018.

As submission of the first regulatory approval application for a licensed product in the People's Republic of China, or the PRC, is not within the control of the Company and was not obtained until December 2019, the achievement of the milestone was not was not deemed probable and the risk of significant reversal of revenue was not resolved until that time. Upon submission, the uncertainty related to this milestone was resolved and a significant reversal of revenue would not occur in future periods. As such, the $3.0 million milestone payment was recognized as revenue at the time of the regulatory approval application submission in the fourth quarter of 2019.

As regulatory approval in the PRC is not within the control of the Company, the achievement of the next milestone was not deemed probable and the risk of significant reversal of revenue was not resolved as of December 31, 2019. As such, the next milestone payment was not recognized as revenue in the year ended December 31, 2019.

There was no deferred revenue as of December 31, 2019 and 2018.

Almirall, LLC

In July 2007, the Company and Warner Chilcott Company, Inc. (which became a part of Allergan plc, or Allergan), entered into a collaborative research and license agreement under which the Company granted Allergan an exclusive license to research, develop, manufacture and commercialize tetracycline products for use in the U.S. for the treatment of acne and rosacea. In September 2018, Allergan assigned to Almirall, its rights under the collaboration agreement, or the Almirall Collaboration Agreement. Since Allergan did not exercise its development option with respect to the treatment of rosacea prior to initiation of a Phase 3 trial for the product, the license grant to Allergan, which was assigned to Almirall, converted to a non-exclusive license for the treatment of rosacea as of December 2014.

Under the terms of the Almirall Collaboration Agreement, Almirall is responsible for and is obligated to use commercially reasonable efforts to develop and commercialize tetracycline compounds that are specified in the agreement for the treatment of acne. The Company has agreed during the term of the Almirall Collaboration Agreement not to directly or indirectly develop or commercialize any tetracycline compounds in the U.S. for the treatment of acne, and Almirall has agreed during the term of the Almirall Collaboration Agreement not to directly or indirectly develop or commercialize any tetracycline compound included as part of the agreement for any use other than as provided in the Almirall Collaboration Agreement.

In February 2020, the Company finalized a license agreement with Almirall granting the Company exclusive rights to develop, manufacture and commercialize sarecycline outside of the U.S., including rights of reference to Almirall's clinical data thus formalizing the Company's rights to develop, manufacture and commercialize sarecycline in the rest of the world. In connection with that license, the Company then exclusively licensed Almirall pursuant to the Almirall China License Agreement, the rights to develop, manufacture and commercialize sarecycline in the greater China region. Almirall currently holds a nonexclusive license to develop and commercialize sarecycline for the treatment of rosacea in the U.S., and in the U.S., Paratek cannot grant rights on back-up compounds, lead candidate(s), or products licensed to Almirall for rosacea.

The Almirall Collaboration Agreement contains two performance obligations: (i) an exclusive license to research, develop and commercialize tetracycline products for use in the U.S. for the treatment of acne and rosacea and (ii) research and development services. The performance obligation to deliver the license was satisfied upon execution of the Almirall Collaboration Agreement in July 2007. All research and development services were completed by December 2010. The options provided to Almirall for additional development services do not provide Almirall with a material right as these services will not be provided at a significant or incremental discount. As such, the option services are not performance obligations. As the performance obligation to deliver the license was satisfied in 2007 and research and development services were completed by December 2010, all subsequent milestone payments are recognized as revenue when the risk of significant reversal is resolved, generally when the milestone event occurs.

The Company received an upfront fee in the amount of $4.0 million upon the execution of the Almirall Collaboration Agreement, $1.0 million upon filing of an Investigational NDA in 2010, $2.5 million upon initiation of Phase 2 trials in 2012 and $4.0 million upon initiation of Phase 3 trials associated with the Almirall Collaboration Agreement in December 2014.

In December 2017, the FDA's acceptance of the NDA for sarecycline was received, triggering a milestone payment of $5.0 million earned upon acceptance of an NDA for a product licensed under the Almirall Collaboration Agreement.

In October 2018, the FDA's regulatory approval of sarecycline, under the tradename SEYSARA, triggered the last milestone payment under the Almirall Collaboration Agreement of $12.0 million. Since FDA approval of SEYSARA was outside of the Company's control and not obtained until October 2, 2018, the achievement of the milestone was not deemed probable and the risk of significant reversal of revenue was not resolved until such time. Upon the FDA approval, the uncertainty related to this milestone was resolved and a significant reversal of revenue would not occur in future periods. As such, the $12.0 million milestone payment was recognized as revenue at the time of FDA approval in the fourth quarter of 2018.

Almirall is also obligated to pay the Company tiered royalties, ranging from the mid-single digits to the low double digits, based on net sales of tetracycline compounds developed under the Almirall Collaboration Agreement, with a standard royalty reduction post patent expiration for such product for the remainder of the royalty term. Almirall's obligation to pay the Company royalties for each tetracycline compound it commercializes under the Almirall Collaboration Agreement expires on the later of the expiration of the last to expire patent that covers the tetracycline compound in the U.S. and the date on which generic drugs that compete with the tetracycline compound reach a certain threshold market share in the U.S.

Royalty payments will be recognized when the sales occur. The Company recognized $1.9 million of royalty revenue recognized for sales of SEYSARA in the U.S. by Almirall for the year ended December 31, 2019 under the Almirall Collaboration Agreement. During the fourth quarter of 2019, royalty revenue recognized for sales of SEYSARA in the U.S. was estimated using third party data and an approximation of discounts and allowances to calculate net product sales, to which the Company then applied the applicable royalty percentage specified in the Almirall Collaboration Agreement. Differences between actual and estimated royalty revenues will be adjusted for in the period in which they become known, which is expected to be the following quarter.

In February 2020, we entered into (i) an ex-U.S. license agreement with Almirall, or the Ex-U.S. License, under which Almirall granted to us an exclusive license in and to certain technology owned or in-licensed by Almirall or its affiliates in order to research, develop, manufacture and commercialize sarecycline for the treatment of acne in all countries other than the U.S. and (ii) a license agreement with Almirall that is specific to China, or the China License, under which we granted to Almirall an exclusive license in and to certain technology owned or in-licensed by us or our affiliates in order to research, develop and commercialize sarecycline for the treatment of acne in the greater China region.

Under the terms of the China License, Almirall is responsible for and is obligated to use commercially reasonable efforts to develop and commercialize sarecycline for the treatment of acne, including requirements to (i) file an Investigational New Drug Application (or analogous foreign submission) for sarecycline for the treatment of acne in the greater China region in calendar year 2020, (ii) receive regulatory approval for sarecycline for the treatment of acne in the greater China region within seven years following such submission and (iii) commercialize sarecycline for the treatment of acne in the greater China region within eighteen months after obtaining regulatory approval. If Almirall does not satisfy the diligence requirements set forth in subclauses ii or iii above, we may terminate the China License.

We have agreed during the term of the Ex-U.S. License to use commercially reasonable efforts to not, directly or indirectly, make sarecycline products commercialized by us, our affiliates or our sublicensees available for resale in U.S., and Almirall has agreed during the term of the Ex-U.S. License to use commercially reasonable efforts to not, directly or indirectly, make sarecycline products commercialized by Almirall, their affiliates or their sublicensees available for resale outside of the greater China region. Similarly, we have agreed during the term of the China License to use commercially reasonable efforts to not, directly or indirectly, make sarecycline products commercialized by us, our affiliates or our sublicensees available for resale in the greater China region, and Almirall has agreed during the term of the China License to use commercially reasonable efforts to not, directly or indirectly, make sarecycline products commercialized by Almirall, their affiliates or their sublicensees available for resale outside of the greater China region, other than as provided in the Almirall Collaboration Agreement.

In connection with the Ex-U.S. License, we pay Almirall, on a country-by-country and product-by-product basis, (i) for eight years following the first commercial sale of a sarecycline product in a country, a royalty in the middle-single digits on our or our affiliates' nets sales of sarecycline products outside of the U.S., subject to certain standard reductions, and (ii) for fifteen years following the first commercial sale of a sarecycline product in a country, a percentage of the consideration (e.g., milestones, royalties) we receive from sublicensees in connection with developing and commercializing sarecycline outside of the U.S., which ranges from one-fifth to one-half of such consideration, subject to certain standard reductions. In connection with the China License, for fifteen years following the first commercial sale of a sarecycline product in China, Almirall pays us a royalty in the high-single digits on their, their affiliates' or their sublicensees' net sales of sarecycline products in the greater China region, subject to certain standard reductions.

Purdue Pharma L.P.

In July 2009, the Company and Purdue Pharma L.P., or Purdue Pharma, entered into a collaboration agreement, or the Purdue Collaboration Agreement, which granted an exclusive license to Purdue Pharma to commercialize Intermezzo in the U.S. in exchange for a non-refundable license fee, certain milestone payments and tiered royalties on net sales of Intermezzo.

In December 2013, Purdue Pharma notified the Company that it intended to discontinue use of the Purdue Pharma sales force to actively market Intermezzo to healthcare professionals during the first quarter of 2014.

In October 2014, the Company announced that its Board of Directors had approved a special dividend of, among other things, the right to receive, on a pro rata basis, 100% of any royalty income received by the Company pursuant to the Purdue Collaboration Agreement and 90% of any cash proceeds from a sale or disposition of Intermezzo, less fees and expenses incurred in connection with such activity, to the extent that either occurred prior to the second anniversary of the closing date of the Merger. On October 28, 2016, in satisfaction of the Company's payment obligation of the proceeds of sale or disposition of the Intermezzo assets to the former Transcept stockholders under the Merger Agreement, the Company executed a royalty sharing agreement, or the Royalty Sharing Agreement, with the Special Committee of the Company's Board of Directors, a committee established in connection with the Merger. Under the Royalty Sharing Agreement, the Company agreed to pay to the former Transcept stockholders 50% of all royalty income received by the Company pursuant to the Purdue Collaboration Agreement, net of all costs, fees and expenses incurred by the Company in connection with the Purdue Collaboration Agreement, related agreements, the Intermezzo product and the administration of the royalty income to the Transcept stockholders. The NDA for Intermezzo was then withdrawn from the FDA by Purdue Pharma as of December 31, 2018 and further sales of the drug are not planned. Neither the Company nor the former shareholders of Transcept will receive future cash payments pursuant to the Royalty Sharing Agreement. As such, the Company impaired the remaining balance of the Intermezzo product rights during the fourth quarter of 2018.

Tufts University

In February 1997, the Company and Tufts University, or Tufts, entered into a license agreement under which the Company acquired an exclusive license to certain patent applications and other intellectual property of Tufts related to the drug resistance field to develop and commercialize products for the treatment or prevention of bacterial or microbial diseases or medical conditions in humans or animals or for agriculture. The Company subsequently entered into eleven amendments to that agreement, collectively the Tufts License Agreement, to include patent applications filed after the effective date of the original license agreement, to exclusively license additional technology from Tufts, to expand the field of the agreement to include disinfectant applications, and to change the royalty rate and percentage of sublicense income paid by the Company to Tufts under sublicense agreements with specified sublicensees. The Company is obligated under the Tufts License Agreement to provide Tufts with annual diligence reports and a business plan and to meet certain other diligence milestones. The Company has the right to grant sublicenses of the licensed rights to third parties, which will be subject to the prior approval of Tufts unless the proposed sublicensee meets a certain net worth or market capitalization threshold. The Company is primarily responsible for the preparation, filing, prosecution and maintenance of all patent applications and patents covering the intellectual property licensed under the Tufts License Agreement at its sole expense. The Company has the first right, but not the obligation, to enforce the licensed intellectual property against infringement by third parties.

The Company issued Tufts 1,024 shares of the Company's common stock on the date of execution of the original license agreement, and the Company was required to make certain payments of up to $0.3 million to Tufts upon the achievement by products developed under the agreement of specified development and regulatory approval milestones. The Company made a payment of $50,000 to Tufts for achieving the first milestone following commencement of the Phase 3 clinical trial for omadacycline and a payment of $100,000 to Tufts for achieving the second milestone following its first marketing application submitted in the U.S. The third, and final, payment of $150,000 became due upon FDA approval of omadacycline in October 2018. The Company is also obligated to pay Tufts a minimum royalty payment in the amount of $25,000 per year. In addition, the Company is obligated to pay Tufts royalties based on gross sales of products, as defined in the agreement, ranging in the low single digits depending on the applicable field of use for such product sale. If the Company enters into a sublicense under the agreement, based on the applicable field of use for such product, the Company will be obligated to pay Tufts (i) a percentage, ranging from 10% to 14% (ten percent to fourteen percent) for compounds other than omadacycline, and a percentage in the single digits for the compound omadacycline, of that portion of any sublicense issue fees or maintenance fees received by the Company that are reasonably attributable to the sublicense of the rights granted to the Company under the Tufts License Agreement and (ii) the lesser of (a) a percentage, ranging from the low tens to the high twenties based on the applicable field of use for such product, of the royalty payments made to the Company by the sublicensee or (b) the amount of royalty payments that would have been paid by the Company to Tufts if it had sold the product.

Unless terminated earlier, the Tufts License Agreement will expire at the same time as the last-to-expire patent in the patent rights licensed to the Company under the agreement and after any such expiration the Company will continue to have an exclusive, fully-paid-up license to such intellectual property licensed from Tufts. Tufts has the right to terminate the agreement upon 30 days' notice should the Company fail to make a material payment under the Tufts License Agreement or commit a material breach of the agreement and not cure such failure or breach within such 30-day period, or if, after the Company has started to commercialize a product under the Tufts License Agreement, the Company ceases to carry on its business for a period of 90 consecutive days. The Company has the right to terminate the Tufts License Agreement at any time upon 180 days' notice. Tufts has the right to convert the Company's exclusive license to a non-exclusive license if the Company does not commercialize a product licensed under the agreement within a specified time period.

The Company incurred $0.2 million of royalty expense for the year ended December 31, 2019 under the Tufts License Agreement.

Past Collaborations

Novartis

In September 2009, the Company and Novartis International Pharmaceutical Ltd., or Novartis, entered into a Collaborative Development, Manufacture and Commercialization License Agreement, or the Novartis Agreement, which provided Novartis with a global, exclusive patent and technology license for the development, manufacturing and marketing of omadacycline. The Novartis Agreement was terminated by Novartis without cause in June 2011 and the termination was effective 60 days later. The Company and Novartis subsequently entered in a letter agreement in January 2012, or the Novartis Letter Agreement, as amended, pursuant to which we reconciled shared development costs and expenses and granted Novartis a right of first negotiation with respect to commercialization rights of omadacycline following approval of omadacycline from the FDA, European Medicines Agency, or EMA, or any regulatory agency, but only to the extent the Company had not previously granted such commercialization rights related to omadacycline to another third party as of any such approval. The Company also agreed to pay Novartis a 0.25% royalty, to be paid from net sales received by the Company in any country following the launch of omadacycline in that country and continuing until the later of expiration of the last active valid patent claim covering such product in the country of sale and 10 years from the date of first commercial sale in such country. The first royalty payment became payable as of March 31, 2019. The amended Novartis Letter Agreement resulted in a long-term liability in the amount of $3.4 million and $3.6 million as of December 31, 2019 and December 31,

2018, respectively, included within “Other Long-Term Liabilities” on the Company’s consolidated balance sheet. In addition, a short-term liability of $0.1 million included within “Other current liabilities” on the Company’s consolidated balance sheet as of December 31, 2019 represents the portion of royalty payments due to Novartis within twelve months. No short-term portion existed as of December 31, 2018. There are no other payment obligations to Novartis under the Novartis Agreement or the amended Novartis Letter Agreement. There are no other payment obligations to Novartis under the Novartis Agreement or the amended Novartis Letter Agreement.

6. Restricted Cash

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated statement of cash flows that sum to the total of the same such amounts shown in the consolidated statement of cash flows (in thousands):

	December 31,	
	2019	2018
Cash and cash equivalents	$ 102,302	$ 46,987
Short-term restricted cash	324	266
Long-term restricted cash	3,007	249
Total cash, cash equivalents and restricted cash shown on the consolidated statement of cash flows	$ 105,633	$ 47,502

Short-term restricted cash

On May 1, 2019, the Company deposited $4.0 million into an interest reserve account in conjunction with the funding of a royalty-backed loan agreement, or the Royalty-Backed Loan Agreement, executed with Healthcare Royalty Partners III, L.P. Payments of interest under the Royalty-Backed Loan Agreement are made quarterly using royalty payments received since the immediately preceding payment date under the Almirall Collaboration Agreement. On each interest payment date, if the royalty payments received do not equal the total interest due for the respective quarter, the Company will cover the balance of the interest payment due from the interest reserve account. Refer to Note 16, *Long-Term Debt*, for further details. As of December 31, 2019, restricted cash of $0.3 million represents the estimated amount that is expected to be paid to Healthcare Royalty Partners III, L.P. out of the interest reserve account within the next twelve months. As of December 31, 2018, restricted cash of $0.3 million primarily represented royalty income received but not yet paid to former stockholders of Transcept Pharmaceuticals, Inc., or Transcept, as part of the royalty sharing agreement, or the Royalty Sharing Agreement, executed by the Company in October 2016 with the Special Committee of the Company’s Board of Directors, which was established in connection with the business combination between privately-held Paratek Pharmaceuticals, Inc. and Transcept in October 2014, or the Merger. This amount was paid to former stockholders of Transcept in the first quarter of 2019.

Long-term restricted cash

The Company leases its Boston, Massachusetts office space under a non-cancelable operating lease. Refer to Note 18, *Commitments and Contingencies*, for further details. In accordance with the lease, the Company has a cash-collateralized irrevocable standby letter of credit in the amount of $0.3 million as of December 31, 2019 and 2018, naming the landlord as beneficiary.

As of December 31, 2019, long term restricted cash of $2.7 million represents the remaining balance in the interest reserve account that is expected to be paid to Healthcare Royalty Partners III, L.P. after December 31, 2020.

7. Cash and Cash Equivalents and Marketable Securities

The following is a summary of available-for-sale securities as of December 31, 2019 and 2018 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
December 31, 2019				
U.S. treasury securities	$ 113,003	$ 89	$ (15)	$ 113,077
Total	$ 113,003	$ 89	$ (15)	$ 113,077
December 31, 2018				
U.S. treasury securities	$ 245,979	$ 65	$ (193)	$ 245,851
Total	$ 245,979	$ 65	$ (193)	$ 245,851

No available-for-sale securities held as of December 31, 2019 and 2018 had remaining maturities greater than twelve months and fifteen months, respectively.

8. Fixed Assets, Net

Fixed assets consist of the following (in thousands):

	Estimated In Years	December 31, 2019	December 31, 2018
Office equipment	5	$ 866	$ 866
Machinery and equipment	5	567	—
Computer equipment	3	412	412
Computer software	3	798	798
Leasehold improvements		920	909
Gross fixed assets		3,563	2,985
Less: Accumulated depreciation and amortization		(2,336)	(1,812)
Net fixed assets		$ 1,227	$ 1,173

In addition, leasehold improvements are amortized over the shorter of the lease term or the estimated useful economic lives of the related assets.

Depreciation expense for the years ended December 31, 2019 and 2018 was approximately $0.5 million and $0.6 million, respectively, which is included in selling, general and administrative and research and development expense on the accompanying consolidated statements of operations and comprehensive loss.

9. Inventories, Net

The following table presents inventories (in thousands):

	December 31, 2019	December 31, 2018
Work in process	$ 9,330	$ 598
Finished goods	2,249	—
Total inventories	$ 11,579	$ 598

When recorded, inventory reserves reduce the carrying value of inventories to their net realizable value. The Company reviews inventories on hand at least quarterly and records provisions for estimated excess, slow-moving and obsolete inventory, as well as inventory with a carrying value in excess of net realizable value. No inventory reserves existed as of December 31, 2019 and 2018.

10. Intangible Assets, Net

No intangible assets existed for the year ended December 31, 2019. In 2018, intangible assets represented Intermezzo product rights and the TO-2070 license rights were acquired through the Merger. Refer to Note 5, *License and Collaboration Agreements*, for further detail concerning Intermezzo. Intangible assets are reviewed when events or circumstances indicate that the assets might be impaired. An impairment loss would be recognized when the estimated undiscounted cash flows to be generated by those assets are less than the carrying amounts of those assets. If it is determined that the intangible asset is not recoverable, an impairment loss would be calculated based on the excess of the carrying value of the intangible asset over its fair value. During 2018, the NDA for Intermezzo was withdrawn from the FDA by Purdue Pharma and further sales of the drug are not planned. As such, the Company impaired the remaining balance of the Intermezzo product rights during 2018.

11. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31,	
	2019	2018
Accrued legal costs	$ 181	$ 366
Accrued other	95	809
Accrued professional fees	876	750
Accrued interest	2,264	1,813
Accrued compensation	7,580	6,070
Accrued contract research	1,612	1,747
Accrued commercial	1,445	1,280
Accrued manufacturing	1,026	2,784
Accrued sales allowances	1,492	—
Accrued inventory	125	—
Total	$ 16,696	$ 15,619

12. Common Stock

Following the Merger, the authorized capital stock of the Company consists of 100,000,000 shares of common stock, par value $0.001 per share, and the preferred stock described in Note 13, *Preferred Stock*.

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders and there are no cumulative rights. Subject to preferences that may be applicable to any outstanding preferred stock, the holders of common stock are entitled to receive ratably any dividends that may be declared from time to time by the board of directors out of funds legally available for that purpose. In the event of liquidation of the Company, dissolution or winding up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock then outstanding. The common stock has no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. The outstanding shares of common stock are fully paid and non-assessable.

The Company completed an underwritten offering on May 5, 2015 of 3,089,000 shares of its common stock at a public offering price of $24.50 per share, which included 229,000 shares of its common stock issued upon the exercise, in part, by the underwriters of an option to purchase additional shares. The net proceeds received by the Company, after underwriting discounts and commissions and other offering expenses, were $70.4 million. The Company also completed an underwritten offering on June 27, 2016 of 4,887,500 shares of its common stock at a public offering price of $13.00 per share, which included 637,500 shares of its common stock issued upon the exercise, in full, by the underwriters of an option to purchase additional shares. The net proceeds received by the Company, after underwriting discounts and commissions and other estimated offering expenses, were $59.3 million.

