

**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, 2017**

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

**33-0960223**  
(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	Name of exchange on which registered
Common Stock, par value \$0.001 per share	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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 June 30, 2017, the last business day of the registrant's second fiscal quarter was: \$600,690,355.

As of February 28, 2018 there were 31,443,149 shares of the registrant's common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement for the registrant's 2018 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A within 120 days of the registrant's year ended December 31, 2017 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:

- 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 plans, strategies and objectives of management for future operations
- proposed new products or developments;
- future economic conditions or performance;
- the therapeutic and commercial potential of our product candidates;
- the timing of regulatory discussions and submissions, and the anticipated timing, scope and outcome of related regulatory actions or guidance;
- our ability to establish and maintain potential new collaborative, partnering or other strategic arrangements for the development and commercialization of our product candidates;
- the anticipated progress of our clinical programs, including whether our ongoing clinical trials will achieve clinically relevant results;
- our ability to obtain regulatory approvals of our product candidates and any related restrictions, limitations and/or warnings in the label of an approved product candidate;
- our ability to market, commercialize and achieve market acceptance for our product candidates, if approved;
- our ability to timely manufacture conforming products;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- 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 Pharmaceuticals, Inc. is our registered and unregistered trademark in the United States and other jurisdictions. Intermezzo is a registered and unregistered trademark of Purdue Pharmaceutical Products L.P. and associated companies in the United States and other jurisdictions and is a registered and unregistered trademark of ours in certain other jurisdictions. Other trademarks and trade names referred to in this Annual Report on Form 10-K are the property of their respective owners.

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 clinical stage biopharmaceutical company focused on the development and commercialization of innovative therapeutics based upon tetracycline chemistry. 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 two lead product candidates are the antibacterials omadacycline and sarecycline.

We have generated innovative small molecule therapeutic candidates based upon medicinal chemistry-based modifications, according to structure-based activity, of all positions of the core tetracycline molecule. These efforts have yielded molecules with broad-spectrum antibiotic properties and narrow-spectrum antibiotic properties, and molecules with potent anti-inflammatory properties to fit specific therapeutic applications. This proprietary chemistry platform has produced many compounds that have shown interesting characteristics in various *in vitro* and *in vivo* efficacy models. Omadacycline and sarecycline are examples of molecules that were synthesized from this chemistry discovery platform. The following table summarizes the primary therapeutic applications for our product candidates:



✓ Positive Efficacy Studies or NDA Filed

\* We have entered into a collaboration agreement with Zai Lab (Shanghai) Co., Ltd., for the greater China region

#### **Omadacycline**

If approved, omadacycline will be the first in a new class of aminomethylcycline antibiotics. Omadacycline is a broad-spectrum, well-tolerated once-daily oral and intravenous, or IV, antibiotic. We believe that omadacycline has the potential to become the primary antibiotic choice of physicians for use as a broad-spectrum monotherapy antibiotic for acute bacterial skin and skin structure infections, or ABSSSI, community-acquired bacterial pneumonia, or CABP, urinary tract infection, or UTI, and other serious community-acquired bacterial infections, where resistance is of concern. We believe omadacycline, if approved, will be used in the emergency room, hospital and community care settings. We have designed omadacycline 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.

In the fall of 2013, the U.S. Food and Drug Administration, or the FDA, agreed to the design of our omadacycline Phase 3 studies for ABSSSI and CABP through the Special Protocol Assessment, or SPA, process. In addition, the FDA confirmed that positive data from the individual studies for ABSSSI and CABP would be sufficient to support approval of omadacycline for each indication and for both oral and IV formulations in the United States. In addition to Qualified Infectious Disease Product, or QIDP, designation, on November 4, 2015, the FDA granted Fast Track designation for the development of omadacycline in ABSSSI, CABP, and complicated urinary tract infections, or complicated UTI. Fast Track designation facilitates the development, and expedites the review of drugs that treat serious or life-threatening conditions and that fill an unmet medical need. In February 2016, we reached agreement with the FDA on the terms of the omadacycline pediatric program associated with the Pediatric Research Equity Act, or

PREA. The FDA has granted Paratek a waiver for conducting studies with omadacycline in children less than eight years old due to the risk of teeth discoloration, a known class effect of tetracyclines. In addition, the FDA has granted a deferral on conducting studies in children eight years and older until safety and efficacy is established in adults. In May 2016, we received confirmation from the FDA that the oral-only ABSSSI study design was acceptable and consistent with the currently posted guidance for the industry. In September 2017, both the oral and IV formations of omadacycline were granted an additional QIDP designation by the FDA for the treatment of uncomplicated urinary tract infection, or uncomplicated UTI.

To date, we have conducted more than 20 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 and completed 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. We plan to include these clinical data in the Market Authorization Applications, or MAA, submission to the European Medicines Agency, or the EMA, which we plan to submit in the second half of 2018. We are working to schedule a date in the second quarter of 2018 to meet with our rapporteurs and the EMA as the last regulatory interaction step before the MAA filing.

Scientific advice received through the centralized procedure in Europe confirmed general agreement on the design and choice of comparators of the Phase 3 clinical program for ABSSSI and CABP and noted that approval based on a single study in each indication could be possible but would be subject to more stringent statistical standards than MAA programs that conduct two pivotal Phase 3 studies per indication. We believe that the inclusion of the second Phase 3 oral-only study in ABSSSI strengthens the data package for submission of an MAA filing for approval in European Union, or EU.

In February 2018, we completed our New Drug Application, or NDA, submissions to the FDA. The NDAs included all the data from the clinical program described above. We anticipate, based on our experience with the FDA, that the applications will be accepted in early April 2018. The FDA review process includes a 60-day evaluation to accept applications for filing. That acceptance will start the final review period of our applications and set the final Prescription Drug User Fee Act, or PDUFA, action date. Assuming a priority review designation, we expect our PDUFA action date to be set eight months from the completed submission, in early October 2018.

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 are 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. Funding support for the trial has been made available through the Defense Threat Reduction Agency, or DTRA/ Joint Science and Technology Office and Joint Program Executive Office for Chemical and Biological Defense / Joint Project Manager Medical Countermeasure Systems / BioDefense Therapeutics.

### ***Sarecycline***

Our second antibacterial product candidate, sarecycline, also known as Seysara™ in the U.S, is a new, once-daily, tetracycline-derived compound designed for use in the treatment of acne and rosacea. We believe that, based upon the data generated to-date, sarecycline possesses favorable anti-inflammatory activity, plus narrow-spectrum antibacterial activity relative to other tetracycline-derived molecules, oral bioavailability, does not cross the blood-brain barrier, and favorable pharmacokinetic properties that we believe make it particularly well-suited for the treatment of inflammatory acne in the community setting. We have exclusively licensed U.S. development and commercialization rights to sarecycline for the treatment of acne to Allergan plc, or Allergan, while retaining development and commercialization rights in the rest of the world.

In March 2017, Allergan announced that two Phase 3 studies of sarecycline for the treatment of moderate to severe acne vulgaris met their 12-week primary efficacy endpoints. In addition, a nine-month long-term safety extension study was completed. The safety results from the long-term study are generally consistent with results from the two 12-week studies. Based on these clinical data, Allergan submitted an NDA to the FDA, which was accepted in December 2017, for the treatment of moderate to severe acne. As a result, we earned a \$5.0 million milestone payment from Allergan under the terms of our collaboration for the development of Seysara™ for the treatment of moderate to severe acne, which became payable upon the FDA's acceptance of Allergan's NDA for Seysara™. We received the milestone payment in January 2018. Allergan plans to commercialize Seysara™ in the U.S. Paratek retains all ex-U.S. rights to sarecycline. We are anticipating the FDA's decision on approval of sarecycline in the second half of 2018.

Allergan currently also holds a non-exclusive license to develop and commercialize sarecycline for the treatment of rosacea in the United States. There are currently no clinical trials with sarecycline in rosacea underway.

## **Corporate History**

### ***Merger of Novacea, Inc. and Transcept Pharmaceuticals, Inc.***

We are a Delaware corporation that was incorporated in February 2001 as D-Novo Therapeutics, Inc., which later changed its corporate name to Novacea, Inc., or Novacea. Novacea previously traded on The Nasdaq Global Market under the ticker symbol “NOVC.” On January 30, 2009, Novacea completed a business combination with privately-held Transcept Pharmaceuticals, Inc., or Old Transcept, pursuant to which Old Transcept became a wholly-owned subsidiary of Novacea, and the corporate name of Novacea was changed to Transcept Pharmaceuticals, Inc., or Transcept. In connection with the closing of such transaction, Transcept common stock began trading on The Nasdaq Global Market under the ticker symbol “TSPT” on February 3, 2009.

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

On October 30, 2014, 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. Paratek estimates this could yield approximately \$2.6 billion in potential sales by 2028. 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. Paratek estimates this could yield approximately \$5.4 billion in potential sales by 2028. 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 *Chlamydomphila 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, if approved, 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, up to 40% in CABP and 70% to 90% in UTI.

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, UTI 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; for CABP, including levofloxacin, moxifloxacin, azithromycin, ceftriaxone, clarithromycin, ceftaroline and tigecycline; and for UTI, including levofloxacin, ciprofloxacin, and trimethoprim/sulfamethoxazole, 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*. The increasing occurrence of multi-drug resistant, ESBL-producing, gram-negative bacteria in community-acquired UTIs has severely curtailed the oral antibiotic treatment options available to physicians for these UTIs. For example, in a recent survey, 95% and 76% of the ESBL isolates of *Escherichia coli* found in UTIs, respectively, were resistant to ceftriaxone and levofloxacin.

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 Omadacycline as a Product Candidate

- *Equivalent Once-daily oral and IV formulations to support transition therapy.* We have studied once-daily IV and oral formulations of omadacycline in approximately 1,900 subjects to-date across multiple Phase 1, Phase 2 and Phase 3 clinical trials. The equivalent exposures of the IV and oral 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, CABP, UTI and other serious, community-acquired bacterial infections where resistance is of concern, if approved by the FDA.
- *Generally safe and well tolerated profile.* To date, we have observed omadacycline to be generally well tolerated in studies involving approximately 1,900 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. There have been observations of a transient, self-limited increase in heart rate, primarily in normal healthy volunteer subjects. These effects appear to be related to peak plasma concentration, or C<sub>max</sub>, and to a specific antagonist effect on the M2 subtype of the muscarinic receptor. These heart rate changes are not accompanied by changes in blood pressure, nor concurrent complaints of palpitations, shortness of breath nor chest pain. 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.

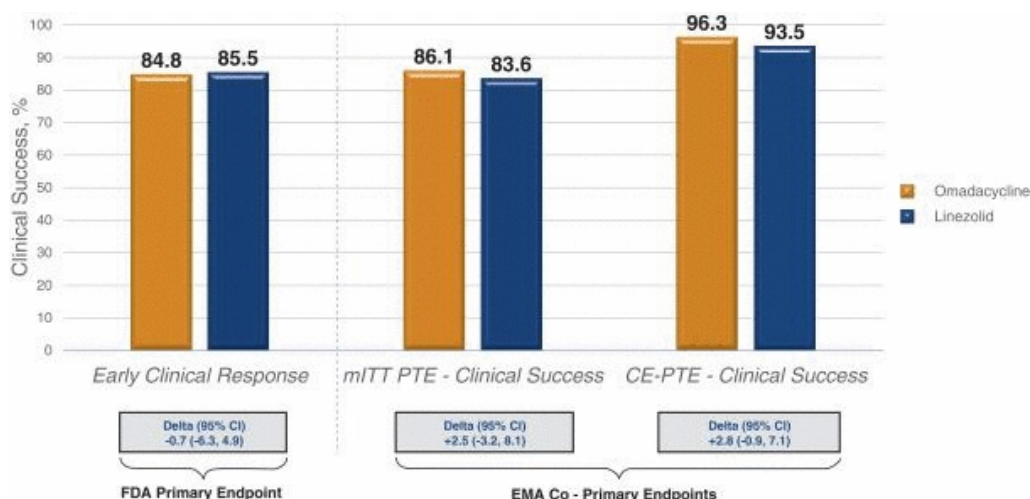


- Tissue Penetration** Omadacycline appears to penetrate tissues broadly, including lung, muscle, and kidney, thereby achieving high concentrations at the sites of infection. Since omadacycline is eliminated from the body (as unchanged parent compound) via the kidneys and intestine in an expected manner, 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. In addition, we have completed a proof-of-principle study in females with uncomplicated UTI, given the high percentage of renal elimination and urinary concentrations, omadacycline may have utility as a treatment option for patients with UTI infections.

**Completed Omadacycline Clinical Studies**

In the two pivotal Phase 3 studies in ABSSSI (OASIS-1 and OASIS-2), omadacycline successfully met the primary endpoint for the FDA by demonstrating statistical non-inferiority based upon the Early Clinical Response, or ECR, assessment at 48 to 72 hours after the first dose of study medication in the modified intent-to-treat, or mITT, population (all randomized subjects without a baseline sole gram-negative causative pathogen). In the same two pivotal Phase 3 studies in ABSSSI, omadacycline also successfully met the primary endpoint for the EMA by demonstrating statistical non-inferiority based upon the investigator’s assessment of clinical outcome at the post therapy evaluation, or PTE, visit (7 to 14 days after the subject’s last day of study therapy), in the mITT and the clinically evaluable, or CE, population (defined as all mITT subjects who received study medication, had a qualifying ABSSSI, an assessment of outcome, and met all other evaluability criteria). Clinical success at the PTE assessment was based on resolution of the infection such that further antibacterial therapy was not needed, and the subject was alive and did not meet any clinical failure or indeterminate criteria.

**Omadacycline OASIS-1 Study Results**

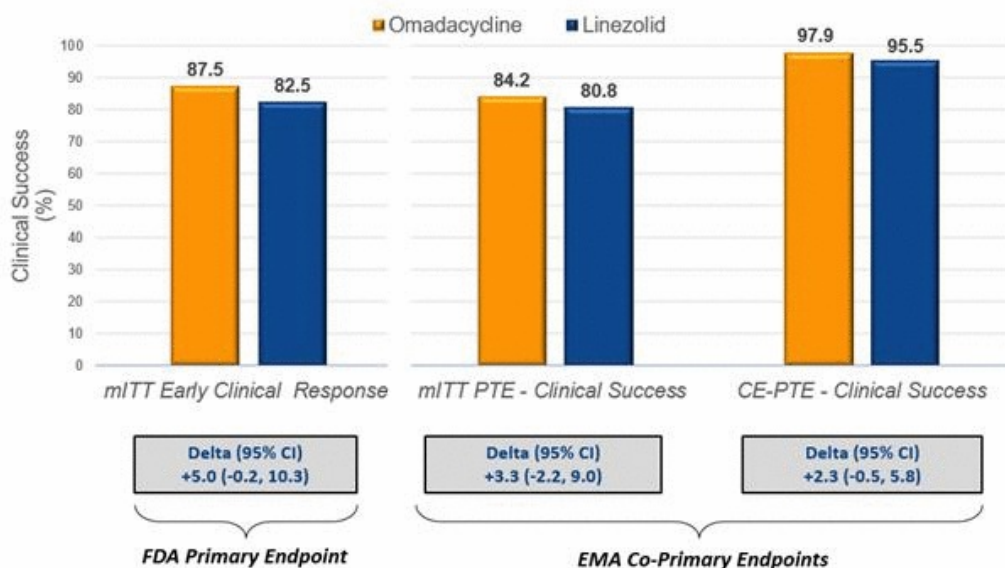


**Clinical Success at PTE by Baseline Pathogen (OASIS-1)**

Baseline Pathogen	Omadacycline (N=228)		Linezolid (N=227)	
	N1	Favorable Response n(%)	N1	Favorable Response n(%)
<i>Staphylococcus aureus</i>	156	130(83.3)	151	126(83.4)
MRSA	69	57(82.6)	50	43(86.0)
MSSA	88	74(84.1)	102	84(82.4)
<i>Streptococcus anginosus group</i>	47	36(76.6)	37	26(70.3)
<i>Streptococcus pyogenes</i>	11	8(72.7)	18	16(88.9)
<i>Enterococcus faecalis</i> (VSE)	10	9(90.0)	13	12(92.3)

- \* 10 or More Isolates for Omadacycline
- \* *S. anginosus* group consists of: *S. anginosus*, *S. intermedius*, and *S. constellatus*.  
MRSA, methicillin-resistant *Staphylococcus aureus*; MSSA, methicillin-susceptible *Staphylococcus aureus*; VSE, vancomycin-susceptible enterococci.

### Omada cycline OASIS-2 Study Results

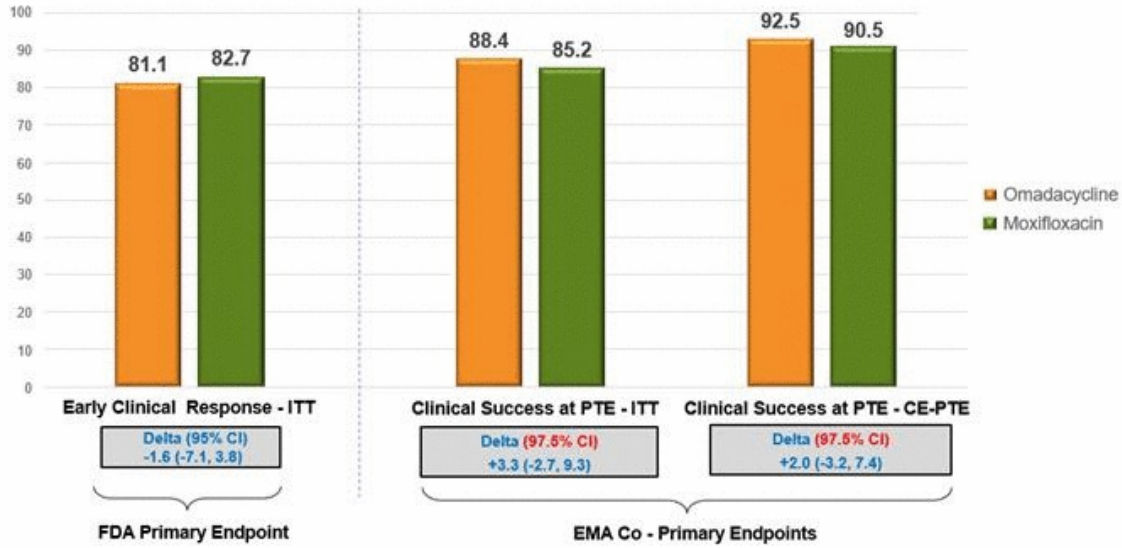


### Clinical Success at PTE by Baseline Pathogen (OASIS-2)

Baseline Pathogen	Omada cycline (n=276)		Linezolid (n=287)	
	N	Clinical Success n(%)	N	Clinical Success n(%)
<i>Staphylococcus aureus</i>	220	182(82.7)	233	186(79.8)
MRSA	104	89(85.6)	107	85(79.4)
MSSA	120	97(80.8)	130	103(79.2)
<i>Staphylococcus lugdunensis</i>	5	4(80.0)	0	0
<i>Streptococcus pyogenes</i>	29	20(69.0)	16	9(56.3)
<i>Streptococcus anginosus</i> group	57	49(86.0)	45	33(73.3)
<i>Streptococcus anginosus</i>	27	24(88.9)	20	16(80.0)
<i>Streptococcus intermedius</i>	23	18(78.3)	24	16(66.7)
<i>Streptococcus constellatus</i>	9	8(88.9)	7	5(71.4)
<i>Enterococcus faecalis</i>	8	8(100.0)	12	9(75.0)
VRE	0	0	2	2(100.0)
VSE	7	7(100.0)	10	7(70.0)

In a single pivotal Phase 3 study in CABP (OPTIC), omadacycline successfully met the primary endpoint for the FDA by demonstrating statistical non-inferiority based upon the ECR assessment at 72 to 120 hours after the first dose of study medication in the intent-to-treat, or ITT, population. In the same pivotal Phase 3 study in CABP, omadacycline also successfully met the primary endpoint for the EMA by demonstrating statistical non-inferiority based upon clinical success, as assessed by the investigator at the PTE visit in both the ITT and CE populations.

## Omadacycline OPTIC Study Results



### Clinical Success at PTE by Baseline Pathogen (OPTIC)

Baseline Pathogen	Omadacycline (N=204)		Moxifloxacin (N=182)	
	N	Clinical Success n(%)	N	Clinical Success n(%)
Atypical Pathogens	118	109(92.4)	106	97(91.5)
Mycoplasma pneumoniae	70	66(94.3)	57	50(87.7)
Chlamydomphila pneumoniae	28	25(89.3)	28	25(89.3)
Legionella pneumophila	37	35(94.6)	37	36(97.3)
Gram-Negative Bacteria (aerobes)	79	67(84.8)	68	55(80.9)
Haemophilus influenzae	32	26(81.3)	16	16(100.0)
Haemophilus parainfluenzae	18	15(83.3)	17	13(76.5)
Klebsiella pneumoniae	13	10(76.9)	13	11(84.6)
Gram-Positive Bacteria (aerobes)	61	52(85.2)	56	49(87.5)
Streptococcus pneumoniae	43	37(86.0)	34	31(91.2)
PSSP	26	23(88.5)	22	21(95.5)
Macrolide Resistant	10	10(100.0)	5	5(100.0)
Staphylococcus aureus	11	8(72.7)	11	9(81.8)

\* 10 or More Isolates for Omadacycline

Overall, omadacycline demonstrated a generally safe and well tolerated profile. The percentage of all subjects from the pivotal Phase 3 studies who had at least 1 Treatment Emergent Adverse Events, or TEAEs, was similar in the omadacycline, linezolid, and moxifloxacin subjects. Gastrointestinal events were the most frequent type of TEAEs across all pools, consistent with the known adverse effect profiles of the tetracycline, oxazolidinone, and fluoroquinolone antibiotic classes. A higher frequency of nausea and vomiting events occurred in the omadacycline group compared to the moxifloxacin and linezolid groups. This was most notable in oral-only OASIS-2 study where higher rates were noted with the loading dose on Days 1 and 2. The most common TEAEs not associated with the disease under study in subjects treated with omadacycline were nausea, vomiting, diarrhea, increased transaminases, and headache.