On December 1, 2017, we filed a registration statement on Form S-3 with the SEC, which was declared effective on December 8, 2017, to sell certain of our securities in an aggregate amount of up to $250.0 million. As of December 31, 2019, $222.6 million remains available on this shelf registration statement, with $22.6 million reserved for potential sales under the 2019 Sales Agreement.

In February 2017, the Company entered into Controlled Equity Offering℠ Sales Agreements, or the 2017 Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, under which the Company could, at its discretion, from time to time sell shares of its common stock, with a sales value of up to $50 million through Cantor. The Company provided Cantor with customary indemnification rights, and Cantor was entitled to a commission at a fixed rate of 3% of the gross proceeds per share sold. Sales of the shares under the Sales Agreements were to be made in transactions deemed to be “at the market offerings”, as defined in Rule 415 under the Securities Act of 1933, as amended. The Company has sold 2,102,315 shares of common stock pursuant to the 2017 Sales Agreement for $47.7 million in proceeds, after deducting commissions of $1.5 million. The Company received $1.7 million in proceeds, after deducting commissions of $0.1 million, from the sale of 96,308 shares of common stock, during the year ended December 31, 2018, under the 2017 Sales Agreement. None of these sales occurred during the year ended December 31, 2019. The 2017 Sales Agreement was terminated effective on June 22, 2019.

The Company completed an underwritten offering on January 22, 2018 of 3,205,128 shares of its common stock. The total proceeds received by the Company were $50.0 million. Offering expenses incurred were approximately $0.2 million.

On July 2, 2019, the Company entered into an At the Market Sales Agreement, or the 2019 Sales Agreement, with Jefferies LLC, or Jefferies, and BTIG, LLC, or BTIG, under which it may offer and sell its common stock having aggregate sales proceeds of up to $50.0 million from time to time through Jefferies or BTIG as its sales agents. Sales of the Company's common stock through Jefferies or BTIG, if any, will be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, including without limitation sales made directly on the Nasdaq Global Market or any other existing trading market for its common stock. Jefferies and BTIG will use commercially reasonable efforts to sell the Company's common stock from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions we may impose). The Company will pay Jefferies or BTIG, as applicable, a commission of 3% of the gross sales proceeds of any common stock sold through Jefferies and BTIG under the 2019 Sales Agreement. The Company has also provided Jefferies and BTIG with customary indemnification rights.

The Company is not obligated to make any sales of common stock under the 2019 Sales Agreement. The Company has sold 6,524,194 shares of common stock pursuant to the 2019 Sales Agreement for $26.6 million in proceeds, after deducting commissions of $0.8 million during the year ended December 31, 2019. As of February 28, 2020, the Company has sold an additional 2,334,107 shares of common stock pursuant to the 2019 Sales Agreement for $9.1 million in proceeds, after deducting commissions of $0.3 million. As of February 28, 2020, $13.2 million remains available for sale under the 2019 Sales Agreement.

The offering of shares of the Company's common stock pursuant to the 2019 Sales Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the 2019 Sales Agreement, or (ii) termination of the 2019 Sales Agreement in accordance with its terms.

Warrants to Purchase Common Stock

Warrants to purchase preferred stock with intrinsic value issued to HBM Healthcare Investments (Cayman) Ltd., Omega Fund III, L.P., and K/S Danish BioVenture, all beneficial owners of more than 5% of the Company's common stock, were exchanged for 9,614 warrants to purchase common stock in connection with the Merger. 9,614 warrants to purchase common stock have an exercise price of $0.15 per share and will, if not exercised, expire in 2021.

In connection with the Loan and Security Agreement, dated September 30, 2015, as amended from time to time, or the Hercules Loan Agreement, into which the Company entered with Hercules Technology II, L.P. and Hercules Technology III, L.P., together, Hercules, and certain other lenders and Hercules Technology Growth Capital, Inc. (as agent), the Company issued to each of Hercules Technology II, L.P. and Hercules Technology III, L.P. a warrant to purchase 16,346 shares of its common stock (32,692 shares of common stock in total) at an exercise price of $24.47 per share, or the Hercules Warrants, on September 30, 2015, which expire five years from issuance or at the consummation of a Public Acquisition, as defined in each of the Hercules Warrant agreements.

In connection with the second amendment to the Hercules Loan Agreement on December 12, 2016, the Company issued to each of Hercules Technology II, L.P. and Hercules Technology III, L.P. a warrant to purchase 18,574 shares of its common stock (37,148 shares of common stock in total) at an exercise price of $13.46 per share, or the Second Amendment Warrants.

In connection with the borrowing under the Hercules Loan Agreement on June 27, 2017, the Company issued an additional warrant to Hercules Capital, Inc. to purchase 5,374 shares of its common stock at an exercise price of $23.26 per share, or the Additional Warrant.

In connection with the fifth amendment to the Hercules Loan Agreement, on August 1, 2018, the Company issued to Hercules Capital, Inc. a warrant to purchase up to 19,627 shares of its common stock at an exercise price of $10.19 per share, or the Fifth Amendment Warrant.

The Hercules Warrants, Second Amendment Warrants, Additional Warrant and the Fifth Amendment Warrant, collectively referred to as the Warrants, may be exercised on a cashless basis. The Warrants are exercisable for a term beginning on the date of issuance and ending on the earlier to occur of five years (or seven years, in the case of the Fifth Amendment Warrant) from the date of issuance or the consummation of certain acquisitions of the Company as set forth in the various agreements for the Warrants.

13. Preferred Stock

The authorized capital stock of the Company consists of 5,000,000 shares of undesignated preferred stock, par value $0.001 per share, and the common stock described in Note 12, *Common Stock*. There are no shares of preferred stock outstanding.

The Company's Board of Directors has the authority, without further action by the stockholders, to issue up to 5,000,000 shares of preferred stock, in one or more series, and to fix the rights, preferences, privileges and restrictions granted to or imposed upon the preferred stock. Any or all of these rights may be greater than the rights of the common stock.

There are no shares of preferred stock issued or outstanding as of December 31, 2019 and 2018.

14. Fair Value Measurements

Financial instruments, including cash, cash equivalents, restricted cash, money market funds, U.S. treasury securities, accounts receivable, accounts payable, accrued expenses, and contingent obligations, are carried on the consolidated financial statements at amounts that approximate fair value. The fair value of the Company's long-term debt is determined using current applicable rates for similar instruments as of the balance sheet date. The fair value of the Company's debt (including the Notes as defined in Note 16, *Long-Term Debt)*, is $191.3 million as of December 31, 2019 and $179.3 million as of December 31, 2018. The fair value of the Company's debt was determined using Level 3 inputs. Fair values are based on assumptions concerning the amount and timing of estimated future cash flows and assumed discount rates, reflecting varying degrees of perceived risk.

The following tables present information about the Company's financial assets and liabilities that have been measured at fair value as of December 31, 2019 and December 31, 2018 and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities or other inputs that are observable market data. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability (in thousands):

Description	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	December 31, 2019
Assets:				
U.S. treasury securities	$ 113,077	$ —	$ —	$ 113,077
Total Assets	$ 113,077	$ —	$ —	$ 113,077

Description	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	December 31, 2018
Assets:				
U.S. treasury securities	$ 245,851	$ —	$ —	$ 245,851
Total Assets	$ 245,851	$ —	$ —	$ 245,851

Marketable Securities

U.S. treasury securities fair values can be obtained through quoted market prices in active exchange markets and are therefore classified as Level 1.

15. Stock-Based and Incentive Compensation

Certain employees, officers, directors and consultants have been granted options and other equity instruments to purchase common shares under plans adopted in 2006, 2014 and 2015, or the 2006 Plan, the 2014 Plan, the 2015 Plan, respectively, the 2015 Inducement Plan and the 2017 Inducement Plan. Upon effectiveness of the 2015 Plan no further awards will be granted under the 2006 Plan and 2014 Plan.

Incentive stock and non-statutory stock options must be granted with exercise prices of not less than the fair market value of the common stock on the date of grant. Incentive stock options granted to a stockholder owning more than 10% of voting stock of the Company must have an exercise price of not less than 110% of the fair market value of the common stock on the date of grant. The Company determined the fair market value of common stock until the Company became publicly traded. Stock options are generally granted with terms of up to ten years and vest over a period of one to four years.

2006 Plan

The 2006 Plan provided for the grant of incentive stock options, non-statutory stock options, restricted stock, performance share awards, performance stock units, dividend equivalents, restricted stock units, stock payments, deferred stock, performance-based awards and stock appreciation rights. The outstanding employee stock options generally vested over four years, are exercisable over a period not to exceed the contractual term of ten years from the date the stock options are issued and are granted at prices equal to the fair market value of the Company's common stock on the grant date. The 2006 Plan was most recently amended and restated effective as of the date of the Company's 2010 Annual Stockholders' Meeting. Unless earlier terminated, the 2006 Plan will terminate on June 2, 2020.

Stock option exercises and restricted stock units are settled with newly issued common stock from the 2006 Plan's previously authorized and available pool of shares. A total of 200,206 shares of common stock was authorized for issuance pursuant to the 2006 Plan at the time of its most recent amendment and restatement in 2010, plus the number of shares of the Company's common stock available for issuance under a previous plan that were not subject to outstanding options, as of the effective date of such amendment and restatement of the 2006 Plan (including shares that are subject to stock options outstanding under the previous plan that expired, were cancelled or otherwise terminated unexercised, or shares that otherwise would have reverted to the share reserve of the 2001 Plan following such effective date). The number of shares of common stock reserved for issuance under the 2006 Plan increased automatically on the first day of each fiscal year by a number of shares equal to the least of: (i) 5.0% of shares of the Company's common stock outstanding on such date; (ii) 125,000 shares; or (iii) a smaller number determined by the Company's Board of Directors. This provision resulted in an additional 125,000 shares, and 125,000 shares, and of the Company's common stock becoming available for issuance on January 1, 2015 and January 1, 2014.

As of December 31, 2019 and 2018, no additional shares remained available for issuance under the 2006 Plan. All shares cancelled or forfeited during the years ended December 31, 2019 and 2018 became available for grant under the 2015 Plan.

2014 Plan

The 2014 Plan provided for the grant of incentive and non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and other stock awards to employees, officers, directors, and consultants of the Company. Under the 2014 Plan, 67,500 shares of common stock were initially approved for grant. 67,500 shares of fully-vested restricted common stock were granted pursuant to the 2014 Plan to current and former employees and directors of the Company in June 2014.

Also in June 2014, the Board of Directors approved an increase in the shares available for grant under the 2014 Plan to 875,531 shares from the 67,500 shares and granted the resulting 808,031 shares that became available for issuance under the 2014 Plan as options to purchase common stock to certain employees in June 2014. The common stock grants and stock option exercises from the 2014 Plan are settled with newly issued common stock from the 2014 Plan's previously authorized and available pool of shares.

Further, in February 2015 the Company's Board of Directors modified the vesting terms of eight grants made to four executives of the Company aggregating 483,114 stock options previously granted under the 2014 Plan from strictly time-based vesting to include certain performance-based vesting terms associated with completion of data lock in the Company's Phase 3 clinical trials of IV-to-oral omadacycline for the treatment of ABSSSI and CABP. The Company recognizes compensation cost for awards with performance conditions if and when it concludes that it is probable that the performance condition will be achieved over the requisite service period. The Phase 3 ABSSSI IV-to-oral study data lock occurred in June 2016. This resulted in the vesting of 212,516 stock options. The Phase 3 CABP IV-to-oral study data lock occurred in March 2017. This resulted in the vesting of 212,516 stock options. The sum of the incremental compensation cost and any remaining unrecognized compensation cost for the original award on the modification date was recognized, on a prospective basis, through the performance achievement dates.

During the year ended December 31, 2015, prior to the effectiveness of the 2015 Plan, the Company's Board of Directors granted 24,000 stock options to directors, officers, employees and consultants to the 2014 Plan with time vesting provisions ranging from one to four years. As of December 31, 2019 and 2018, no additional shares remained available for issuance the 2014 Plan. All shares cancelled or forfeited during the years ended December 31, 2019 and 2018 became available for grant under the 2015 Plan.

2015 Plans

The Company's Board of Directors adopted a 2015 Inducement Plan in accordance with Nasdaq Rule 5635(c)(4), reserving 360,000 shares of common stock solely for the grant of inducement stock options to new employees, and granting 353,500 stock options under the plan to executives and employees of the Company under the 2015 Inducement Plan with time vesting provisions ranging from one to four years.

The Company has not made any additional grants under the 2015 Inducement Plan since December 31, 2015. Although the Company does not currently anticipate the issuance of additional stock options under the 2015 Inducement Plan, 306,500 shares remain available for grant under that plan, as well as any shares underlying outstanding stock options that may become available for grant pursuant to the plan's terms. It is therefore possible that the Company may, based on the business and recruiting needs of the Company, issue additional stock options under the 2015 Inducement Plan.

The Company's Board of Directors also adopted the 2015 Plan, which was approved by Company stockholders at the Annual Meeting held on June 9, 2015, reserving 1,200,000 shares of common stock for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards and other stock awards to directors, officers, employees and consultants. The 2015 Plan is intended to be the successor to and continuation of the 2006 Plan and the 2014 Plan, or collectively, the Prior Plans. When the 2015 Plan became effective, no additional stock awards were granted under the Prior Plans, although all outstanding stock awards granted under the Prior Plans will continue to be subject to the terms and conditions as set forth in the agreements evidencing such stock awards and the terms of the Prior Plans.

The number of shares available for issuance under the 2015 Plan was initially 1,200,000 shares, plus the number of shares that again become available for grant as a result of forfeited or terminated awards or shares withheld in satisfaction of the exercise price of withholding obligations associated with awards under the Prior Plans, not to exceed 2,000,000 shares. 1,991,387, 1,612,969 and 1,397,050 shares of common stock were automatically added to the shares authorized for issuance under the 2015 Plan on January 1, 2020, January 1, 2019 and January 1, 2018, respectively, pursuant to a "Share Reserve" provision contained in the 2015 Plan. The Share Reserve will automatically increase on January 1st of each year, for the period commencing on (and including) January 1, 2016 and ending on (and including) January 1, 2025, in an amount equal to 5% of the total number of shares of common stock outstanding on December 31st of the preceding calendar year. Notwithstanding the foregoing, the Board of Directors of the Company may act prior to January 1st of a given year to provide that there will be no January 1st increase in the Share Reserve for such year or that the increase in the Share Reserve for such year will be a lesser number of shares of common stock than would otherwise occur.

During the year ended December 31, 2017, the Company's Board of Directors granted restricted stock unit awards to executives and employees of the Company. Certain of the grants included PRSU awards to certain executives and employees of the Company. The PRSU awards issued in February 2017 have vested as follows: 20% of the PRSUs vested upon achievement of data lock for Study 16301 (oral only ABSSSI), which occurred in July 2017; 30% of the PRSUs vested upon achievement of IV and oral NDA filing acceptances, which occurred in April 2018; and 50% of the PRSUs vested upon FDA approval of omadacycline, which occurred in October 2018. 400,500 shares vested during the year ended December 31, 2018 related to the February 2017 PRSU award resulting in compensation cost of $4.2 million.

The PRSU awards issued in August 2017 and January 2018 were earned upon FDA approval of omadacycline, or the Milestone, and shall, upon achievement of the Milestone, which occurred in October 2018, be eligible to vest as to 100% of the PRSUs subject to the award on the first anniversary of the Milestone achievement date. No shares vested under the August 2017 or January 2018 PRSU awards during the year ended December 31, 2018. Since the Milestone was achieved, the Company recognized compensation cost of $1.0 million and $4.0 million for the performance condition during the years ended December 31, 2019 and 2018, respectively using the accelerated attribution method. 250,500 shares vested during the year ended December 31, 2019 on the first anniversary of the Milestone achievement date.

During the year ended December 31, 2018, the Company's Board of Directors granted PRSU awards to certain executives and employees of the Company and have vested or will vest as follows: (a)10/55 shall be earned and time vest on achievement of EMA filing preliminary validation, which occurred in October 2018, (b) 20/55 shall be earned and time vest on achievement of EMA approval, and (c) 25/55 shall be earned on achievement of the launch of omadacycline in the U.S. and time vest on the date that is 15 months following such launch date. 86,750 shares vested during the year ended December 31, 2018 related to milestone (a) above, resulting in compensation cost of $1.2 million. Since the Company believes it is probable that milestone (c) above will be achieved, the Company recognized compensation cost, for a total of $0.8 million and $1.2 million for the performance condition during the years ended December 31, 2019 and 2018, respectively, using the accelerated attribution method. During the year ended December 31, 2019, the Company's Board of Directors modified the vesting terms related to the PRSUs in (b) above which were expected to time vest on achievement of EMA approval. The Company determined the awards were probable of vesting under the modified conditions. The modification resulted in 136,000 shares vesting during the year ended December 31, 2019 and total compensation cost of $0.5 million.

During the year ended December 31, 2019, the Company's Board of Directors granted 2,211,740 restricted stock unit, or RSU, awards and 56,210 stock options to directors, officers, employees and consultants of the Company under the 2015 Plan. The stock option awards are generally subject to time-based vesting over a period of one to four years. The RSU awards made to officers of the Company are subject to time-based vesting, with 1/4 of the award vesting on December 10, 2019, or the Initial Vesting Date, and an additional 3/8 vesting on each anniversary of the Initial Vesting Date. The grants also included PRSU awards to certain executives and employees of the Company and will vest as follows: (a) 25/60 and (b) 25/60, each, on certain next product revenue achievements and (c) the remaining 10/60 on certain other business achievements. Since the Company believes it is probable that milestone (a) and (b) above will be achieved, the Company recognized compensation cost, for a total of $1.3 million for the performance conditions during the year ended December 31, 2019 using the accelerated attribution method.

546,923 RSUs and 442,770 stock options granted under the 2015 Plan were cancelled, forfeited or expired during the year ended December 31, 2019.

2017 Inducement Plan

In June 2017, the Company's Board of Directors adopted the 2017 Inducement Plan in accordance with Nasdaq Rule 5635(c)(4), reserving 550,000 shares of common stock solely for the grant of inducement stock options to employees entering into employment or returning to employment after a bona fide period of non-employment with the Company. In October 2018, the Company's Board of Directors adopted an amendment in accordance with Nasdaq Listing Rule 5635(c)(4) to increase the aggregate number of shares of common stock that may be issued pursuant to awards under the 2017 Inducement Plan from 550,000 shares to 1,050,000 shares.

During the year ended December 31, 2019, the Company's Board of Directors granted 140,350 stock options and 63,600 RSUs to employees of the Company under the 2017 Inducement Plan. The stock option awards are generally subject to time-based vesting over a period of one to four years. The RSU awards are generally time-based with 100% of the shares of common stock subject to the RSUs vesting three years from the grant date. 30,700 RSUs and 37,315 stock options granted under the 2017 Inducement Plan were forfeited during the year ended December 31, 2019.

Total shares available for future issuance under the 2015 Plan, 2015 Inducement Plan and 2017 Inducement Plan are 533,556, 306,500 and 403,015 shares, respectively, as of December 31, 2019.

A summary of stock option activity and related information through December 31, 2019 follows:

	Number of Shares	Weighted Average Exercise Price	Weighted–Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding				
Balances at December 31, 2018	3,777,162	$ 16.65	7.10	$ 506
Granted	196,560	4.60		
Cancelled or forfeited	(737,649)	18.29		
Balances at December 31, 2019	3,236,073	$ 15.54	6.30	$ 90
Exercisable				
December 31, 2019	2,798,600	$ 16.10	5.93	$ —

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair market value of the common stock for the options that were in the money at December 31, 2019 and 2018.

During the years ended December 31, 2019 and 2018, the Company granted stock options to purchase an aggregate of 196,560 shares and 316,275 shares of its common stock, under the equity plans described above, respectively, with weighted-average grant date fair values of options granted of $2.69 and $7.63 and respectively.

No stock options were exercised during the year ended December 31, 2019. The total intrinsic value of stock options exercised was $0.4 million for the year ended December 31, 2018.

Restricted Stock Units

The following is a summary of restricted stock unit activity for the year ended December 31, 2019:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Unvested balance at December 31, 2018	1,470,237	$ 15.28
Granted	2,275,340	6.01
Released	(862,546)	14.04
Forfeited	(577,623)	11.01
Unvested balance at December 31, 2019	2,305,408	$ 7.66

During the year ended December 31, 2019 the Company granted 2,275,340 restricted stock units with a weighted-average grant date fair value per share of $6.01. During the year ended December 31, 2018 the Company granted 1,273,958 restricted stock units with a weighted-average grant date fair value per share of $13.97. The aggregate fair value of restricted shares that vested during the years ended December 31, 2019 and 2018 was $12.1 million and $16.7 million, respectively.

Stock-Based Compensation Expense

For stock options issued to employees and members of the Board of Directors, the Company estimates the grant date fair value of each option using the Black-Scholes option-pricing model. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock.

The relevant data used to determine the value of the stock option grants is as follows:

	Year Ended December 31,	
	2019	2018
Volatility	63.4%	67.3%
Weighted average risk-free interest rate	2.0%	2.7%
Expected dividend yield	0.0%	0.0%
Expected life of options (in years)	5.9	5.9

The following table presents stock-based compensation expense included in the Company's consolidated statements of operations (in thousands):

	Year Ended December 31,	
	2019	2018
Research and development expense	$ 3,568	$ 8,727
Selling, general and administrative expense	10,727	16,758
Total stock-based compensation expense	$ 14,295	$ 25,485

Total unrecognized stock-based compensation expense for all stock-based awards was $13.5 million at December 31, 2019. This amount will be recognized over a weighted-average period of 1.57 years.