**Most Frequent Treatment Emergent Adverse Events (TEAEs) in the OASIS-1, OASIS-2 and OPTIC studies**

	Selected TEAEs Occurring in $\geq 2\%$ of Patients Receiving Omadacycline in the Pooled Phase 3 CABP and ABSSSI Clinical Trials		
	Omadacycline (N=1073)	Linezolid (N=689)	Moxifloxacin (N=388)
Nausea <sup>1</sup>	14.9	8.7	5.4
Vomiting <sup>1</sup>	8.3	3.9	1.5
Diarrhea <sup>2</sup>	2.4	2.9	8.0
Transaminase Elevations Increased	4.3	4.4	5.2
Headache	2.9	3.0	1.3

	Events of Nausea and Vomiting in Phase 3 CABP and ABSSSI Clinical Trials					
	CABP IV/Oral		ABSSSI IV/Oral		ABSSSI Oral-Only	
	IV	Oral	IV	Oral	Oral (D1 thru D2)	Oral (D3 thru EOT)
Nausea <sup>1</sup>	0.5	2.4	4.3	9.1	25.2	4.1
Vomiting	1.8	1.0	1.2	4.5	12.5	4.1

- Nearly all events of nausea and vomiting were mild or moderate in severity, resolved, and were not treatment limiting. Only 4 patients (0.4%) discontinued omadacycline treatment for nausea or vomiting.
- Diarrhea occurred in 2.4% of omadacycline patients and no cases of *C. Difficile* infection were reported in omadacycline patients.

***In Vitro* Microbiology Studies**

The tables below compare the *in vitro* activity of omadacycline and various antibiotics for ABSSSI, CABP and UTI pathogens against various strains of bacteria, including those resistant to current antibiotics.

*Key Pathogens—ABSSSI*

Organism (Number of Isolates)	MIC <sub>90</sub> (µg/ml)						
	Omadacycline	Ceftriaxone	Linezolid	Levofloxacin	Vancomycin	TMP-SMX <sup>(1)</sup>	Azithromycin
<i>Staphylococcus aureus</i> (MRSA) (942)	0.12	>8 <sup>(2)</sup>	1	>4	1	≤0.5	N/A
<i>Staphylococcus aureus</i> (MSSA) (1206)	0.12	4	1	4	1	≤0.5	N/A
<i>Streptococcus pyogenes</i> (286)	0.06	≤0.03	1	1	0.25	N/A	N/A

- Trimethoprim-sulfamethoxazole.
  - ">" indicates the highest concentration tested.
- "N/A" indicates that the antibiotic was not tested against this organism and/or has no useful therapeutic activity

*Key Anaerobe Pathogens—ABSSSI*

Organism (Number of Isolates)	MIC <sub>90</sub> (µg/ml)				
	Omadacycline	Cefotaxime	Metronidazole	Clindamycin	Amox-Clav
Anaerobic gram-positive cocci (101)	0.5	16	>64 <sup>(1)</sup>	8	16

- ">" indicates the highest concentration tested.

Key Typical Pathogens—CABP

Organism (Number of Isolates)	MIC <sub>90</sub> (µg/ml)						
	Omadacycline	Ceftriaxone	Linezolid	Levofloxacin	Vancomycin	Amox-Clav	Azithromycin
<i>Staphylococcus aureus</i> (MRSA) (942)	0.12	>8 <sup>(1)</sup>	1	>4 <sup>(1)</sup>	1	N/A	N/A
<i>Streptococcus pneumoniae</i> , PRSP (86)	0.12	2	1	1	0.25	>4 <sup>(1)</sup>	N/A
<i>Haemophilus influenzae</i> (2000)	1	≤0.06	N/A	≤0.12	N/A	2	2
<i>Moraxella catarrhalis</i> (639)	0.12	0.5	8	≤0.12	N/A	≤1	≤0.03

(1) “>” indicates the highest concentration tested.

“N/A” indicates that the antibiotic was not tested against this organism and/or has no useful therapeutic activity

Key Atypical Pathogens—CABP

Organism (Number of Isolates)	MIC <sub>90</sub> (µg/ml)						
	Omadacycline	Ceftriaxone	Linezolid	Moxifloxacin	Vancomycin	Amox-Clav	Azithromycin
<i>Legionella pneumophila</i> (90)	0.25	N/A	N/A	0.016 <sup>(1)</sup>	N/A	N/A	0.5

“N/A” indicates that the antibiotic was not tested against this organism and/or has no useful therapeutic activity.

(1) DuBois, J. et al. 2016. In vitro Bacterial and Intracellular Activity of Omadacycline Against *Legionella pneumophila*. 26th ECCMID. Poster P1323

Key Pathogens—UTI

Organism (Number of Isolates)	MIC <sub>90</sub> (µg/ml)						
	Omadacycline	Ceftriaxone	Linezolid	Levofloxacin	Vancomycin	Amox-clav	
<i>Escherichia coli</i> ESBL pos. (1152)	2	>8	N/A	>4	N/A	>8	
<i>Staphylococcus aureus</i> (MRSA) (942)	0.12	>8 <sup>(2)</sup>	1	>4	1	N/A	
CoNS, MR (843) <sup>(1)</sup>	1	>8	1	>4	2	>8	
<i>Enterococcus species</i> (897)	0.12	N/A	1	>4	>16	N/A	

(1) CoNS, MR: Coagulase-negative Staphylococcus species (not *Staphylococcus aureus*), methicillin resistant.

(2) “>” indicates the highest concentration tested.

“N/A” indicates that the antibiotic was not tested against this organism and/or has no useful therapeutic activity.

Ongoing Omadacycline UTI Program

We conducted a Phase 1b proof-of-principle study last year that provides the evidence to continue to explore the development of omadacycline in UTI. The Phase 1b study results are highlighted below.

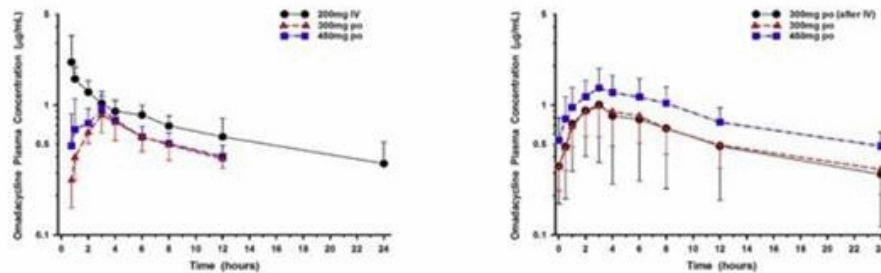
*Phase 1 Clinical Study to Evaluate the Safety and Pharmacokinetics of Omadacycline in Female Adults with Cystitis (uncomplicated UTI):*

*Study Design.* The primary objectives were to evaluate the urine and plasma concentrations of omadacycline. The secondary objectives were to evaluate the safety and efficacy of omadacycline in female adults with cystitis. This study was a randomized (1:1:1), open-label, parallel-designed Phase 1b study evaluating three dosing regimens of omadacycline in the treatment of female adults with cystitis. Following a Screening period of up to 48 hours, eligible subjects were randomly assigned to 1 of 3 groups and received dosing regimens of omadacycline. Dosing was as follows:

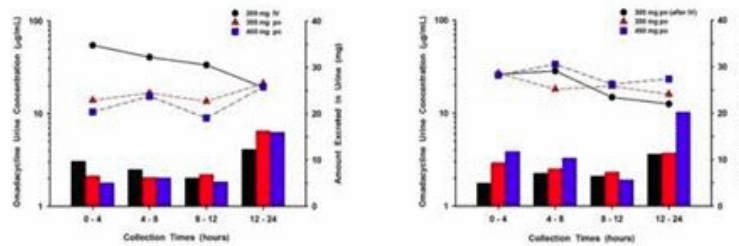
Dose Time	Study Day	Group 1 omadacycline IV Load, Oral Daily	Group 2 omadacycline Oral Load, Oral Daily	Group 3 omadacycline High oral Load, High oral Daily
t = 0 h	1	200 mg iv	300 mg po	450 mg po
t = 12 h	1	—	300 mg po	450 mg po
t = 24 h	2	300 mg po	300 mg po	450 mg po
t = 48 h	3	300 mg po	300 mg po	450 mg po
t = 72 h	4	300 mg po	300 mg po	450 mg po
t = 96 h	5	300 mg po	300 mg po	450 mg po

**Study Results.** Overall, 31 subjects (11 in Group 1 and 10 in each of Groups 2 and 3) were randomized and received the study drug at three study sites. All but one subject completed the intended five days of study treatment (1 subject in Group 1 withdrew consent). Subjects were females and they ranged in age from 19 to 75 years (mean 42 years overall). Plasma PK results on Day 1 showed the highest omadacycline exposure following the 200-mg IV dose in Group 1 (geometric mean AUC<sub>0-24</sub> 15557 h\*ng/mL). The Day 1 geometric mean AUC<sub>0-12</sub> value for Group 2 was 6152 h\*ng/mL (following the first 300 mg po dose) and, for Group 3, the value was 6686 h\*ng/mL (following the first 450 mg po dose). By Day 5 the geometric mean AUC<sub>0-24</sub> values for Groups 1 and 2 were 9555 h\*ng/mL and 12375 h\*ng/mL, respectively following 300 mg po doses, and for Group 3 the value was 18693 h\*ng/mL following the 450 mg po dose. At steady state (Day 5), the geometric mean cumulative amount of drug excreted in urine from time t<sub>0</sub> to t<sub>24</sub> (Ae<sub>0-24</sub>) values for Groups 1, 2, and 3 were 21.72 mg, 31.46 mg, and 43.60 mg, respectively. Relative to the absorbed amount of omadacycline, this corresponds to geometric mean fraction of the dose excreted unchanged in urine from 0 to 24 hours after dosing (Fe<sub>0-24</sub>) for Groups 1, 2, and 3 on Day 5 of 20.7%, 30.0%, and 27.7%, respectively. The highest mean omadacycline urine concentration value (65360 ng/mL [65.4 µg/mL]) was observed in Group 1 over 0 to 4 hours after the 200 mg IV dose on Day 1. The mean values across all other intervals/Groups ranged from 11699 to 48117 ng/mL (i.e., 11.7 to 48.1 µg/mL). The most common TEAEs in all groups were gastrointestinal, most notably nausea (60% to 73% per group) and vomiting (20% to 40% per group), all of which were of mild or moderate intensity. No subjects in the study discontinued study treatment because of these TEAEs. No subjects in this study experienced severe TEAEs or serious adverse events, leading to premature discontinuation of the study drug.

*Mean (± SD) Plasma Concentrations of Omadacycline Three Dose Levels on Days 1 (Left Panel) and 5 (Right Panel)*

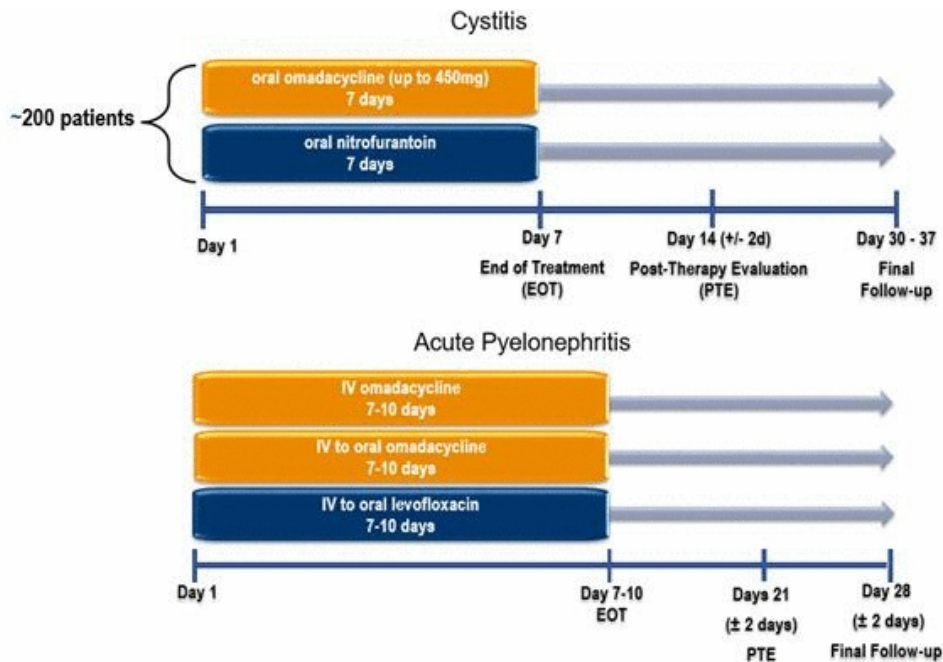


Mean ( $\pm$ SD) Urine Concentrations of Omadacycline Three Dose Levels on Days 1 (Left Panel) and 5 (Right Panel)



**Study Conclusions.** Omadacycline is partially excreted in urine in adult female subjects with cystitis. With the treatment regimens studied, observed urine concentrations of omadacycline compared favorably with minimum inhibitory concentration values for common UTI pathogens, and a high percentage of subjects achieved clinical success and favorable microbiological response. There was a higher than expected incidence of gastrointestinal, or GI, TEAEs (particularly nausea and vomiting), which contrasts with the notably lower rates of nausea and vomiting observed in other clinical studies using comparable dosing regimens. Omadacycline may be a useful treatment for certain UTIs and warrants evaluation in larger controlled studies, with continued close monitoring of GI tolerability.

Based on the above data results, in December 2017, we initiated sites for the first of two planned Phase 2 clinical studies evaluating omadacycline for the treatment of UTI. The first study will evaluate the efficacy, safety, tolerability and pharmacokinetics of omadacycline in female patients with cystitis, a common uncomplicated UTI. The second study, which we plan to initiate later this year, will evaluate the efficacy, safety, tolerability and pharmacokinetics of omadacycline in patients with acute pyelonephritis, a common complicated UTI. We plan to enroll approximately 200 patients in each study at multiple sites. The results of the Phase 2 UTI program are expected in the second half of 2019. The following illustration highlights the adaptive design we plan to employ in the cystitis and acute pyelonephritis studies.



## **Sarecycline**

Sarecycline, also known as Seysara™ in the U.S, is a novel, next generation, narrow spectrum tetracycline that we designed specifically for dermatological use. We exclusively licensed the U.S. rights to sarecycline for the treatment of acne to Allergan, who funds all U.S. development costs for this program. In exchange for license rights, we have the right to receive (i) milestone payments upon the achievement of development and regulatory progress; and (ii) a royalty on eventual net sales, if any. We retain development and commercialization rights outside of the United States, which are available for licensing to other partners in key international markets, such as the EU, Japan, the rest of Asia, Canada, and Latin America.

In March 2017, Allergan announced that two Phase 3 studies of sarecycline for the treatment of moderate to severe acne vulgaris met their 12-week primary efficacy endpoints. In addition, a 9-month long-term safety extension study was completed. The safety results from the long-term study are generally consistent with results from the two 12-week studies. Based on these clinical data, Allergan submitted an NDA to the FDA in the fourth quarter of 2017 for the treatment of moderate to severe acne. Development and regulatory milestones we have earned as a result of Allergan's progress include a \$4.0 million milestone payment for the initiation of the Phase 3 acne vulgaris clinical studies in December 2014 and a \$5.0 million milestone payment for acceptance by the FDA of Allergan's NDA for sarecycline in December 2017, with \$12.0 million remaining to be achieved.

We have also granted Allergan an exclusive license to develop and commercialize sarecycline for the treatment of rosacea in the United States, which converted to a non-exclusive license in December 2014 after Allergan did not exercise its development option with respect to rosacea. There are currently no clinical trials in rosacea underway.

## **Market**

Both acne and rosacea can be disfiguring conditions with significant social and medical costs. According to IMS sales data, over \$3.0 billion was spent on treatments for acne in 2013. In excess of \$1.3 billion was spent in 2011 on various oral formulations of doxycycline or minocycline to treat these conditions. Periostat, reformulated doxycycline, and Solodyn, reformulated minocycline, recorded peak sales of approximately \$300 million in 2012 and \$750 million in 2011, respectively. In November 2015, at an investor day conference, Allergan estimated peak U.S. revenue for sarecycline to potentially reach \$250 to \$300 million.

The most common oral treatments prescribed by dermatologists are generic tetracycline derivatives, which dermatologists widely accept as a therapy for moderate to severe acne. A common side effect associated with the use of any broad-spectrum antibacterial agent is gastrointestinal upset and antibiotic-associated infections caused by the destruction of the normal bacterial flora. In addition, we believe there is a growing concern and awareness of the development of antibiotic-resistant bacteria from the heavy use of broader-spectrum antibiotics, such as these older-generation tetracyclines, when broad-spectrum antibacterial therapy is not necessary.

Similarly, for patients with severe acne, we believe that oral retinoid drugs remain a leading option, but these drugs do carry potentially serious side effects. Therefore, we believe there is an unmet need for an improved narrow spectrum tetracycline.

## **Development**

In the treatment of acne, we believe a new product that targets a narrower spectrum of bacterial types, including *Propionibacterium acnes*, a key bacterium associated with acne, would offer advantages over the existing therapies, including older tetracycline derivatives. As compared to existing tetracyclines being used for the treatment of acne, preclinical studies suggest that sarecycline may have an improved profile that includes a narrow spectrum of antibacterial activity, oral bioavailability, anti-inflammatory activity, favorable GI tolerability, and favorable PK properties.

## **Omadacycline Commercialization Strategy**

Assuming approval from regulatory authorities, we currently intend to market omadacycline as an empiric monotherapy that will 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 United States 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.



If the FDA approves our NDA for omadacycline on the projected timeline, we anticipate a launch by the first quarter of 2019. In preparation for the commercial launch we are building out our sales and marketing infrastructure, including key hires in marketing, market access, medical affairs, sales management, and compliance. Recently we entered into an arrangement with a third party to provide a contract field sales force of between 80-85 sales representatives with associated training and other services. These representatives will call on approximately 850 hospitals. In addition, we plan on conducting research for pricing and adoption, as well as conduct payer reimbursement and trade discussions starting after acceptance of our NDAs.

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

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, if approved, to capture meaningful market share from our competitors.

If approved by the FDA, omadacycline will compete 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.; 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 Theravance, Inc.; ceftaroline, marketed as Teflaro by Allergan; and generic trimethoprim/sulfamethoxazole and clindamycin.

Further, we expect that product candidates currently in review with the FDA, or 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, delafloxacin for CABP, submitted for FDA review in October 2016 by Melinta Therapeutics, Inc.; CG-400549, under development by Crystal Genomics; GSK2140944, under development by GSK; nemonoxacin, under development by TaiGen Biotechnology; avarofloxacin, under development by Allergan; brilacidin, under development by Cellceutix; and radezolid, under development by Melinta Therapeutics, Inc.

If approved by the FDA, omadacycline will also compete 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. We are also aware of various drugs that are or may eventually be under development for the treatment of CABP, delafloxacin and radezolid, under development by Melinta Therapeutics; solithromycin, under development by Cempra, Inc.; GSK2140944, under development by GSK; lefamulin, under development by Nabriva Therapeutics; nemanoxacin, under development by TaiGen Biotechnology; and avarofloxacin, under development by Allergan.

A number of competitors exist in the UTI indication. Generic potential competitors include levofloxacin, ciprofloxacin, trimethoprim/sulfamethoxazole, ceftriaxone and amoxicillin/clavulanic acid. Several branded and generic injectable-only antibiotics are also used in hospitals, including imipenem/cilastatin, piperacillin/tazobactam, and gentamicin. A limited number of companies are developing new oral antibiotics for the treatment of UTI infections, finafloxacin by MerLion Pharmaceuticals and sulopenem by Iterum Therapeutics.

Many of our potential competitors have substantially greater financial, technical and human resources than we do, as well as greater experience in the 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 any product candidate we may commercialize and may render our 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 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 product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We generally develop the initial synthesis routes for our compounds and partner with third-party manufacturers to scale-up and develop these processes, analytical methods and formulations. Our product candidates have to date been organic compounds of low molecular weight, commonly referred to as small molecules. They are manufactured in synthetic processes from starting materials that have to date been generally available. We currently rely on a small number of third-party contract manufacturers for all of our required raw materials, drug substance and finished product for our preclinical research and clinical trials. We have entered into agreements with third-party contract manufacturers for the commercial production of those product candidates to ensure that commercial supply is available should those product candidates be approved.

For omadacycline, the manufacturing process has been refined to commercial scale. The active pharmaceutical ingredient manufacturing process is an efficient three-step synthesis followed by purification and salt formation. The starting material is minocycline, which is a well characterized generic active ingredient. We have produced stable IV and oral drug product formulations. In 2017, we completed three registration batches each for the IV and oral formulations of omadacycline, which have subsequently been put on stability testing. We have entered into commercial supply agreements with qualified commercial manufacturers, as described below, that also provided omadacycline for Phase 3 clinical use, and we intend to use these same manufacturers to complete process validation, which has now initiated, in support of potential market authorization filing, approval and launch.

### ***CIPAN***

In November 2016, we entered into a manufacturing and services agreement with CIPAN – Companhia Industrial Produtora de Antibióticos, or CIPAN. The agreement 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 as the active pharmaceutical ingredient. Under this agreement, we are obligated to pay a CIPAN Product price in the high three-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 an outsourcing agreement with CARBOGEN AMCIS AG, or Carbogen. The agreement provides for the terms and conditions under which Carbogen will manufacture and supply to us the active pharmaceutical ingredient for our omadacycline product 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 initially pay Carbogen an amount in the low 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 both parties are obligated to use diligent efforts to come to a subsequent long-term agreement to replace this agreement no later than the end of such initial term. If we have not executed a replacement agreement with Carbogen by such time, this agreement will automatically be extended for a fixed period of time. We may terminate this agreement by delivering notice of termination to Carbogen prior to the expiration of the initial or subsequent 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.

### ***Almac***

In December 2016, we 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 us omadacycline oral solid dosage tablets in bulk form, or the Almac Products. Under this 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 per batch of the Almac Products, subject to adjustments as provided in the agreement. 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.

Our agreement with Almac will remain in effect for a fixed initial term, after which the agreement will continue for successive renewal terms unless either we 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 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 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. If our omadacycline product is approved, we will also be subject to an annual minimum purchase requirement in the six-digit euro 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 \$60.1 million, \$83.5 million and \$50.8 million in 2017, 2016 and 2015, 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 United States 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 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, 2017, our patent portfolio of owned or exclusively licensed patents and applications includes 62 issued U.S. patents, 27 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 2037, excluding any additional terms from patent term adjustments or patent term extensions under the Hatch-Waxman Amendments.