2009 Employee Stock Purchase Plan

On June 3, 2009, at the annual meeting of stockholders, the stockholders of the Company approved the 2009 Employee Stock Purchase Plan, or the 2009 ESPP. The Company's 2009 ESPP is designed to allow eligible employees of the Company to purchase shares of common stock through periodic payroll deductions and during specified offering periods under the plan. The price of common stock purchased under the 2009 ESPP is equal to 85% of the lower of the fair market value of the common stock on the commencement date of each offering period or the specified purchase date. As of December 31, 2019 and 2018, 36,539 shares were available for issuance under the 2009 ESPP. Since the Merger, the Company has not made the 2009 ESPP available to employees.

2018 Employee Stock Purchase Plan

The Company's Board of Directors adopted, and in June 2018 Company's stockholders approved, the Paratek Pharmaceuticals, Inc. 2018 Employee Stock Purchase Plan, or the 2018 ESPP. The 2018 ESPP was amended in October 2018 to change the commencement dates of the offering periods. The maximum aggregate number of shares of our common stock that may be purchased under the 2018 ESPP will be 943,294 shares, or the ESPP Share Pool, subject to adjustment as provided for in the 2018 ESPP. The ESPP Share Pool represented 3% of the total number of shares of our common stock outstanding as of March 31, 2018. The 2018 ESPP allows eligible employees to purchase shares during certain offering periods, which will be six-month periods commencing June 1 and ending November 30 and commencing December 1 and ending May 31 of each year. The first offering under the 2018 ESPP was December 1, 2018. As of December 31, 2019, 761,648 shares remained available for issuance under the 2018 ESPP. During the year ended December 31, 2019, the Company issued 181,646 shares of common stock with proceeds of $0.5 million.

Reserved Shares

At December 31, 2019, the Company has reserved shares of common stock for future issuance as follows:

	Number of Shares
Equity plans:	
Shares subject to outstanding options and unvested restricted stock units	5,541,481
Shares available for future grants	1,243,071
Shares subject to warrants to purchase common stock	104,455
Shares issuable under employee stock purchase plan	798,187
Common stock issuable under outstanding convertible notes	10,377,361
Total	18,064,555

Revenue Performance Incentive Plan

On October 4, 2018, the Company adopted the Revenue Performance Incentive Plan, or the Plan, to grant performance-based cash incentive awards to key employees and consultants of the Company. The Plan provides for an incentive pool of up to $50.0 million, plus accrued interest during the period between the awards' vesting date and payment dates. Each participant will be allocated a percentage of the incentive pool.

The incentive pool will be divided into two equal tranches with the first tranche vesting upon the Company's achievement of cumulative net product revenues over $300.0 million by December 31, 2025, or Tranche 1, and the second tranche vesting upon the Company's achievement of cumulative product revenues over $600.0 million by December 31, 2026, or Tranche 2. Participants will vest annually in each tranche of their awards in four equal installments on December 31, 2019, December 31, 2020, December 31, 2021, and December 31, 2022, subject to their continued employment with the Company through the applicable vesting date. If a participant's employment terminates prior to December 31, 2022 due to death or disability, the participant will automatically vest in an additional 25% of each tranche of his or her award. Upon the achievement of a Tranche 1 or Tranche 2 milestone (but not a deemed achievement in connection with a change of control), each participant who has remained in continuous employment with the Company through December 31, 2022 will be 100% vested in the applicable tranche. In the event of a change of control of the Company prior to December 31, 2026, participants whose employment has terminated prior to such date will be eligible for payouts under the Plan based on the then-vested portion of their awards, and participants who have remained employed through the change of control will be deemed to have time vested in full in each tranche of their awards.

Upon the achievement of a Tranche 1 or Tranche 2 milestone (but not a deemed achievement in connection with a change of control), each participant's payout in respect of the applicable tranche of his or her award will equal (a) the participant's then-vested percentage, multiplied by (b) $25 million, multiplied by (c) the participant's individual percentage allocation of the incentive pool.

If a change of control occurs prior to December 31, 2026, and the Tranche 1 milestone was not achieved prior to the change of control, the Tranche 1 milestone will be deemed to be achieved at a percentage equal to the greater of (1) 50% and (2) the cumulative product revenues as of the change of control, divided by $300.0 million. If a change of control occurs prior to December 31, 2026, and the Tranche 2 milestone was not achieved prior to the change of control, the Tranche 2 milestone will be deemed to be achieved at a percentage equal to the greater of (1) 30% and (2) the cumulative product revenues as of the change of control, divided by $600.0 million. A participant's payout in respect of each tranche of his or her award in a change of control will equal (1) the participant's then-vested percentage of such tranche, multiplied by (2) the percentage of that tranche's milestone that has been achieved or is deemed to have been achieved, multiplied by (3) $25.0 million, multiplied by (4) the participant's individual percentage allocation of the incentive pool.

Amounts that become payable upon achievement of the Tranche 1 milestone will be paid in a lump-sum in the first quarter of 2026 and amounts that become payable upon achievement of the Tranche 2 milestone will be paid in a lump-sum in the first quarter of 2027. In the event of a change of control, any portion of the incentive pool that is earned, but unpaid, or deemed earned in connection with the change of control will be paid at the time of the change of control.

If a change of control occurs prior to the achievement of either or both of the Tranche 1 and Tranche 2 milestones, the awards will remain outstanding and the remaining unpaid portion of the incentive pool applicable to the Tranche 1 or Tranche 2 milestone, as applicable, will be paid following the achievement of either such milestone at the time or times the bonuses would otherwise be paid out. Any successor in interest to the Company upon or following a change of control will be required to assume all obligations under the Plan.

Awards may be paid out in cash or in a combination of cash and registered securities of equal value (based on the Company's 20-day trailing average closing common stock price), with the portion paid in registered securities not to exceed 50% of the aggregate payment amount with respect to each tranche; provided, however, that any amounts payable with respect to an award in connection with a change in control will be paid in cash.

The Company will recognize the compensation cost over the requisite service period, to the extent achievement of the performance condition is deemed probable relative to targeted performance. The performance condition is not yet deemed probable; as such, no amounts were accrued under the Plan during the year ended December 31, 2019.

16. Long-Term Debt

Hercules Loan Agreement

On June 27, 2019, the Company entered into an Amended and Restated Loan and Security Agreement, or the Amended Hercules Loan Agreement, with Hercules Technology III, L.P., certain other lenders, together, the Lenders, and Hercules Capital, Inc. (as agent), under which the Company may borrow up to $100.0 million in multiple tranches, each, a Term Loan Tranche. The Amended Hercules Loan Agreement amends and restates in its entirety the prior Hercules Loan and Security Agreement with the Lenders dated as of September 30, 2015 to, among other things, provide for an extension of the scheduled maturity date of the $60.0 million Term Loan Tranche, or the First Tranche, from September 1, 2021 to September 1, 2023, upon certain events set forth in the Amended Hercules Loan Agreement, and an extension of the scheduled maturity date of the $10.0 million Term Loan Tranche, or the Second Tranche, and additional Term Loan Tranches (if any), from August 1, 2022 to August 1, 2024, upon certain events set forth in the Amended Hercules Loan Agreement. The Amended Hercules Loan Agreement also provides for an additional $10.0 million of additional Term Loan Tranches (up to a total of $30.0 million of additional Term Loan Tranches) that may be available to the Company, subject to approval by Hercules, in its sole discretion, whether to provide such tranches. As such there can be no assurance as to whether or not the additional Term Loan Tranches shall be funded.

The interest rate with respect to the First Tranche is a floating per annum rate equal to the greater of (i) 8.50% plus the prime rate as reported from time to time in The Wall Street Journal minus 5.75%, and (ii) 8.50%. The interest rate with respect to the Second Tranche is, and the interest rate with respect to additional Term Loan Tranches (if any) will be, a floating per annum rate equal to the greater of (i) 7.85% plus the prime rate as reported from time to time in The Wall Street Journal minus 5.75%, and (ii) 7.85%. An end of term charge equal to 4.5% with respect to $50.0 million of the First Tranche and equal to 2.25% with respect to the remaining $10.0 million of the First Tranche of the issued principal balance of the term loans is payable in September of 2020, and an end of term charge equal to 6.95% of the Second Tranche, and the Additional Term Loan Tranches (if any), of the issued principal balance of the term loans is payable at maturity, including in the event of any prepayment, and is being accrued as interest expense over the term of the term loans using the effective interest method. Payments under the Amended Hercules Loan Agreement with respect to the First Tranche are interest only until January 1, 2021, followed by equal monthly payments of principal and interest through the scheduled maturity date. Payments under the Amended Hercules Loan Agreement with respect to the Second Tranche are, and with respect to additional Term Loan Tranches (if any) will be, interest only until January 1, 2021 (which can be extended to May 1, 2021 or September 1, 2021, upon certain events set forth in the Amended Hercules Loan Agreement), followed by equal monthly payments of principal and interest through the scheduled maturity date. The Company's obligations under the Amended Hercules Loan Agreement are secured by a security interest in substantially all of its and Paratek Pharma, LLC's assets, other than intellectual property.

If the Company prepays the loan prior to maturity, it will pay the Lenders a prepayment charge, based on a percentage of the then outstanding principal balance, equal to 1.75% if the prepayment occured prior to January 1, 2020, or equal to 0% if the prepayment occurs on or after January 1, 2020. The Company did not prepay the loan prior to January 1, 2020.

The Amended Hercules Loan Agreement includes customary affirmative and restrictive covenants, including a liquidity covenant and a covenant against suffering a “change of control,” and also includes customary events of default, including payment defaults, breaches of covenants following any applicable cure period, a material impairment in the perfection or priority of Lenders’ security interest or in the value of the collateral, cross acceleration to the debt and certain events relating to bankruptcy or insolvency. Upon the occurrence of an event of default, a default interest rate of an additional 5% may be applied to the outstanding loan balances, and the Lenders may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Amended Hercules Loan Agreement.

Borrowings under the Amended Hercules Loan Agreement are collateralized by substantially all of the assets of the Company.

Upon an Event of Default, an additional 5.0% interest would be applied, and Hercules could, at its option, accelerate and demand payment of all or any part of the term loans together with the prepayment and end of term charges. An Event of Default is defined in the Amended Hercules Loan Agreement as (i) failure to make required payments; (ii) failure to adhere to financial, operating and reporting loan covenants; (iii) an event or development occurs that would be reasonably expected to have a material adverse effect; (iv) false representations in the Amended Hercules Loan Agreement; (v) insolvency, as described in the Amended Hercules Loan Agreement; (vi) levy or attachments on any of the Company's assets; and (vii) default of any other agreement or subordinated debt greater than $1.0 million. In the event of insolvency, this acceleration and declaration would be automatic. In addition, in connection with the Amended Hercules Loan Agreement, the Company agreed to provide Hercules with a contingent security interest in the Company's bank accounts. The Company's control of its bank accounts is not adversely affected unless Hercules elects to obtain unilateral control of the Company's bank accounts by declaring that an Event of Default has occurred. The principal of the term loans, which is not due within 12 months of December 31, 2019, has been classified as long-term debt.

The modified terms under the Amended Hercules Loan Agreement were not considered substantially different as compared to the terms of the Amended Hercules Loan Agreement immediately prior to the Amended Hercules Loan Agreement, pursuant to ASC 470-50, *Modification and Extinguishment*. As such, the Amended Hercules Loan Agreement was accounted for as a debt modification.

The Company recognized interest expense of $6.8 and $7.4 million for the years ended December 31, 2019 and 2018, respectively.

The following table summarizes the impact of the Amended Hercules Loan Agreement, as amended, on the Company’s consolidated balance sheets at December 31, 2019 and 2018 (in thousands):

	Year Ended December 31,	
	2019	2018
Gross proceeds	$ 70,000	$ 70,000
Unamortized debt discount costs	(361)	(606)
Carrying Value	$ 69,639	$ 69,394

Debt issuance costs are presented on the consolidated balance sheet as a direct deduction from the related debt liability rather than capitalized as an asset in accordance with ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*.

Future principal payments, which exclude the end of term charges, in connection with the Amended Hercules Loan Agreement, as amended, as of December 31, 2019 are as follows (in thousands):

2019	$ —
2020	—
2021	65,835
2022	4,165
2023 and thereafter	—
Total	$ 70,000

Convertible Senior Subordinated Notes

On April 18, 2018, the Company entered into a Purchase Agreement, or the Purchase Agreement, with several initial purchasers, or the Initial Purchasers, for whom Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Partners LLC acted as representatives, relating to the sale of $135.0 million aggregate principal amount of 4.75% Convertible Senior Subordinated Notes due 2024, or the Notes, to the Initial Purchasers. The Company also granted the Initial Purchasers an option to purchase up to an additional $25.0 million aggregate principal amount of Notes, which was exercised in full on April 20, 2018.

The Purchase Agreement includes customary representations, warranties and covenants. Under the terms of the Purchase Agreement, the Company agreed to indemnify the Initial Purchasers against certain liabilities.

In addition, J. Wood Capital Advisors LLC, the Company's financial advisor, purchased $5.0 million aggregate principal amount of Notes in a separate, concurrent private placement on the same terms as other investors.

The Notes were issued by the Company on April 23, 2018, pursuant to an Indenture, dated as of such date, or the Indenture, between the Company and U.S. Bank National Association, as trustee, or the Trustee. The Notes bear cash interest at the annual rate of 4.75%, payable on November 1 and May 1 of each year, beginning on November 1, 2018, and mature on May 1, 2024 unless earlier repurchased, redeemed or converted. The Company will settle conversions of the Notes through delivery of shares of common stock of the Company, in accordance with the terms of the Indenture. The initial conversion rate for the Notes is 62.8931 shares of common stock (subject to adjustment as provided for in the Indenture) per $1,000 principal amount of the Notes, which is equal to an initial conversion price of approximately $15.90 per share, representing a conversion premium of approximately 20% above the closing price of the common stock of $13.25 per share on April 18, 2018.

Holders of the Notes may convert all or any portion of their Notes, in multiples of $1,000 principal amount, at their option at any time prior to the close of business on the second scheduled trading day immediately preceding the stated maturity date.

The Company may not redeem the Notes prior to May 6, 2021. The Company may redeem for cash all or part of the Notes, at its option, on or after May 6, 2021 if the last reported sale price of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

If the Company experiences a fundamental change, as described in the Indenture, prior to the maturity date of the Notes, holders of the Notes will, subject to specified conditions, have the right, at their option, to require the Company to repurchase for cash all or a portion of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any, to, but not including, the fundamental change repurchase date. In addition, following certain corporate events that occur prior to the maturity date of the Notes and following a notice of redemption of the notes, the Company will increase the conversion rate for a holder who elects to convert its Notes in connection with such corporate event or redemption.

The Indenture provides for customary events of default. In the case of an event of default with respect to the Notes arising from specified events of bankruptcy or insolvency, all outstanding Notes will become due and payable immediately without further action or notice. If any other event of default with respect to the Notes under the Indenture occurs or is continuing, the Trustee or holders of at least 25% in aggregate principal amount of the then outstanding Notes may declare the principal amount of the Notes to be immediately due and payable.

In certain circumstances if, at any time during the six-month period beginning on, and including, the date that is six months after the last date of original issuance of the Notes, the Company fails to timely file certain documents or reports required under the Securities Exchange Act of 1934, as amended, or the Notes are not otherwise freely tradable by holders of the Notes other than the Company's affiliates or holders that were the Company's affiliates at any time during the three months immediately preceding, additional interest will accrue on the Notes during the first 90-day period in which its failure to file has occurred and is continuing or such Notes are not otherwise freely tradable by holders other than the Company's affiliates (or holders that were the Company's affiliates at any time during the three months immediately preceding).

After deducting costs incurred of $6.0 million, the Company raised net proceeds from the issuance of long-term convertible debt of $159.0 million in April 2018. All costs were deferred and are being amortized over the life of the Notes at an effective interest rate of 5.47% and recorded as additional interest expense.

The Company has evaluated the Indenture for derivatives pursuant to ASC 815, *Derivatives and Hedging*, or ASC 815, and identified an embedded derivative that requires bifurcation as the feature is not clearly and closely related to the host instrument. The embedded derivative is a default provision, which could require additional interest payments. The Company has determined that the fair value of this embedded derivative was nominal during the year ended December 31, 2019.

The Company evaluated the conversion feature and determined it was not within the scope of ASC 815 and therefore is not required to be accounted for separately. The Company concluded that the embedded conversion option is not subject to separate accounting pursuant to either the cash conversion guidance or the beneficial conversion feature guidance. Under the general conversion guidance in ASC 470, *Debt*, all of the proceeds received from the Notes was recorded as a liability on the consolidated balance sheet.

The following table summarizes how the issuance of the Notes is reflected in the Company's consolidated balance sheets at December 31, 2019 and 2018 (in thousands):

	Year Ended December 31,	
	2019	2018
Gross proceeds	$ 165,000	$ 165,000
Unamortized debt discount costs	(4,531)	(5,434)
Carrying Value	$ 160,469	$ 159,566

The Company recognized coupon interest expense of $7.8 million and amortization expense on the debt issuance costs of $0.9 million for the year ended December 31, 2019. The Company recognized coupon interest expense of $5.4 million and amortization expense on the debt issuance costs of $0.6 million for the year ended December 31, 2018.

Royalty-Backed Loan Agreement

On February 25, 2019, the Company, through its wholly-owned subsidiary Paratek Royalty Corporation, or the Subsidiary, entered into a royalty-backed loan agreement, or the Royalty-Backed Loan Agreement, with Healthcare Royalty Partners III, L.P., or the Lender. Pursuant to the terms of the Royalty-Backed Loan Agreement, the Subsidiary borrowed a $32.5 million loan, which was secured by, and is being repaid based upon, royalties from the Almirall Collaboration Agreement. On May 1, 2019, the Company received $27.8 million, net of $0.5 million lender discount, $0.2 million in lender expenses incurred, and $4.0 million that was deposited into an interest reserve account. The Company also paid $1.2 million in other lender fees related to the Royalty-Backed Loan Agreement.

Under the Royalty-Backed Loan Agreement, the outstanding principal balance will bear interest at an annual rate of 12.0%. Payments of interest under the Royalty-Backed Loan Agreement will be made quarterly, beginning in August 2019, using the Almirall Collaboration Agreement royalty payments received since the immediately preceding payment date. On each interest payment date, any royalty payments in excess of accrued interest on the loan will be used to repay the principal of the loan until the balance is fully repaid. In addition, the Subsidiary will make up-front payments to the Lender of (i) a 1.5% fee and (ii) up to $300,000 for the Lender's expenses. The Royalty-Backed Loan Agreement matures on May 1, 2029, at which time, if not earlier repaid in full, the outstanding principal amount of the loan, together with any accrued and unpaid interest, and all other obligations then outstanding, shall be due and payable in cash. The Company has entered into a Pledge and Security Agreement in favor of the Lender, pursuant to which the Subsidiary's obligations under the Loan Agreement are secured by a pledge of all of the Company's holdings of the Subsidiary's capital stock.

The Royalty-Backed Loan Agreement contains certain customary affirmative covenants, including those relating to: use of proceeds; maintenance of books and records; financial reporting and notification; compliance with laws; and protection of Company intellectual property. The Royalty-Backed Loan Agreement also contains certain customary negative covenants, barring the Subsidiary from: certain fundamental transactions; issuing dividends and distributions; incurring additional indebtedness outside of the ordinary course of business; engaging in any business activity other than related to the Almirall Collaboration Agreement; and permitting any additional liens on the collateral provided to Lender under the Royalty-Backed Loan Agreement.

The Royalty-Backed Loan Agreement contains customary defined events of default, upon which any outstanding principal and unpaid interest shall be immediately due and payable. These include: failure to pay any principal or interest when due; any uncured breach of a representation, warranty or covenant; any uncured failure to perform or observe covenants; any uncured cross default under a material contract; any uncured breach of the Company's representations, warranties or covenants under its Contribution and Servicing Agreement with the Subsidiary; any termination of the Almirall Collaboration Agreement; and certain bankruptcy or insolvency events.

The Company recognized interest expense of $2.7 million for the year ended December 31, 2019.

The following table summarizes the impact of the Royalty-Backed Loan Agreement on the Company's consolidated balance sheets for the years ended December 31, 2019 and December 31, 2018 (in thousands):

	Year Ended December 31,	
	2019	2018
Gross proceeds	$ 32,500	$ —
Unamortized debt discount costs	(1,880)	—
Carrying Value	$ 30,620	$ —

Long-term debt on the Company's consolidated balance sheets at December 31, 2019 includes the carrying value of the Amended Hercules Loan Agreement, the Notes and the Royalty-Backed Loan Agreement. Long-term debt on the Company's consolidated balance sheet at December 31, 2018 includes the carrying value of the Amended Hercules Loan Agreement and the Notes.

17. Income Taxes

Loss before income taxes consists of the following:

	Year Ended December 31,	
(in thousands)	2019	2018
United States	$ (120,302)	$ (106,654)
Foreign	(8,187)	(5,200)
Total	$ (128,489)	$ (111,854)

The components of income tax expense consist of the following:

	Year Ended December 31,	
(in thousands)	2019	2018
Foreign	301	502
Total	$ 301	$ 502

There is no provision for income taxes in the U.S. because the Company has historically incurred net operating losses and maintains a full valuation allowance against its net deferred tax assets. The provision for income taxes in foreign jurisdictions relate to withholding taxes incurred in connection with the Zai Collaboration Agreement. The reported amount of income tax expense for the years differs from the amount that would result from applying domestic federal statutory tax rates to pretax losses primarily because of changes in valuation allowance.

A reconciliation of the Company's effective tax rate to the statutory federal income tax rate is as follows:

	Year Ended December 31,	
	2019	2018
Federal statutory rate	21.00%	21.00%
Change in valuation allowance	(20.43)	(22.16)
Non-deductible interest	(1.43)	(1.12)
Stock compensation	(3.00)	(0.69)
Permanent differences	(0.03)	(0.71)
State taxes, net of federal benefits	4.07	4.16
Withholding tax	(0.23)	(0.45)
Foreign rate differential	(1.34)	(0.98)
Federal R&D credits	1.06	1.13
Other	0.10	(0.63)
	(0.23)%	(0.45)%

Significant components of the Company's net deferred tax assets at December 31, 2019 and 2018 are as follows:

(in thousands)	Year Ended December 31, 2019	2018
Non-current deferred tax assets		
Net operating losses	$ 125,341	$ 95,273
Accrued expenses	2,869	245
Capitalized research and development	17,195	21,296
Tax credit carryforwards	13,413	12,757
Other	100	95
Stock compensation and other	8,943	11,334
Total non-current deferred tax assets	167,861	141,000
Non-current deferred tax liabilities		
Right-of-use asset	(668)	—
Total non-current deferred tax liabilities	(668)	—
Net non-current deferred tax asset	167,193	141,000
Less: valuation allowance	(167,193)	$ (141,000)
Net deferred tax asset	$ —	$ —

As of December 31, 2019, the Company had federal and state net operating loss carryforwards of $482.2 million and $362.5 million, respectively, which begin to expire in 2024 and 2034, respectively. The Company's federal net operating losses include $202.3 million, which can be carried forward indefinitely.

As of December 31, 2019, the Company had federal and state research and development tax credits carryforwards of $11.7 million and $2.1 million, respectively, which begin to expire in 2020.

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are composed principally of net operating loss carryforwards and research and development credits. Under the applicable accounting standards, management has considered the Company's history of losses and concluded that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets. Accordingly, a full valuation allowance of $167.2 million and $141.0 million, respectively, was established as of December 31, 2019 and 2018. A change in the Company's valuation allowance was recorded in 2019, in the amount of $26.2 million due primarily to the generation of net operating losses.

Utilization of the net operating loss and research and development credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively.

The Company conducted an analysis under Section 382 and 383 of the Internal Revenue Code of 1986, as amended, to determine if historical changes in ownership through December 31, 2017 would limit or otherwise restrict its ability to utilize its net operating loss and research and development credit carryforwards. As a result of that study, the Company has identified certain net operating losses that might expire unused. The Company has established a full valuation allowance against these attributes.

The Company follows the provisions of ASC 740-10, *Accounting for Uncertainty in Income Taxes—an interpretation of ASC 740*, which requires it to determine whether a tax position of the Company is more likely than not to be sustained upon examination, including resolution of any related appeals of litigation processes, based on the technical merits of the position. For tax positions meeting the more likely than not threshold, the tax amount recognized in the financial statements is reduced by the largest benefit that has a greater than fifty percent likelihood of being realized upon the ultimate settlement with the relevant taxing authority.

The Company completed a study of its research and development credits. As a result of this study the Company adjusted its deferred tax asset related to research and development credit carryforwards. The Company has not identified or recorded any uncertain tax positions related to this study. A full valuation allowance has been provided against the Company's research and development credits, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheets or statements of operations if an adjustment were required.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The earliest tax years that remain subject to examination by jurisdiction is 2016 for both federal and Massachusetts. However, to the extent the Company utilizes net operating losses from years prior to 2016, the statute remains open to the extent of the net operating losses or other credits are utilized. The Company's policy is to record interest and penalties related to income taxes as part of the tax provision. There was no interest or penalties pertaining to uncertain tax positions in 2019 or 2018.

18. Commitments and Contingencies

Leases

The Company leases its Boston, Massachusetts and King of Prussia, Pennsylvania office spaces under non-cancelable operating leases expiring in 2021 and 2024, respectively.

The Company entered into the original King of Prussia and Boston leases in January 2015 and April 2015, respectively. The lease terms under the original agreements were for six and four years, respectively. Each agreement had one renewal option for an extended term. The King of Prussia and Boston lease terms under the original agreements began in June 2015 and July 2015, respectively.

The Company executed an amended lease agreement on its Boston office space in July 2016. The amended lease agreement added 4,153 rentable square feet of office space and extended the original lease term by two years. In accordance with the amended lease agreement, the Company paid a security deposit of $0.1 million. Subsequent to the amended lease agreement, the Company records monthly lease expense of approximately $49,000 for the Boston office space. In applying the ASC 842 transition guidance, the Company retained the classification of this lease to be operating and recorded a lease liability and a right-of-use asset on the ASC 842 effective date.

The Company executed an amended lease agreement on its King of Prussia office space in October 2016. The amended lease agreement is for 19,708 rentable square feet of office space and the Company took control of this office space during the first quarter of 2017. The total lease commitment is over a seven-year and seven-month lease term. The amended lease agreement contains rent escalation and a partial rent abatement period, which is accounted for as rent expense under the straight-line method. In applying the ASC 842 transition guidance, the Company retained the classification of this lease to be operating and recorded a lease liability and a right-of-use asset on the ASC 842 effective date.

The reporting results for fiscal year 2019 reflect the application of ASC 842 guidance while the historical results for fiscal year 2018 were prepared under the guidance of ASC 840.

The following table contains a summary of the lease costs recognized under Topic 842 and other information pertaining to the Company's operating leases for year ended December 31, 2019:

Lease cost (in thousands)		
Operating lease cost	$	1,021
Variable lease cost		124
Total lease cost	$	1,145
Cash paid for amounts included in the measurement of lease liabilities:	$	1,060
Other information		
Weighted average remaining lease term (in years)		3.6
Weighted average discount rate		8.75%

Future minimum operating lease obligations under non-cancelable operating leases with initial terms of more than one-year as of December 31, 2019, are as follows:

Maturity of lease liabilities (in thousands)		**As of December 31, 2019**
2020	$	1,178
2021		964
2022		508
2023		518
2024 and thereafter		396
Total lease payments	$	3,564
Less: imputed interest		(512)
Total operating lease liabilities	$	3,052

The total operating liability is presented on the Company's consolidated balance sheet based on maturity dates. $1.0 million of the total operating liabilities is classified under "other current liabilities" for the portion due within twelve months, and $2.1 million is classified under "long-term lease liability".

The Company is party to a manufacturing and services agreement for which space within the manufacturing facility will be leased. This lease has not yet commenced as of the reporting date and is not included in the maturity table above.

Deferred rent of $0.5 million is included in other liabilities in the consolidated balance sheet as of December 31, 2018.

Rent expense, exclusive of related taxes, insurance, and maintenance costs, for continuing operations totaled approximately $1.0 million the year ended December 31, 2018 and is reflected in operating expenses.

Commercial Supply Agreements

CIPAN

In November 2016, the Company entered into a manufacturing and services agreement with CIPAN – Companhia Industrial Produtora de Antibióticos, or CIPAN. The agreement, as subsequently amended, provides the terms and conditions under which CIPAN will manufacture and supply to the Company increased quantities of minocycline starting material and crude omadacycline, or the CIPAN Products, for purification into omadacycline and, subsequently, for use in the Company's products that contain omadacycline tosylate as the active pharmaceutical ingredient. Under this agreement, the Company is obligated to pay a CIPAN Product price in the four-digit U.S. dollar range per kilogram for minocycline starting material and in the four-digit or five-digit U.S. dollar range per kilogram for crude omadacycline, based on the annual volume of crude omadacycline that the Company orders, subject to adjustments as set forth in the agreement. CIPAN will also perform certain services related to development, technology transfer and manufacturing of the CIPAN Products as provided in one or more statements of work, which shall set forth the fees payable by the Company to CIPAN for such services.

The Company's agreement with CIPAN will remain in effect for a fixed initial term, after which the agreement will continue, with respect to each CIPAN Product, for successive renewal terms unless either the Company or CIPAN have given written notice of termination within a certain period prior to the expiration of either the initial or then-current renewal term. The agreement may also be terminated under certain other circumstances, including by either party due to a material uncured breach by the other party or the other party's insolvency.

Carbogen

In December 2016, the Company entered into a manufacturing and services agreement with CARBOGEN AMCIS AG, or Carbogen. The agreement, as subsequently amended, provides for the terms and conditions under which Carbogen will manufacture and supply to the Company the active pharmaceutical ingredient for our omadacycline drug products in bulk quantities, or the Carbogen Product. Under this agreement, the Company is responsible for the cost and supply of crude omadacycline that Carbogen requires to manufacture the Carbogen Products and perform related services. The Company is obligated to pay Carbogen an amount in the seven-digit U.S. dollar range per batch of Carbogen Product that the Company orders, depending on the size of the campaign, and the price may be adjusted in accordance with the terms of the agreement. The Company may also request that Carbogen perform certain services related to the Carbogen Product, for which the Company will pay reasonable compensation to Carbogen.

The Company's agreement with Carbogen will remain in effect for a fixed initial term and subsequent renewal terms. Both parties, however, are required to use diligent efforts to replace the existing agreement with a subsequent long-term agreement. The Company may terminate this agreement by delivering notice of termination to Carbogen. The agreement may also be terminated under certain other circumstances, including by either party due to a material uncured breach by the other party or the other party's insolvency.

Almac

In December 2016, the Company entered into a manufacturing and services agreement with Almac Pharma Services Limited, or Almac. The agreement provides for the terms and conditions under which Almac will manufacture, package and supply to the Company omadacycline oral solid dosage tablets in bulk form, or the Almac Products. Under this agreement, the Company is required to use commercially reasonable efforts to timely provide Almac with the active pharmaceutical ingredient needed to manufacture the Almac Products and perform related services. The Company is obligated to pay a supply price in the five-digit range in Great Britain Pounds per batch of the Almac Products, subject to adjustments as provided in the agreement. Beginning in February 2020, the Company is also subject to an annual minimum revenue commitment in the six-digit GBP range. The Company will also negotiate with Almac, as part of each individual scope of work, the reasonable costs for the services to be performed for the Company by Almac.

In July 2019, the Company entered into a separate packaging and supply agreement with Almac to expand the packaging services performed by Almac. This packaging agreement provides for the terms and conditions under which Almac will provide primary packaging, labelling, storage and related services for Almac Products and the secondary packaging, labelling, storage and related services for injectable omadacycline in vials, which are manufactured and supplied by a third party to Almac. Under this agreement, the Company is required to provide certain intermediate materials necessary for Almac to perform these packaging services. The Company is obligated to pay a supply price in the five to six-digit range in U.S. Dollars per batch of packaged products, subject to adjustments as provided in the agreement. The Company will also negotiate with Almac the reasonable costs for any additional services to be performed for the Company by Almac as set forth in individual scopes of work; such services are governed by the packaging agreement.

Each of the Company's agreements with Almac will remain in effect for a fixed initial term, after which each agreement will continue for successive renewal terms unless either the Company or Almac have given written notice of termination within a certain period prior to the expiration of the initial or then-current renewal term. The manufacturing agreement or packaging agreement may also be terminated under certain other circumstances, including by either party due to a material uncured breach of the other party or the other party's insolvency.

Patheon

In July 2017, the Company entered into a master manufacturing services agreement and corresponding product agreement with Patheon UK Limited, or Patheon. The product agreement was amended in January 2019 to reflect exchange rate and pricing updates. The agreements provide for the terms and conditions under which Patheon will manufacture, package and supply to the Company, omadacycline in injectable form, or the Patheon Products. Under these agreements, the Company is required to deliver to Patheon the active pharmaceutical ingredient needed to manufacture the Patheon Products. The Company is obligated to pay a supply price in the six-digit dollar range per batch of the Patheon Products, subject to adjustments as provided in the agreements. Now that the Company's omadacycline product has been approved, the Company is also subject to an annual minimum purchase requirement in the six-digit U.S. dollar range. If the Company desires for Patheon to conduct additional services other than those expressly set forth in the agreements, those would be subject to additional fees.

The Company's agreements with Patheon will remain in effect for a fixed initial term, after which they will continue for successive renewal terms unless either the Company or Patheon have given written notice of termination within a certain period prior to the expiration of the applicable initial or then-current renewal term. The agreements may also be terminated under certain other circumstances, including by either party due to a material uncured breach of the other party or the other party's insolvency.

Litigation

The following pending litigation was assumed through the Merger.

Patent Term Adjustment Suit

In January 2013, the Company filed suit in the Eastern District of Virginia against the U.S. Patent and Trademark Office, or the USPTO, seeking recalculation of the patent term adjustment of the '131 Patent. Purdue Pharma has agreed to bear the costs and expenses associated with this litigation. In June 2013, the judge granted a joint motion to stay the proceedings pending a remand to the USPTO, in which the USPTO is expected to reconsider its patent term adjustment award in light of decisions in a number of appeals to the Federal Circuit, including Novartis AG v. Lee 740 F.3d 593 (Fed. Cir. 2014), or the Novartis decision. Since having issued final rules implementing the Novartis decision, the USPTO has been working through the civil action cases and issuing remand decisions. The Company's case was on remand until the USPTO made its decision on the recalculation of the patent term adjustment. On September 28, 2016, the USPTO issued a decision that the patent term adjustment is 1,038 days, from which the '131 Patent expiration would be March 26, 2029.

Other Legal Proceedings

From time to time the Company is involved in legal proceedings arising in the ordinary course of business. The Company believes there is no other litigation pending that could have, individually, or in the aggregate, a material adverse effect on its results of operations or financial condition. The Company does not believe that any of the above matters will result in a liability that is probable or estimable at December 31, 2019.

19. 401(k) Savings Plan

The Company maintains a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code, or the 401(k) Plan. The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. The Plan provides for matching contributions on a portion of participant contributions pursuant to the 401(k) Savings Plan's matching formula. All matching contributions and participant contributions vest immediately. Contributions totaled $0.9 million and $0.5 million for the years ended December 31, 2019 and 2018, respectively and have been recorded in the consolidated statements of operations.

20. Quarterly Results (Unaudited)

	Three Months Ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
	(in thousands, except per share data) (unaudited)			
Revenue	$ 1,598	$ 2,045	$ 3,934	$ 8,967
Operating expenses	34,914	32,166	32,944	32,149
Loss from operations	(33,316)	(30,121)	(29,010)	(23,182)
Other expense, net	(2,294)	(3,080)	(3,604)	(3,882)
Provision for income tax	—	—	—	301
Net loss	$ (35,610)	$ (33,201)	$ (32,614)	$ (27,365)
Net loss per share - basic and diluted	$ (1.10)	$ (1.02)	$ (1.00)	$ (0.81)

	Three Months Ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
	(in thousands, except per share data) (unaudited)			
Revenue	$ 10	$ 40	$ 50	$ 17,017
Operating expenses	26,722	27,769	29,660	37,051
Loss from operations	(26,712)	(27,729)	(29,610)	(20,034)
Other expense, net	(1,038)	(2,004)	(2,473)	(2,253)
Provision for income tax	—	—	—	502
Net loss	$ (27,750)	$ (29,733)	$ (32,083)	$ (22,789)
Net loss per share - basic and diluted	$ (0.91)	$ (0.94)	$ (1.01)	$ (0.71)

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of December 31, 2019, management, with the participation of our Chief Executive Officer and Principal Financial and Accounting Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Principal Financial and Accounting Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective. Based on this evaluation, our Chief Executive Officer and Principal Financial and Accounting Officer concluded that, as of December 31, 2019, the design and operation of our disclosure controls and procedures were effective.

Internal Control Over Financial Reporting

(a) Management's Annual Report on Internal Control over Financial Reporting

Our management, with the participation of our Chief Executive Officer and Principal Financial and Accounting Officer, is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policy or procedures may deteriorate. Under the supervision and with the participation of our management, including our Chief Executive Officer and Principal Financial and Accounting Officer, management has conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2019 based upon the Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this evaluation, management, including our Chief Executive Officer and Principal Financial and Accounting Officer, has concluded that our internal control over financial reporting was effective as of December 31, 2019.

The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by Ernst & Young LLP, our independent registered public accounting firm, as stated in their report which is included herein.

(b) Report of Independent Registered Public Accounting Firm on Internal Control over Financial Reporting

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of Paratek Pharmaceuticals, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Paratek Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Paratek Pharmaceuticals, Inc. (the Company) maintained in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Paratek Pharmaceuticals, Inc. as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for the years then ended, and the related notes and our report dated March 10, 2020 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ Ernst & Young LLP
Boston, Massachusetts
March 10, 2020

(c) Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the fiscal quarter 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

None.

PART III

The information required by Part III is omitted from this report because we will file a definitive proxy statement within 120 days after the end of our 2019 fiscal year pursuant to Regulation 14A for our 2020 Annual Meeting of Stockholders, or the 2020 Proxy Statement, and the information to be included in the 2020 Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item will be contained in the 2020 Proxy Statement and is hereby incorporated by reference.

Code of Business Conduct and Ethics

Our Board of Directors has adopted a code of business conduct and ethics. The code of business conduct applies to all of our employees, officers and directors. The full texts of our code of business conduct and ethics are posted on our website at http://www.paratekpharma.com under the Investor Relations section. We intend to disclose future amendments to our code of business conduct and ethics, or certain waivers of such provisions, at the same location on our website identified above and also in public filings. The inclusion of our website address in this report does not include or incorporate by reference the information on our website into this report.

Item 11. Executive Compensation

The information required by this item will be contained in the 2020 Proxy Statement and is hereby incorporated by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item will be contained in the 2020 Proxy Statement and is hereby incorporated by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item will be contained in the 2020 Proxy Statement and is hereby incorporated by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item will be contained in the 2020 Proxy Statement and is hereby incorporated by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements

See Index to Financial Statements under Item 8 of Part II of this Annual Report on Form 10-K, which listing is incorporated herein by reference.

(a)(2) Financial Statement Schedules

Financial statement schedules are omitted because they are not applicable or are not required or the information required to be set forth therein is included in the Financial Statements or notes thereto.

(a)(3) Exhibits

EXHIBIT INDEX

Exhibit No.	Exhibit Description	Incorporated by Reference			Filing Date
		Schedule/ Form	File Number	Exhibit	
2.1	Agreement and Plan of Merger and Reorganization by and among Transcept Pharmaceuticals, Inc., Tigris Merger Sub, Inc., Tigris Acquisition Sub, LLC and Paratek Pharmaceuticals, Inc. dated as of June 30, 2014.	Form 8-K	001-36066	2.1	July 1, 2014
3.1	Amended and Restated Certificate of Incorporation.	Form 8-K	001-36066	3.1	October 31, 2014
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation.	Form 8-K	001-36066	3.2	October 31, 2014
3.3	Certificate of Elimination of Series A Junior Participating Preferred Stock.	Form 8-K	001-36066	3.1	July 24, 2015
3.4	Amended and Restated Bylaws.	Form 8-K	001-36066	3.1	April 16, 2015
4.1	Specimen Common Stock Certificate.	Form S-3	333-201458	4.2	January 12, 2015
4.2	Form of Warrant Agreement issued to Hercules Technology II, L.P. and Hercules Technology III, L.P.	Form 8-K	001-36066	4.1	October 5, 2015
4.3	Form of Warrant Agreement issued to Hercules Technology II, L.P. and Hercules Technology III, L.P.	Form 8-K	001-36066	4.1	December 13, 2016
4.4	Form of Warrant Agreement issued to Hercules Capital, Inc.	Form 8-K	001-36066	4.1	June 29, 2017
4.5	Warrant Agreement issued to Hercules Capital, Inc.	Form 10-Q	001-36066	4.5	August 2, 2018
4.6	Warrant, dated as of April 7, 2014, issued to HBM Healthcare Investments (Cayman) Ltd.	Form 10-K	001-36066	10.22	April 2, 2015
4.7	Warrant, dated as of April 18, 2014 issued to K/S Danish BioVenture.	Form 10-K	001-36066	10.23	April 2, 2015
4.8	Warrant, dated as of April 7, 2014 issued to Omega Fund III, L.P.	Form 10-K	001-36066	10.24	April 2, 2015
4.9	Indenture, dated as of April 23, 2018, by and between the Company and U. S. Bank National Association (including the form of the 4.75% Convertible Senior Subordinated Note due 2024).	Form 8-K	001-36066	4.1	April 23, 2018
4.10	Form of 4.75% Convertible Senior Subordinated Note due 2024 (included in Exhibit 4.9)	Form 8-K	001-36066	4.1	April 23, 2018
4.11*	Description of Securities				
10.1A+	2006 Incentive Award Plan, as amended and restated.	Form 10-K	001-36066	10.1A	March 9, 2016
10.1B+	Form of Stock Option Grant Notice and Stock Option Agreement under 2006 Incentive Award Plan.	Form S-8	333-172041	99.2	February 3, 2011

Exhibit No.	Exhibit Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit	Filing Date
10.1C+	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2006 Incentive Award Plan, as amended.	Form 8-K	001-36066	10.1	February 10, 2015
10.2+	2009 Employee Stock Purchase Plan.	Form 8-K	000-51967	10.1	June 9, 2009
10.3+	2018 Employee Stock Purchase Plan, as amended.	Form 10-Q	001-36066	10.4	November 6, 2018
10.4A+	2014 Equity Incentive Plan, as amended.	Form S-8	333-201204	4.1	December 22, 2014
10.4B+	Form of Option Agreement under the 2014 Equity Incentive Plan, as amended.	Form S-8	333-201204	4.2	December 22, 2014
10.5A+	2015 Inducement Plan.	Form 8-K	001-36066	10.2	February 10, 2015
10.5B+	Form of Stock Option Grant Notice and Option Agreement under the 2015 Inducement Plan.	Form 8-K	001-36066	10.3	February 10, 2015
10.6A+	Paratek Pharmaceuticals, Inc. 2017 Inducement Plan, as amended	Form 8-K	001-36066	10.1	October 18, 2018
10.6B+	Form of Stock Option Grant Notice and Option Agreement under the 2017 Inducement Plan.	Form 8-K	001-36066	10.2	June 16, 2017
10.6C+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2017 Inducement Plan.	Form 8-K	001-36066	10.3	June 16, 2017
10.7A+	2015 Equity Incentive Plan	Form S-8	333-205482	99.5	July 2, 2015
10.7B+	Form of Stock Option Grant Notice and Option Agreement under the 2015 Equity Incentive Plan	Form S-8	333-205482	99.6	July 2, 2015
10.7C+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2015 Equity Incentive Plan.	Form S-8	333-205482	99.7	July 2, 2015
10.7D+	Form of Leadership Team Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2015 Equity Incentive Plan.	Form 8-K	001-36066	10.1	August 4, 2017
10.7E+	Form of Director Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2015 Equity Incentive Plan.	Form 10-K	001-36066	10.6E	March 6, 2018
10.7F+	Form of Director Stock Option Grant Notice and Option Agreement under the 2015 Equity Incentive Plan.	Form 10-K	001-36066	10.6F	March 6, 2018
10.8+	Paratek Pharmaceuticals, Inc. Annual Incentive Plan.	Form 8-K	001-36066	10.4	June 16, 2017
10.9+	Non-Employee Director Compensation Policy.	Form 10-K	001-36066	10.8	March 6, 2018