### ***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 United States (U.S. Patent No. 7,553,828), if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, is expected to expire in 2023. We believe that an additional term of potentially up to five years for one of our omadacycline patents may result from the patent term extension provision of the Hatch-Waxman Amendments of 1984. Omadacycline has received 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 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 2037, excluding any additional terms from patent term adjustments or patent term extensions under the Hatch-Waxman Amendments.

### ***Sarecycline***

The patent portfolio for our acne and rosacea program is directed to cover compositions of matter, methods of use, as well as salts and polymorphs of sarecycline. As of December 31, 2017, 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 2031, and the '223 Patent is expected to expire in 2029, if the appropriate maintenance, renewal, annuity or other governmental fees are paid. We may also be entitled to an extension of the patent term for one of the patents covering sarecycline pursuant to the patent term extension provision of the Hatch-Waxman Amendments.

### ***Intermezzo***

As of December 31, 2017, our patent portfolio of owned or exclusively licensed patents and applications includes four issued U.S. patents, two pending U.S. patent applications and corresponding foreign national or regional counterpart patents and applications which are 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, and PARATEK POSITIVE PATIENT STORIES, 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. In connection with the ongoing development and advancement of our products and services in the United States 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.

### *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. Under the terms of the Zai Collaboration Agreement, Paratek Bermuda Ltd. 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 Bermuda Ltd.

Under the terms of the Zai Collaboration Agreement, Paratek Bermuda Ltd. earned an upfront cash payment of \$7.5 million, before taxes, and is eligible to receive up to \$14.0 million in potential regulatory milestone payments and \$40.5 million in potential commercial milestone payments, the next being \$5.0 million upon approval by the FDA of an NDA submission in the CABP indication. Zai will also pay Paratek Bermuda Ltd. 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.

### *Allergan plc*

In July 2007, we and Warner Chilcott Company, Inc. (now part of Allergan), entered into a collaborative research and license agreement, or the Allergan Collaboration Agreement, under which we granted Allergan an exclusive license to research, develop and commercialize tetracycline products for use in the United States for the treatment of acne and rosacea. 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 converted to a non-exclusive license for the treatment of rosacea as of December 2014. Under the terms of the Allergan Collaboration Agreement, we and Allergan 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 Allergan, 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. Allergan has agreed to reimburse us for its costs and expenses, including third-party costs, incurred in conducting any such development activities.

Under the terms of the Allergan Collaboration Agreement, Allergan 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. Allergan failed to elect to advance the development of sarecycline for the treatment of rosacea in accordance with the terms of the agreement so the license granted to Allergan was converted to a non-exclusive license for the treatment of rosacea as of December 2014. We have agreed during the term of the Allergan Collaboration Agreement not to directly or indirectly develop or commercialize any tetracycline compounds in the United States for the treatment of acne and rosacea, and Allergan has agreed during the term of the Allergan 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 agreement.

We earned an upfront fee in the amount of \$4.0 million upon the execution of the Allergan Collaboration Agreement, \$1.0 million upon filing of an Investigational New Drug Application, or IND, in 2010, and \$2.5 million upon initiation of Phase 2 trials in 2012. In December 2014, we also earned \$4.0 million upon initiation of Phase 3 trials associated with the Allergan Collaboration Agreement and, in December 2017, we earned a \$5.0 million payment for NDA acceptance by the FDA. In addition, Allergan may be required to pay us \$12.0 million upon the receipt of commercialization regulatory approval from the FDA. Allergan 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 Allergan Collaboration Agreement, with a standard royalty reduction post patent expiration for such product for the remainder of the royalty term. Allergan's obligation to pay us royalties for each tetracycline compound it commercializes under the Allergan Collaboration Agreement expires on the later of the expiration of the last to expire patent that covers the tetracycline compound in the United States and the date on which generic drugs that compete with the tetracycline compound reach a certain threshold market share in the United States.

Either we or Allergan may terminate the Allergan Collaboration Agreement for certain specified reasons at any time after Allergan has commenced development of any tetracycline compound, including if Allergan 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 Allergan may terminate the Allergan 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 Allergan Collaboration Agreement by Allergan for our breach, Allergan's license will continue following the effective date of termination, subject to the payment by Allergan 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 Allergan to pay us any further royalty or milestone payments will terminate. Upon the termination of the Allergan Collaboration Agreement by us for Allergan's breach or the voluntary termination of the agreement by Allergan, Allergan's license under the agreement 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 United States. 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. We paid a sublicense issue fee in the low six figures to Tufts during the year ended December 31, 2017 upon earning the \$7.5 million upfront payment under the Zai Collaboration Agreement.

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.

***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 grants an exclusive license to Purdue Pharma to commercialize Intermezzo in the United States and pursuant to which:

- Purdue Pharma paid us a \$25.0 million non-refundable license fee in August 2009;
- Purdue Pharma paid us a \$10.0 million non-refundable intellectual property milestone in December 2011 when the first of two issued formulation patents was listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book;
- Purdue Pharma paid us a \$10.0 million non-refundable intellectual property milestone in August 2012 when the first of two issued methods of use patents was listed in the FDA's Orange Book;
- We transferred the Intermezzo NDA to Purdue Pharma, and Purdue Pharma is obligated to assume the expense associated with maintaining the NDA and further development of Intermezzo in the United States, including any expense associated with post-approval studies;
- Purdue Pharma is obligated to commercialize Intermezzo in the United States at its expense using commercially reasonable efforts;
- Purdue Pharma is obligated to pay us tiered base royalties on net sales of Intermezzo in the United States ranging from the mid-teens up to the mid-20% level, with each such royalty tiers subject to an increase by a percentage in the low single digits upon a specified anniversary of regulatory approval of Intermezzo. The base royalty is tiered depending upon the achievement of certain fixed net sales thresholds by Purdue Pharma, which net sales levels reset each year for the purpose of calculating the royalty. The royalty tiers are subject to reductions upon generic entry and patent expiration. Purdue Pharma is obligated to pay royalties until the later of 15 years from the date of first commercial sale in the United States or the expiration of patent claims related to Intermezzo; and
- Purdue Pharma is obligated to pay us up to an additional \$70.0 million upon the achievement of certain net sales targets for Intermezzo in the United States.

We had an option to co-promote Intermezzo to psychiatrists in the United States and such option was terminated as a result of the Merger.

The Purdue Collaboration Agreement expires on the expiration of Purdue Pharma's royalty obligations. Purdue Pharma has the right to terminate the Purdue Collaboration Agreement at any time upon advance notice of 180 days. The Purdue Collaboration Agreement is also subject to termination by Purdue Pharma in the event of FDA or governmental action that materially impairs Purdue Pharma's ability to commercialize Intermezzo or the occurrence of a serious event with respect to the safety of Intermezzo. The Purdue Collaboration Agreement may also be terminated by us upon Purdue Pharma commencing an action that challenges the validity of Intermezzo related patents. We also have the right to terminate the Purdue Collaboration Agreement immediately if Purdue Pharma is excluded from participation in federal healthcare programs. The Purdue Collaboration Agreement may also be terminated by either party in the event of a material breach by or insolvency of the other party.

We also granted Purdue Pharma and an associated company the right to negotiate for the commercialization of Intermezzo in Mexico in 2013 but retained the rights to commercialize Intermezzo in the rest of the world.

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 fifty percent of all royalty income received by us 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.

### ***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 are 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. Funding support for the trial has been made available through the Defense Threat Reduction Agency, or DTRA/ Joint Science and Technology Office and Joint Program Executive Office for Chemical and Biological Defense / Joint Project Manager Medical Countermeasure Systems / BioDefense Therapeutics.

### **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 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, 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 \$3.6 million for the year ended December 31, 2017 and 2016 included within "Other Long-Term Liabilities" on our consolidated balance sheet. There are no other payment obligations to Novartis under the Novartis Agreement or the amended Novartis Letter Agreement.

### **Government Regulation**

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, packaging, promotion, storage, advertising, distribution, marketing and export and import of products such as those we are developing. Our drugs must be approved by the FDA through the NDA process before they may be legally marketed in the United States.

#### ***U.S. Government Regulation***

##### ***NDA Approval Processes***

In the United States, 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 United States 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 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. These points may be prior to submission of an IND, at the end of Phase 2 and before an NDA is submitted. Meetings at other times may 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 that they believe will support approval of the new drug. If this type of discussion occurred, a sponsor may be able to request an SPA agreement, the purpose of which is to reach agreement with the FDA on the design of the 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 provide information regarding 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 a request for additional information. An SPA agreement request must be made before the proposed clinical trial begins, and all open issues must be resolved before the 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 documented 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. An 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 PREA requires a sponsor to conduct pediatric studies for most drugs and biologic, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs, biologics license applications, or BLAs and supplements thereto must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or the FDA may request a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data needs to be collected before the pediatric studies begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or submit a request for approval of a pediatric formulation. On February 16, 2016 we reached agreement with the FDA on the terms of the pediatric program associated with PREA. The FDA has granted Paratek a waiver from conducting studies with omadacycline in children less than 8 years old and a deferral in conducting studies in children 8 years and older until safety and efficacy is established 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 an NDA requesting approval to market the product for one or more indications. The submission of an 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 an 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 treatment, prevention or diagnosis of disease 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 new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA 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 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. The FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval and 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 and fill an unmet medical need. Priority review is designed to give drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists, an expedited review within eight months from the completed submission as compared to a standard review time of twelve months from the completed submission 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 that are resistant to treatment, or that treat qualifying resistant 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 United States Congress has initiated a significant number of legislative proposals to provide further incentives in anti-infective development. Such legislation includes the following:

- The Antibiotic Development to Advance Patient Treatment Act of 2013, or ADAPT Act, was introduced in July 2014 to provide an accelerated antibiotic development pathway;
- The Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms Act of 2014, or DISARM Act, was introduced in January 2015 to provide a new antibiotics reimbursement framework; and
- The 21<sup>st</sup> 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.

### *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 patent covering 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. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the extension must be applied for prior to expiration of the patent and within applicable deadlines. The U.S. Patent and Trademark Office, or the USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restoration of patent term for omadacycline beyond its current composition of matter expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the omadacycline NDA.

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 United States 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 for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. 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 conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. 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.

### *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. If the Written Request does not include studies in neonates, the FDA is required to include its rationale for not requesting those studies. 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 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, and our product labeling, advertising, and promotion will be subject to continuing regulatory review. If approved, physicians nevertheless may prescribe our products to their patients in a manner that is inconsistent with the approved label or that is off-label. Positive clinical trial results for any approved products that are also subject to further review for additional indications increase the risk that the approved product may be used off-label. 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.

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. Furthermore, although we currently have no products approved for commercial sale, we may be subject to various federal and state laws pertaining to health care “fraud and abuse,” including anti-kickback laws and false claims laws if any of our product candidates may in the future receive regulatory and marketing approval. 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. 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 anti-kickback laws. 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 been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers with marketed products. The laws and regulations generally limit financial interactions between manufacturers and health care providers and/or require disclosure to the government of such interactions. Other laws may also affect the activities of pharmaceutical manufacturers, such as laws that protect the privacy and security of patient information. 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, any future activities (if we obtain approval and/or reimbursement from federal healthcare programs for our product candidates) could be subject to the penalty provisions of the pertinent laws and regulations.

## **Foreign Regulation**

In addition to regulations in the United States, 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.

## **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 extent to which our products will be covered by third-party payors, such as government or government-sponsored health programs, including Medicaid and Medicare Part B and Part D, private health insurers and managed healthcare organizations. The process for determining whether a third-party payor will provide coverage for a drug product typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that the payor will pay for the drug product once coverage is approved. 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 decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products once approved. Moreover, 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. As a result, the coverage determination process will require us to provide scientific, clinical support and healthcare pharmacoeconomic rationale for the use of our products to each payor and or healthcare system separately and will be a time-consuming process.

These third-party payors are increasingly reducing reimbursements for medical products and services. 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 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 product candidates or a decision by a third-party payor to not cover our product candidates could reduce physician usage of the product candidate 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. The report "Reforming Biopharmaceutical Pricing at Home and Abroad" issued by the White House in February 2018 identified a wide range of potential reforms to address the cost of drugs. 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 United States, if we obtain appropriate approval in the future to market any of our current therapeutic candidates, 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 price 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 United States and generally tend to be significantly lower.

### ***Health Care and Other Reform***

In the United States, 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 United States 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. The Trump administration may also take executive action in the absence of legislative action. For example, in October 2017, the President announced that his administration will withhold the cost-sharing subsidies paid to health insurance exchange plans serving low-income enrollees. Actions by the administration are widely expected to lead to fewer Americans having more comprehensive health insurance compliant with the Healthcare Reform Act, even in the absence of a legislative repeal. Tax reform legislation was also enacted at the end of 2017 that includes provisions that will affect healthcare insurance coverage and payment, such as the elimination of the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019 (the so-called "individual mandate"). In a November 2017 report, the Congressional Budget Office estimates that the elimination will increase the number of uninsured by 4 million in 2019 and 13 million in 2027. The Bipartisan Budget Act of 2018 contained various provisions that affect coverage and reimbursement of drugs, including an increase in 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.

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 2025 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 product candidates 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.

## **Employees**

As of February 28, 2018, we had 83 total employees, 82 of whom are full-time employees, 39 of whom were primarily engaged in research and development activities. A total of seven 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. The public may read and copy any of our filings at the SEC's Public Reference Room at 100 F Street N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Because we make filings with the SEC electronically, you may access this information at the SEC's Internet site: [www.sec.gov](http://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](http://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. We have no products approved for commercial sale, and to date we have not generated any revenue or profit from product sales. We may never achieve or sustain profitability.***

We are a clinical stage biopharmaceutical company and we have not generated any revenue or profit from product sales. We completed the submission of two NDAs to the FDA for our once-daily oral and IV formulations of omadacycline. In addition, our partner Allergan's NDA was accepted by the FDA for the treatment of moderate to severe acne in December 2017. We have not yet submitted any other product candidates for approval by regulatory authorities and we do not currently have rights to any significant products that have been approved for marketing in any territory. Our net loss for the year ended December 31, 2017 was \$89.1 million. As of December 31, 2017, our accumulated deficit was \$470.1 million. We expect to continue to incur losses for the foreseeable future as we continue our clinical development of, and seek regulatory approvals for, our product candidates, prepare to commercialize any approved products and add infrastructure and personnel to support our product development 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 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 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 revenues or achieve profitability. For example, our expenses could increase if we are required by the FDA, or other regulatory agencies outside the United States, to perform studies in addition to those that we currently expect to perform, or if there are any delays in completing our currently planned clinical trials or in the development of any of our product candidates.

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 for which we are only in the pre-registration, pre-clinical and clinical stages, including developing product candidates, obtaining regulatory approval for them and manufacturing, marketing and commercializing approved products. 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 will 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 operations.***

As of December 31, 2017, our cash, cash equivalents and marketable securities were \$151.7 million. We will require substantial additional funding to complete the commercialization of omadacycline, fund the development of omadacycline in other indications, and to continue to advance the development of our 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 existing capital resources as well as the \$50.0 million in proceeds from our January 2018 public offering of common stock, future contingent regulatory and commercial milestone payments from our collaborations with Allergan and Zai, anticipated extension of our interest-only period for the Hercules Term Loan as defined in Note 14, *Long-term Debt*, and estimated omadacycline product sales will enable us to fund our operating expenses and capital expenditure requirements into late 2019. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and to commercialize our product candidates.

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

- the progress of clinical development of omadacycline;
- the scope, progress, timing, cost and results of research, preclinical development and clinical trials;
- the costs, timing and outcome of seeking and obtaining 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 to hire additional management, scientific, operations and medical personnel;
- the effect of competing products that may limit market penetration of our product candidates;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing and success of our existing 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 these agreements.

Until we generate a sufficient amount of product 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 and strategic collaborations. 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 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 through the sale of equity or convertible debt securities, which would dilute shareholder ownership interest. Additionally, the terms of these new securities may include liquidation or other preferences that adversely affect shareholders' rights as common stockholders. 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, 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 product candidates that we would 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 September 30, 2015, we entered into a Loan and Security Agreement, or the Loan Agreement, 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). We executed three amendments to the Loan Agreement subsequent to September 30, 2015, providing access to term loans with an aggregate principal amount of up to \$60.0 million. As of December 31, 2017, we have drawn down on the full \$60.0 million available to us. The last amendment executed in June 2017 extended the date on which we are required to begin making monthly principal installments from January 1, 2019 to January 1, 2020, subject to our receipt of marketing approval for our lead product candidate, omadacycline, or the Interest Only Period Extension Event. Beginning on January 1, 2019, or, if we achieve the Interest Only Period Extension Event, beginning on January 1, 2020, we will make payments in equal monthly installments of principal and interest, with the balance of outstanding loans due on the original maturity date of the Loan Agreement, as amended.

All obligations under the Loan Agreement, as amended, 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 restrictive covenants in the Loan Agreement, as amended, could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and Hercules could seek to enforce its security interest in the assets securing such indebtedness.

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

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

Failure to satisfy our current and future debt obligations under the Loan Agreement, as amended, 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 Loan Agreement, as amended, 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 Loan Agreement, as amended, 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 Regulatory Review and Approval of Our Product Candidates**

***If we fail to obtain FDA approval of and to commercialize our most advanced product candidate, omadacycline, our business would be materially harmed.***

We have invested a significant portion of our time, financial resources and collaboration efforts in the development of our most advanced product candidate, omadacycline. Accordingly, our ability to generate revenue and our future success depend substantially on our ability to successfully obtain regulatory approval for and commercialize omadacycline. Except for our collaboration with Allergan for our product candidate, sarecycline, we are not currently developing any of the other product candidates in our portfolio. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. If we are unable to obtain FDA approval for and successfully commercialize omadacycline for ABSSSI, CABP or any other indication, or for any other product candidate, we may never realize product revenue. As a result, our business, financial condition and results of operations would be materially harmed.

***Although we obtained SPA agreements for our Phase 3 clinical trials of omadacycline, these SPA agreements do not guarantee any particular outcome from regulatory review of these trials of omadacycline.***

Although we had SPA agreements with the FDA with respect to our Phase 3 clinical trial designs for omadacycline in both ABSSSI and CABP, SPA agreements are not a guarantee of 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. Therefore, even if all the conditions of our SPA agreements appear to be met, we cannot predict whether the FDA will interpret the data and results in the same way that we do, nor whether the agency will ultimately approve omadacycline for the treatment of ABSSSI and/or CABP. In addition, the FDA is afforded the ability to modify and ignore a SPA agreement, in light of other factors not necessarily related to omadacycline.

***If clinical trials for our product candidate, omadacycline, are prolonged, delayed or stopped, we may be unable to obtain regulatory approval and commercialize omadacycline on a timely basis, which would require us to incur additional costs, raise additional capital and delay our receipt of any product revenue.***

We conducted and completed three Phase 3 clinical studies. We have initiated sites for the first of two planned Phase 2 clinical studies evaluating omadacycline for the treatment of UTI. The first study will evaluate the efficacy, safety, tolerability and pharmacokinetics of omadacycline in female patients with cystitis, a common uncomplicated UTI. The second study, which we intend to initiate in the second half of 2018, will evaluate the efficacy, safety, tolerability and pharmacokinetics of omadacycline in patients with acute pyelonephritis, a common complicated UTI. The completion of these planned clinical trials 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;
- changes in the regulatory guidance for development in ABSSSI and CABP by the FDA or other regulatory agencies regarding the scope or design of 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 IRB/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;
- the need to repeat or terminate clinical trials as a result of inconclusive or negative results or unforeseen complications during clinical trial testing;
- delay or failure to obtain sufficient supplies of the product candidate for our clinical trials; and
- delay or failure to obtain sufficient supplies of the comparator antibiotic for our clinical trials.

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. For example, in the Phase 2 clinical trials of omadacycline in UTI, patients who have previously taken potentially effective antibiotics for the treatment of an infection within 72 hours of receiving the first dose of study medication will be excluded from the clinical trial. Depending upon a region's or a clinical site's standard of care for the administration of antibiotics, this could affect our ability to enroll patients in these clinical trials in a timely fashion.

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/IRBs/ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial. For example, we stopped our previous Phase 3 clinical trial of omadacycline after the FDA notified us that its guidance relating to the conduct of studies in complicated skin and skin structure infections, or cSSSI, would be modified to change the eligibility criteria, revise the disease indication from cSSSI to ABSSSI and change the primary efficacy endpoint for clinical trials in this indication from a TOC assessment to an ECR assessment. As a result of these changes, we chose to terminate enrollment in the previous Phase 3 clinical trial and, following discussion with the FDA, designed two new Phase 3 clinical trials, one for ABSSSI and one for CABP, taking into account the revised FDA regulatory guidance. Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB 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.

Any failure or significant delay in completing clinical trials for our product candidates would adversely affect our ability to obtain regulatory approval and our commercial prospects and ability to generate product revenue will be diminished.

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

We currently have no products approved for sale, and we may not ever have marketable products. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any future partners may decide, or regulators may require us, to conduct additional clinical or preclinical testing which would delay submission of an 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 flaws in the design of a clinical trial may not become apparent until the clinical trial is underway, well advanced or completed. Further, if omadacycline, sarecycline or our other potential 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.

Results in our randomized Phase 2 and Phase 3 clinical studies of omadacycline in cSSSI, ABSSSI and CABP evaluated omadacycline in serious skin infections and pneumonia, and may not be predictive of the results to be obtained in our on-going Phase 2 clinical studies in any other indications such as UTI. 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 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 SPA 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 product candidates. If an unforeseen safety issue arises, the FDA always has the option to initiate a REMS or add additional warnings to the 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 in the United States or in other countries until we receive approval of an NDA from the FDA or marketing approval from applicable regulatory authorities outside the United States. Our primary product candidates, omadacycline and sarecycline, are still in development and are subject to the risks of failure inherent in drug development. Neither we nor our partners have received marketing approval for any of our product candidates. Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. In addition, 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;
- civil and criminal penalties;
- injunctions;

- suspension or withdrawal of regulatory approvals;
- 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 might not approve our third-party manufacturer's processes or facilities; 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 if we or our partners obtain regulatory approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our product candidates, which could materially impair our ability to generate revenue.***

Once regulatory approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and regulation. Any approved product may only be promoted for its approved uses. In addition, if the FDA and/or non-U.S. regulatory authorities approve any of our product candidates, among other things, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the product will be subject to extensive regulatory requirements. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMP 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 contract manufacturers will be subject to ongoing review and periodic inspections to assess compliance with cGMPs.