Exhibit No.	Exhibit Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit	Filing Date
10.10A+	Revenue Performance Incentive Plan	Form 8-K	001-36066	10.1	October 4, 2018
10.10B+	Form of Award Agreement under the Revenue Performance Incentive Plan	Form 8-K	001-36066	10.2	October 4, 2018
10.11+	Form of Indemnification Agreement between the Company, its executive officers and directors.	Form 10-K	001-36066	10.8	March 9, 2016
10.12†	Collaborative Research and License Agreement by and between the Company and Warner Chilcott, dated as of July 2, 2007.	Form 10-K	001-36066	10.16	April 2, 2015
10.13†	License and Collaboration Agreement by and between Paratek Bermuda Ltd. and Zai Lab (Shanghai) Co., Ltd., dated April 21, 2017.	Form 10-Q	001-36066	10.11	August 2, 2017
10.14†	License Agreement by and between the Company and Tufts University dated as of February 1, 1997, as amended.	Form 10-K	001-36066	10.17	March 6, 2018
10.15	Amendment No. 10, dated as of March 21, 2017, to the License Agreement by and between the Company and Tufts University	Form 10-Q	001-36066	10.1	May 4, 2017
10.16†	Amendment No. 11, dated as of November 15, 2017, to the License Agreement by and between the Company and Tufts University	Form 10-K	001-36066	10.19	March 6, 2018
10.17+	Amended and Restated Employment Agreement by and between the Company and Douglas W. Pagán, dated as of August 4, 2017.	Form 10-Q	001-36066	10.4	November 8, 2017
10.18	Consulting Agreement dated March 15, 2019 between the Company and Douglas Pagán.	Form 8-K	001-36066	10.1	March 18, 2019
10.19+	Amended and Restated Employment Agreement, by and between the Company and Michael F. Bigham, dated as of June 25, 2019.	Form 10-Q	001-36066	10.2	August 6, 2019
10.20+	Amended and Restated Employment Agreement, by and between the Company and Evan Loh, M.D., dated as of June 25, 2019.	Form 10-Q	001-36066	10.3	August 6, 2019
10.21+	Amended and Restated Employment Agreement, by and between the Company and Adam Woodrow, dated as of June 25, 2019.	Form 10-Q	001-36066	10.4	August 6, 2019
10.22	Amended and Restated Employment Agreement, by and between the Company and William M. Haskel, dated as of August 4, 2017.	Form 10-Q	001-36066	10.2	November 8, 2017

Exhibit No.	Exhibit Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit	Filing Date
10.23	Stock Purchase Agreement dated October 1, 2015, by and between Paratek Pharmaceuticals, Inc. and Hercules Technology Growth Capital, Inc.	Form 8-K	001-36066	10.1	October 5, 2015
10.24	Boston Lease Agreement between Paratek Pharma LLC and TDC Heritage LLC, dated as of April 24, 2015, as amended.	Form 10-Q	001-36066	10.3	May 4, 2017
10.25	King of Prussia Lease Agreement between Paratek Pharma LLC and Atlantic American Properties Trust, dated as of January 23, 2015, as amended.	Form 10-Q	001-36066	10.2	May 4, 2017
10.26†	Manufacturing and Services Agreement by and between the Company and Almac Pharma Services Limited, dated as of December 30, 2016.	Form 10-K/A	001-36066	10.27	May 5, 2017
10.27†	Amended and Restated Manufacturing and Services Agreement, by and between the Company and CIPAN - Companhia Industrial Produtora de Antibióticos, S.A., dated as of April 18, 2018.	Form 10-Q	001-36066	10.2	August 2, 2018
10.28†	First Amendment of Amended and Restated Manufacturing and Services Agreement, by and between the Company and CIPAN – Companhia Industrial Produtora de Antibióticos, S.A., dated as of February 18, 2019.	Form 10-K	001-36066	10.33	March 6, 2019
10.29†	Outsourcing Agreement by and between the Company and CARBOGEN AMCIS AG, dated as of December 30, 2016.	Form 10-K/A	001-36066	10.29	May 5, 2017
10.30†	First Amendment of Outsourcing Agreement, by and between the Company and CARBOGEN AMCIS AG, dated as of December 18, 2018.	Form 10-K	001-36066	10.35	March 6, 2019
10.31†	Master Manufacturing Service Agreement by and between the Company and Patheon UK Limited dated as of July 28, 2017 and Product Agreement by and between the Company and Patheon UK Limited dated as of July 28, 2017.	Form 10-Q/A	001-36066	10.12	November 6, 2017
10.32^	Amendment Agreement - Amendment No. 1 to Patheon Product Agreement by and between the Company and Patheon UK Limited dated as of January 1, 2019.	Form 10-Q	001-36066	10.1	May 8, 2019
10.33	Loan Agreement by and between the Company and Healthcare Royalty Partners III, L.P. dated as of February 25, 2019.	Form 10-Q	001-36066	10.2	May 8, 2019

Exhibit No.	Exhibit Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit	Filing Date
10.34	Amended and Restated Loan and Security Agreement, dated June 27, 2019, by and among Paratek Pharmaceuticals, Inc., Paratek Pharma, LLC, Hercules Technology III and certain other lenders, and Hercules Capital Inc. as agent.	Form 8-K	001-36066	10.1	July 2, 2019
10.35*^	Contract, dated as of December 18, 2019, between Paratek Pharmaceuticals, Inc. and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services.				
10.36*^	Notice of Assignment to Affiliate for License and Collaboration Agreement by and between Paratek Bermuda Ltd. and Zai Lab (Shanghai) Co., Ltd., dated as of December 19, 2019.				
21.1*	Subsidiaries of the Company.				
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.				
24.1	Power of Attorney (included on signature page)				
31.1*	Certification of the Company's Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act of 1934, as amended, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of the Company's Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act of 1934, as amended, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*	Certification of the Company's Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2*	Certification of the Company's Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	XBRL Instance Document.				
101.SCH*	XBRL Taxonomy Extension Schema Document.				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.				

Exhibit No.	Exhibit Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit	Filing Date
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document.				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.				

* Filed herewith.

† Confidential treatment has been granted as to certain portions, which portions have been omitted and submitted separately to the Securities and Exchange Commission.

^ Certain confidential information contained in this exhibit has been omitted because it (i) is not material and (ii) would be competitively harmful if publicly disclosed.

\+ Management contract or compensatory plan, contract or arrangement.

(b) Exhibits

See Exhibits listed under Item 15(a)(3) above.

(c) Financial Statement Schedules

Financial statement schedules are omitted because they are not applicable or are not required or the information required to be set forth therein is included in the Financial Statements or notes thereto.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boston, State of Massachusetts, on the 10th day of March, 2020.

Paratek Pharmaceuticals, Inc.

By: /s/ Evan Loh, M.D.
Evan Loh, M.D.
Chief Executive Officer
(Principal Executive Officer)

By: **/s/** Sarah Higgins
Sarah Higgins
Vice President, Finance and Controller
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of William M. Haskel and Sarah Higgins his or her true and lawful attorney-in-fact and agent, with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, each of the undersigned has executed this Power of Attorney as of the date indicated opposite his name.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Evan Loh, M.D. **Evan Loh, M.D.**	Chief Executive Officer and Director *(Principal Executive Officer)*	March 10, 2020
/s/ Sarah Higgins **Sarah Higgins**	Vice President, Finance and Controller *(Principal Financial and Accounting Officer)*	March 10, 2020
/s/ Michael F. Bigham **Michael F. Bigham**	Executive Chairman of the Board of Directors	March 10, 2020
/s/ Thomas J. Dietz, Ph.D. **Thomas J. Dietz, Ph.D.**	Director	March 10, 2020
/s/ Timothy R. Franson, M.D. **Timothy R. Franson, M.D.**	Director	March 10, 2020
/s/ Rolf K. Hoffmann **Rolf K. Hoffmann**	Director	March 10, 2020
/s/ Kristine Peterson **Kristine Peterson**	Director	March 10, 2020
/s/ Robert S. Radie **Robert S. Radie**	Director	March 10, 2020
/s/ Jeffrey Stein, Ph.D. **Jeffrey Stein, Ph.D.**	Director	March 10, 2020

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2019, Paratek Pharmaceuticals, Inc. ("Paratek," "we," "our," or "us") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock, $0.001 par value per share.

DESCRIPTION OF CAPITAL STOCK

The following summary of the terms of our capital stock is based upon our amended and restated certificate of incorporation (the "Certificate of Incorporation"), and our amended and restated bylaws (the "Bylaws"). The summary is not complete, and is qualified by reference to our Certificate of Incorporation and our Bylaws, which are filed as exhibits to this Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our Certificate of Incorporation, our Bylaws, and the applicable provisions of the Delaware General Corporation Law for additional information.

Authorized Shares of Capital Stock

Our authorized capital stock consists of 100,000,000 shares of our common stock, par value $0.001 per share, and 5,000,000 shares of our preferred stock, par value $0.001 per share. As of February 28, 2020, we had 42,219,278 shares of our common stock issued and outstanding and no shares of our preferred stock issued and outstanding.

Voting Rights

The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of stockholders. The holders of our common stock do not have cumulative voting rights in the election of directors.

Dividend Rights.

Subject to preferences that may be applicable to any outstanding shares of preferred stock, the holders of common stock are entitled to receive ratably such dividends as may be declared by our board of directors out of legally available funds.

Liquidation Rights.

Upon our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preferences of any outstanding shares of preferred stock.

Other Rights and Preferences

Holders of common stock have no preemptive rights and no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to our common stock.

Listing

Our common stock is listed on The Nasdaq Global Market under the trading symbol “PRTK.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar’s address is 6201 15th Avenue, Brooklyn, New York 11219.

Preferred Stock Rights

Our Certificate of Incorporation provides that our board of directors has the authority, without further action by the stockholders (unless such stockholder action is required by applicable law or Nasdaq rules), to designate and issue up to 5,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the designations, voting powers, preferences and rights of the shares of each wholly unissued series, and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock.

Anti-Takeover Effects of Provisions of Delaware Law and Our Charter Documents

Delaware Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation such as us from engaging in a “business combination” with an “interested stockholder” for a period of three years following the time that the stockholder became an interested stockholder, unless:

- prior to the time the stockholder became an interested stockholder, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers and (b) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the time the stockholder became an interested stockholder, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2⁄3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, lease, exchange, mortgage, pledge, transfer or other disposition (in one transaction or a series of transactions) involving the interested stockholder of 10% or more of the assets of the corporation (or its majority-owned subsidiary);
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect, directly or indirectly, of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit, directly or indirectly (except proportionately as a stockholder of such corporation), of any loans, advances, guarantees, pledges or other financial benefits, other than certain benefits set forth in Section 203, provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person that is an affiliate or associate of such entity or person.

Charter Documents

Our Certificate of Incorporation provides for our board of directors to be divided into three classes serving staggered terms. Approximately one-third of our board of directors will be elected each year. The provision for a classified board could prevent a party who acquires control of a majority of the outstanding voting stock from obtaining control of our board of directors until the second annual stockholders' meeting following the date the acquirer obtains the controlling stock interest. Our Certificate of Incorporation provides that directors may be removed with cause by the affirmative vote of the holders of a majority of the voting power of all outstanding stock or without cause by the affirmative vote of the holders of at least 66 2⁄3% of the voting power of all outstanding stock.

Our Certificate of Incorporation requires that certain amendments of our Certificate of Incorporation and amendments by the stockholders of our Bylaws require the approval of at least 66 2⁄3% of the voting power of all outstanding stock. Our Bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of persons for election to our board of directors. At an annual meeting of stockholders, stockholders may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors. Stockholders may also consider a proposal or nomination by a person who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given to our corporate secretary timely written notice, in proper form, of his or her intention to bring that business before the meeting. Our Bylaws do not give our board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting of stockholders. However, our Bylaws may have the effect of precluding the conduct of business at a meeting if the proper procedures are not followed.

Our Bylaws provide that only our board of directors, the chairperson of the board, the chief executive officer or, in the absence of a chief executive officer, the president may call a special meeting of stockholders. Because our stockholders do not have the right to call a special meeting, a stockholder could not force stockholder consideration of a proposal over the opposition of our board of directors by calling a special meeting of stockholders prior to such time as a majority of our board of directors, the

chairperson of the board, the chief executive officer or, in the absence of a chief executive officer, the president believed the matter should be considered or until the next annual meeting of stockholders. The restriction on the ability of stockholders to call a special meeting means that a proposal to replace members of our board of directors could be delayed until the next annual meeting of stockholders. Our Certificate of Incorporation does not allow stockholders to act by written consent without a meeting. Without the availability of stockholders' actions by written consent, a holder controlling a majority of our capital stock would not be able to amend our Bylaws or remove directors without holding a stockholders' meeting. Other provisions contained in our Certificate of Incorporation and our Bylaws could delay or discourage some types of transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares over then-current prices, and may limit the ability of stockholders to remove current management or approve transactions that stockholders may deem to be in their best interests and, therefore, could adversely affect the price of our common stock.

Limitation of Liability and Indemnification of Officers and Directors

Our Certificate of Incorporation provides that no director shall be personally liable to us or any of our stockholders for monetary damages for breach of fiduciary duty as a director, except to the extent such exemption from liability or limitation thereof is not permitted under Delaware General Corporation Law. Our Bylaws require us to indemnify our directors and officers to the fullest extent not prohibited by Delaware General Corporate Law. may expand the extent of such indemnification by individual contracts with our directors and officers. Further, we may decline to indemnify any director or officer in connection with any proceeding initiated by such person, unless such proceeding was authorized by our board of directors. Our Bylaws also provide that, subject to applicable law, we may, by action of our board of directors, grant rights to indemnification to persons other than our directors and officers with such scope and effect as the board of directors may then determine. We have entered into customary indemnification agreements with each of our directors that provide them, in general, with customary indemnification in connection with their service to us or on our behalf.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED WITH [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES 1 3
2. CONTRACT (*Proc. Inst. Ident)* NO. 75A50120C00001	3. EFFECTIVE DATE See Block 20C	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. See Schedule	

5. ISSUED BY CODE	ASPR-BARDA	6. ADMINISTERED BY (*if other than item 5)* CODE	ASPR-BARDA
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201		ASPR-BARDA US DEPT OF HEALTH & HUMAN SERVICES BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUT 200 INDEPENDENCE AVE, S.W. Washington DC 20201	
7. NAME AND ADDRESS OF CONTRACTOR (*No., street, country, State and ZIP Code)*		8. DELIVERY FOR ORIGIN ☒ OTHER (*See below*)	
PARATEK PHARMACEUTICALS INC 15490007 Attn: [***] PARATEK PHARMACEUTICALS, INC. 75 PARK PLZ FL 4 BOSTON MA 021163934		9. DISCOUNT FOR PROMPT PAYMENT	
CODE 1549007	FACILITY CODE	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN ➡	ITEM

11. SHIP TO/MARK FOR CODE	HHS	12. PAYMENT WILL BE MADE BY CODE	PSC
HHS 200 Independence Avenue, SW Washington DC 20201		PSC Program Support Center 7700 Wisconsin Ave Bethesda MD 20814	
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION 10 U.S.C. 2304 (c) ( ) ☒ 41 U.S.C. 3304 (a)( )		14. ACCOUNTING AND APPROPRIATION DATA 2020.1990051.25106	

15A ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	153. UNIT PRICE	15F AMOUNT
	Continued				
15G. TOTAL AMOUNT OF CONTRACT ➡				$59,380,559.00	

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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT *(Contractor is required to sign this document and return _1_ copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services and set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein).*		18. ☐ SEALED-BID AWARD *(Contractor is not required to sign this document.)* Your bid on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract).	
19A. NAME AND TITLE OF SIGNER (*Type or print)* [***]		20A. NAME OF CONTRACTING OFFICER [***]	
19B. NAME OF CONTRACTOR By [***] *(Signature of person authorized to sign)*	19C. DATE SIGNED 12/18/2019	20B. UNITED STATE OF AMERICA By [***] *(Signature of the Contracting Officer)*	20C. DATE SIGNED 12/18/2019

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED	PAGE 2 OF 2

NAME OF OFFEROR OR CONTRACTOR
PARATEK PHARMACEUTICALS INC 1549007

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 33-0960223 DUNS Number: [***] Appr. Yr.: 2020 CAN: [***] Object Class: [***] Period of Performance: 12/18/2019 to 12/17/2024				[***]
1	Late Stage Development to Support Licensure of Antibiotic through EUA or FDA Marketing Authorization Requisition No: [***]				[***]
2	Initial Purchase, Storage, and Delivery of Antibiotic as FDP to VMI or SNS Obligated Amount: [***] Requisition No: [***]				0.00
3	Supplemental Late Stage Development as Requested by FDA to Support Licensure of Antibiotics through FDA Marketing Authorization Amount: $12,672,339.00(Option Line Item)				0.00
4	BARDA Security Requirements Amount: $20,435,260.00(Option Line Item)				0.00
5	Post-Marketing Study Commitments/Requirements for Authorized Commercial Indication including Relabeling of Approved Drug in the ASPR/SNS or VMI Amount: $76,774,872.00(Option Line Item)				0.00
6	Additional Procurement of Antibiotics as Final Drug Product ([***]) Amount: [***] (Option Line Item)				0.00
7	Additional Procurement of Antibiotics as Final Drug Product ([***]) Amount: [***] (Option Line Item)				0.00
8	Additional Procurement of Antibiotics as Final Drug Product ([***]) Amount: [***] (Option Line Item)				0.00

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICE AND PRICE / COST

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

Paratek is developing NUZYRA® (omadacycline), an oral and parenteral antibiotic to treat pulmonary anthrax. The drug product is also suitable for prophylactic use as a priority medical countermeasure.

Under the base period-of-performance, Paratek will conduct development activities necessary to achieve an Emergency Use Authorization (EUA) licensure of NUZYRA® followed by the supplemental NDA submission and drug product manufacturing of the drug product to be stored as vendor managed inventory (VMI) and subsequently delivered to the Strategic National Stockpile (SNS). The contract options may be exercised to perform additional studies necessary for licensure, support post-licensure commitments as required by the FDA, implement additional security requirements and procure additional treatment courses.

The Research and Development (R&D) effort will progress in specific stages that cover the base performance segment and several options, if necessary, as specified in this contract. The period of performance for the base period is 60 months.

ARTICLE B.2. BASE PERIOD

Base Period Cost Reimbursement CLIN					
CLIN	**Period of Performance**	**Supplies/Services**	**Estimated Cost**	**Fixed Fee**	**Cost + Fixed Fee (CPFF)**
0001 (Base)	[***]	Late stage development activities towards FDA approval for treatment of pulmonary Anthrax	[***]	[***]	[***]

Base Period Fixed Price CLINs					
CLIN	**Period of Performance**	**Supplies/Services**	**Treatment Courses (# of Product)**	**Unit Price ($)**	**Total ($)**
0002 (Base)	[***]	Initial purchase and delivery of NUZYRA® via VMI	2,500	[***]	[***]

*Total funded to date is $59,380,559

ARTICLE B.3. OPTIONS

Optional Cost Reimbursement CLINs					
CLIN	**Period of Performance**	**Supplies/ Services**	**Total Est. Cost**	**Fixed Fee**	**Total Cost Plus Fixed Fee ($)**
0003 (Option)	[***]	Supplemental Late stage development as requested by FDA to support licensure of antibiotic(s) through FDA marketing authorization (nonclinical, clinical, regulatory)	[***]	[***]	$12,672,339
0004 (Option)	06/01/2020 – [***]	BARDA Security Requirements	[***]	[***]	$20,435,260
0005 (Option)	04/01/2020 – [***]	Post-Marketing Study Commitments/ Requirements for the authorized commercial indication including relabeling of approved drug in the ASPR/SNS or VMI (this is an option that may or may not be exercised as required by the FDA)	[***]	[***]	$76,774,872

Optional Fixed Price CLINs					
CLIN	**Period of Performance**	**Supplies/Services**	**Treatment Courses (# of Product)**	**Unit Price (SNS/VMI)**	**Total ($)**
0006 (Option)	[***]	Additional procurement of antibiotic(s) as final drug product (FDP) to Vendor managed inventory (VMI) and/or ASPR/SNS sites.	**[***]**	**[***]**	**[***]**
0007 (Option)	[***]	Additional procurement of antibiotic(s) as final drug product (FDP) to Vendor managed inventory (VMI) and/or ASPR/SNS sites.	[***]	[***]	[***]
0008 (Option)	[***]	Additional procurement of antibiotic(s) as final drug product (FDP) to Vendor managed inventory (VMI) and/or ASPR/SNS sites.	[***]	[***]	[***]

ARTICLE B.4. ADVANCE UNDERSTANDINGS

a. Subcontracts and Consultants

Award of **any FFP subcontract or FFP consulting agreement in excess of $250,000 or any cost reimbursement subcontract or consulting agreement** shall not proceed without the prior written consent of the Contracting Officer via a Contracting Officer Authorization (COA) Letter. COA letters will only be issued upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract and consulting agreement shall be provided to the Contracting Officer within ten (10) calendar days of full execution.

b. Site Visits, Inspections and General Audits

At the discretion of the USG and independent of activities conducted by the Contractor, with 48 hours' notice to the Contractor, the USG reserves the right to conduct site visits and inspections on an as needed basis in connection with technical performance issues, including collection of product samples and intermediates held by the Contractor, or subcontractor. In case of subcontractor visits and inspections related to performance under this contract that are independent of activities conducted by the Contractor, the USG shall demonstrate cause for such visit and/or inspection. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs. The Contractor shall coordinate these visits and shall have the opportunity to accompany the USG on any such visits. Under time-sensitive or critical situations, the USG reserves the right to suspend the 48 hour notice to the Contractor. If the Government, Contractor, or other party identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government for review and acceptance.