Accordingly, assuming regulatory approval for one or more of our product candidates, 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. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our products. We and our partners will also be 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. Accordingly, we will not be able to promote our products for indications or uses for which they are not approved. 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 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, we could be subject to significant penalties.

If we are not able to maintain regulatory compliance, we would likely not be permitted to manufacture and market any future product candidates and 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 product candidates may have undesirable side effects that may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, include safety warnings or otherwise limit their sales.***

Although our product candidates, omadacycline and sarecycline, have undergone or will undergo safety testing in humans and in laboratory animals, not all adverse effects of drugs can be predicted or anticipated from these preclinical safety and toxicology studies. Unforeseen side effects from either of our product candidates could arise either during clinical development or, if approved by regulatory authorities, after the approved product has been marketed. Each of omadacycline and sarecycline are still in clinical development, and our other product candidates, which are in the pre-clinical phase, are not currently being further developed. 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. Although, not tested statistically due to the typically small trial size for Phase 1 and Phase 2 trials, these clinical trials to date for omadacycline and sarecycline appear to have shown a favorable safety profile. The results from the Phase 3 registration clinical trials may not confirm these preliminary observations. The results of future clinical trials may show that our product candidates, including omadacycline and sarecycline, cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings or potential product liability claims. If any of our product candidates receive marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us or our partners to take our approved product off the market;
- we may be subject to litigation or product liability claims; 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.

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

Even if our product candidates are approved for sale by the appropriate regulatory authorities, market acceptance and sales of these products and our partners' products will depend on coverage and reimbursement policies. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish reimbursement levels. Coverage may not be available and reimbursement may not be adequate for any 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 any of our approved products.

The process for determining whether a third-party payor will provide coverage for a drug product typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that the payor will pay for the drug product once coverage is approved. 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. Third-party payors frequently require drug companies to negotiate agreements that provide discounts or rebates from list prices. We may be required to provide such discounts and rebates to some third-party payors in relation to our product(s). There is no guarantee that we would be able to negotiate agreements with third-party payors at price levels that are profitable to us, or at all. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products once approved. Moreover, 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 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. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process. Furthermore, some countries, other than the United States, have single-payer healthcare systems. In countries with such systems, a positive reimbursement determination is essential to the commercial viability of a drug product.

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

The United States 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 any of our future approved products profitably. Among policymakers and payors in the United States 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 United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of any products that we or our partners develop due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals.

The U.S. government and individual states have aggressively pursued healthcare reform, as evidenced by the passing 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. Other aspects of healthcare reform, such as expanded government enforcement authority and heightened standards that could increase compliance-related costs, could also affect our business. Modifications have been implemented under the Trump Administration and additional modifications or repeal may occur. 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.

Other legislative changes have been proposed and adopted in the United States since the Healthcare Reform Act was enacted. 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 2025 unless additional Congressional action is taken.

There is no assurance that federal or state health care 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.



***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 United States, several other types of state and federal healthcare laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. At such time, if ever, as we or any of our partners market any of our future approved products, some of our or our partner's business activities could possibly be subject to challenge under one or more of these laws. The laws 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 laws, 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;
- 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 product and medical device 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 physicians and teaching hospitals to the federal government for re-disclosure to the public; 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 health care 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. 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.

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.

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. 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.

Outside the United States, foreign laws may also regulate our activities, or those of our collaboration partners, in order to prevent fraud and abuse in the healthcare system

## Risks Related to Our Business

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

The life sciences industry is highly competitive and subject to rapid and significant technological change. We are currently developing products that, if approved, 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 United States 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 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 FDA approval or discovering, developing and commercializing antibiotics before we do so for any of our product candidates.

The GAIN Act is intended to provide incentives for the development of new QIDPs. 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.

If approved by the FDA, omadacycline will compete 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.; 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 Theravance, Inc.; ceftaroline, marketed as Teflaro by Allergan; and generic trimethoprim/sulfamethoxazole and clindamycin.

Further, we expect that product candidates currently in review with the FDA, or 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, delafloxacin for CABP, submitted for FDA review in October 2016 by Melinta Therapeutics, Inc.; CG-400549, under development by Crystal Genomics; GSK2140944, under development by GSK; nemonoxacin, under development by TaiGen Biotechnology; avarofloxacin, under development by Allergan; brilacidin, under development by Cellceutix; and radezolid, under development by Melinta Therapeutics, Inc.

If approved by the FDA, omadacycline will also compete 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. We are also aware of various drugs that are or may eventually be under development for the treatment of CABP, delafloxacin and radezolid, under development by Melinta Therapeutics; solithromycin, under development by Cempra, Inc.; GSK2140944, under development by GSK; lefamulin, under development by Nabriva Therapeutics; nemanoxacin, under development by TaiGen Biotechnology; and avarofloxacin, under development by Allergan.

A number of competitors exist in the UTI indication. Generic potential competitors include levofloxacin, ciprofloxacin, trimethoprim/sulfamethoxazole, ceftriaxone and amoxicillin/clavulanic acid. Several branded and generic injectable-only antibiotics are also used in hospitals, including imipenem/cilastatin, piperacillin/tazobactam, and gentamicin. A limited number of companies are developing new oral antibiotics for the treatment of UTI infections, finafloxacin by MerLion Pharmaceuticals and sulopenem by Iterum Therapeutics.

Many of our potential competitors have substantially greater financial, technical and human resources than we do, as well as greater experience in the 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 any product candidate we may commercialize and may render our 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 product candidates non-competitive or obsolete.

We and our partner, Allergan, will also face 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.

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 results of our registration clinical trials, in particular 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;
- the efficacy, safety and reliability of our and our partners' product candidates;
- our and our partners' ability to reliably manufacture any of our formulations;
- the speed at which we and our partners develop our product candidates;
- our and our partners' ability to commercialize and market, or find partners to help or exclusively commercialize and market, any of our product candidates that receive regulatory approval;
- our and our partners' ability to design and successfully execute appropriate 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;
- 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 our product candidates;
- our and our partners' ability to manufacture and sell commercial quantities at a reasonable cost of any approved products to the market; and
- acceptance of any approved products by physicians and other healthcare providers.

If our competitors market products that are more effective, safer or less expensive than, or that reach the market sooner than, our or any of our partners' future products, if any, we may not achieve commercial success. 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.

In addition, in the event that our or any of our partners' products receives regulatory approval, 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.

***We rely and will continue to rely on outsourcing arrangements for manufacturing of our product candidates. Reliance on third-party manufacturers could delay approval or commercialization of our products.***

We do not currently own or operate manufacturing facilities for the production of any of our product candidates, nor do we intend to manufacture the pharmaceutical products that we plan to sell. We currently depend on third-party contract manufacturers for the supply of the active pharmaceutical ingredients for our product candidates, including drug substance for our preclinical research and clinical trials. 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, and (iv) a manufacturing and services agreement with Patheon under which Patheon will manufacture, package and supply to us, omadacycline in injectable form. 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 omadacycline or any of our other product candidates. Additionally, we anticipate that the facilities used by any contract manufacturer to manufacture any of our 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, our product candidates will not be approved or, if already approved, may be subject to delays in release and/or product recalls. While third-party manufacturers of our product candidates, including omadacycline, have previously passed FDA and other regulatory agency inspections, we cannot provide assurance that they will pass such inspections in the future.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates itself, 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 we may not be able to secure a manufacturer 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 approval or commercialization of our products, cause us to incur higher costs or prevent us from commercializing our product candidates successfully. Furthermore, if any of our product candidates are approved and 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 for our product candidates and to have any such new source approved by the FDA or any other relevant regulatory authorities.

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

Once an NDA or marketing authorization application outside the United States 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 United States. 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 United States 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' product candidates, including omadacycline. 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 any sales of our products, if approved.

***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 have exclusively licensed rights to sarecycline for the treatment of acne in the United States to Allergan, and Allergan is responsible for all clinical development, registration and commercialization in the United States of sarecycline for the treatment of acne. In addition, we have granted Allergan an exclusive license to develop and commercialize sarecycline for the treatment of rosacea in the United States, which converted to a non-exclusive license in December 2014 after Allergan did not exercise its development option with respect to rosacea. There are currently no clinical trials in rosacea underway. 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 People's Republic of China, Hong Kong, Macau and Taiwan 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 Bermuda Ltd.

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 timelines for sarecycline and omadacycline would result in a potential loss of milestone payments and future royalties (if any) from the partnership under the Allergan Collaboration Agreement and the Zai Collaboration Agreement; and
- if the rights to sarecycline in the U.S. are returned to us by Allergan, 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. or omadacycline in the Zai Territory. There can be no assurance that we would be able to find such a partner.

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

We anticipate that we will require additional funding to support commercialization of omadacycline and to continue the development of any of our 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 for sarecycline in the United States and Zai for omadacycline in the People's Republic of China, Hong Kong, Macau and Taiwan.

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 the United States, 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 for the development of omadacycline.

***We currently have no sales or distribution infrastructure with respect to our product candidates. 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 our product candidates.***

While we recently entered into an arrangement with a third party to provide a contract field sales force, we currently have no sales or distribution capabilities within our organization. In anticipation of omadacycline's approval, we are in the process of establishing a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize omadacycline, or to outsource this function to a third party. Either of these options would be expensive and time consuming. Some or all of these costs may be incurred in advance of any approval of omadacycline. In addition, we may not be able to hire a sales force in the United States 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 internal sales, marketing and distribution capabilities would adversely impact the commercialization of omadacycline.

With respect to our existing and 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.

***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 Phase 2 studies in UTI. CROs may also assist us and our partners in the collection and analysis of data. 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 cGCP, 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 cGCP could adversely affect the clinical development of our product candidates and harm our business.

***Our success is currently dependent on the successful development and commercialization of our most advanced product candidates, omadacycline and sarecycline.***

Our success is currently dependent on the successful development and commercialization of our most advanced product candidate, omadacycline, which is also being developed by Zai in the People's Republic of China, Hong Kong, Macau and Taiwan, and sarecycline, which is currently being developed by Allergan. We are not currently developing any of our other product candidates that are in the pre-clinical phase. If omadacycline and sarecycline are not successfully developed and commercialized, we will not have any product candidates under development from which we might generate revenue. We currently have no such plans to develop any other product candidates and will need additional financing to fund such development should we decide to do so in the future.

***Even if approved, if omadacycline or sarecycline does 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 our product candidates will depend upon their acceptance among physicians, patients and the medical community. The degree of market acceptance of our product candidates will depend on a number of factors, including:

- limitations or warnings contained in a product candidate's FDA or foreign regulatory approved labeling;
- changes in the standard of care for the targeted indications for any of our product candidates;
- limitations in the approved clinical indications for our product candidates;
- 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 reimbursement for our product(s);
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness of our product candidates;
- availability of alternative therapies at similar or lower cost, including generics and over-the-counter products;
- the extent to which the product candidate 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;
- adverse publicity about our product candidates or favorable publicity about competitive products;

- convenience and ease of administration of our products; and
- potential product liability claims.

If our product candidates are approved, but 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 our product candidates may require significant resources and may never be successful

***Even if we obtain FDA approval of our current or any future product candidates, we or our partners may never obtain approval or commercialize our products outside of the United States, which would limit our ability to realize their full market potential.***

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding clinical trial design, safety and efficacy. 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. We and our partners do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we or our partners fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be harmed. Further, while we obtained SPA agreements with the FDA for our Phase 3 registration clinical trial designs for omadacycline in ABSSI and CABP, these agreements are not binding with any international regulatory authorities.

***Bacteria might develop resistance to any of our antibiotic product candidates, which would decrease the efficacy and commercial viability of those product candidates.***

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. Our product candidate omadacycline is being developed to treat patients infected with drug-resistant bacteria. If physicians, rightly or wrongly, associate the resistance issues of older generations of tetracyclines with omadacycline, physicians might not prescribe omadacycline for treating a broad range of infections. In addition, bacteria might develop resistance to omadacycline if such bacteria are improperly dosed or treated repeatedly with omadacycline over multiple years, causing the efficacy of omadacycline to decline, which would negatively affect our potential to generate revenue from omadacycline.

***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 development of omadacycline and other 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 product candidates.***

We face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. 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 future approved 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 any of our future approved products;
- injury to our reputation;
- 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 to commercialize our product candidates.

If any of our product candidates are approved for commercial sale, we will be 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. We may need to increase our insurance coverage when we begin the commercialization of our product candidates. 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 develop or commercialize our 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 and development and approval of our 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, our ability to raise additional capital and our ability to implement our business strategy.

***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, 2018, we had 82 full-time employees. Assuming our development and commercialization plans and strategies develop, 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 commercialize omadacycline and our other 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 the United States. 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 United States;
- 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.

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 Commonwealth of Massachusetts 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 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 biotechnology 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 United States. Because patent applications in the United States 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 United States 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.

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 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 United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries. Outside of the United States, patent protection must be sought in individual jurisdictions, further adding to the cost and uncertainty of obtaining adequate patent protection outside of the United States. Accordingly, additional patents protecting our technology may not issue in the United States 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 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 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 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 future approved products or impair our competitive position. Patents 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 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 requires 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 or 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 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 United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and 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 product candidates.

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.

***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 United States 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 omadacycline. 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.***

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, 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. 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

#### **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 clinical-stage 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:

- our ability to obtain regulatory approvals for omadacycline or other product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates, if approved, to achieve commercial success;
- issues in manufacturing our approved products, if any, or product candidates;
- the results of our current and any future clinical trials of our 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 potential 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.***

On May 14, 2014, we announced that our Board of Directors had approved a special cash dividend of \$15.96 per share. Cash was distributed for this dividend to our stockholders of record at the close of business on May 26, 2014. On October 14, 2014, we announced that our Board of Directors had approved a special dividend of \$8.01 per share. Cash was distributed for this dividend to our stockholders of record at the close of business on October 24, 2014.

Other than future special dividends of any royalty income we may receive pursuant to the Purdue Collaboration Agreement, 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 February 28, 2018, approximately 3.0 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 2.4 million shares of common stock that are subject to outstanding options and restricted stock units as of February 28, 2018 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, 2017, we had research coverage by 10 securities analysts. If the analysts who cover us downgrades our common stock or publishes 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**

### ***Intermezzo Patent Litigation***

In July 2012, the Company received notifications from three companies, Actavis Elizabeth LLC, or Actavis Elizabeth, Watson Laboratories, Inc.—Florida, or Watson, and Novel Laboratories, Inc., or Novel, in September 2012, from each of Par Pharmaceutical, Inc. and Par Formulations Private Ltd., together, the Par Entities, in February 2013 from Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd., together, Dr. Reddy's, and in July 2013 from TWi Pharmaceuticals, Inc., or Twi, stating that each has filed with the FDA an ANDA, that references Intermezzo. Refer to Item 3, "*Legal Proceedings*", of the Company's Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC on March 9, 2016, for a full description of the history of this litigation.

The United States District Court for the District of New Jersey, or the New Jersey District Court, held a consolidated trial between December 1, 2014 and December 15, 2014 involving Paratek, Purdue Pharma, and their patent infringement claims against Actavis Elizabeth, Novel, and Dr. Reddy's. The New Jersey District Court then received post-trial briefing and held a February 13, 2015 post-trial hearing. On March 27, 2015, the New Jersey District Court issued an order and accompanying opinion finding that: (a) the asserted claims of U.S. Patent Nos. 7,682,628, 8,242,131, and 8,252,809, are invalid as obvious; (b) Actavis Elizabeth, Novel, and Dr. Reddy's infringe the '131 patent; (c) Novel infringes the '628 patent; and (d) Novel and Dr. Reddy's infringe the '809 patent. On April 9, 2015, the New Jersey District Court entered final judgment consistent with the March 27, 2015 opinion and order referenced above.

The Company and Purdue Pharma jointly appealed the New Jersey District Court's final judgment as to the '131 patent to the United States Court of Appeals for the Federal Circuit on May 6, 2015. On January 8, 2016, the United States Court of Appeals for the Federal Circuit affirmed the decision of the New Jersey District Court, and no opinion accompanied the judgment. On September 14, 2016, the defendants filed a warrant of satisfaction of judgment in the New Jersey District Court for the costs having been fully paid to the defendants.

### ***Patent Term Adjustment Suit***

In January 2013, the Company filed suit in the Eastern District of Virginia against the United States 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, 2017.

## **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."

The following table sets forth the range of high and low sales prices of our common stock for the quarterly periods indicated as reported by The Nasdaq Global Market.

	Sales Price	
	High	Low
<b>Year ended December 31, 2016</b>		
First quarter	\$ 19.45	\$ 12.05
Second quarter	\$ 18.92	\$ 12.05
Third quarter	\$ 14.34	\$ 12.39
Fourth quarter	\$ 15.70	\$ 9.80
<b>Year ended December 31, 2017</b>		
First quarter	\$ 19.40	\$ 13.95
Second quarter	\$ 25.95	\$ 18.45
Third quarter	\$ 29.00	\$ 18.70
Fourth quarter	\$ 26.10	\$ 17.20

The closing price of our common stock as reported by The Nasdaq Global Market on February 28, 2018 was \$13.10 per share. As of February 28, 2018, there were 31,443,149 holders of record of our common stock.

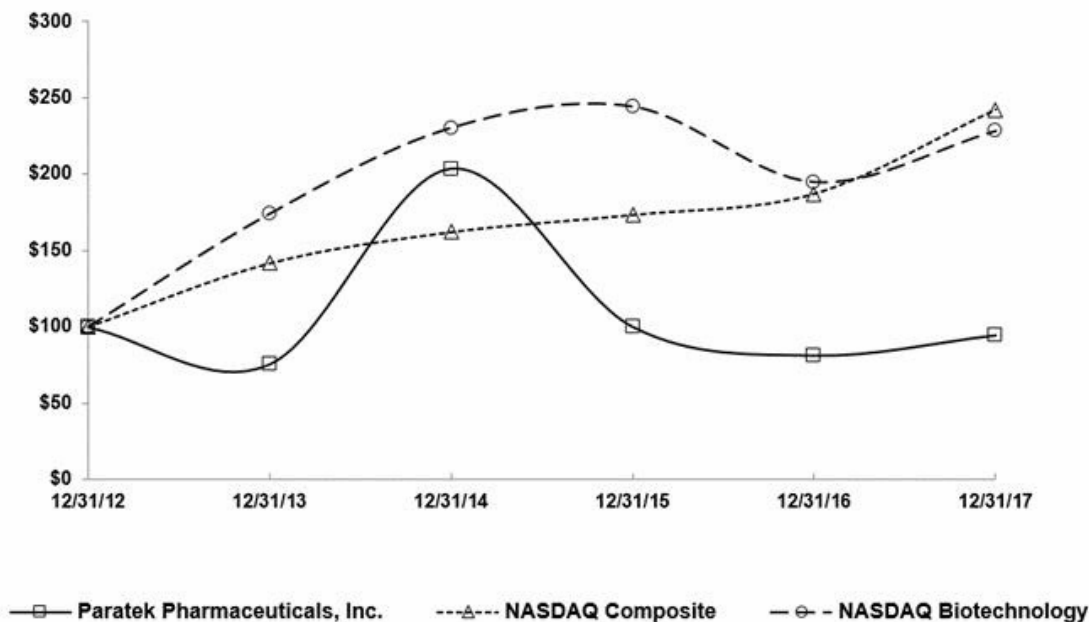
#### Stock Performance Graph

The following graph compares cumulative total return of our common stock with the cumulative total return of (i) The Nasdaq Global Select Index, and (ii) The Nasdaq Biotechnology Index. The graph assumes (a) \$100 was invested on December 31, 2011 in each of our Common Stock, the stocks comprising The Nasdaq Global Select Index and the stocks comprising The Nasdaq Biotechnology Index, and (b) the reinvestment of dividends. The comparisons shown in the graph are based on historical data and the stock price performance shown in the graph is not necessarily indicative of, or intended to forecast, future performance of our stock. Prior to the Reverse Merger on October 30, 2014, the stock of Transcept traded under the symbol "TSPT" on The Nasdaq Global Market and any comparison with Transcept's historical stock prices may not be meaningful.

This performance graph shall not be deemed "soliciting material" or to be "filed" with the Securities and Exchange Commission, or the SEC, for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed incorporated by reference into any filing of Paratek Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Act.

## COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\*

Among Paratek Pharmaceuticals, Inc., the NASDAQ Composite Index and the NASDAQ Biotechnology Index



\* \$100 invested on 12/31/12 in stock or index, including reinvestment of dividends.  
Fiscal year ending December 31.

### Dividend Policy

Other than future special dividends of any royalty income we may receive pursuant to the collaboration agreement entered into with Purdue Pharma, L.P., or Purdue Pharma, or the Purdue Collaboration Agreement, we do not anticipate that we will pay any additional cash dividends on our common stock in the foreseeable future.

### Recent Sales of Unregistered Securities

Set forth below is information regarding securities sold by us during 2017 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 June 27, 2017, we entered into the third amendment to the Loan Agreement with Hercules. In connection with the amendment, we issued to Hercules Capital, Inc. a warrant to purchase our common stock, or the Additional Warrant. The Additional Warrant is exercisable for an aggregate of 5,374 shares of our common stock at an exercise price of \$23.26 per share. The Additional Warrant's total relative fair value of \$0.1 million was determined using a Black-Scholes option-pricing model, as described in Note 10, *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 14, *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 Additional Warrant is exercisable at any time until the earlier of five years from issuance and the consummation of a Public Acquisition, as defined in the Additional 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 sales of securities. The securities were issued to investors 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. The purchaser of securities described above 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. The purchaser 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, 2017:

<u>Plan Category</u>	<u>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</u>	<u>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights</u>	<u>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans<sup>(1)</sup></u>
Equity compensation plans approved by stockholders <sup>(1)</sup>	4,314,605 <sup>(2)</sup>	\$ 11.79 <sup>(3)</sup>	50,753 <sup>(4)</sup>
Equity compensation plans not approved by stockholders	546,833 <sup>(5)</sup>	21.57 <sup>(6)</sup>	363,167 <sup>(7)</sup>
<b>Total</b>	<b>4,861,438</b>	<b>\$ 12.89</b>	<b>413,920</b>

- (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 3,101,274 shares relating to outstanding options, 1,128,503 relating to restricted stock units and 84,828 warrants outstanding.
- (3) Represents the weighted-average exercise price of outstanding options, warrants and rights.
- (4) Includes 36,539 shares available under the 2009 Employee Stock Purchase Plan, or the ESPP. All shares cancelled or forfeited during the years ended December 31, 2017 and 2016 under the 2006 and 2014 Plans became available for grant under the 2015 Plan.
- (5) Includes 507,633 shares relating to outstanding options and 39,200 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 73,167 shares that remain available for grant under the 2015 Inducement Plan that the Company does not currently anticipate issuing as of December 31, 2017.

#### Issuer Purchases of Equity Securities

There were no repurchases of our common stock during the fourth quarter of 2017.

#### Item 6. Selected Financial Data

Prior to October 30, 2014 we were known as Transcept Pharmaceuticals, Inc., or Transcept. On October 30, 2014, 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, these mergers

together, the Merger. For accounting purposes, Transcept was deemed to be the acquired entity in the Merger, and the Merger was accounted for as a reverse acquisition. In connection with the Merger, we changed our name to Paratek Pharmaceuticals, Inc. and effected a 1-for-12 reverse stock split of our common stock. Our consolidated financial statements reflect the historical results of Old Paratek prior to the Merger and that of the combined company following the Merger, and do not include the historical results of Transcept Pharmaceuticals, Inc. prior to the completion of the Merger. All share and per share disclosures have been retroactively adjusted to reflect the exchange of shares in the Merger, and the 1-for-12 reverse split of our common stock on October 30, 2014.

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. All per share amounts reflect the conversion of Old Paratek common stock to our common stock on October 30, 2014 at the rate of 0.0675 shares of common stock, after giving effect to the 1-for-12 reverse stock split, for each share of Old Paratek common stock outstanding on October 30, 2014.

	Year Ended December 31,				
	2017	2016	2015	2014	2013
	(in thousands, except per share and data)				
<b>Consolidated Statements of Operations Data:</b>					
Revenue	\$ 12,616	\$ 29	\$ —	\$ 4,342	\$ 478
Operating expenses:					
Research and development	60,072	83,460	50,765	5,014	4,631
General and administrative	36,965	26,400	19,988	5,848	3,387
Merger-related costs	—	—	—	1,278	—
Impairment of intangible assets	743	—	2,860	—	—
Change in fair value of contingent consideration	(584)	(345)	(3,560)	—	—
Total operating expenses	97,196	109,515	70,053	12,140	8,018
Loss from operations	(84,580)	(109,486)	(70,053)	(7,798)	(7,540)
Non-operating (expense) income, net	(3,736)	(2,150)	(807)	(10,037)	2,887
Net loss	(88,316)	(111,636)	(70,860)	(17,835)	(4,653)
Unaccrued dividends on convertible preferred stock	—	—	—	(1,927)	(6,766)
Provision for income taxes	753	—	—	—	—
Net loss attributable to common stockholders	\$ (89,069)	\$ (111,636)	\$ (70,860)	\$ (19,762)	\$ (11,419)
Net loss per share, basic and diluted	\$ (3.32)	\$ (5.51)	\$ (4.29)	\$ (7.82)	\$ (185.13)
Weighted average common shares outstanding, basic and diluted	26,827,253	20,253,082	16,501,912	2,528,595	61,680

	As of December 31,	
	2017	2016
<b>Selected Consolidated Balance Sheet Data:</b>		
Cash, cash equivalents and marketable securities	\$ 151,723	\$ 128,038
Total assets	163,698	135,732
Working capital	143,697	111,688
Current liabilities	16,789	20,412
Long-term obligations, less current portion	64,431	43,728
Common stock and additional paid-in capital	552,748	451,970
Accumulated deficit	(470,112)	(380,362)
Total stockholders' equity	82,478	71,592

## 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 clinical stage biopharmaceutical company focused on the development and commercialization of innovative therapeutics based upon tetracycline chemistry. 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. We have generated innovative small molecule therapeutic candidates based upon medicinal chemistry-based modifications, according to structure-based activity, of all positions of the core tetracycline molecule. These efforts have yielded molecules with broad-spectrum antibiotic properties and narrow-spectrum antibiotic properties, and molecules with potent anti-inflammatory properties to fit specific therapeutic applications. This proprietary chemistry platform has produced many compounds that have shown interesting characteristics in various *in vitro* and *in vivo* efficacy models. Omadacycline and sarecycline are examples of molecules that were synthesized from this chemistry discovery platform. Our two lead product candidates are the antibacterials omadacycline and sarecycline.

If approved, omadacycline will be the first in a new class of aminomethylcycline antibiotics. Omadacycline is a broad-spectrum, well-tolerated, once-daily oral and intravenous, or IV, antibiotic. We believe that omadacycline has the potential to become the primary antibiotic choice of physicians for use as a broad-spectrum monotherapy antibiotic for acute bacterial skin and skin structure infections, or ABSSSI, community-acquired bacterial pneumonia, or CABP, urinary tract infection, or UTI, and other serious community-acquired bacterial infections where resistance is of concern. We believe omadacycline, if approved, will be used in the emergency room, hospital and community care settings. We have designed omadacycline 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.

In the fall of 2013, the U.S. Food and Drug Administration, or the FDA, agreed to the design of our omadacycline Phase 3 studies for ABSSSI and CABP through the Special Protocol Assessment, or SPA, process. In addition, the FDA confirmed that positive data from the individual studies for ABSSSI and CABP would be sufficient to support approval of omadacycline for each indication and for both oral and IV formulations in the United States. In addition to Qualified Infectious Disease Product, or QIDP, designation, on November 4, 2015, the FDA granted Fast Track designation for the development of omadacycline in ABSSSI, CABP, and complicated urinary tract infection, or complicated UTI. Fast Track designation facilitates the development and expedites the review of drugs that treat serious or life-threatening conditions and that fill an unmet medical need. In February 2016, we reached agreement with the FDA on the terms of the omadacycline pediatric program associated with the Pediatric Research Equity Act. The FDA has granted Paratek a waiver for conducting studies with omadacycline in children less than eight years old due to the risk of teeth discoloration, a known class effect of tetracyclines. In addition, the FDA has granted a deferral on conducting studies in children eight years and older until safety and efficacy is established in adults. In May 2016, we received confirmation from the FDA that the oral-only ABSSSI study design was acceptable and consistent with the currently posted guidance for the industry. In September 2017, both the oral and IV formations of omadacycline were granted an additional QIDP designation by the FDA for the treatment of uncomplicated urinary tract infection, or uncomplicated UTI.

Scientific advice received through the centralized procedure in Europe confirmed general agreement on the design and choice of comparators of the Phase 3 clinical trials for ABSSSI and CABP and noted that approval based on a single study in each indication could be possible but would be subject to more stringent statistical standards than Market Authorization Applications, or MAA, programs that conduct two pivotal Phase 3 studies per indication. We believe that the inclusion of the second Phase 3 oral-only study in ABSSSI strengthens the data package for submission of an MAA filing for approval in the European Union, or the EU.

To date, we have conducted more than 20 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 and completed 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 favorable safe and well tolerated profile. We included these clinical data in the New Drug Application, or NDA, submission to the FDA for the treatment of ABSSSI and CABP on February 2, 2018. We plan to include these clinical data in the MAA submission to the European Medicines Agency, or the EMA, in the second half of 2018.



In the two pivotal Phase 3 studies in ABSSSI (OASIS-1 and OASIS-2), omadacycline successfully met the primary endpoint for the FDA by demonstrating statistical non-inferiority based upon the Early Clinical Response, or ECR, assessment at 48 to 72 hours after the first dose of study medication in the modified intent-to-treat, or mITT, population (all randomized subjects without a baseline sole gram-negative causative pathogen). In the same two pivotal Phase 3 studies in ABSSSI, omadacycline also successfully met the primary endpoint for the EMA by demonstrating statistical non-inferiority based upon the investigator's assessment of clinical outcome at the post therapy evaluation, or PTE, visit (7 to 14 days after the subject's last day of study therapy), in the mITT and the clinically evaluable, or CE, population (defined as all mITT subjects who received study medication, had a qualifying ABSSSI, an assessment of outcome, and met all other evaluability criteria). Clinical success at the PTE assessment was based on resolution of the infection such that further antibacterial therapy was not needed, and the subject was alive and did not meet any clinical failure or indeterminate criteria.

In May 2016, we initiated our first oral-only and IV-to-oral study of omadacycline dosed for five days in a Phase 1b clinical study in patients with a UTI. This Phase 1b UTI study was completed. Data from this study showed that omadacycline achieved proof of principle, by demonstrating high concentration levels of omadacycline in urine, across IV-to-oral and oral-only dosing regimens. The QIDP designation, which is designed to speed the development of novel antibiotics for the treatment of pathogens with the potential to pose a serious threat to public health, provides an opportunity for more frequent interactions with the FDA, and a priority review of the supplemental new drug application for omadacycline in uncomplicated UTI once submitted. We have initiated sites for the first of our two planned Phase 2 clinical trials evaluating omadacycline for the treatment of UTI. The first study will evaluate the efficacy, safety, tolerability and pharmacokinetics of omadacycline in female patients with cystitis, a common uncomplicated UTI. The second study, which we plan to initiate in the second half of 2018, will evaluate the efficacy, safety, tolerability and pharmacokinetics of omadacycline in patients with acute pyelonephritis, a common complicated UTI. We plan to enroll approximately 200 patients in each study at multiple sites.

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 are 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. Funding support for the trial has been made available through the Defense Threat Reduction Agency, or DTRA/ Joint Science and Technology Office and Joint Program Executive Office for Chemical and Biological Defense / Joint Project Manager Medical Countermeasure Systems / BioDefense Therapeutics.

Our second antibacterial product candidate, sarecycline, also known as Seysara™ in the U.S. is a new, once-daily, tetracycline-derived compound designed for use in the treatment of acne and rosacea. We believe that, based upon the data generated to-date, sarecycline possesses favorable anti-inflammatory activity, plus narrow-spectrum antibacterial activity relative to other tetracycline-derived molecules, oral bioavailability, does not cross the blood-brain barrier, and favorable pharmacokinetic properties that we believe make it particularly well-suited for the treatment of inflammatory acne in the community setting. We have exclusively licensed U.S. development and commercialization rights to sarecycline for the treatment of acne to Allergan plc, or Allergan, while retaining development and commercialization rights in the rest of the world.

In March 2017, Allergan announced that two Phase 3 studies of sarecycline for the treatment of moderate to severe acne vulgaris met their 12-week primary efficacy endpoints. In addition, a nine-month long-term safety extension study was completed. The safety results from the long-term study are generally consistent with results from the two 12-week studies. Based on these clinical data, Allergan submitted an NDA to the FDA, which was accepted in December 2017 for the treatment of moderate to severe acne.

Allergan currently holds a nonexclusive license to develop and commercialize sarecycline for the treatment of rosacea in the United States. There are currently no clinical trials with sarecycline in rosacea underway.

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 general and administrative support for these operations. We completed the submission of two NDAs to the FDA for our once-daily oral and IV formulations of omadacycline. In addition, our partner Allergan submitted an NDA to the FDA, which was accepted in December 2017 for the treatment of moderate to severe acne. We have not yet submitted any other product candidates for approval by regulatory authorities. We do not currently have rights to any products that have been approved for marketing in any territory. We have not generated any revenue from product sales and to date have financed our operations primarily through sale of our common and convertible preferred stock, debt financings, strategic collaborations, and grant funding.

In April 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 pursuant to which the Company granted Zai an exclusive license to develop, manufacture and commercialize omadacycline 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 the Company. Under the terms of the Zai Collaboration Agreement, Paratek Bermuda Ltd. earned an upfront, nonrefundable license payment of \$7.5 million during the year ended December 31, 2017.

We have incurred significant losses since our inception in 1996. Our accumulated deficit at December 31, 2017 was \$470.1 million and our net loss for the year ended December 31, 2017 was \$89.1 million. A substantial amount of our net losses resulted from costs incurred in connection with our research and development programs and 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 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 foreseeable future.

We do not expect to generate revenue from product sales unless and until we or either of our partners, Allergan or Zai, successfully complete development and obtain marketing approval for one or more of our product candidates. Accordingly, we anticipate that we will need to raise additional capital in order to complete the development and commercialization of omadacycline and to advance the development of our other product candidates. Until we can generate a sufficient amount of product revenue to finance our cash requirements, we expect to finance our future cash needs primarily through a combination of public and private equity offerings, debt or other structured financings and strategic collaborations. 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***

We have not yet generated any revenue from product sales. All of our revenue to date has been derived from license fees, milestone payments, royalty income, reimbursements for research, development and manufacturing activities under licenses and collaborations, grant payments received from the National Institute of Health, or NIH, and other non-profit organizations. If the FDA approves our NDA for omadacycline on the projected timeline, we intend to begin selling the product by the first quarter of 2019.

Collaboration revenue represents upfront fees and milestone payments received in connection with our collaboration agreements. Royalty revenue represents fifty percent of Intermezzo royalty income received pursuant to the royalty sharing agreement, or the Royalty Sharing Agreement, entered into by us in October 2016 with the Special Committee of our Board of Directors.

### ***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 product candidates for which we or any partner obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will 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 2017, 2016 and 2015, are as follows:

(in thousands)	Year Ended December 31,		
	2017	2016	2015
Omadacycline	\$ 41,786	\$ 71,709	\$ 43,654
Other external research and development	—	—	100
Total external costs	41,786	71,709	43,754
Other research and development costs	18,286	11,751	7,011
Total	\$ 60,072	\$ 83,460	\$ 50,765

#### ***General and Administrative Expense***

General and administrative expense consists primarily of salaries and other related costs for personnel and professional, legal and consulting fees.

#### ***Interest Expense***

Interest expense represents interest incurred on the Loan Agreement (as defined below), as amended, entered into with Hercules (as defined below) and 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, 2017 and 2016

	Year Ended December 31,		
	2017	2016	Change
Revenue			
Collaboration and royalty revenue	\$ 12,616	\$ 29	\$ 12,587
Total revenue	12,616	29	12,587
Operating expenses:			
Research and development	60,072	83,460	(23,388)
General and administrative	36,965	26,400	10,565
Impairment of intangible assets	743	—	743
Changes in fair value of contingent consideration	(584)	(345)	(239)
Total operating expenses	97,196	109,515	(12,319)
Loss from operations	(84,580)	(109,486)	24,906
Other income and expenses:			
Interest income	1,377	1,069	308
Interest expense	(5,079)	(3,223)	(1,856)
Other gains (and losses), net	(34)	4	(38)
Net loss	(88,316)	(111,636)	23,320
Provision for income taxes	753	—	753
Net loss attributable to common stockholders	<u>\$ (89,069)</u>	<u>\$ (111,636)</u>	<u>\$ 22,567</u>

#### Revenue

Revenue for the year ended December 31, 2017 consists of a \$5.0 million milestone payment earned from Allergan with sarecycline (Seysara™) NDA acceptance, a \$7.5 million upfront payment received as part of the Zai Collaboration Agreement and \$0.1 million of revenue earned under the Royalty Sharing Agreement. Revenue for the year ended December 31, 2016 consists of revenue earned under the Royalty Sharing Agreement.

#### Research and Development Expense

Research and development expenses were \$60.1 million for the year ended December 31, 2017, compared to \$83.5 million for the year ended December 31, 2016. The decrease was driven primarily by lower clinical study costs associated with the completion of our Phase 3 program for omadacycline. This decrease is partially offset by higher employee compensation costs, NDA preparation and related user fees, and an increase in medical affairs activity.

We anticipate that our research and development expenses will increase in future periods as a result of our Phase 2 UTI program, augmenting our medical affairs team prior to our anticipated launch of omadacycline, if approved by the FDA, building up commercial supply, expanding our manufacturing capacity, and securing secondary suppliers to ensure a robust supply chain for the years beyond launch.

#### General and Administrative Expense

General and administrative expenses were \$37.0 million for the year ended December 31, 2017, compared to \$26.4 million for the year ended December 31, 2016. The increase was driven primarily by higher employee compensation costs as we continue to expand our commercial team, costs associated with pre-commercial activities, and business development efforts.

We anticipate that our general and administrative expenses will increase in future periods as we prepare for commercial launch of omadacycline and, if approved in the U.S., to support commercialization efforts.

#### Impairment of Intangible Assets

We recorded an impairment charge of \$0.7 million during the year ended December 31, 2017. No such impairment was recorded during the year ended December 31, 2016. The impairment charge was recorded in connection with an expected decline in Intermezzo sales.

### **Changes in Fair Value of Contingent Obligations**

During the years ended December 31, 2017 and 2016, we recorded a \$0.6 million decrease and \$0.3 million decrease, respectively, in the fair value of our contingent obligation to former Transcept stockholders. The decrease in the fair value of our contingent obligation reflects a corresponding decline in projected Intermezzo sales.

### **Other Income and Expenses**

Interest expense for the year ended December 31, 2017 represents interest incurred on the Loan Agreement, as amended, of \$4.9 million and the net amortization of our marketable securities of \$0.2 million. Interest income for the year ended December 31, 2017 represents interest earned on our money market funds and marketable securities of \$1.4 million. Interest expense for the year ended December 31, 2016 represents interest incurred on the Loan Agreement, as amended, of \$2.6 million as well as net amortization of our marketable securities of \$0.6 million. Interest income for the year ended December 31, 2016 represents \$1.0 million of interest earned on our money market funds and marketable securities.

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

(in thousands)	Year Ended December 31,		Change
	2016	2015	
<b>Revenue</b>			
Royalty revenue	\$ 29	\$ —	\$ 29
Total revenue	29	—	29
<b>Operating expenses:</b>			
Research and development	83,460	50,765	32,695
General and administrative	26,400	19,988	6,412
Impairment of intangible assets	—	2,860	(2,860)
Changes in fair value of contingent consideration	(345)	(3,560)	3,215
Total operating expenses	109,515	70,053	39,462
Loss from operations	(109,486)	(70,053)	(39,433)
<b>Other income and expenses:</b>			
Interest income	1,069	—	1,069
Interest expense	(3,223)	(770)	(2,453)
Other (losses) and gains, net	4	(37)	41
Net loss	\$ (111,636)	\$ (70,860)	\$ (40,776)

### **Revenue**

Revenue for the year ended December 31, 2016 consists of revenue received under the Royalty Sharing Agreement. We did not earn revenue during the year ended December 31, 2015.

### **Research and Development Expense**

The increase in research and development expense for the year ended December 31, 2016 was primarily the result of our ongoing clinical development of omadacycline. During the year ended December 31, 2016, we incurred approximately \$43.8 million in expense associated with Phase 3 studies for the treatment of ABSSSI and CABP, including an oral-only Phase 3 study, which represents an increase of \$19.6 million compared to \$24.2 million in the same period in prior year. This increase is associated primarily with strong enrollment performance in both the ABSSSI and CABP registration studies and initiation of a Phase 3 ABSSSI oral-only study, resulting in an increased recognition of expenses related to study start-up, CRO fees, investigator fees, and costs associated with clinical sites and laboratories. We also incurred \$9.6 million in production costs for omadacycline registration batches and manufacturing process validation work, which represents a decrease of \$0.9 million compared to the same period in prior year. In addition, we incurred \$20.4 million in costs related to omadacycline research and development activities, including Phase 1 studies, and \$9.7 million in salaries and benefits, including stock-based compensation, which represents an increase of \$9.5 million and \$4.5 million, respectively, compared to the same period in prior year.

### **General and Administrative Expense**

The increase in general and administrative costs for the year ended December 31, 2016 was primarily due to growth in our corporate infrastructure to support a public company. Salaries and benefits, including stock-based compensation, increased \$6.4 million for the year ended December 31, 2016.

### **Impairment of Intangible Assets**

We recorded impairment charges of \$2.9 million against our intangible assets, Intermezzo and TO-2070 product rights, during the year ended December 31, 2015. Intermezzo products rights were impaired by \$2.8 million as a result of the outcome of litigation that invalidated several Intermezzo patents as obvious and triggered an evaluation of the carrying value and related contingent liability in light of an expected decline in Intermezzo sales. TO-2070 product rights were impaired by \$0.1 million due to significant uncertainty concerning the ability of Shin Nippon Biomedical Laboratories Ltd., or SNBL, to find a potential partner to co-develop the rights as of December 31, 2015 and triggered an evaluation of the carrying value and related contingent liability. Refer to Note 8, *Intangible Assets, Net*, in the accompanying notes to the consolidated financial statements for additional information. No such impairment was recorded during the year ended December 31, 2016.

### **Changes in Fair Value of Contingent Obligations**

We recorded a \$0.3 million reduction in the fair value of our contingent obligations to former Transcept stockholders during the year ended December 31, 2016. A decrease of \$0.2 million is attributable to the results of lower projected future sales of the Intermezzo product due to generic market entry. The remainder is due to the elimination of the contingent obligation for the TO-2070 license rights, as no payments were received by us pursuant to the termination of the license agreement with the Company entered into with SNBL, or SNBL License Agreement, prior to the second anniversary of the Merger.

The reduction in fair value of contingent obligation of \$3.6 million for the year ended December 31, 2015 was identified in conjunction with the outcome of litigation that invalidated several Intermezzo patents as obvious and triggered an evaluation of the carrying value of the Intermezzo product rights and related contingent obligations in light of an expected decline in Intermezzo sales. In addition, during the fourth quarter, we were made aware of the unlikelihood that SNBL will find a potential partner to co-develop the TO-2070 license rights. This significant uncertainty triggered an evaluation of the carrying value of the TO-2070 product rights and related contingent obligation to former Transcept stockholders.

### **Other Income and Expenses**

Interest income represents \$1.0 million of interest earned on our money market funds and marketable securities during the year ended December 31, 2016. We began investing in marketable securities during the year ended December 31, 2016. Interest expense, net for the year ended December 31, 2016 represents a full year of interest incurred on the Term Loan, as defined in Note 14, *Long-term Debt*, and the Loan Agreement amendments entered into entered into with Hercules on September 30, 2015 and December 12, 2016, respectively, of \$2.6 million as well as net amortization of our marketable securities of \$0.6 million. Interest expense for the year ended December 31, 2015 represents the accretion of interest expense on the Intermezzo Reserve plus three months of interest incurred on the Term Loan.

### **Liquidity and Capital Resources**

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

On September 30, 2015, we entered into a Loan and Security Agreement, or the Loan Agreement, 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). We executed three amendments to the Loan Agreement subsequent to September 30, 2015, providing access to term loans with an aggregate principal amount of up to \$60.0 million. As of December 31, 2017, we have drawn down on the full \$60.0 million available to us. The last amendment executed in June 2017 extended the date on which we are required to begin making monthly principal installments from January 1, 2019 to January 1, 2020, subject to our receipt of marketing approval for our lead product candidate, omadacycline, or the Interest Only Period Extension Event. Beginning on January 1, 2019, or, if we achieve the Interest

Only Period Extension Event, beginning on January 1, 2020, we will make payments in equal monthly installments of principal and interest, with the balance of outstanding loans due on the original maturity date of the Loan Agreement, as amended. 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 also have 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.