- If issues are identified during the audit, Contractor shall submit an issue report to the CO and COR within 10 business days detailing the finding and corrective action(s) of the audit.
- COR and CO will review the issues report and provide a response to the Contractor within 10 business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR within a time frame negotiated with the COR in writing after review of the issues report.

c. QA Audits

BARDA reserves the right to participate in QA audits of the Contractor's subcontractors to the extent related to performance of this contract. Upon completion of the QA audit the Contractor shall provide a report capturing the findings, results, and next steps in proceeding with any potential subcontractors. If action is requested for a subcontractor, detailed corrective and preventative plans for addressing areas of non-conformance to ICH and FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to the COR for review and acceptance. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors by the Contractor as part of bi-weekly communications;
- Contractor shall notify the COR and CO within 10 business days of report completion. The Contractor shall complete the report within 60 days of the audit/site visit, or as negotiated with the COR in writing dependent upon the audit findings;
- COR and CO will review the issues report and provide a response to the Contractor within 10 business days;

- Once corrective action is completed, the Contractor will provide a final report to the CO and COR within a time frame negotiated with the COR and CO after review of the issues report.
- If additional details are needed for clarification of role, responsibility and processes between the Contractor and USG, it will be defined in the Quality Agreement outlined in Article B.5, Section h, below.

d. Man-in-Plant

At the discretion of the Government and seven calendar (7) days advance notice to the Contractor in writing from the Contracting Officer, the Government may place a man-in-plant in the Contractor's facility, who shall be subject to the Contractor's policies and procedures regarding security and facility access at all times while in the Contractor's facility. Consistent with federal law, the Government will ensure that no Government representative will publish, divulge, disclose, or make known in any manner, to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a contractor plant.

e. Sharing of contract deliverables within United States Government (USG)

In an effort to build a robust medical countermeasure pipeline through increased collaboration, BARDA may share technical deliverables with USG entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise Review, agreements established in the Integrated Portfolio's Portfolio Advisory Committee (PAC) Charter, and agreements between BARDA and the Department of Defense and the National Institutes of Health, BARDA may share technical deliverables and data created in the performance of this contract with colleagues within the Integrated Portfolio. This advance understanding does not authorize BARDA to share financial information outside HHS. The Contractor is advised to review the terms of FAR 52.227-14, Rights in Data – General, regarding the Government's rights to deliverables submitted during performance as well as the Government's rights to data contained within those deliverables.

f. Overtime Compensation

No overtime (premium) compensation is authorized under the subject contract.

g. Contract Number Designation

On all correspondence submitted under this contract, the Contractor agrees to clearly identify the contract number that appears on the face page of the contract as follows:

75A50120C00001

h. Quality Agreement

The Quality Agreement shall define, establish, and document the responsibilities of both the Contractor and the USG (i.e. – CDC/SNS-Quality Control and BARDA) for event-

driven and product shipping, receiving, acceptance into the inventory and/or custody by the USG. These documents shall be drafted, approved, and signed by all parties prior to the commencement of product procurement and acceptance, transport and custody of the product under the VMI/DMI or the CDC/SNS. The Contractor shall provide documentation and resolution for all concerns raised by USG and commits to cooperation in execution of this agreement. A COA will be required prior to invoicing against procurement CLINs.

i. Liquidated Damages

If the Contractor fails to deliver the supplies or perform the services within the time specified and agreed upon by both parties in this contract, and such failure is not excusable or remedied within 14 calendar days. Beyond this time frame the Contractor shall, in place of damages, pay the Government liquidated damages an amount per calendar day of delay to be agreed upon prior to the execution of FFP optional procurement CLINs.

j. [***]

k. [***]

l. [***]

m. [***]

n. [***]

ARTICLE B.5. PROVISIONS TO APPLICABLE COSTS

This section prohibits or restricts the use of contract funds to reimburse direct cost expenditures for the following items (costs unallowable unless otherwise approved by the Contracting Officer):

a) Acquisition, by purchase or lease, of any interest in real property;
b) Rearrangement or alteration of facilities;
c) Purchase of lease of any item of general purpose office furniture or office equipment regardless of dollar value;
d) Accountable Government Property;
e) Overtime
f) General scientific meetings/conferences;
g) Travel costs including foreign travel;
h) Costs incurred in the performance of any cost-reimbursement type subcontract (including consulting agreements);
i) Costs to be paid for the performance of a fixed-price subcontract that exceeds $150,000.00;
j) Refreshments and Meal Expenditures;
k) Promotional Items
l) Printing

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work dated December 18, 2019 set forth in SECTION J - List of Attachments, attached hereto and made a part of the contract.

ARTICLE C.2. REPORTING REQUIREMENTS

See Section F for specific reporting requirements.

All reports required herein shall be submitted in electronic format. All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post-consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b).

ARTICLE C.3. MEETINGS/SITE VISITS

The Contractor and BARDA shall participate in regular meetings to coordinate and oversee the contracting effort as requested by the Contracting Officer (CO)/Contracting Officer's Representative (COR). Such meetings may include, but are not limited to, a kickoff meeting to be held at a location determined by the COR, status update meetings and/or teleconferences, site visits to the Contractor's and/or subcontractor's facilities, and meetings with individual Contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor shall provide data, reports, and presentations to groups of outside experts and USG personnel and USG-contracted subject matter experts as required by the CO/COR facilitating review of activities.

The purpose of the kickoff meeting will be to orient the Contractor to HHS/BARDA and review contract requirements. This meeting usually occurs within a month after contract award.

Bi-weekly (i.e. – every two weeks) or monthly status update meetings/teleconferences shall be scheduled and established by the Contracting Officer's Representative (COR), the Contractor's Project Leaders/delegates and Contracting Officer (CO). During this meeting the Contractor's Project Leaders/delegates and designees will discuss the activities since the last call, any problems that have arisen and the activities planned until the next call takes place. The Contractor's Project Leaders/delegates may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the Contracting Officer's Representative.

Within five (5) calendar days of Paratek's receipt of the audit report of an FDA audit of Contractor or subcontractor facilities related to activities performed under this contract, the Contractor shall provide copies of the audit findings, final report, and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

Other U.S. Government Audits

The USG reserves the right to conduct an audit of the Contractor with 72 hours advance notice in connection with technical performance issues. The USG reserves the right to accompany the Contractor on routine and for-cause site-visits/audits of subcontractor(s) related to work performed under this contract. At the discretion of the USG and independent of testing conducted by the Contractor, BARDA reserves the right to conduct site visits/audits and collect samples of product held produced under this contract and held by the Contractor and subcontractors.

Pre-award site visits may be made with short notice. Contractors are expected to guarantee the availability of key staff or other staff determined by the Government as essential for purposes of this site visit.

SECTION D – PACKAGING, MARKING AND SHIPPING

ARTICLE D.1. METHOD OF DELIVERY

Unless otherwise specified by the Contracting Officer, all deliverable items to be furnished to the Government under this contract (including invoices) shall be made by first class mail, overnight carrier, or email as described in SECTION F.3.

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor's name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

ARTICLE D.2. FOB DESTINATION DELIVERIES

The Contractor shall describe the storage conditions for each product, specifically noting the acceptable temperature range required to maintain product quality. The Contractor shall be responsible for maintaining product temperature control until the product(s) arrives at the ASPR/SNS and has completed product acceptance by the USG. The Contractor shall provide the Government with an ambient exposure letter that covers the time the product(s) leaves the Contractor's validated storage facility until arrival at the ASPR/SNS. Upon Government acceptance of the product(s) to the Government, the responsibility for temperature control shall transfer to the Government as well as the responsibility for logging ambient exposure time (temperatures between 8-25°C). The Contractor will provide and place TempTale(s) on each pallet of product while the product is inside the Contractor's validated storage facility prior to placing the product(s) onto the truck(s) or other mode of transportation of the designated carrier. The Government's acceptance of the aforementioned responsibility applies only to temperature control and does not indicate its acceptance of the lot(s).

SECTION E – INSPECTION AND ACCEPTANCE

ARTICLE E.1. INSPECTION AND ACCEPTANCE

Inspection and acceptance of reports will be performed by the Contracting Officer or a duly authorized representative. Technical inspection and acceptance for reports will take place at:

Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response
200 C Street, S.W.
Washington, D.C. 20024

Inspection or acceptance of product will take place at the VMI or SNS location.

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duty authorized representative within 30 days of receipt.

ARTICLE E.2. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR 52.246-2, Inspection of Supplies – Fixed Price (August 1996)

FAR 52.246-4, Inspection of Services - Fixed Price (August 1996)

FAR 52.246-5, Inspection of Services - Cost-Reimbursement (April 1984)

FAR 52.246-8, Inspection of Research and Development – Cost-Reimbursement (May 2001)

FAR 52.246-9, Inspection of Research and Development (Short Form) (April 1984)

FAR 52.246-16, Responsibility for Supplies (April 1984)

SECTION F -- DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The base period of performance of this contract shall be for sixty (60) months from the date of award. The period of performance may be extended up to an additional 5 years (10 years total for base plus options) with the exercise of option(s), structured as CLINs, as set forth in SECTION B. The period of performance for the base period and option periods shall be consistent with the dates set forth in SECTION B.

ARTICLE F.2. Reporting Requirements

The Contractor shall submit to the CO and the COR technical progress reports as identified below. These reports shall be subject to the technical inspection and requests for clarification by the COR, and approval by the CO/COR. These reports shall be brief, factual, and prepared in accordance with the following format:

a. Monthly Progress Report

This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The Contractor shall submit a Monthly Progress Report on or before the 15th calendar day following the last day of each reporting period and shall include the following:

Title Page: The title page for this report shall include the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission.

Distribution List: A list of individuals receiving the Technical Progress report.

Progress:

SECTION I - An introduction covering the purpose and scope of the contract effort.

SECTION II Part A: SUMMARY - A description or table summarizing ongoing activities.

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE – This section shall include a description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating and managing subcontractor performance and personnel changes). Please include all Quality Management System, Quality Control, and Quality Assurance Plans as part of this report or as requested by the COR.

SECTION II Part C: TECHNICAL PROGRESS – This section shall document the results of work completed and costs incurred during the period covered in relation to the proposed progress, effort, and budget. The report shall be in sufficient detail to explain comprehensively the results achieved.

SECTION II Part D: ISSUES – This section shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress; why the differences have occurred and what corrective actions are planned; and if a project activity is delinquent, then what corrective action steps are planned. Revised timelines shall be provided.

SECTION II Part E: PROPOSED WORK – This section shall include a summary of work proposed as a rolling three (3) month forecast for the next reporting period, by a certain date, and by whom.

SECTION II Part F: MANUFACTURING AND SUPPLY CHAIN MANAGEMENT – This section shall include a summary of the manufacturing and supply-chain related activities. Also include in this section updates to the production plan, capacity projections, stability results, inventory and shipment/distribution information.

SECTION II Part G: CONTRACTING OFFICER APPROVALS – This section shall include a table indicating each Contracting Officer Approval (COA) request, its current status (e.g. date submitted, date approved, date returned), amount requested, and the vendor for which the COA authorizes subcontracted work to be performed.

Invoices: Summary of any invoices submitted during the reporting period.

A Monthly Progress Report will not be required in the same month Annual Progress Reports or a Final Report are due.

b. Annual Progress Report

This report shall include a summation of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year.

The Contractor shall submit an Annual Progress Report on or before the 30th calendar day following the last day of each annual reporting period and shall include the following:

Title Page: The title page for this report shall include the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission.

Distribution List: A list of individuals receiving the Technical Progress report.

Progress:

SECTION I - An introduction covering the purpose and scope of the contract effort.

SECTION II Part A: SUMMARY - A description or table summarizing ongoing activities.

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE – This section shall include a description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating and managing subcontractor performance and personnel changes). Please include all Quality Management System, Quality Control, and Quality Assurance Plans as part of this report or as requested by the COR.

SECTION II Part C: TECHNICAL PROGRESS – This section shall document the results of work completed and costs incurred during the period covered in relation to proposed progress, effort, and budget. The report shall be in sufficient detail to explain comprehensively the results achieved.

SECTION II Part D: ISSUES – This section shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress; why the differences have occurred and what corrective actions are planned; and if a project activity is delinquent, then what corrective action steps are planned. Revised timelines shall be provided.

SECTION II Part E: PROPOSED WORK – This section shall include a summary of work proposed as a rolling three (3) month forecast for the next reporting period, by a certain date, and by whom.

SECTION II Part F: MANUFACTURING AND SUPPLY CHAIN MANAGEMENT – This section shall include a summary of the manufacturing and supply-chain related activities. Also include in this section updates to the production plan, capacity projections, stability results, inventory and shipment/distribution information.

SECTION II Part G: CONTRACTING OFFICER APPROVALS – This section shall include a table indicating each Contracting Officer Approval (COA) request, its current status (e.g. date submitted, date approved, date returned), amount requested, and the vendor for which the COA authorizes subcontracted work to be performed.

Invoices: Summary of any invoices submitted during the reporting period.

An Annual Progress Report will not be required for the period when the Final Technical Progress Report is due.

c. Draft Final Report and Final Report

These reports are to include a summation of the work performed and results obtained for execution of various studies or technical work packages during the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Progress Report shall be due forty-five (45) calendar

days prior to the expiration date of the contract and the Final Progress Report is due no later than 30 days following the expiration date of the contract. The report shall conform to the following format:

Title Page: The title for these reports shall include the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e- mail address; and the date of submission.

Distribution List: A list of individuals receiving the Technical Progress report.

Progress:

SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.

SECTION II: RESULTS - A detailed description of the work performed and the results obtained including all expenses for the entire contract period of performance.

d. FDA Regulatory Agency Correspondence, Meeting Summaries, and Submissions.

a) Within five business days of any formal meeting with the FDA or other regulatory agency that relates to performance of this contract, the Offeror shall forward the initial draft minutes to the COR. The Offeror shall forward the final minutes when available.

b) If related to performance of this contract, the Contractor shall forward the dates and times of any meeting with the FDA and other regulatory agencies to the COR as soon as the meeting times are known and make arrangements for appropriate BARDA staff to attend the meetings.

c) If related to performance of this contract, the Contractor shall provide the COR the opportunity to review and comment upon any documents to be submitted to the FDA or other regulatory agency. The Contractor shall provide the COR with five (5) business days in which to review and provide comments back to the Contractor prior to the Contractor's submission to the FDA.

d) The Contractor shall forward Standard Operating Procedures (SOPs) upon request from the COR.

e) The Contractor shall provide raw data and/or specific analysis of data generated with USG funds upon request from the COR.

f) If related to performance of this contract, the Contractor shall notify the Contracting Officer's Representative and Contracting Officer within 24 hours of all FDA arrivals to conduct site visits/audits by any regulatory agency. The Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) to the extent related to performance of this

contract. The Offeror shall provide the Contracting Officer's Representative and Contracting Officer copies of the plan for addressing areas of non-conformance to FDA regulations for GLP guidelines as identified in the audit report, status updates during the plans execution, and a copy of all final responses to the FDA to the extent related to performance of this contract. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The redactions shall be limited to issues that are unrelated to the subcontractor's performance on any award made under this RFP. The Contractor shall make arrangements with the COR for the appropriate BARDA representative(s) to be present during the final debrief by the regulatory inspector.

e. Other Requirements/Deliverables

a) Integrated Master Project Plan

The Contractor shall provide an Integrated Master Project Plan (including tabular and Gantt forms) to the COR that clearly indicates the critical path to annual deliverables and Work Breakdown Structure (WBS) elements. Attention shall be placed on providing sufficient turnaround time for the USG (BARDA, FDA, and CDC) for review of critical documentation. The Contractor shall integrate to demonstrate interdependencies among all CLINS. The Integrated Master Project Plan shall be incorporated into any potential contract and will be used to monitor performance of the contract. This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR.

I. Critical Path Milestones

The Integrated Master Project Plan shall outline key, critical path milestones, with "Go/No Go" decision criteria (entrance and exit criteria for each phase of the project). This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR.

II. Work Breakdown Structure

The WBS shall be discernable and consistent. The COR may require the Contractor to furnish WBS data at the work package level or at a lower level if there is significant complexity and risk associated with the task. This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR.

III. Risk Mitigation Plan/Matrix

The Contractor shall develop and maintain a risk management plan that highlights potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans. This plan shall reference relevant WBS/SOW elements where appropriate. The USG has provided a Risk Mitigation Matrix template (See **http://www.phe.gov/about/amcg/contracts/Pages/toolkit.aspx**) to be completed

by any prospective Contractor. This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR.

1. **Technology Packages**

   Technology packages developed under the contract that includes complete protocols must be submitted at the request of the Contracting Officer's Representative. See FAR clauses 52.227-11, Patent Rights-Ownership by the Contractor, and 52.227-14, Rights in Data, Alternate II. This report shall be due upon request from the COR.

2. **Experimental Protocols**

   The Contractor shall submit to the COR all study/experiment/test plans, designs, and protocols prior to execution for approval or upon request by the COR when required.

3. **Annual/Final Invention Report**

   All reports and documentation required by FAR Clause 52.227-11, Patent Rights- Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification. An Annual Invention Report shall be due on or before the 30th calendar day after the completion of each reporting period. A Final Invention Report (see FAR 27.303 (b)(2)(ii)) shall be due on or before the expiration date of the contract. If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer.

4. **Publications**

   Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to COR for review prior to submission. Reports shall be due within 30 calendar days for manuscripts and 15 calendar days for abstracts.

5. **Press Releases**

   The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. The Contractor shall ensure the Contracting Officer has received and approved an advanced copy of any press release not less than five (5) business days prior to the issuance of any potential press release.

6. **Security Report**

   To the extent related to performance of this contract, the Contractor shall report to the government any activity; or incident that is in violation of

established security standards; or indication of loss or theft of government products. Reports shall be due within 24 hours after occurrence of an activity or incident.

7. Security Plan

Final plan due within 90 days of contract award.

8. Quality Management System Plan

The Contractor shall submit to the COR a Quality Management System Plan for approval no later than 90 days from the date of award.

9. Manufacturing Plan

The Contractor shall submit to the COR a comprehensive manufacturing plan for review and approval no later than 90 days from the date of award.

ARTICLE F.3. DELIVERABLE SCHEDULE

Item No.	Description	Addresses	Deliverable Schedule
1	Monthly Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due on or before the 15th of each month following the end of each reporting period.
2	Annual Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due on or before the 30th calendar day following the end of each reporting period.
3	Draft Final Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Report is due 45 Calendar days prior to the expiration date of the contract.
4	Final Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Report is due no later than 30 calendar days after the expiration date of the contract.
5	FDA/ Regulatory Agency Correspondence and Meeting Summaries	CO: (1) electronic copy COR: (1) electronic copy	Meeting summaries/minutes are due within 5 business days of receipt from the FDA/regulatory agency, or upon request from the COR.

Item No.	Description	Addresses	Deliverable Schedule
6	Integrated Master Project Plan -Critical Path Milestones -Work Breakdown Structure -Risk Mitigation Plan/Matrix	CO: (1) electronic copy COR: (1) electronic copy	Report is due within 90 days of contract award. Updates are due as requested by the COR.
7	Technology Packages	CO: (1) electronic copy COR: (1) electronic copy	Upon request from the COR.
8	Experimental Protocols	CO: (1) electronic copy COR: (1) electronic copy	Upon request from the COR.
9	Annual/Final Invention Report	CO: (1) electronic copy COR: (1) electronic copy	An Annual Invention Report is due on or before the 30th calendar day after the completion of each annual reporting period. A Final Invention Report is due on or before the expiration date of the contract.
10	Publications	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within 30 calendar days for manuscripts and 15 calendar days for abstracts.
11	Press Releases	CO: (1) electronic copy COR: (1) electronic copy	Reports/Notices are due for review by the CO not less than five (5) business days prior to the issuance of any potential press release.
12	Security Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within 24 hours after occurrence of an activity or incident.
13	Security Plan	CO: (1) electronic copy COR: (1) electronic copy	Final plan due within 90 days of contract award.
14	Manufacturing Plan	CO: (1) electronic copy COR: (1) electronic copy	Due within 90 days of contract award.
15	Quality Management System Plan	CO: (1) electronic copy COR: (1) electronic copy	Due within 90 days of contract award
16	Delivery Schedule to the ASPR/SNS or product maintained as VMI	CO: (1) electronic copy COR: (1) electronic copy	Due within 30 days of agreement on delivery location.

ARTICLE F.4. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. The full text of each clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html.

FAR 52.242-15, Stop-Work Order (August 1989)

FAR 52.242-15, Stop-Work Order, Alternate 1 (April 1984)

SECTION G– CONTRACT ADMINISTRATION

ARTICLE G.1. CONTRACTING OFFICER (CO)

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

[***]
DHHS/OS/ASPR/BARDA
200 C St.
O'Neill House Office Building
Washington, D.C. 20515

The Contracting Officer is the only individual who can legally commit and bind the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions or other stipulations of this contract. Any other commitment, either explicit or implied, is invalid.

The CO is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of objectives; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) obligate or de-obligate funds into the contract; (6) sign written licensing agreements; or (7) otherwise change any terms and conditions of this contract.

No information, other than that which may be contained in an authorized modification to this contract duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

The Government may unilaterally change its CO designation.

ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this contract:

[***]
Contracting Officer's Representative
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services
[***]

Mailing Address:
200 C St.
O'Neill House Office Building (BARDA)
Washington, D.C. 20515

The COR is responsible for:

a. Monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;

b. Assisting the Contracting Officer in interpreting the statement of work and any other technical performance requirements;

c. Performing technical evaluation as required;

d. Performing technical inspections and assisting the Contracting Officer in acceptances of deliverables required by this contract;

e. Assisting in the resolution of technical problems encountered during performance;

f. The Government may unilaterally change its COR designation(s).

ARTICLE G.3. CONTRACTOR'S POINTS OF CONTACT

The Offeror shall provide primary and secondary points of contact that will be available 24 hours per day, 7 days per week, to be notified in case of a public health emergency.