In October 2015 and February 2017, we entered into Controlled Equity Offering<sup>SM</sup> Sales Agreements, or the 2015 Sales Agreement and 2017 Sales Agreement, respectively, with Cantor Fitzgerald & Co., or Cantor, under which we could, at our discretion, from time to time sell shares of our common stock, with a sales value of up to \$50.0 million under each Sales Agreement 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 of our common stock 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. We have sold all \$50.0 million of shares of our common stock under the 2015 Sales Agreement. We received \$36.9 million in proceeds, after deducting commissions of \$1.1 million, from the sale of 2,326,119 shares of common stock under the 2015 Sales Agreement during the year ended December 31, 2017. We received \$47.7 million in proceeds, after deducting commissions of \$1.5 million, from the sale of 2,102,315 shares of common stock, as of February 28, 2018, under the 2017 Sales Agreement. As of February 28, 2018, no amount remains available for sale under the 2015 Sales Agreement and \$0.8 million remains available for sale under the 2017 Sales Agreement.

On December 12, 2016, we filed a registration statement on Form S-3 with the SEC, which was declared effective on December 20, 2016, to sell certain of our securities in an aggregate amount of up to \$225.0 million. Additionally, on December 2, 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.

On October 16, 2015, we filed a registration statement on Form S-3 with the SEC, which was declared effective on October 29, 2015, to sell certain of our securities in an aggregate amount of up to \$100.0 million. Under this shelf registration statement, we completed an underwritten offering on January 22, 2018 of 3,205,128 shares of our common stock, resulting in total proceeds of \$50.0 million. Offering expenses incurred were approximately \$0.2 million.

We have used and we intend to continue to use the net proceeds from the above offerings, as well as the Loan Agreement as amended, together with our existing capital resources, to fund our ongoing and future clinical studies of omadacycline, to fund commercial launch readiness, and for working capital and other general corporate purposes. As of December 31, 2017, we had cash, cash equivalents and marketable securities of \$151.7 million.

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

	Year Ended December 31,		
	2017	2016	2015
Net cash used in operating activities	\$ (78,574)	\$ (94,098)	\$ (54,682)
Net cash used in investing activities	(42,002)	(74,757)	(603)
Net cash provided by financing activities	103,030	90,515	90,731

### **Operating Activities**

Cash used in operating activities for the year ended December 31, 2017 of \$78.6 million is primarily the result of our \$89.1 million net loss, \$4.2 million increase in accounts payable and accrued expenses due to completion of our Phase 3 IV-to-oral CABP study and end of enrollment in our Phase 3 oral-only study in ABSSSI and a \$4.8 million decrease in prepaid expenses mainly associated with the clinical development of omadacycline. This is offset partially by a \$0.8 million decrease in other liabilities and other assets due to the cancellation of a VAT letter of credit during 2017. The remainder represents the net impact of \$18.7 million in non-cash items, including \$18.2 million in depreciation, amortization and stock-based compensation expense, \$0.4 million in non-cash interest expense, a \$0.7 million impairment charge and decrease in fair value of contingent consideration of \$0.6 million.

Cash used in operating activities for the year ended December 31, 2016 of \$94.1 million is primarily the result of our \$111.6 million net loss offset in part by a \$2.1 million increase in accounts payable and accrued expenses, and a \$5.0 million decrease in prepaid expenses mainly associated with the clinical development of omadacycline, and a net decrease in the Intermezzo reserve of \$2.4 million representing final payout, with the exception of unpaid legal fees, on the second anniversary of the Merger. The remainder represents the net impact of \$13.0 million in non-cash items, including \$13.1 million in depreciation, amortization and stock-based compensation expense, \$0.2 million in non-cash interest expense, and a \$0.3 million decrease in contingent obligations to former Transcept stockholders.

Cash used in operating activities for the year ended December 31, 2015 of \$54.7 million is primarily the result of our \$70.9 million net loss offset in part by a \$14.0 million increase in accounts payable and accrued expenses mainly associated with the clinical development of omadacycline. The remainder of the increase represents the net impact of \$5.6 million in non-cash items, offset by a \$3.6 million reduction in contingent obligations to former Transcept stockholders.

#### ***Investing Activities***

Cash used in investing activities for the ended December 31, 2017, is primarily the result of purchasing \$180.3 million of short-term marketable securities (U.S. treasury and government agency securities) and \$1.4 million of fixed asset purchases, offset by proceeds by sales and maturities of marketable securities of \$138.7 million, \$0.3 million of fixed asset disposals, and a decrease in restricted cash of \$0.7 million.

Cash used in investing activities for the ended December 31, 2016, is primarily the result of purchasing \$135.8 million of short-term marketable securities (U.S. treasury and government agency securities), partially offset by proceeds by maturities of marketable securities of \$60.1 million. The remainder represents an increase in restricted cash of \$1.6 million offset by \$0.7 million of fixed asset purchases.

Net cash used in investing activities for the year ended December 31, 2015 is the result of purchases of fixed assets and a decrease in restricted cash representing payments made from the Intermezzo Reserve.

#### ***Financing Activities***

Net cash provided by financing activities for 2017 is primarily comprised of the following:

- \$82.8 million from the sale of 4,332,126 shares of common stock under the 2015 and 2017 Sales Agreements with Cantor;
- \$19.9 million, net of issuance costs, on the Hercules Loan Agreement, as amended; and
- \$0.3 million in proceeds from the exercise of stock options.

Net cash provided by financing activities for 2016 is primarily comprised of the following:

- \$59.3 million from an underwritten offering of 4,887,500 shares of common stock;
- \$11.6 million from the sale of 860,014 shares of common stock under the 2015 Sales Agreement with Cantor; and
- \$19.6 million, net of issuance costs, on the Hercules Term Loan.

Net cash provided by financing activities for 2015 is primarily comprised of the following

- \$70.4 million from an underwritten offering of 3,089,000 shares of common stock;
- \$19.2 million, net of issuance costs, on the Hercules Term Loan beginning in the fourth quarter of 2015; and
- \$1.0 million in proceeds received from the sale of 44,782 shares of common stock to Hercules.

#### **Future Funding Requirements**

We have not generated any revenue from product sales. We do not know when, if ever, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales unless and until either we or either of our partners, Allergan or Zai, obtain regulatory approval of and commercialize one or more of our product candidates. Subject to obtaining regulatory approval of any of our product candidates, we anticipate that we will need substantial additional funding in connection with our continuing operations to support pre-launch and commercial activities associated with our lead product candidate, omadacycline.

We have not obtained regulatory approval of any product candidates. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we:

- conduct additional clinical trials of omadacycline;
- seek regulatory approvals for omadacycline;



- establish a sales, marketing and distribution infrastructure and increases to our manufacturing demand and capabilities to commercialize omadacycline; and add personnel to support our product development and planned commercialization efforts.

Based upon our current operating plan, we anticipate that our cash, cash equivalents and available for sale securities of \$151.7 million as of December 31, 2017 as well as the \$50.0 million in proceeds from our January 2018 public offering of common stock, future contingent regulatory and commercial milestone payments from our collaborations with Allergan and Zai, anticipated extension of our interest-only period for the Hercules Term Loan as defined in Note 14, *Long-term Debt*, and estimated omadacycline product sales will enable us to fund our operating expenses and capital expenditure requirements into late 2019. 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 product candidates, and the unknown extent to which we will enter into collaborations with third parties to participate in the development and commercialization of our product candidates, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future capital requirements will depend on many factors, including:

- the progress of clinical development of omadacycline;
- the number and characteristics of other product candidates that we pursue;
- the scope, progress, timing, cost and results of research, preclinical development and clinical trials;
- the costs, timing and outcome of seeking and obtaining FDA and non-U.S. regulatory approvals;
- the costs associated with manufacturing and establishing sales, marketing and distribution capabilities;
- 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 and medical personnel;
- the effect of competing products that may limit market penetration of our product candidates;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing and success of our existing 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 these arrangements.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, we expect to finance our future cash needs primarily through a combination of public and private equity offerings, debt or other structured financings and strategic collaborations. We do not have any committed external sources of funds other than contingent milestone payments and royalties under the Allergan Collaboration Agreement and the Zai Collaboration Agreement, which are terminable by Allergan 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. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through 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, 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 product candidates that we would otherwise prefer to develop and market ourselves.

#### **Off-Balance Sheet Arrangements**

As of December 31, 2017, 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 United States of America. 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, intangible assets, goodwill, contingent liabilities, stock-based compensation arrangements, 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

We enter into product development agreements with collaborators for the research and development of therapeutic products. The terms of these agreements may include nonrefundable signing and licensing fees, funding for research, development and manufacturing, milestone payments, and royalties on any product sales derived from collaborations. We assess these multiple elements in accordance with the Financial Accounting Standards Board, or FASB ASC 605 *Revenue Recognition*, in order to determine whether particular components of the arrangement represent separate units of accounting.

Deliverables under the arrangement will be separate units of accounting provided that a delivered item has value to the customer on a stand-alone basis and if the arrangement does not include a general right of return relative to the delivered item and delivery or performance of the undelivered item is considered probable and substantially in the control of the vendor. The fair value of deliverables under the arrangement may be derived using a best estimate of selling price if vendor-specific objective evidence and third-party evidence are not available.

We recognize upfront license payments as revenue upon delivery of the license only if the license has stand-alone value and the fair value of the undelivered performance obligations can be determined. If the fair value of the undelivered performance obligations could be determined, such obligations are accounted for separately as the obligations are fulfilled. If the license is considered to either not have stand-alone value or have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement is accounted for as a single unit of accounting, and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations will be performed.

Whenever we determine that an arrangement should be accounted for as a single unit of accounting, we determine the period over which the performance obligations will be performed and revenue will be recognized. If we are not able to reasonably estimate the timing and the level of effort to complete our performance obligations under an arrangement, then we recognize revenue under the arrangement on a straight-line basis over the period that we expected to complete our performance obligations, which is reassessed at each subsequent reporting period.

We also adopted guidance that permits the recognition of revenue contingent upon the achievement of a milestone in its entirety, in the period in which the milestone is achieved, only if the milestone meets certain criteria and is considered to be substantive. As such, we plan to recognize revenue in the period in which the milestone is achieved, only if the milestone is considered to be substantive based on the following criteria:

- a. The milestone is commensurate with either of the following:

The vendor's performance to achieve the milestone.

The enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the vendor's performance to achieve the milestone.

- b. The milestone relates solely to past performance.
- c. The milestone is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

We also record deferred revenue when payments are received in advance of the culmination of the earnings process. This revenue is recognized in future periods when the applicable revenue recognition criteria have been met.

*Allergan plc*

We determined whether the performance obligations under the collaborative research and license agreement, we entered into with Allergan, or the Allergan Collaboration Agreement, could be accounted for separately or as a single unit of accounting. We determined that the license, participation on steering committees and research and development services performance obligations during the research period of the Allergan Collaboration Agreement represented a single unit of accounting. As we could not reasonably estimate its level of effort, we recognized revenue from the upfront payment, milestone payment and research and development services payments using the contingency-adjusted performance model over the expected development period. The development period was completed in June 2010. Under this model, when a milestone was earned or research and development services were rendered, revenue was immediately recognized on a pro-rata basis in the period the milestone was achieved or services were delivered based on the time elapsed from the effective date of the agreement. Thereafter, the remaining portion was recognized on a straight-line basis over the remaining development period. We have determined that each potential future clinical, regulatory and commercialization milestone is substantive. In making this determination, pursuant to the accounting guidance on revenue recognition for milestone payments, we considered and concluded that each individual milestone: (i) relates solely to the past performance of the intellectual property to achieve the milestone; (ii) is reasonable relative to all of the deliverables and payment terms in the arrangement; and (iii) is commensurate with the enhanced value of the intellectual property as a result of the milestone achievement. As our obligations under this arrangement have been completed, all future milestones, which are all considered substantive, will be recognized as revenue when achieved.

Also, at our discretion, we may provide manufacturing process development services to Allergan in exchange for full-time equivalent based cost reimbursements. We determined that the manufacturing process development services are considered a separate unit of accounting as (i) they are set at our discretion, (ii) they have stand-alone value, as these services could be performed by third parties, and (iii) the full-time equivalent rate paid for such services rendered is considered fair value. Therefore, we recognize cost reimbursements for manufacturing process development services as revenue as the services are performed.

During the year ended December 31, 2017, we recognized revenue of \$5.0 million as a milestone payment earned from Allergan upon NDA submission of sarecycline to the FDA. No such revenue was recognized for the year ended December 31, 2016.

*Zai Lab (Shanghai) Co., Ltd.*

During the year ended December 31, 2017, we entered into the Zai Collaboration Agreement, pursuant to which Paratek Bermuda Ltd. granted Zai an exclusive license to develop, manufacture and commercialize omadacycline in the People's Republic of China, Hong Kong, Macau and Taiwan 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 Bermuda Ltd. Refer to Note 4, *License and Collaboration Agreements*, for further details surrounding the Zai Collaboration Agreement.

We evaluated the Zai Collaboration Agreement under ASC Subtopic 605-25, "*Multiple Element Arrangements*". We determined that there were five deliverables under the Zai Collaboration Agreement: (i) an exclusive license to develop, manufacture and commercialize omadacycline in the Zai Territory; (ii) an initial transfer of technology; (iii) a transfer of certain materials and materials know-how (iv) an additional transfer of materials; and (v) participation on a joint steering committee, or JSC, and joint development committee, or JDC. We determined that all five deliverables listed above had value to us on a stand-alone basis and therefore five units of accounting were identified. We determined, however, that the best estimate for the selling price of the initial transfer of technology, transfer of certain materials and materials know-how, the additional transfer of materials and participation on the JSC and JDC were all inconsequential. As such, we recognized the total arrangement consideration as revenue during the year ended December 31, 2017. Under the Zai Collaboration Agreement, Zai will pay taxes incurred in the Zai Territory by us on our behalf and deduct these taxes from the payments due to us. Withholding and other value-added taxes of \$0.8 million were incurred on the \$7.5 million upfront payment. As such, we received \$6.7 million, net of taxes, during the year ended December 31, 2017. These taxes were paid by Zai on behalf of us.

### *Purdue Pharma L.P.*

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 our Board of Directors, a committee established in connection with the Merger. Under the Royalty Sharing Agreement, we agreed to pay to the former Transcept stockholders fifty percent 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. We recognize all royalty income received from Purdue Pharma upon the sale of Intermezzo.

For the years ended December 31, 2017 and 2016, we recognized \$0.1 million and \$29,000, respectively, of royalty revenue from our Purdue Collaboration Agreement. No royalty revenue was recognized for the years ended December 31, 2015 and 2014. We will continue to recognize royalty revenue upon the sale of the relevant products, provided there are no remaining performance obligations under the arrangement.

We did not enter into any significant multiple element arrangements during the years ended December 31, 2016 and 2015. We did not materially modify any of our other existing multiple element arrangements during the years ended December 31, 2017, 2016 or 2015.

### ***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, 2017 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 and government agency 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 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, 2017 and 2016.

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, 2017 and 2016.

### ***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, or CMOs, with respect to clinical material supply;

- 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 account for stock-based awards to non-employees using the fair value method on a straight-line basis over the associated service period of the award in accordance with FASB ASC Topic 505-50, *Equity-Based Payments to Non-Employees*.

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-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.

As of January 1, 2017, we adopted ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, or ASU 2016-09. In connection with the adoption, we made an accounting policy change. Prior to adoption, we estimated forfeitures at the time of grant and revised those estimates in subsequent periods if actual forfeitures differed from the estimates. We used historical data to estimate pre-vesting option forfeitures to the extent that actual forfeitures differed from our estimates, the difference was recorded as a cumulative adjustment in the period the estimates were revised. Upon adoption, we recognize the effect of forfeitures in compensation cost when they occur. We recorded a cumulative-effect catch-up adjustment to equity of \$0.7 million upon adoption. See Note 2, *Summary of Significant Accounting Policies*, to our consolidated financial statements included in Part II, Item 8, "Financial Statements and Supplementary Data," of this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our business.

## 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.

Between May 2014 and May 2016, the FASB issued three ASUs changing the requirements for recognizing and reporting revenue, or together, herein referred to as the Revenue ASUs: (i) ASU No. 2014-09, *Revenue from Contracts with Customers*, or ASU 2014-09, (ii) ASU No. 2016-08, *Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, or ASU 2016-08, and (iii) ASU No. 2016-12, *Narrow-Scope Improvements and Practical Expedients*, or ASU 2016-12. ASU 2014-09 provides guidance for revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2016-08 is intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations. ASU 2016-12 provides practical expedients and improvements on the previously narrow scope of ASU 2014-09. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, or ASU 2015-14. ASU 2015-14 defers the effective date of ASU 2014-09 by one year to fiscal years, and interim periods within, beginning after December 15, 2017. All subsequent ASUs related to ASU 2014-09, including ASU 2016-08 and ASU 2016-12, assumed the deferred effective date enforced by ASU 2015-14. Early adoption of the Revenue ASUs is permitted for annual periods, and interim periods within, beginning after December 15, 2016. A reporting entity may apply the amendments in the Revenue ASUs using either a modified retrospective approach, by recording a cumulative-effect adjustment to equity as of the beginning of the fiscal year of adoption or full retrospective approach.

The Company adopted ASC 606, *Revenue from Contracts with Customers*, or ASC 606, as of January 1, 2018 using the full retrospective approach. The Company is evaluating the complete impact of the adoption of ASC 606 on its consolidated financial position and results of operations and currently does not expect ASC 606 to have a material impact on revenue previously recognized under the Company's Allergan, Zai and Purdue Collaboration Agreements. The Company implemented appropriate changes to its internal controls to support revenue recognition, including controls to monitor the probability of achievement of contingent milestone payments, and additional revenue-related disclosures under the new standard.

Upon adoption of ASC 606, the accounting for contingent milestone payments under the Company's collaboration agreements changed. ASC 606 does not contain guidance specific to milestone payments, thereby requiring contingent milestone payments to be considered in accordance with the overall model of ASC 606 as variable consideration. Revenue from contingent milestone payments may be recognized earlier under ASC 606 than under ASC 605, *Revenue Recognition*, based on an assessment at each reporting date of the probability of achievement of the underlying milestone event. This assessment may, in certain circumstances, result in the recognition of revenue related to a contingent milestone payment before the milestone event has been achieved. The Company will recognize all future milestone payments in accordance with ASC 606.

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 maximum possible 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. This ASU is effective for fiscal years beginning after December 15, 2018, including those interim periods within those fiscal years. We are currently evaluating the impact the adoption of the ASU will have on our consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230)*, which simplifies certain elements of cash flow classification. The new standard clarifies certain aspects of the statement of cash flows, including the classification of contingent consideration payments made after a business combination and several other clarifications not currently applicable to the Company. The new standard also clarifies that an entity should determine each separately identifiable source or use within the cash receipts and cash payments on the basis of the nature of the underlying cash flows. In situations in which cash receipts and payments have aspects of more than one class of cash flows and cannot be separated by source or use, the appropriate classification should depend on the activity that is likely to be the predominant source or use of cash flows for the item. The ASU is effective for annual periods beginning after December 15, 2017. The adoption of this standard is not expected to have a material impact on our consolidated statements of cash flows upon adoption.

In October 2016, the FASB issued ASU No. 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory*, or ASU 2016-16. The amendments in ASU 2016-16 require an entity to recognize the income tax consequences of intra-entity transfers of assets other than inventory at the time that the transfer occurs. Current guidance does not require recognition of tax consequences until the asset is eventually sold to a third party. ASU 2016-16 is effective for fiscal years, and interim periods within, beginning after December 15, 2017. Early adoption is permitted as of the first interim period presented in a year. A reporting entity must apply the amendments in

ASU 2016-16 using a modified retrospective approach by recording a cumulative-effect adjustment to equity as of the beginning of the fiscal year of adoption. We are evaluating the impact of the adoption of ASU 2016-16 on January 1, 2018 to our consolidated financial position and results of operations. We do not expect the adoption of ASU 2016-16 to have a material impact on our consolidated financial position or results of operations.

In November 2016, the FASB issued ASU No. 2016-18, *Restricted Cash*, or ASU 2016-18. The amendments in ASU 2016-18 require an entity to reconcile and explain the period-over-period change in total cash, cash equivalents and restricted cash within its statements of cash flows. ASU 2016-18 is effective for fiscal years, and interim periods within, beginning after December 15, 2017. Early adoption is permitted. A reporting entity must apply the amendments in ASU 2016-18 using a full retrospective approach. We expect the adoption to have an impact on our consolidated statement of cash flows as, upon adoption, it will include our restricted cash balance in the cash and cash equivalents reconciliation of operating, investing and financing activities.

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, including interim periods within, 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 do not expect the adoption of ASU 2017-04 to have a material impact to our consolidated financial position or results of operations.

In May 2017, the FASB issued ASU 2017-09, *Compensation – Stock Compensation* (Topic 718): Scope Modification Accounting. The new standard is intended to reduce the diversity in practice and cost and complexity when applying the guidance in Topic 718 to a change to the terms or conditions of a share-based payment award. The new standard will be effective beginning January 1, 2019. The adoption of this standard is not expected to have a material impact on our consolidated financial position or results of operations upon adoption.

### Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2017 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
Operating lease obligations	\$ 5,804	\$ 1,084	\$ 3,298	\$ 1,422	\$ —
Licenses	275	25	50	50	150
Long-term debt	60,000	—	60,000	—	—
Total contractual cash obligations	<u>\$ 66,079</u>	<u>\$ 1,109</u>	<u>\$ 63,348</u>	<u>\$ 1,472</u>	<u>\$ 150</u>

### 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. The total revised lease commitment of \$3.4 million is over a remaining four-year lease term. In accordance with the amended lease agreement, we paid a security deposit of \$0.1 million. We are required to make additional payments under the facility operating leases for taxes, insurance, and other operating expenses incurred during the lease period. In addition, the lease provided an incentive from the landlord of up to \$0.2 million in tenant improvements. We capitalized all leasehold improvements as fixed assets. Accordingly, we also recorded a related financing obligation in "other long-term liabilities" on our consolidated balance sheet. These amounts will be treated as a reduction to rent expense over the lease term. Subsequent to the amended lease agreement, we will record monthly rent expense of approximately \$54,000 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, for a total commitment of \$3.3 million with respect to which lease payments became due beginning once 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 are 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, \$150,000 of which has 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 % (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 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. We paid a sublicense issue fee in the low six figures to Tufts during the year ended December 31, 2017 upon earning the \$7.5 million upfront payment under the Zai Collaboration Agreement.