ARTICLE G.4. KEY PERSONNEL

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

The following individuals are considered to be essential to the work being performed hereunder:

Name	**Title**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

ARTICLE G.5. INVOICE SUBMISSION

a. The Contractor shall submit an electronic copy of contract monthly invoices/financial reports to the Contracting Officer as defined above, in SECTION G of this contract.

b. Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests made a part of the contract at Section J, Attachments 2 & 3.

c. Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

d. The Contractor agrees to immediately notify the Contracting Officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the estimated costs for the base period or any options (See estimated costs under Articles B.2 and B.3) and the reasons for the variance. Also refer to the requirements of FAR Clause 52.232-20, Limitation of Cost.

e. The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed below in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

f. All invoice submissions shall be in accordance with FAR Clause 52.232-25, Prompt Payment (Alternate I for cost-reimbursement CLINs)

g. The Contractor may not invoice for any CLIN prior to delivery and acceptance of supplies or services except to the extent that this Contract otherwise permits the Contractor to invoice every thirty days under cost-reimbursement CLINs.

h. Invoices shall be delivered electronically to the Contracting Officer (CO), the Contracting Officer's Representative (COR), PSC, and e-Room electronically. Unless otherwise specified by the Contracting Officer, all deliverables, invoices, and reports furnished to the Government under the resultant contract shall be addressed as follows:

[***] Officer HHS/ASPR/BARDA 200 C Street, S.W. O'Neill House Office Building Washington, DC 20515 [***]	[***] Contracting Officer Representative HHS/ASPR/BARDA 200 C Street, S.W. O'Neill House Office Building Washington, DC 20515 [***]	[***]

ARTICLE G.6. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (DECEMBER 2013)

a. Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

b. The acceleration of payments under this clause does not provide any new rights under the Prompt Payment Act.

c. Include the substance of this clause; include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

ARTICLE G.7. CONTRACT COMMUNICATIONS/CORRESPONDENCE

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting the contract number 75A50120C00001 from Page 1 of the contract.

ARTICLE G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) will be prepared annually as to coincide with the Anniversary date of the contract.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

2. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure website for review and comment at the following:

http://cpars.gov

ARTICLE G.9. REIMBURSEMENT OF COST

The Government shall reimburse the Contractor those costs determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with FAR 52.216-7, Allowable Cost and Payment and FAR Subpart 31.2.

ARTICLE G.10. GOVERNMENT PROPERTY

1. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, "Contractor's Guide for Control of Government Property," which is incorporated into this contract by reference. This document can be accessed at:

   http://www.hhs.gov/hhsmanuals/ (HHS Logistics Management Manual)

   Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

2. Notwithstanding the provisions outlined in the HHS Publication, "Contractor's Guide for Control of Government Property," which is incorporated in this contract in paragraph 1. above, the Contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee. This form is included as an attachment in SECTION J of this contract.

3. Title will vest in the Government for equipment purchased as a direct cost.

ARTICLE G.11. INDIRECT COST RATES

The following provisional indirect rates will be utilized for billing purposes during the period of performance:

Overhead: [***]

Fringe: [***]

Final indirect rates will be established annually through an internal auditor.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

The Contractor is responsible for following the requirements below in conducting its own work under this Contract. The Contractor also is responsible for incorporating these provisions into any subcontract awarded, if applicable to the specific nature of the work in the subcontract. Accordingly, those provisions shall be flowed-down as applicable.

ARTICLE H.1. PROTECTION OF HUMAN SUBJECTS

a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in accordance with the protocol(s) approved by either the IRB or IEC. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

c. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP website at: http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf).

d. If at any time during the performance of this contract, the Contracting Officer determines, in consultation with OHRP that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part, and the Contractor's

name may be removed from the list of those Contractors with approved Human Subject Assurances.

ARTICLE H.2. CLINICAL RESEARCH

These Clinical Terms apply to all grants and contracts that involve clinical research.

The Government shall have unlimited rights to all protocols, data generated from the execution of these protocols, and final reports, funded by the Government under this contract, as defined in Rights in Data Clause in FAR 52.227-14, Alternate II. The Government reserves the right to request that the Contractor provide any contract deliverable in a non-redacted form, to ensure the Government has the ability to review and distribute the deliverables, as the Government deems necessary.

H.2.1 Safety and Monitoring Issues

Institutional Review Board (IRB) or Independent Ethics Committee (IEC) Approval

Before award and then with Annual Progress Reports, the Contractor shall submit to the Government a copy of the current IRB or IEC approved informed consent document, documentation of continuing review and approval and the Office of Human Research Protections (OHRP) FWA number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each institution's IRB or IEC must review and approve the protocol. They must also provide the Government initial and annual documentation of continuing review and approval, including the current approved informed consent document and FWA number.

The grantee institution must ensure that the applications as well as all protocols are reviewed by their IRB or IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide the Government a summary explanation and copies of documents related to all major changes in the status of ongoing protocols, including the following:

1. All amendments or changes to the protocol, identified by protocol version number, date, or both and date it is valid.
2. All changes in informed consent documents, identified by version number, date, or both and dates it is valid.
3. Termination or temporary suspension of patient accrual.
4. Termination or temporary suspension of the protocol.
5. Any change in IRB approval.
6. Any other problems or issues that could affect the participants in the studies.

Contractors must notify BARDA through the Contracting Officer's Representative (COR) and Contracting Officer (CO) of any of the above changes within 24 hours by email, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an Institutional Bio-safety Committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

H.2.2. Data and Safety Monitoring Requirements

The Contractor may be required to conduct independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trials of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must have an assigned independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. Consistent with other audit provisions in this contract, the Contractor shall inform the Government of any upcoming site visits and/or audits of Contractor facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of Contractors and Subcontractors as the Government deems necessary.

The type of monitoring to be used shall be mutually agreed upon between the Contractor and the Government before enrollment starts. Discussions with the responsible COR regarding appropriate safety monitoring and approval of the final monitoring plan by the COR must occur before patient enrollment begins and may include discussions about the appointment of one of the following:

1. **Independent Safety Monitor** – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.

2. **Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC)** – a small group of independent investigators and biostatisticians who review data from a particular study.

3. **Data and Safety Monitoring Board** – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may be required to use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) for Oversight of Clinical Trials Policy. The Government retains the right to place a nonvoting member on the DSMB.

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and

roster and *curriculum vitae* from all members must be submitted to and approved by the Government before enrollment starts.

Additionally, the Contractor must submit written blinded summaries of all reviews conducted by the monitoring group to the Government within 30 days of reviews or meetings.

H.2.3. BARDA Protocol Review Process Before Patient Enrollment Begins

BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must provide the following (as applicable) for review and approval by the Government:

4. IRB or IEC approved clinical research protocol identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria;

5. Documentation of IRB or IEC approval, including OHRP FWA number, IRB or IEC registration number, and IRB or IEC name;

6. IRB or IEC approved informed consent document, identified by version number, date, or both and date it is valid;

7. Plans for the management of side effects;

8. Procedures for assessing and reporting adverse events;

9. Plans for data and safety monitoring (see B above) and monitoring of the clinical study site, pharmacy, and laboratory;

10. Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received Good Clinical Practice (GCP) training in the protection of human subjects.

BARDA comments will be forwarded to the Contractor within two weeks (10 business days) of receipt of the above information. The Contractor must address in writing all study design, safety, regulatory, ethical, and conflict of interest concerns raised by the COR to the satisfaction of the Government before patient accrual or participant enrollment can begin. After the Government receives the corrected documentation, a written Contracting Officer Authorization (COA) letter may be provided to the Contractor. This COA provides authorization to the Contractor to execute the specific clinical study funded in part or in whole by the Government.

Documentation of IRB approval, including OHRP FWA number, IRB registration number, and IRB and name, must be provided to the COR within 24 hours of receipt by the Contractor.

H.2.4. Required Time-Sensitive Notification

Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit copies to the responsible Contracting Officer's representative (COR) as follows:

1. *Expedited safety report of unexpected or life-threatening experience or death* – A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven days after the IND sponsor's receipt of the information, must be submitted to the CO and the COR within 24 hours of FDA notification.

2. *Expedited safety reports of serious and unexpected adverse experiences* – A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 calendar days after the IND sponsor's receipt of the information, must be submitted to the Contracting Officer's Representative within 24 hours of FDA notification.

3. *IDE reports of unanticipated adverse device effect* – A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to the Contracting Officer's Representative within 24 hours of FDA notification.

4. *Expedited safety reports* – shall be sent to the COR concurrently with the report to FDA.

5. Other adverse events documented during the course of the trial shall be included in the annual IND or IDE report and reported to the BARDA annually.

In case of problems or issues, the COR will contact the Contractor within 10 working days by email, followed within 7 calendar days by an official letter to the Contractor. The Contractor shall forward the official letter to the principal investigator listing issues and appropriate actions to be discussed.

Safety reporting for research not performed under an IND or IDE.

Ongoing safety reporting requirements for research not performed under an IND or IDE shall be mutually agreed upon by the Contracting Officer's Representative and the Contractor.

ARTICLE H.3. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.4. NEEDLE EXCHANGE

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

ARTICLE H.5. ACKNOWLEDGEMENT OF FEDERAL FUNDING

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.6. RESTRICTIONS ON ABORTIONS

The Contractor shall not use funds for any abortion.

ARTICLE H.7. GUN CONTROL

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

ARTICLE H.8. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

The Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term “human embryo or embryos” includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with the March 4, 1997 Presidential Memorandum entitled “Prohibition on Federal Funding for Cloning of Human Beings”, federal funds may not be used for cloning of human beings.

ARTICLE H.9. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

ARTICLE H.10. CARE OF LIVE VERTEBRATE ANIMALS

a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United Sates Department of Agriculture (USDA), the

Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under **7 U.S.C. 2133** and **9 CFR 2.1 through 2.11**, or from a source that is exempt from licensing under those sections.

c. The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see **7 U.S.C. 2131** et seq. and **9 CFR subchapter A, Parts 1-4**). In case of conflict between standards, the more stringent standard shall govern.

d. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with Animal Welfare Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (Email: ace@aphis.usda.gov ; Web site: (http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare).

ARTICLE H.11. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: http://grants1.nih.gov/grants/olaw/references/phspol.htm

ARTICLE H.12. PAPERWORK REDUCTION ACT

a. This contract involves a requirement to collect or record information calling either for answers to identical questions from 10 or more persons other than Federal employees, or information from Federal employees which is outside the scope of their employment, for

use by the Federal government or disclosure to third parties; therefore, the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) shall apply to this contract. No plan, questionnaire, interview guide or other similar device for collecting information (whether repetitive or single time) may be used without the Office of Management and Budget (OMB) first providing clearance. Contractors and the Contracting Officer's Representative shall be guided by the provisions of 5 CFR part 1320, Controlling Paperwork Burdens on the Public, and seek the advice of the HHS operating division or Office of the Secretary Reports Clearance Officer to determine the procedures for acquiring OMB clearance.

b. The Contractor shall not expend any funds or begin any data collection until the Contracting Officer provides the Contractor with written notification authorizing the expenditure of funds and the collection of data. The Contractor shall allow at least 120 days for OMB clearance. The Contracting Officer will consider excessive delays caused by the Government which arise out of causes beyond the control and without the fault or negligence of the Contractor in accordance with the Excusable Delays or Default clause of this contract.

ARTICLE H.13. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

ARTICLE H.14. CERTIFICATION OF FILING AND PAYMENT OF TAXES

The Contractor must be in compliance with Section 518 of title V of division H of the Consolidated Appropriations Act of FY 2014.

ARTICLE H.15. CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ARTICLE H.16. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR CONFLICTS OF INTERESTS

The Institution (includes any Contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under BARDA contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: http://www.ecfr.gov/cgi- bin/textidx? c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51 &idno=45

As required by 45 CFR Part 94, the Institution shall, at a minimum:

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

    1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;

2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or

3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and

2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any BARDA funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.

c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the BARDA funded research.

d. Require that each Investigator who is planning to participate in the BARDA funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for BARDA funded research. Require that each Investigator who is participating in the BARDA funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to BARDA funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to BARDA funded research when the Institution, thorough its designated official(s), reasonably determines that the significant financial interest: Could be affected by the BARDA funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated

official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the BARDA funded research.

f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).

g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).

h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the BARDA funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the BARDA funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the BARDA funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

ARTICLE H.17. PUBLICATION AND PUBLICITY

The Contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. 75A50120C00001.

Press Releases:

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by non-Governmental sources.

ARTICLE H.18. REPORTING MATTERS INVOLVING FRAUD, WASTE, AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.19. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Offeror acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and Pub. L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Offeror to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

ARTICLE H.20. ACCESS TO DOCUMENTATION/DATA

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all data documenting Contractor performance, all data generated, all communications and correspondence with regulatory agencies and bodies to

include all audit observations, inspection reports, milestone completion documents, and all Contractor commitments and responses. The Contractor shall provide the Government with an electronic copy of all correspondence with the FDA relating to performance under this contract within 24 hours of receipt. The Government shall acquire unlimited rights to all data funded under any contract awarded in response to this RFP in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14, Alternate II.

ARTICLE H.21. IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (HHS). HHS reserves the right to review any other data determined by HHS to be relevant to this contract. The Contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

ARTICLE H.22. DISSEMINATION OF INFORMATION

No data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading or as may otherwise be required to comply with the public company disclosure requirements; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions or contractual obligations, or other business transactions.

ARTICLE H.23. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

ARTICLE H.24. PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM ASPR FUNDED RESEARCH

All ASPR-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, of any peer-reviewed scientific publications resulting from research supported in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response. ASPR defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and ASPR. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov .
Additional information is available at http://www.phe.gov/Preparedness/planning/science/Pages/AccessPlan.aspx

ARTICLE H.25. CONFLICT OF INTEREST

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR 2.101 and Subpart 9.5, or that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the Contracting Officer promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days. The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken. Remedies include termination of this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the Contracting Officer, the Government may terminate the contract for default, debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

ARTICLE H.26. IN-PROCESS REVIEW

In Process Reviews (IPR) will be conducted at the discretion of the Government to discuss the progression of the milestones. The Government reserves the right to revise the milestones and budget pending the development of the project. Deliverables may be required when the IPRs are conducted. The Contractor's success in completing the required tasks under each work segment must be demonstrated through the Deliverables and Milestones specified under SECTION F. Those deliverables will constitute the basis for the Government's decision, at its sole discretion, to proceed with the work segment, or unilaterally institute changes to the work segment, or terminate the work segment.

IPRs may be scheduled at the discretion of the Government to discuss progression of the contract. The Contractor shall provide a presentation following a prescribed template which will be provided by the Government at least 30 days prior to the IPR. The Contractor shall provide a draft presentation to the Contracting Officer at least 10 days prior to the IPR.

ARTICLE H.27. PRIVACY ACT APPLICABILITY

1. Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations, may be obtained at http://www.gpoaccess.gov/cfr/index.html

2. The Project Officer/COR is hereby designated as the official who is responsible for monitoring Contractor compliance with the Privacy Act.

3. The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200. This document may be obtained at the following link:
http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm

ARTICLE H.28. SECURITY REPORTING REQUIREMENT

Violations of established security protocols shall be reported to the CO and COR upon discovery within 24 hours of its receipt of any compromise, intrusion, loss or interference of its security processes and procedures. The Contractor shall ensure that all software components that are not required for the operation and maintenance of the database/control system has been removed and/or disabled. The Contractor shall provide to the CO and the COR information appropriate to Information and Information Technology software and service updates and/or workarounds to mitigate all vulnerabilities associated with the data and shall maintain the required level of system security.

The Contractor will investigate violations to determine the cause, extent, loss or compromise of sensitive program information, and corrective actions taken to prevent future violations. The CO in coordination with BARDA will determine the severity of the violation. Any contractual actions resulting from the violation will be determined by the CO.

ARTICLE H.29. [***]

PART II – CONTRACT CLAUSES

SECTION I – CONTRACT CLAUSES

FAR 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. FAR clauses incorporated into this contract apply to work performed under fixed-price and cost-reimbursement CLINs respectively based on the implementing instructions for each clause.

I.1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR Chapter 1) CLAUSES

Full text of the FAR clauses may be accessed electronically at:
https://www.acquisition.gov/far/index.html

Reg	Clause	Date	Clause Title
FAR	52.202-1	Nov 2013	Definitions
FAR	52.203-3	Apr 1984	Gratuities
FAR	52.203-5	May 2014	Covenant Against Contingent Fees
FAR	52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	May 2014	Anti-Kickback Procedures
FAR	52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Oct 2015	Contractor Code of Business Ethics and Conduct
FAR	52.203-14	Oct 2015	Display of Hotline Poster(s)
FAR	52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
FAR	52.203-19	Jan 2017	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
FAR	52.204-10	Oct 2018	Reporting Executive Compensation and First-Tier Subcontract Awards
FAR	52.204-13	Oct 2018	System for Award Management Maintenance
FAR	52.209-6	Oct 2015	Protecting the Government’s Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment

Reg	Clause	Date	Clause Title
FAR	52.209-9	Oct 2018	Updates of Publicly Available Information Regarding Responsibility Matters
FAR	52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
FAR	52.210-1	Apr 2011	Market Research
FAR	52.215-2	Oct 2010	Audit and Records – Negotiation
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-11	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data—Modifications.
FAR	52.215-13	Oct 2010	Subcontractor Certified Cost or Pricing Data—Modifications
FAR	52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data -Modifications
FAR	52.215-23	Oct 2009	Limitations on Pass-Through Charges
FAR	52.216-7	Aug 2018	Allowable Cost and Payment
FAR	52.216-8	Jun 2011	Fixed Fee
FAR	52.219-8	Oct 2018	Utilization of Small Business Concerns
FAR	52.219-28	July 2013	Post-Award Small Business Program Representation
FAR	52.222-1	Feb 1997	Notice to the Government of Labor Disputes
FAR	52.222-2	July 1990	Payment for Overtime Premiums
FAR	52.222-3	Jun2003	Convict Labor
FAR	52.222-21	Apr 2015	Prohibition of Segregated Facilities
FAR	52.222-26	Sept 2016	Equal Opportunity
FAR	52.222-29	Apr 2015	Notification of Visa Denial.
FAR	52.222-35	Oct 2015	Equal Opportunity for Veterans
FAR	52.222-36	Jul 2014	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Feb 2016	Employment Reports on Veterans
FAR	52.222-38	Feb 2016	Compliance with Veterans' Employment Reporting Requirements
FAR	52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-50	Jan 2019	Combating Trafficking in Persons

Reg	Clause	Date	Clause Title
FAR	52.222-54	Oct 2015	Employment Eligibility Verification
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-18	Aug 2011	Encouraging Contractor Policies to Ban Text Messaging While Driving
FAR	52.224-1	April 1984	Privacy Act Notification
FAR	52.224-2	April 1984	Privacy Act
FAR	52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
FAR	52.227-1	Dec 2007	Authorization and Consent, Alternate 1 (APR 1984)
FAR	52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-11	May 2014	Patent Rights – Ownership by the Contractor
FAR	52.227-14	May 2014	Rights in Data – General, Alternate II
FAR	52.227-16	June 1987	Additional Data Requirements
FAR	52.228-7	Mar 1996	Insurance – Liability to Third Persons
FAR	52.229-3	Feb 2013	Federal, State and Local Taxes
FAR	52.232-1	Apr 1984	Payments
FAR	52.232-2	Apr 1984	Payments under Fixed-Price Research and Development Contracts
FAR	52.232-8	Feb 2002	Discounts for Prompt Payment
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-11	Apr 1984	Extras
FAR	52.232-17	May 2014	Interest
FAR	52.232-18	Apr 1984	Availability of Funds
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-22	Apr 1984	Limitation of Funds
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jan 2017	Prompt Payment, Alternate I
FAR	52.232-33	Oct 2018	Payment by Electronic Funds Transfer--System for Award Management
FAR	52.232-40	Dec 2013	Providing Accelerated Payments to Small Business Subcontractors
FAR	52.233-1	May 2014	Disputes
FAR	52.233-3	Aug 1996	Protest After Award
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim

Reg	Clause	Date	Clause Title
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2014	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.243-1	Aug 1987	Changes - Fixed-Price Alternate V (Apr 1984).
FAR	52.243-2	Aug 1987	Changes—Cost-Reimbursement Alternate V (Apr 1984).
FAR	52.243-6	Apr 1984	Change Order Accounting.
FAR	52.243-7	Jan 2017	Notification of Changes
FAR	52.244-2	Oct 2010	Subcontracts, Alternate 1 (Jun 2007)
FAR	52.244-5	Dec 1996	Competition in Subcontracting
FAR	52.244-6	Jan 2019	Subcontracts for Commercial Items
FAR	52.245-1	Jan 2017	Government Property
FAR	52.245-9	Apr 2012	Use and Charges
FAR	52.246-23	Feb 1997	Limitation of Liability.
FAR	52.246-25	Feb 1997	Limitation of Liability—Services
FAR	52.248-1	Oct 2010	Value Engineering
FAR	52.249-2	Apr 2012	Termination for the Convenience of the Government (Fixed-Price)
FAR	52.249-6	May 2004	Termination (Cost-Reimbursement)
FAR	52.249-8	Apr 1984	Default (Fixed-Price Supply and Service)
FAR	52.249-9	Apr 1984	Default (Fixed-Price Research and Development)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms

I.2. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR Chapter 3) CLAUSES

Full text of the HHSAR clauses can be found at
https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html

HHSAR	352.203-70	Dec 2015	Anti-Lobbying
HHSAR	352.222-70	Dec 2015	Offeror Cooperation in Equal Employment Opportunity Investigations
HHSAR	352.223-70	Dec 2015	Safety and Health
HHSAR	352.224-70	Dec 2015	Privacy Act
HHSAR	352.233-71	Dec 2015	Litigation and Claims
HHSAR	352.270-6	Dec 2015	Restriction on use of Human Subjects

I.3. ADDITIONAL CONTRACT CLAUSES

I.3.1. Additional HHS Acquisition Regulation (HHSAR) Clauses – In Full Text

352.231-70 Salary rate limitation (Dec 2015)

(a) The Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date the funding was obligated

(b) For purposes of the salary rate limitation, the terms ‘‘direct salary,’’ ‘‘salary,’’ and ‘‘institutional base salary’’ have the same meaning and are collectively referred to as ‘‘direct salary’’ in this clause. An individual’s direct salary is the annual compensation that the Contractor pays for an individual’s direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative costs).