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 \$3.6 million for the year ended December 31, 2017 and 2016 included within "Other Long-Term Liabilities" on our consolidated balance sheet. There are no other payment obligations to Novartis under either the Novartis Agreement or the amended Novartis Letter Agreement.

### ***Long-Term Debt***

On September 30, 2015, we entered into the Loan Agreement with Hercules and certain other lenders and Hercules Technology Growth Capital, Inc. (as agent). We executed three amendments to the Loan Agreement subsequent to September 30, 2015, providing access to term loans with an aggregate principal amount of up to \$60.0 million. As of December 31, 2017, we have drawn down on the full \$60.0 million available to us. The last amendment executed in June 2017 extended the date on which we are required to begin making monthly principal installments from January 1, 2019 to January 1, 2020, subject to our receipt of marketing approval for our lead product candidate, omadacycline. Beginning on January 1, 2019, or, if we achieve the Interest Only Period Extension Event, beginning on January 1, 2020, we will make payments in equal monthly installments of principal and interest, with the balance of outstanding loans due on the original maturity date of the Loan Agreement, as amended.

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 also have 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.

As of December 31, 2017 and 2016, we have recorded a long-term debt obligation of \$59.2 million, net of debt discount of \$0.8 million and \$39.0 million, net of debt discount of \$1.1 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*, or ASU 2015-03.



### ***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***

#### *CIPAN*

In November 2016, we entered into a manufacturing and services agreement with CIPAN – Companhia Industrial Produtora de Antibióticos, or CIPAN. The agreement 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 as the active pharmaceutical ingredient. Under this agreement, we are obligated to pay a CIPAN Product price in the high three-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 an outsourcing agreement with CARBOGEN AMCIS AG, or Carbogen. The agreement provides for the terms and conditions under which Carbogen will manufacture and supply to us the active pharmaceutical ingredient for our omadacycline product 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 initially pay Carbogen an amount in the low 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 both parties are obligated to use diligent efforts to come to a subsequent long-term agreement to replace this agreement no later than the end of such initial term. If we have not executed a replacement agreement with Carbogen by such time, this agreement will automatically be extended for a fixed period of time. We may terminate this agreement by delivering notice of termination to Carbogen prior to the expiration of the initial or subsequent 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.

#### *Almac*

In December 2016, we 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 us omadacycline oral solid dosage tablets in bulk form, or the Almac Products. Under this 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 per batch of the Almac Products, subject to adjustments as provided in the agreement. 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.

Our agreement with Almac will remain in effect for a fixed initial term, after which the agreement will continue for successive renewal terms unless either we 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 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 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. If our omadacycline product is approved, we will also be subject to an annual minimum purchase requirement in the six-digit euro 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.

#### **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, 2017 consisted of cash and cash equivalents and U.S. treasury and government agency 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 10% of total liabilities as of December 31, 2017.

**Item 8. Financial Statements and Supplementary Data**

**Index to Financial Statements**

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## 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, 2017 and 2016, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, 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, 2017, 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 6, 2018 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 6, 2018

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders  
Paratek Pharmaceuticals, Inc.

We have audited the accompanying consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows of Paratek Pharmaceuticals, Inc. for the year ended December 31, 2015. Paratek Pharmaceuticals, Inc.'s management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of the operations and cash flows of Paratek Pharmaceuticals, Inc. for the year ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

/s/ CohnReznick LLP

Vienna, Virginia  
March 9, 2016

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

	December 31,	
	2017	2016
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 35,416	\$ 52,962
Marketable securities	116,307	75,076
Restricted cash	162	817
Accounts receivable	5,041	—
Other receivables	848	323
Prepaid and other current assets	2,712	2,922
Total current assets	<u>160,486</u>	<u>132,100</u>
Long-term restricted cash	250	250
Fixed assets, net	1,711	1,188
Intangible assets, net	142	1,015
Goodwill	829	829
Other long-term assets	280	350
Total assets	<u>\$ 163,698</u>	<u>\$ 135,732</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable	\$ 3,555	\$ 4,418
Other accrued expenses	10,874	6,372
Accrued contract research	2,360	9,566
Current portion of Intermezzo reserve	—	56
Total current liabilities	<u>16,789</u>	<u>20,412</u>
Long-term debt	59,186	38,974
Contingent obligations	71	655
Other liabilities	5,174	4,099
Total liabilities	<u>81,220</u>	<u>64,140</u>
Commitments and contingencies (Note 16)		
Stockholders' equity		
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, 27,941,015 and 23,358,637 issued and outstanding at December 31, 2017 and 2016, respectively	28	23
Additional paid-in capital	552,720	451,947
Accumulated other comprehensive loss	(158)	(16)
Accumulated deficit	(470,112)	(380,362)
Total stockholders' equity	<u>82,478</u>	<u>71,592</u>
Total liabilities and stockholders' equity	<u>\$ 163,698</u>	<u>\$ 135,732</u>

*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,		
	2017	2016	2015
Revenue			
Collaboration and royalty revenue	\$ 12,616	\$ 29	\$ —
Total revenue	<u>12,616</u>	<u>29</u>	<u>—</u>
Operating expenses:			
Research and development	60,072	83,460	50,765
General and administrative	36,965	26,400	19,988
Impairment of intangible assets	743	—	2,860
Changes in fair value of contingent consideration	(584)	(345)	(3,560)
Total operating expenses	<u>97,196</u>	<u>109,515</u>	<u>70,053</u>
Loss from operations	(84,580)	(109,486)	(70,053)
Other income and expenses:			
Interest income	1,377	1,069	—
Interest expense	(5,079)	(3,223)	(770)
Other gains (and losses), net	(34)	4	(37)
Net loss	<u>(88,316)</u>	<u>(111,636)</u>	<u>(70,860)</u>
Provision for income taxes	753	—	—
Net loss attributable to common stockholders	<u>\$ (89,069)</u>	<u>\$ (111,636)</u>	<u>\$ (70,860)</u>
Other comprehensive loss			
Unrealized loss on available-for-sale securities, net of tax	(142)	(16)	—
Other comprehensive loss	(142)	(16)	—
Comprehensive loss	<u>\$ (89,211)</u>	<u>\$ (111,652)</u>	<u>\$ (70,860)</u>
Net loss per share attributable to common stockholders:			
Basic and diluted net loss per common share	\$ (3.32)	\$ (5.51)	\$ (4.29)
Weighted average common shares outstanding			
Basic and diluted	26,827,253	20,253,082	16,501,912

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

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

	Common Stock		Additional Paid-in Capital	Accumulated other comprehensive income (loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balances at December 31, 2014</b>	14,417,936	\$ 14	\$ 293,076	\$ —	\$ (197,866)	\$ 95,224
Exercise of stock options	56,897	1	246	—	—	247
Issuance of common stock, net of expenses	3,133,782	2	71,277	—	—	71,279
Issuance of warrants for common stock	—	—	288	—	—	288
Stock-based compensation expense	—	—	5,062	—	—	5,062
Net loss	—	—	—	—	(70,860)	(70,860)
<b>Balances at December 31, 2015</b>	17,608,615	\$ 17	\$ 369,949	\$ —	\$ (268,726)	\$ 101,240
Exercise of stock options	2,508	—	11	—	—	11
Issuance of common stock, net of expenses	5,747,514	6	70,924	—	—	70,930
Issuance of warrants for common stock	—	—	271	—	—	271
Unrealized loss on available-for-sale securities, net of tax	—	—	—	(16)	—	(16)
Stock-based compensation expense	—	—	10,792	—	—	10,792
Net loss	—	—	—	—	(111,636)	(111,636)
<b>Balances at December 31, 2016</b>	23,358,637	\$ 23	\$ 451,947	\$ (16)	\$ (380,362)	\$ 71,592
Exercise of stock options	66,455	—	320	—	—	320
Issuance of common stock, net of expenses	4,332,126	5	82,791	—	—	82,796
Vesting of restricted stock unit awards	183,797	—	—	—	—	—
Issuance of warrants for common stock	—	—	79	—	—	79
Retroactive adjustment to beginning accumulated deficit and additional paid-in capital resulting from adoption of ASU 2016-09	—	—	681	—	(681)	—
Unrealized loss on available-for-sale securities, net of tax	—	—	—	(142)	—	(142)
Stock-based compensation expense	—	—	16,902	—	—	16,902
Net loss	—	—	—	—	(89,069)	(89,069)
<b>Balances at December 31, 2017</b>	27,941,015	\$ 28	\$ 552,720	\$ (158)	\$ (470,112)	\$ 82,478

*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,		
	2017	2016	2015
Net loss	\$ (89,069)	\$ (111,636)	\$ (70,860)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,268	2,303	714
Stock-based compensation expense	16,902	10,792	5,062
Noncash interest expense	406	241	548
Impairment of intangible assets	743	—	2,860
Change in fair value of contingent consideration	(584)	(345)	(3,560)
Other gains, net	—	—	17
Changes in operating assets and liabilities			
Accounts receivable, prepaid, and other current assets	(4,833)	4,960	(2,705)
Accounts payable and accrued expenses	(4,223)	2,062	14,021
Other liabilities and other assets	816	(2,475)	(779)
Net cash used in operating activities	<u>(78,574)</u>	<u>(94,098)</u>	<u>(54,682)</u>
<b>Investing activities</b>			
Purchase of fixed assets	(1,117)	(690)	(856)
Purchase of marketable securities	(180,289)	(135,799)	—
Proceeds from maturities of marketable securities	131,250	60,106	—
Proceeds from sales of marketable securities	7,499	—	—
Decrease in restricted cash	655	1,626	253
Net cash used in investing activities	<u>(42,002)</u>	<u>(74,757)</u>	<u>(603)</u>
<b>Financing activities</b>			
Proceeds from exercise of stock options	320	11	247
Proceeds from issuance of long-term debt, net of costs	19,915	19,574	19,205
Proceeds from issuance of common stock, net	82,795	70,930	71,279
Net cash provided by financing activities	<u>103,030</u>	<u>90,515</u>	<u>90,731</u>
Net increase (decrease) in cash	(17,546)	(78,340)	35,446
Cash at beginning of year	52,962	131,302	95,856
Cash at end of year	<u>\$ 35,416</u>	<u>\$ 52,962</u>	<u>\$ 131,302</u>
<b>Supplemental disclosure of noncash financing activities</b>			
Fair value of warrants issued	<u>\$ 79</u>	<u>\$ 271</u>	<u>\$ 288</u>
<b>Supplemental disclosure of cash flow information</b>			
Cash paid for interest	<u>\$ 3,705</u>	<u>\$ 1,582</u>	<u>\$ 292</u>

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

**Paratek Pharmaceuticals, Inc.**  
**Notes to 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.

The Company is a clinical stage biopharmaceutical company focused on the development and commercialization of innovative therapeutics based upon tetracycline chemistry. The Company has used its expertise in biology and tetracycline chemistry to create chemically diverse and biologically distinct small molecules derived from the minocycline core structure. The Company's two lead product candidates are the antibacterials omadacycline and sarecycline.

Prior to October 30, 2014, the name of the Company was Transcept Pharmaceuticals, Inc., or Transcept. On October 30, 2014, 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 (the Company refers 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." Following the completion of the Merger, the business conducted by Paratek Pharmaceuticals Inc. became primarily the business conducted by Paratek.

The Company has incurred significant losses since inception in 1996. The Company has generated an accumulated deficit of \$470.1 million through December 31, 2017 and will require substantial additional funding in connection with the Company's continuing operations to support commercial activities associated with its lead product candidate, omadacycline. Based upon the Company's current operating plan, it anticipates that cash, cash equivalents and available for sale marketable securities of \$151.7 million as of December 31, 2017, together with the \$50.0 million in proceeds received in January 2018 from the sale of 3,205,128 shares of common stock, 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 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 SEC. Accounts payable and accrued expenses were reclassified on the Company's balance sheet as of December 31, 2016 to conform to the current presentation.

**Principles of Consolidation**

The accompanying audited condensed 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., and Paratek Ireland Limited. 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, intangible assets, goodwill, contingent liabilities, stock-based compensation arrangements, 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, 2017 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 and government agency 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 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, 2017 and 2016.

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, 2017 and 2016.

## 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 in the next twelve months, the restricted cash account is classified as current.

#### 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, 2017, revenue consisted of upfront fees and milestone payments received in connection with the Company’s collaboration agreements with Allergan and Zai Lab (Shanghai) Co., Ltd., or Zai, and royalty income pursuant to the royalty sharing agreement, or the Royalty Sharing Agreement, entered into by the Company in October 2016 with the Special Committee of the Company’s Board of Directors, or the Special Committee. Revenue for the year ended December 31, 2016 represents royalty income under the Royalty Sharing Agreement. For the year ended December 31, 2017, Allergan and Zai represented approximately 40% and 59%, respectively, of collaboration and royalty income. Allergan represented approximately 99% of “Accounts receivable” on the Company’s consolidated balance sheet as of December 31, 2017.

#### Fixed Assets

Fixed assets, including leasehold improvements, are recoded 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
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.

#### 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, which range from three to thirteen years. 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.

In accordance with the Company's policy, the Company reviews the estimated useful lives of its long-lived intangible assets on an ongoing basis.

### **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, 2017, 2016 and 2015.

### **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**

The Company leases its facilities under non-cancelable operating leases that expire at various dates through 2024. The leases contain rent escalation and rent holiday, which are being accounted for as rent expense under the straight-line method. Deferred rent is included in accounts payable and other accrued expenses in the consolidated balance sheet. During 2016, the Company recorded a lease incentive obligation on the consolidated balance sheets representing a landlord incentive to reimburse the Company up to \$0.2 million for construction on additional lease space in accordance with the Company's executed amended lease agreement at its Boston office location. These amounts are treated as reduction to rent expense over the lease term.

### **Revenue Recognition**

The Company enters into product development agreements with collaborators for the research and development of therapeutic products. The terms of these agreements may include nonrefundable signing and licensing fees, funding for research, development and manufacturing, milestone payments and royalties on any product sales derived from collaborations. The Company assesses these multiple elements in accordance with the FASB, Accounting Standards Codification, or ASC 605, *Revenue Recognition*, in order to determine whether particular components of the arrangement represent separate units of accounting.

The Company recognizes upfront license payments as revenue upon delivery of the license only if the license has stand-alone value. If the license does not have stand-alone value, the revenue under the arrangement is recognized as revenue over the estimated period of performance.

Whenever the Company determines that an arrangement should be accounted for as a single unit of accounting, the Company determines the period over which the performance obligations will be performed and revenue will be recognized. If the Company cannot reasonably estimate the timing and the level of effort to complete its performance obligations under the arrangement, then revenue under the arrangement is recognized on a straight-line basis over the period that the Company expects to complete its performance obligations, which is reassessed at each subsequent reporting period.

The Company's collaboration agreements may include additional payments upon the achievement of performance-based milestones. As milestones are achieved, a portion of the milestone payment, equal to the percentage of the total time that the Company has performed the performance obligations to date over the total estimated time to complete the performance obligations, multiplied by the amount of the milestone payment, is recognized as revenue upon achievement of such milestone. The remaining portion of the milestone will be recognized over the remaining performance period. If the Company has no future obligations under the collaboration agreement, the milestone payments are recognized as revenue in the period the milestone is received. Milestones that are tied to regulatory approval are not considered probable of being achieved until such approval is received. Milestones tied to counterparty performance are not included in the Company's revenue model until the performance conditions are met.

The Company entered into a License and Collaboration Agreement with Zai, or the Zai Collaboration Agreement, in April 2017, pursuant to which Paratek Bermuda Ltd. granted Zai an exclusive license to develop, manufacture and commercialize omadacycline in the People's Republic of China, Hong Kong, Macau and Taiwan 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 Bermuda Ltd. Refer to Note 4, *License and Collaboration Agreements*, for further details surrounding the Zai Collaboration Agreement.

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 the Royalty Sharing Agreement in October 2016. Under the Royalty Sharing Agreement, the Company agreed to pay to the former Transcept stockholders fifty percent of all royalty income received by the Company pursuant to the collaboration agreement with Purdue Pharma, L.P., or Purdue Pharma, or 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 Company recognizes all royalty income received from Purdue upon the sale of Intermezzo.

The Company also adopted guidance that permits the recognition of revenue contingent upon the achievement of a milestone in its entirety, in the period in which the milestone is achieved, only if the milestone meets certain criteria and is considered to be substantive. As such, the Company plans to recognize revenue in the period in which the milestone is achieved, only if the milestone is considered to be substantive based on the following criteria:

- a. The milestone is commensurate with either of the following:
  - The vendor's performance to achieve the milestone.
  - The enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the vendor's performance to achieve the milestone.
- b. The milestone relates solely to past performance.
- c. The milestone is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

For the year ended December 31, 2017, the Company recognized revenue under the Zai Collaboration Agreement of \$7.5 million, which represents an upfront payment made by Zai upon execution of the Zai Collaboration Agreement. The Company also recognized revenue of \$5.0 million as a milestone payment earned from Allergan upon NDA acceptance of sarecycline by the FDA. The Company did not enter into any significant multiple element arrangements during the years ended December 31, 2016 and 2015. The Company did not materially modify any of its other existing multiple element arrangements during the years ended December 31, 2017, 2016 or 2015.

For the years ended December 31, 2017 and 2016, , Company recognized \$0.1 million and \$29,000, respectively, of royalty revenue from the Purdue Collaboration Agreement. No royalty revenue was recognized for the year ended December 31, 2015. The Company will continue to recognize royalty revenue upon the sale of the relevant products, provided there are no remaining performance obligations under the arrangement.

The Company records deferred revenue when payments are received in advance of the culmination of the earnings process. This revenue is recognized in future periods when the applicable revenue recognition criteria have been met.

### **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 Accounting Standards Codification 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, 2017, 2016 and 2015.

### **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 doesn't affect the grant-date fair value or quantity of awards to be recognized) is recognized prospectively over the remaining requisite service period. The Company accounts for stock-based awards to non-employees using the fair value method on a straight-line basis over the associated service period of the award. 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.

Share-based payments issued to non-employees are recorded at their fair values, are periodically revalued as the equity instruments vest and are recognized as expense over the related service period in accordance with the provisions of ASC 718 and ASC Topic 505 (ASC 505), *Equity*.

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 highly subjective 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.

As of January 1, 2017, the Company adopted ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, or ASU 2016-09. In connection with the adoption, the Company made an accounting policy change. Prior to adoption, the Company estimated forfeitures at the time of grant and revised those estimates in subsequent periods if actual forfeitures differed from the estimates. The Company used historical data to estimate pre-vesting option forfeitures to the extent that actual forfeitures differed from our estimates, the difference was recorded as a cumulative adjustment in the period the estimates were revised. Upon adoption, the Company recognizes the effect of forfeitures in compensation cost when they occur. The Company recorded a cumulative-effect catch-up adjustment to equity of \$0.7 million upon adoption.

### **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.

Between May 2014 and May 2016, the FASB issued three ASUs changing the requirements for recognizing and reporting revenue, or together, herein referred to as the Revenue ASUs: (i) ASU No. 2014-09, *Revenue from Contracts with Customers*, or ASU 2014-09, (ii) ASU No. 2016-08, *Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, or ASU 2016-08, and (iii) ASU No. 2016-12, *Narrow-Scope Improvements and Practical Expedients*, or ASU 2016-12. ASU 2014-09 provides guidance for revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2016-08 is intended to improve the operability



and understandability of the implementation guidance on principal versus agent considerations. ASU 2016-12 provides practical expedients and improvements on the previously narrow scope of ASU 2014-09. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, or ASU 2015-14. ASU 2015-14 defers the effective date of ASU 2014-09 by one year to fiscal years, and interim periods within, beginning after December 15, 2017. All subsequent ASUs related to ASU 2014-09, including ASU 2016-08 and ASU 2016-12, assumed the deferred effective date enforced by ASU 2015-14. Early adoption of the Revenue ASUs is permitted for annual periods, and interim periods within, beginning after December 15, 2016. A reporting entity may apply the amendments in the Revenue ASUs using either a modified retrospective approach, by recording a cumulative-effect adjustment to equity as of the beginning of the fiscal year of adoption or full retrospective approach.

The Company adopted ASC 606, *Revenue from Contracts with Customers*, or ASC 606, as of January 1, 2018 using the full retrospective approach. The Company is evaluating the complete impact of the adoption of ASC 606 on its consolidated financial position and results of operations and currently does not expect ASC 606 to have a material impact on revenue previously recognized under the Company's Allergan, Zai and Purdue Collaboration Agreements. The Company implemented appropriate changes to its internal controls to support revenue recognition, including controls to monitor the probability of achievement of contingent milestone payments, and additional revenue-related disclosures under the new standard.

Upon adoption of ASC 606, the accounting for contingent milestone payments under the Company's collaboration agreements changed. ASC 606 does not contain guidance specific to milestone payments, thereby requiring contingent milestone payments to be considered in accordance with the overall model of ASC 606 as variable consideration. Revenue from contingent milestone payments may be recognized earlier under ASC 606 than under ASC 605, *Revenue Recognition*, based on an assessment at each reporting date of the probability of achievement of the underlying milestone event. This assessment may, in certain circumstances, result in the recognition of revenue related to a contingent milestone payment before the milestone event has been achieved. The Company will recognize all future milestone payments in accordance with ASC 606.

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 maximum possible 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. This ASU is effective for fiscal years beginning after December 15, 2018, including those interim periods within those fiscal years. The Company is currently evaluating the impact the adoption of the ASU will have on its consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230)*, which simplifies certain elements of cash flow classification. The new standard clarifies certain aspects of the statement of cash flows, including the classification of contingent consideration payments made after a business combination and several other clarifications not currently applicable to the Company. The new standard also clarifies that an entity should determine each separately identifiable source or use within the cash receipts and cash payments on the basis of the nature of the underlying cash flows. In situations in which cash receipts and payments have aspects of more than one class of cash flows and cannot be separated by source or use, the appropriate classification should depend on the activity that is likely to be the predominant source or use of cash flows for the item. The ASU is effective for annual periods beginning after December 15, 2017. The adoption of this standard is not expected to have a material impact on the Company's consolidated statements of cash flows upon adoption.