The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Department of Health and Human Services contract or order; it merely limits the portion of that salary that may be paid with federal funds.

(c) The salary rate limitation also applies to individuals under subcontracts.

(d) If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act used to fund this contract.

(e) See the salaries and wages pay tables on the U.S. Office of Personnel Management website for federal Executive Schedule salary levels.

(End of clause)

I.3.2. Additional Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clauses – In Full Text

52.217-7 Option for Increased Quantity -- Separately Priced Line Item (Mar 1989)

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

52.217-8 Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to

prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days.

52.217-9 Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 30 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed ten years.

PART III – ATTACHMENTS

SECTION J– LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

11. Statement of Work, dated December 18, 2019, 12 pages
12. Invoice/Financing Instructions for Cost-Reimbursement Type Contracts
13. Invoice Instructions for Fixed-Priced Type Contracts
14. Sample Invoice Form
15. Report of Government Owned, Contractor Held Property, 1 page
16. Form SF-LLL, Disclosure of Lobbying Activities, 2 pages
17. Paratek Intellectual Property, 20 Pages
18. VMI/SNS Requirements, 3 Pages

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K – REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

19. The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

20. Animal Welfare Assurance Numbers (Prime and Subcontractors).

21. Human Subjects Assurance Identification Numbers (Prime and Subcontractors).

The following FAR clause is incorporated by reference:
FAR 52.225-25 – Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran – Representation and Certifications (Aug 2018)

Statement of Work

PREAMBLE

Independently and not as an agency of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work submitted in response to the BARDA Request for Proposal (RFP) BARDA CBRN 19-100-SOL-00011.

The Government reserves the right to modify the milestones, progress, schedule, budget, or deliverables to add or delete deliverables, process, or schedules if the need arises. Because of the nature of this research and development (R&D) contract and the complexities inherent in this and prior programs, at designated milestones the Government will evaluate whether work should be redirected, removed, or whether schedule or budget adjustments should be made.

Overall Objectives and Scope

The overall objective of this contract is to procure an antibiotic that can be used under Emergency Use Authorization (EUA) pre-approval or marketing authorization for the treatment and/or post- exposure prophylaxis treatment of pulmonary anthrax. The Contractor will develop NUZYRA® for Animal Rule licensure, with the objective of making it suitable for stockpiling and use to treat infections with *B. anthracis*. Once suitable regulatory authorization has been achieved or under an applicable stockpiling authority, NUZYRA® will be purchased and delivered to the SNS stockpile or these supplies will become part of a VMI program managed by Paratek. Optional objectives cover activities to help secure the NUZYRA® supply chain, activities to support the commercial sustainability of NUZYRA® with the objective to ensuring continued supply, activities intended to expand the Animal Rule licenses of NUZYRA®, and further purchases for VMI managed by Paratek. The scope of work for this contract includes preclinical, clinical, manufacturing and procurement activities that fall into the following areas: nonclinical activities; clinical activities; manufacturing activities; procurement activities and all associated regulatory, quality assurance, management, and administrative activities. The Research and Development (R&D) efforts and procurement of NUZYRA® will progress in specific stages that cover the base performance (CLINs 1 and 2) segment and seven (7) option segments (CLINs 4 to 10) as specified in this contract. The Contractor must complete specific tasks required in each of the discrete work segments. The scope of work has been broken into the following phases which are discrete work segments:

22. CLIN 1: LATE STAGE DEVELOPMENT TO SUPPORT LICENSURE OF ANTIBIOTIC (ANTHRAX)
23. CLIN 2: INITIAL PURCHASE, STORAGE AND DELIVERY OF ANTIBIOTIC AS FINAL DRUG PRODUCT (FDP)
24. CLIN 3: Not Applicable - NUZYRA IS ALREADY FDA APPROVED FOR COMMUNITY ACQUIRED BACTERIAL PNEUMONIA AND ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS.
25. CLIN 4: SUPPLEMENTAL LATE STAGE DEVELOPMENT FOR ANTHRAX
26. CLIN 5: BARDA SECURITY REQUIREMENTS, [***]

27. CLIN 6: POST-MARKETING STUDY COMMITMENTS/ REQUIREMENTS FOR COMMERCIAL CABP AND ABSSSI INDICATIONS
28. [***]
29. CLIN 8: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)
30. CLIN 9: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)
31. CLIN 10: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)

1. CLIN 1: LATE STAGE DEVELOPMENT TO SUPPORT LICENSURE OF ANTIBIOTIC (ANTHRAX)

The Contractor will continue to develop of NUZYRA® for the treatment of pulmonary Anthrax with the objective of obtaining approval through the FDA Animal Rule.

[***]

2. CLIN 2: INITIAL PURCHASE, STORAGE AND DELIVERY OF ANTIBIOTIC AS FINAL DRUG PRODUCT (FDP)

The Contractor will supply 2,500 drug product treatment courses of NUZYRA®

[***]

3. CLIN 3: NOT APPLICABLE – NUZYRA IS ALREADY FDA APPROVED FOR COMMUNITY ACQUIRED BACTERIAL PNEUMONIA AND ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS.

4. CLIN 4: SUPPLEMENTAL LATE STAGE DEVELOPMENT FOR ANTHRAX

[***]

5. CLIN 5: BARDA SECURITY REQUIREMENTS, [***]

[***]

6. CLIN 6: POST-MARKETING STUDY COMMITMENTS/ REQUIREMENTS FOR COMMERCIAL CABP AND ABSSSI INDICATIONS

[***]

8. CLIN 8: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)

The Contractor shall store and maintain under the recommended storage conditions purchased NUZYRA® drug product inventory for the US Government in a VMI or deliver such inventory to the ASPR/SNS in the manner described in CLIN 2.

9. CLIN 9: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)

The Contractor shall store and maintain under the recommended storage conditions purchased NUZYRA® drug product inventory for the US Government in a VMI or deliver such inventory to the ASPR/SNS in the manner described in CLIN 2.

10. CLIN 10: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)

The Contractor shall store and maintain under the recommended storage conditions purchased NUZYRA® drug product inventory for the US Government in a VMI or deliver such inventory to the ASPR/SNS in the manner described in CLIN 2.

Timeline View of all CLINs provided in this SOW

[***]

WBS	Milestone	Deliverable	Success Criteria	Go/No-Go	Year/Qtr Achieved
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[***]	[***]	[***]	[***]	[***]	[***]
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	WBS	Milestone	Deliverable	Success Criteria	Go/No-Go	Year/Qtr Achieved
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ATTACHMENT #2

INVOICE/FINANCING REQUEST INSTRUCTIONS - FOR COST-REIMBURSEMENT TYPE CONTRACTS

Format: Payment requests shall be submitted on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

Number of Copies: Payment requests shall be submitted in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

Frequency: Payment requests shall not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks when authorized by the Contracting Officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by pre-contract cost provisions.

Billing of Costs Incurred: If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall site the amount(s) and month(s) in which it incurred such costs.

Contractor's Fiscal Year: Payment requests shall be prepared in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

Currency: All BARDA contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the Contracting Officer's approval, including those set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Contractor shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.

Invoice/Financing Request Identification: Each payment request shall be identified as either:

(a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice:** The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.

(c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request.

(a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(b) **Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. Provide the Contractor's Vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of contact, VIN, and DUNS).

(c) **Invoice/Financing Request Number:** Insert the appropriate serial number of the payment request.

(d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (if applicable).

(f) **Effective Date:** Insert the effective date of the contract or if billing under an order, the effective date of the order.

(g) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed- fee. For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

(h) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable) or the portion of the fixed-fee applicable to a particular invoice as defined in the contract.

(i) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three- way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.

(j) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(k) **Central Point of Distribution:** Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(l) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(m) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(n) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(o) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled “Costs Requiring Prior Approval” on page 1 of these instructions.

(1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract. List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by personnel, and amount claimed.

(2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.

(3) **Accountable Personal Property:** Include any property having a unit acquisition cost of $5,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS *Contractor’s Guide for Control of Government Property*)(e.g. personal computers). Note this is not permitted for reimbursement without pre-authorization from the CO.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. Include reference to the following (as applicable):

-Item number for the specific piece of equipment listed in the Property Schedule, and

-COA number, if the equipment is not covered by the Property Schedule.

The Contracting Officer may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

(4) **Materials and Supplies:** Include all consumable material and supplies regardless of amount. Detailed line-item breakdown (e.g. receipts, quotes, etc.) is required.

(5) **Premium Pay:** List remuneration in excess of the basic hourly rate.

(6) **Consultant Fee:** List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.

(7) **Travel:** Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) **Subcontract Costs:** List subcontractor(s) by name and amount billed. Provide subcontract invoices/receipts as backup documentation. If subcontract is of the cost-reimbursement variety, detailed breakdown will be required. Regardless, include backup documentation (e.g. subcontractor invoices, quotes, etc.).

(9) **Other:** Include all other direct costs not fitting into an aforementioned category. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(p) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed, if applicable.

(q) **Indirect Costs:** Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.

(r) **Fixed-Fee:** Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract.

(s) **Total Amounts Claimed:** Insert the total amounts claimed for the current and cumulative periods.

(t) **Adjustments:** Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(u) **Grand Totals**

(v) **Certification of Salary Rate Limitation:** If required by the contract (see Invoice Submission Instructions in Section G of the Contract Schedule), the C**ontractor shall include the following certification at the bottom of the payment request:**

"I hereby certify that the salaries billed in this payment request are in compliance with the Salary Rate Limitation Provisions in Section H of the contract."

**Note the Contracting Officer may require the Contractor to submit detailed support for costs claimed on payment requests. Every cost must be determined to be allocable, reasonable, and allowable per FAR Part 31.

ATTACHMENT #3

INVOICE/FINANCING REQUEST INSTRUCTIONS FOR FIXED PRICE TYPE CONTRACTS

General The Contractor shall submit vouchers or invoices as prescribed herein.

Format Standard Form l034, Public Voucher for Purchases and Services Other Than Personal, and Standard Form l035, Public Voucher for Purchases and Services Other than Personal--Continuation Sheet, and the payee's letterhead or self-designed form should be used to submit claims for reimbursement.

Number of Copies: As indicated in the contract.

Frequency Invoices submitted in accordance with the Payment Clause shall be submitted monthly upon delivery of goods or services unless otherwise authorized by the Contracting Officer.

Preparation and Itemization of the Invoice The invoice shall be prepared as follows:

(a) Designated Billing Office and address:

HHS/ASPR/BARDA
330 Independence Ave, Room G640
Washington DC 20201
ATTN: Contracting Officer

(b) Invoice Number

(c) Date of Invoice

(d) Contract number and date

(e) Payee's name and address. Show the Contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the Contractor, or a different payee has been designated, then insert the name and address of the payee instead of the Contractor.

(f) Description of goods or services, quantity, unit price, (where appropriate), and total amount.

(g) Charges for freight or express shipments other than F.O.B. destination. (If shipped by freight or express and charges are more than $25, attach prepaid bill.)

(h) Equipment - If there is a contract clause authorizing the purchase of any item of equipment, the final invoice must contain a statement indicating that no item of equipment was purchased or include a completed form HHS-565, Report of Capitalized Nonexpendable Equipment.

Currency: Where payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

ATTACHMENT #4 - SAMPLE INVOICE FORM

Company Name

Designated Billing Office Name and Address: DHHS/OS/ASPR/AMCG Attn: Contracting Officer 200 C St., S.W. Washington, D.C. 20201 **Contractor's Address and Contact Information:** POC: Name of accountant or COO or signatory authority for invoice Title: Phone: E-Mail: **TIN:** **DUNS #:**	**Invoice/Finance Number:** **Date Invoice Prepared:** **Contract No. and Title:** **Effective Date & Period of Performance:** **Total Estimated Cost of Order:** **Office of Acquisitions:** Contracting Officer (insert name here) Office of Acquisitions Management, Contracts, and Grants (AMCG) **Central Point of Distribution:**

This invoice represents reimbursable costs for the period from

Expenditure Category	Amount Billed		
	Current	Cumulative	Contract Value
Direct Costs:			
Direct Labor			
Fringe Benefits **0.00%**			
Total Labor Costs:			
Overhead 0.00%			
Travel			
Subcontracts			
Consultant Fees			
Materials and Supplies			
Other			
Total Direct Costs			

G&A Rate	**0.00%**			
Subtotal:				
Fixed Fee	**0.0%**			
Total Amount Claimed				
Adjustments				
Grand Total		**$ -**		

I certify that all payments requested are for appropriate purposes and in accordance with the contract.

Name/signature of signatory authority for invoicing

Attachment 5

REPORT OF GOVERNMENT OWNED, CONTRACTOR HELD PROPERTY							
CONTRACTOR:				**CONTRACT NUMBER:**			
ADDRESS:				**REPORT DATE:**			
ADDRESS1:							
ADDRESS2:				**FISCAL YEAR:**			
CITY:							
STATE:							
ZIP:							
CLASSIFICATION	**BEGINNING OF PERIOD**		**ADJUSTMENTS**			**END OF PERIOD**	
	#ITEMS	VALUE	GFP ADDED	CAP ADDED	DELETIONS	#ITEMS	VALUE
LAND >=$25K							
LAND <$25K							
OTHER REAL >=$25K							
OTHER REAL <$25K							
PROPERTY UNDER CONST >=$25K							
PROPERTY UNDER CONST <$25K							
PLANT EQUIP >=$25K							
PLANT EQUIP <$25K							
SPECIAL TOOLING >=$25K							
SPECIAL TOOLING <$25K							
SPECIAL TEST EQUIP >=$25K							
SPECIAL TEST EQUIP <$25K							
AGENCY PECULIAR >=$25K							
AGENCY PECULIAR <$25K							
MATERIAL >=$25K (CUMULATIVE)							
PROPERTY UNDER MFR >=$25K							
PROPERTY UNDER MFR <$25K							
SIGNED BY:							

SIGNATURE		DATE SIGNED:	
NAME PRINTED		Email	
TITLE		TELEPHONE	

Attachment 6

Approved by OMB
0348-0046

DISCLOSURE OF LOBBYING ACTIVITIES

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action: ☐ a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	2. Status of Federal Action: ☐ a. bid/offer/application b. initial award c. post-award	3. Report Type: a. initial filing b. material change For Material Change Only: year ____ quarter ____ date of last report ____

4. Name and Address of Reporting Entity: ☐ Prime ☐ Subawardee Tier ____, *if known :* Congressional District, *if known:*4c	5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime: Congressional District, *if known* :
6. Federal Department/Agency:	7. Federal Program Name/Description: CFDA Number, *if applicable :*
8. Federal Action Number, *if known :*	9. Award Amount, *if known :* $
10. a. Name and Address of Lobbying Registrant *(if individual, last name, first name, MI)*:	b. Individuals Performing Services *(including address if different from No. 10a)* *(last name, first name, MI)*:
11.Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.	Signature:_____ Print Name:_____ Title:_____ Telephone No.:_____ Date:_____

Federal Use Only:	Authorized for Local Reproduction Standard Form LLL (Rev. 7-97)

PRINT

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a follow-up report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, State and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks “Subawardee,” then enter the full name, address, city, State and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., “RFP-DE-90-001.”

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, State and zip code of the lobbying registrant under the Lobbying Disclosure Act of 1995 engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).

11. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Paratek Patent Applications and Issued Patents [***]

Attachment #7

[***]

ATTACHMENT #8

Contract requirements for DSNS Logistics Support

[***]

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED WITH [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

PARATEK®

PARATEK PHARMACEUTICALS
paratekpharma.com

75 Park Plaza
Boston, MA 02116
617.807.6600
617.275.0039 fax

December 19, 2019

Zai Lab (Shanghai Co., Ltd.)
1043 Halei Road, Building 8, Suite 502
Zhangjiang Hi-tech Park, Shanghai, PRC 201203
[***]

Cooley LLP
3175 Hanover Street
Palo Alto, CA 94304
[***]

Re: Notice of Assignment to Affiliate

We refer to the License and Collaboration Agreement (the "**Agreement**"), dated as of April 21, 2017, by and between Paratek Bermuda Ltd. a corporation organized and existing under the laws of Bermuda (the "**Paratek Bermuda**"), and Zai Lab (Shanghai) Co., Ltd., an exempted company organized and existing under the laws of P.R. of China ("**Zai**", and each, a "**Party**").

Pursuant to Section 16.2 of the Agreement, providing for assignment of the Agreement to either Party's Affiliate, as defined therein, we are notifying you that, effective as of December 18, 2019, Paratek Bermuda assigned to its parent and sole stockholder, Paratek Pharmaceuticals, Inc. (the "**Assignee**"), all of its rights, title, duties, obligations, interest and benefits in and to the Agreement and Assignee consented to such assignment.

All future correspondence, dealings, deliveries and payments in respect to the Agreement should be made to the Assignee whose details are as follows:

Paratek Pharmaceuticals, Inc.
75 Park Plaza, 4th Floor
Boston, MA 02116

[***]

We would appreciate if you could kindly acknowledge receipt of this notice by signing and returning the attached acknowledgement.

Signed /s/ William M. Haskel
Paratek Pharmaceuticals, Inc.

Signed /s/ William M. Haskel
Paratek Bermuda Ltd.

December 19, 2019

Paratek Pharmaceuticals, Inc.
75 Park Plaza, 4th Floor
Boston, MA 02116
[***]
Fax: 617-275-0039

Re: Acknowledgement Notice of Assignment

We acknowledge receipt of the Notice of Assignment from Paratek Bermuda Ltd. (the "**Assignor**") and Paratek Pharmaceuticals, Inc. (the "**Assignee**") dated December 18, 2019 (the "**Notice**") and confirm that following the assignment described in the Notice, the Assignee shall be entitled to all the Assignor's rights, title, interest and benefits in and to the License and Collaboration Agreement.

Signed /s/ James Yan
For and on behalf of Zai Lab (Shanghai) Co., Ltd.

Exhibit 21.1

Paratek Pharmaceuticals, Inc.

Subsidiaries

Paratek Bermuda Ltd.

Paratek Ireland Limited

Paratek Pharma, LLC

Paratek Royalty Corporation

Paratek Securities Corporation

Paratek UK Limited

Transcept Pharma, Inc.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 No. 333-221843) of Paratek Pharmaceuticals, Inc.,
(2) Registration Statement (Form S-8 No. 333-135506) pertaining to the Novacea, Inc. 2006 Incentive Award Plan,
(3) Registration Statement (Form S-8 No. 333-150869) pertaining to the Novacea, Inc. 2006 Incentive Award Plan,
(4) Registration Statement (Form S-8 Nos. 333-157927, 333-164468, 333-172041, 333-180517, 333-187254 and 333-194624) pertaining to the 2006 Incentive Award Plan of Transcept Pharmaceuticals, Inc.,
(5) Registration Statement (Form S-8 No. 333-160222) pertaining to the 2009 Employee Stock Purchase Plan of Transcept Pharmaceuticals, Inc.,
(6) Registration Statement (Form S-8 No. 333-201204) pertaining to the Paratek Pharmaceuticals, Inc. 2014 Equity Incentive Plan, as amended,
(7) Registration Statement (Form S-8 No. 333-205482) pertaining to the Paratek Pharmaceuticals, Inc. 2006 Incentive Award Plan, as amended and restated, the Paratek Pharmaceuticals, Inc. 2015 Equity Incentive Plan, and the Paratek Pharmaceuticals, Inc. 2015 Inducement Plan,
(8) Registration Statements (Form S-8 Nos. 333-210053, 333-217660, 333-224781, and 333-230097) pertaining to the Paratek Pharmaceuticals, Inc. 2015 Equity Incentive Plan,
(9) Registration Statement (Form S-8 Nos. 333-218847 and 333-228218) pertaining to the Paratek Pharmaceuticals, Inc. 2017 Inducement Plan, as amended, and
(10) Registration Statement (Form S-8 No. 333-226507) pertaining to the Paratek Pharmaceuticals, Inc. 2018 Employee Stock Purchase Plan;

of our reports dated March 10, 2020, with respect to the consolidated financial statements of Paratek Pharmaceuticals, Inc. and the effectiveness of internal control over financial reporting of Paratek Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Paratek Pharmaceuticals, Inc. for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 10, 2020

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Evan Loh, certify that:

1. I have reviewed this Annual Report on Form 10-K of Paratek Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) 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(s) 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/ EVAN LOH, M.D.

Evan Loh, M.D.
Chief Executive Officer
March 10, 2020

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sarah Higgins, certify that:

1. I have reviewed this Annual Report on Form 10-K of Paratek Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) 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(s) 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/ SARAH HIGGINS

Sarah Higgins
Principal Financial Officer
March 10, 2020

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Evan Loh, M.D., Chief Executive Officer of Paratek Pharmaceuticals, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the year ended December 31, 2019 (the "Annual Report"), to which this Certification is attached as Exhibit 32.1 fully complies with the requirements of Section 13(a) or Section 15(d), of the Exchange Act; and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations the Company.

In Witness Whereof, the undersigned has set his hand hereto as of the 10th day of March, 2020.

/s/ EVAN LOH, M.D.

Evan Loh, M.D.
Chief Executive Officer

This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Paratek Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Annual Report on Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Sarah Higgins, Principal Financial Officer of Paratek Pharmaceuticals, Inc. (the "Company"), hereby certifies that, to the best of her knowledge:

1. The Company's Annual Report on Form 10-K for the year ended December 31, 2019 (the "Annual Report"), to which this Certification is attached as Exhibit 32.2 fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned has set her hand hereto as of the 10th day of March, 2020.

/s/ SARAH HIGGINS

Sarah Higgins
Principal Financial Officer

This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Paratek Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Annual Report on Form 10-K), irrespective of any general incorporation language contained in such filing.