In October 2016, the FASB issued ASU No. 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory*, or ASU 2016-16. The amendments in ASU 2016-16 require an entity to recognize the income tax consequences of intra-entity transfers of assets other than inventory at the time that the transfer occurs. Current guidance does not require recognition of tax consequences until the asset is eventually sold to a third party. ASU 2016-16 is effective for fiscal years, and interim periods within, beginning after December 15, 2017. Early adoption is permitted as of the first interim period presented in a year. A reporting entity must apply the amendments in ASU 2016-16 using a modified retrospective approach by recording a cumulative-effect adjustment to equity as of the beginning of the fiscal year of adoption. The Company is evaluating the impact of the adoption of ASU 2016-16 on January 1, 2018 to its consolidated financial position and results of operations. The Company does not expect the adoption of ASU 2016-16 to have a material impact to its consolidated financial position or results of operations.

In November 2016, the FASB issued ASU No. 2016-18, *Restricted Cash*, or ASU 2016-18. The amendments in ASU 2016-18 require an entity to reconcile and explain the period-over-period change in total cash, cash equivalents and restricted cash within its statements of cash flows. ASU 2016-18 is effective for fiscal years, and interim periods within, beginning after December 15, 2017. Early adoption is permitted. A reporting entity must apply the amendments in ASU 2016-18 using a full retrospective approach. The Company expects the adoption to have an impact on its consolidated statement of cash flows as, upon adoption, it will include the Company's restricted cash balance in the cash and cash equivalents reconciliation of operating, investing and financing activities.

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, including interim periods within, 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 does not expect the adoption of ASU 2017-04 to have a material impact to its consolidated financial position or results of operations.

In May 2017, the FASB issued ASU 2017-09, *Compensation – Stock Compensation* (Topic 718): Scope Modification Accounting. The new standard is intended to reduce the diversity in practice and cost and complexity when applying the guidance in Topic 718 to a change to the terms or conditions of a share-based payment award. The new standard will be effective beginning January 1, 2019. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial position or results of operations upon adoption.

### 3. Net Loss Per Share Available to Common Stockholders

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

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

	Year Ended December 31,		
	2017	2016	2015
<b>Numerator</b>			
Net loss attributable to common stockholders	(89,069)	(111,636)	(70,860)
<b>Denominator</b>			
Weighted-average common shares outstanding— basic and diluted	26,827,253	20,253,082	16,501,912
Net loss per share—basic and diluted	\$ (3.32)	\$ (5.51)	\$ (4.29)

The following outstanding shares subject to options and warrants to purchase common stock were antidilutive due to a net loss in the years presented and, therefore, were excluded from the dilutive securities computation as of the dates indicated below (in thousands):

	Year Ended December 31,		
	2017	2016	2015
<b>Excluded potentially dilutive securities (1):</b>			
Shares subject to options to purchase common stock	3,608,907	2,780,791	2,242,890
Unvested restricted stock units	1,167,703	454,000	275,500
Shares subject to warrants to purchase common stock	84,828	79,454	47,426
Shares issuable under employee stock purchase plan	36,539	36,539	36,539
Totals	4,897,977	3,350,784	2,602,355

(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.

#### 4. License and Collaboration Agreements

##### *Zai Lab (Shanghai) Co., Ltd.*

On April 21, 2017, Paratek Bermuda Ltd., a wholly-owned subsidiary of Paratek Pharmaceuticals, Inc., and Zai entered into the Zai Collaboration Agreement. Under the terms of the Zai Collaboration Agreement, Paratek Bermuda Ltd. 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 Bermuda Ltd.

Under the terms of the Zai Collaboration Agreement, Paratek Bermuda Ltd. earned an upfront cash payment of \$7.5 million, before taxes, and is eligible to receive up to \$14.0 million in potential regulatory milestone payments and \$40.5 million in potential commercial milestone payments, the next being \$5.0 million upon approval by the FDA of an NDA submission in the CABP indication. Zai will also pay Paratek Bermuda Ltd. 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 Subtopic 605-25, "*Multiple Element Arrangements*". The Company determined that there were five deliverables under the Zai Collaboration Agreement: (i) an exclusive license to develop, manufacture and commercialize omadacycline in the territory; (ii) an initial transfer of technology; (iii) a transfer of certain materials and materials know-how (iv) an additional transfer of materials; and (v) participation on a joint steering committee, or JSC, and joint development committee, or JDC.

The consideration allocable to the delivered unit or units of accounting is limited to the amount that is not contingent upon the delivery of additional items or meeting other specified performance conditions. The Company determined that each potential future clinical, regulatory and commercialization milestone is substantive. In making this determination, pursuant to the accounting guidance on revenue recognition for milestone payments, the Company considered and concluded that each individual milestone: (i) relates solely to the past performance of the intellectual property to achieve the milestone; (ii) is reasonable relative to all of the deliverables and payment terms in the arrangement; and (iii) is commensurate with the enhanced value of the intellectual property as a result of the milestone achievement. As the Company's obligations under this arrangement have been completed, all future milestones, which are all considered substantive, will be recognized as revenue when achieved. Therefore, the Company excluded from the allocable consideration the milestone payments and royalties, regardless of the probability that such milestone and royalty payments will be made, until the events that give rise to such payments occur. In addition, all regulatory milestones in the Zai Collaboration Agreement are considered substantive on the basis of the contingent nature of the milestone, including factors such as regulatory and other risks that must be overcome to achieve each milestone as well as the level of effort and investment required. Accordingly, such amounts will be recognized in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. All commercial milestones will be accounted for in the same manner as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

The Company determined that all five deliverables listed above had value to the Company on a stand-alone basis and therefore five units of accounting were identified. The Company determined, however, that the best estimate for the selling price of the initial transfer of technology, transfer of certain materials and materials know-how, the additional transfer of materials and participation on the JSC and JDC were all inconsequential. As such, the Company recognized the total arrangement consideration as revenue during the year ended December 31, 2017.

Under the Zai Collaboration Agreement, Zai will pay taxes incurred in the Zai territory by Paratek on Paratek's behalf and deduct these taxes from the payments due to Paratek. Withholding and other value-added taxes of \$0.8 million were incurred on the \$7.5 million upfront payment. As such, the Company received \$6.7 million, net of taxes, during the year ended December 31, 2017. These taxes were paid by Zai on behalf of the Company.

During the year ended December 31, 2017, the Company recognized revenue under the Zai Collaboration Agreement of \$7.5 million, which represents an upfront payment made by Zai upon execution of the Zai Collaboration Agreement.

## *Allergan plc*

In July 2007, the Company and Warner Chilcott Company, Inc. (now part of Allergan), entered into a collaborative research and license agreement, or the Allergan Collaboration Agreement, under which the Company granted Allergan an exclusive license to research, develop and commercialize tetracycline products for use in the United States for the treatment of acne and rosacea. 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 converted to a non-exclusive license for the treatment of rosacea as of December 2014. Under the terms of the Allergan Collaboration Agreement, the Company and Allergan 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 Allergan, the Company may conduct certain additional development activities to the extent the Company determines in good faith that the Company has the necessary resources available for such activities. Allergan has agreed to reimburse the Company for its costs and expenses, including third-party costs, incurred in conducting any such development activities.

Under the terms of the Allergan Collaboration Agreement, Allergan 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. Allergan failed to elect to advance the development of sarecycline for the treatment of rosacea in accordance with the terms of the agreement so the license granted to Allergan was converted to a non-exclusive license for the treatment of rosacea as of December 2014. The Company has agreed during the term of the Allergan Collaboration Agreement not to directly or indirectly develop or commercialize any tetracycline compounds in the United States for the treatment of acne and rosacea, and Allergan has agreed during the term of the Allergan 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 agreement.

The Company earned an upfront fee in the amount of \$4.0 million upon the execution of the Allergan Collaboration Agreement, \$1.0 million upon filing of an Investigational New Drug Application in 2010, and \$2.5 million upon initiation of Phase 2 trials in 2012. In December 2014, the Company earned \$4.0 million upon initiation of Phase 3 trials associated with the Allergan Collaboration Agreement. The Company also earned a \$5.0 million milestone payment from Allergan upon the FDA's acceptance of Allergan's NDA for sarecycline, or Seysara™, in December 2017. The \$5.0 million milestone payment is included within "Accounts receivable" on the Company's consolidated balance sheet and "Collaboration and royalty revenue" on the Company's consolidated statements of operations and comprehensive loss as and for the year ended December 31, 2017, respectively. The amount was subsequently collected in 2018.

Allergan may be required to pay the Company a future milestone payment of \$12.0 million upon receipt of commercialization regulatory approval from the FDA. Allergan 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 Allergan Collaboration Agreement, with a standard royalty reduction post patent expiration for such product for the remainder of the royalty term. Allergan's obligation to pay the Company royalties for each tetracycline compound it commercializes under the Allergan Collaboration Agreement expires on the later of the expiration of the last to expire patent that covers the tetracycline compound in the United States and the date on which generic drugs that compete with the tetracycline compound reach a certain threshold market share in the United States.

Either the Company or Allergan may terminate the Allergan Collaboration Agreement for certain specified reasons at any time after Allergan has commenced development of any tetracycline compound, including if Allergan 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 the Company or Allergan may terminate the Allergan 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 Allergan Collaboration Agreement by Allergan for the Company's breach, Allergan's license will continue following the effective date of termination, subject to the payment by Allergan 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 Allergan to pay us any further royalty or milestone payments will terminate. Upon the termination of the Allergan Collaboration Agreement by us for Allergan's breach or the voluntary termination of the agreement by Allergan, Allergan's license under the agreement will terminate.

The Company determined whether the performance obligations under the Allergan Collaboration Agreement could be accounted for separately or as a single unit of accounting. The Company determined that the license, participation on steering committees and research and development services performance obligations during the research period of the Allergan Collaboration Agreement represented a single unit of accounting. As the Company could not reasonably estimate its level of effort, the Company recognized revenue from the upfront payment, milestone payment and research and development services payments using the contingency-adjusted performance model over the expected development period. The development period was completed in June 2010. Under this model, when a milestone was earned or research and development services were rendered, revenue was immediately recognized on a

pro-rata basis in the period the milestone was achieved or services were delivered based on the time elapsed from the effective date of the agreement. Thereafter, the remaining portion was recognized on a straight-line basis over the remaining development period. The Company has determined that each potential future clinical, regulatory and commercialization milestone is substantive. In making this determination, pursuant to the accounting guidance on revenue recognition for milestone payments, the Company considered and concluded that each individual milestone: (i) relates solely to the past performance of the intellectual property to achieve the milestone; (ii) is reasonable relative to all of the deliverables and payment terms in the arrangement; and (iii) is commensurate with the enhanced value of the intellectual property as a result of the milestone achievement. As the Company's obligations under this arrangement have been completed, all future milestones, which are all considered substantive, will be recognized as revenue when achieved. As such, the Company recognized revenue from the \$5.0 million milestone payment from Allergan upon the FDA's acceptance of Allergan's NDA for sarecycline upon achievement of the milestone in December 2017.

Also, the Company, at its discretion, may provide manufacturing process development services to Allergan in exchange for full-time equivalent based cost reimbursements. The Company determined that the manufacturing process development services are considered a separate unit of accounting as (i) they are set at the Company's discretion, (ii) they have stand-alone value, as these services could be performed by third parties, and (iii) the full-time equivalent rate paid for such services rendered is considered fair value. Therefore, the Company recognizes cost reimbursements for manufacturing process development services as revenue as the services are performed.

### ***Tufts University***

In February 1997, the Company and 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 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. The Company has 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 its first marketing application (NDA) submitted in the United States. 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. The Company paid a sublicense issue fee to Tufts during the year ended December 31, 2017 upon earning the \$7.5 million upfront payment under the Zai Collaboration Agreement.

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.

### ***Purdue Pharma L.P.***

In July 2009, the Company and Purdue Pharma entered into the Purdue Collaboration Agreement, which grants an exclusive license to Purdue Pharma to commercialize Intermezzo in the United States and pursuant to which:

- Purdue Pharma paid the Company a \$25.0 million non-refundable license fee in August 2009;
- Purdue Pharma paid the Company a \$10.0 million non-refundable intellectual property milestone in December 2011 when the first of two issued formulation patents was listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book;
- Purdue Pharma paid the Company a \$10.0 million non-refundable intellectual property milestone in August 2012 when the first of two issued methods of use patents was listed in the FDA's Orange Book;
- The Company transferred the Intermezzo NDA to Purdue Pharma, and Purdue Pharma is obligated to assume the expense associated with maintaining the NDA and further development of Intermezzo in the United States, including any expense associated with post-approval studies;
- Purdue Pharma is obligated to commercialize Intermezzo in the United States at its expense using commercially reasonable efforts;
- Purdue Pharma is obligated to pay the Company tiered base royalties on net sales of Intermezzo in the United States ranging from the mid-teens up to the mid-20% level, with each such royalty tiers subject to an increase by a percentage in the low single digits upon a specified anniversary of regulatory approval of Intermezzo. The base royalty is tiered depending upon the achievement of certain fixed net sales thresholds by Purdue Pharma, which net sales levels reset each year for the purpose of calculating the royalty. The royalty tiers are subject to reductions upon generic entry and patent expiration. Purdue Pharma is obligated to pay royalties until the later of 15 years from the date of first commercial sale in the United States or the expiration of patent claims related to Intermezzo; and
- Purdue Pharma is obligated to pay the Company up to an additional \$70.0 million upon the achievement of certain net sales targets for Intermezzo in the United States.

The Company had an option to co-promote Intermezzo to psychiatrists in the United States and such option was terminated as a result of the Merger.

The Purdue Collaboration Agreement expires on the expiration of Purdue Pharma's royalty obligations. Purdue Pharma has the right to terminate the Purdue Collaboration Agreement at any time upon advance notice of 180 days. The Purdue Collaboration Agreement is also subject to termination by Purdue Pharma in the event of FDA or governmental action that materially impairs Purdue Pharma's ability to commercialize Intermezzo or the occurrence of a serious event with respect to the safety of Intermezzo. The Purdue Collaboration Agreement may also be terminated by the Company upon Purdue Pharma commencing an action that challenges the validity of Intermezzo related patents. The Company also has the right to terminate the Purdue Collaboration Agreement immediately if Purdue Pharma is excluded from participation in federal healthcare programs. The Purdue Collaboration Agreement may also be terminated by either party in the event of a material breach by or insolvency of the other party.

The Company also granted Purdue Pharma and an associated company the right to negotiate for the commercialization of Intermezzo in Mexico in 2013 but retained the rights to commercialize Intermezzo in the rest of the world.

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 occurs 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 the Royalty Sharing Agreement with the Special Committee. Under the Royalty Sharing Agreement, the Company agreed to pay to the former Transcept stockholders fifty percent 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.

## 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. 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 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 amended Novartis Letter Agreement resulted in a long-term liability in the amount of \$3.6 million for the year ended December 31, 2017 and 2016 included within "Other Long-Term Liabilities" on the Company's consolidated balance sheet. There are no other payment obligations to Novartis under the Novartis Agreement or the amended Novartis Letter Agreement.

## 5. Restricted Cash

### Short-term restricted cash

#### Intermezzo Reserve

As of December 31, 2017, restricted cash of \$0.2 million represents royalty income received but not yet paid to former Transcept stockholders as part of the royalty sharing agreement, or the Royalty Sharing Agreement, executed by the Company on October 28, 2016 with the Special Committee. See Note 12, *Fair Value Measurements*, for more information on the Royalty Sharing Agreement. Included in the balance as of December 31, 2016, was the remainder of the Intermezzo reserve of \$0.1 million, established in accordance with the Merger Agreement, which was comprised of unpaid legal fees.

#### Letter of Credit

During the year ended December 31, 2016, the Company obtained a letter of credit in the amount of \$0.8 million, which is collateralized with a bank account at a financial institution, to secure value-added tax registration in certain foreign countries. The letter of credit was cancelled by the Company during the first quarter of 2017.

### Long-term restricted cash

#### Letter of Credit

The Company leases its Boston, Massachusetts office space under a non-cancelable operating lease. Refer to Note 16, *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, 2017 and 2016, naming the landlord as beneficiary.

## 6. Cash and Cash Equivalents and Marketable Securities

The following is a summary of available-for-sale securities as of December 31, 2017 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
<b>December 31, 2017</b>				
U.S. treasury securities	\$ 114,666	\$ —	\$ (158)	\$ 114,508
Government agencies	1,799	—	—	1,799
Total	<u>\$ 116,465</u>	<u>\$ —</u>	<u>\$ (158)</u>	<u>\$ 116,307</u>
<b>December 31, 2016</b>				
U.S. treasury securities	\$ 62,574	\$ —	\$ (18)	\$ 62,556
Government agencies	12,518	2	—	12,520
Total	<u>\$ 75,092</u>	<u>\$ 2</u>	<u>\$ (18)</u>	<u>\$ 75,076</u>

No available-for-sale securities held as of December 31, 2017 have remaining maturities greater than one year.

## 7. Fixed Assets, Net

Fixed assets consist of the following (in thousands):

	Estimated Useful Life In Years	December 31,	
		2017	2016
Office equipment	5	\$ 866	\$ 443
Computer equipment	3	412	251
Computer software	3	787	787
Leasehold improvements		860	137
Construction-in-progress		—	391
Gross fixed assets		2,925	2,009
Less: Accumulated depreciation and amortization		(1,214)	(821)
Net fixed assets		\$ 1,711	\$ 1,188

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, 2017, 2016 and 2015 was approximately \$0.6 million, \$0.3 million, and \$0.1 million, respectively, which is included in general and administrative and research and development expense on the accompanying consolidated statements of operations.

Construction-in-progress as of December 31, 2016 includes \$0.4 million related to construction costs incurred by the Company at its Boston office location.

During 2017 and 2016, the Company retired a small amount of fixed assets with no gain or loss recognized.

## 8. Intangible Assets, Net

Intermezzo product rights and the TO-2070 license rights were acquired through the Merger. Refer to Note 4, *License and Collaboration Agreements*, for further detail concerning Intermezzo and TO-2070. 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.

Intermezzo product sales projections significantly declined during the year ended December 31, 2017 and as such, a recoverability test was performed each reporting period during 2017. The Company determined that the summation of the undiscounted cash flows through the year of patent expiration, or the estimated useful life of the asset, were less than the carrying value of the asset resulting in total impairment of \$0.7 million for the year ended December 31, 2017.

The Company performed a recoverability test each reporting period during 2016. It was determined that the summation of the undiscounted future cash flow of the Intermezzo product rights were greater than the carrying value for all reporting periods. As such, the Company did not record an impairment charge during the year ended December 31, 2016.

In accordance with the Company's policy, the estimated useful lives of long-lived intangible assets are reviewed on an ongoing basis. During the year ended December 31, 2016, the execution of the Royalty Sharing Agreement prompted a change in the estimated useful life of the Intermezzo product rights. The Company extended the estimated useful life to better reflect the projected period it will receive royalties from Intermezzo product sales. The estimated useful life of Intermezzo product rights was increased from five years to fifteen years. The effect of this change in estimate reduced amortization expense and net loss recognized during the year ended December 31, 2016 by \$60,000 and increased 2016 basic and diluted earnings per share by an immaterial amount. The remaining carrying amount of the Intermezzo product rights will be amortized prospectively over the revised remaining useful life.



Intangible assets consist of the following (in thousands):

	December 31,	
	2017	2016
Intermezzo product rights	\$ 142	\$ 1,410
TO-2070 asset	170	170
Gross intangible assets	312	1,580
Less: Accumulated amortization	(170)	(565)
Net intangible assets	<u>\$ 142</u>	<u>\$ 1,015</u>

After the impairment charge, the Intermezzo product rights are being amortized over a remaining useful life of 12 years as of December 31, 2017. TO-2070 product rights are fully amortized as of December 31, 2017.

Total amortization expense for the years ended December 31, 2017, 2016, and 2015 was \$0.1 million, \$0.3 million and \$0.6 million, respectively.

Amortization expense is expected to be as follows for the next five-year period (in thousands):

Years Ended December 31,	Amortization	
2018	\$	12
2019		12
2020		12
2021		12
2022		12
Total	<u>\$</u>	<u>60</u>

## 9. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31,	
	2017	2016
Accrued legal costs	\$ 257	\$ 358
Accrued compensation	3,403	2,609
Intermezzo payable	124	49
Accrued professional fees	1,864	1,118
Accrued contract manufacturing	4,964	1,940
Accrued other	262	298
Total	<u>\$ 10,874</u>	<u>\$ 6,372</u>

## 10. 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 11, *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.

In October 2015 and February 2017, the Company entered into Controlled Equity Offering<sup>SM</sup> Sales Agreements, or the 2015 Sales Agreement and 2017 Sales Agreement, respectively, and collectively, the Sales Agreements, 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 \$50.0 million under each Sales Agreement 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 of the Company's common stock 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. The Company has sold all \$50.0 million of shares of its common stock under the 2015 Sales Agreement. The Company received \$36.9 million in proceeds, after deducting commissions of \$1.1 million, from the sale of 2,326,119 shares of common stock under the 2015 Sales Agreement during the year ended December 31, 2017. The Company received \$47.7 million in proceeds, after deducting commissions of \$1.5 million, from the sale of 2,102,315 shares of common stock, as of February 28, 2018, under the 2017 Sales Agreement. As of February 28, 2018, no amount remains available for sale under the 2015 Sales Agreement and \$0.8 million remains available for sale under the 2017 Sales Agreement.

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.

#### **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. A further 5,120 warrants to purchase common stock with an exercise price of \$73.66 per share expired in April 2016.

As described in Note 14, *Long-term Debt*, in connection with the Loan Agreement, the Company issued to each one 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. The Hercules Warrants' total relative fair value of \$0.3 million was determined using a Black-Scholes option-pricing model. The Loan Amendment Warrants' total fair value of \$0.3 million was determined using a Black-Scholes option-pricing model with the following assumptions:

	<b>December 31, 2016</b>
Volatility	60.2%
Weighted average risk-free interest rate	1.9%
Expected dividend yield	0.0%
Expected term	5 years

Additionally, in connection with the borrowing of the Third Tranche (as defined in Note 14, *Long-term Debt*) 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. The Additional Warrant's total relative fair value of \$0.1 million was determined using a Black-Scholes option-pricing model with the following assumptions:

	<b>June 30, 2017</b>
Volatility	67.8%
Weighted average risk-free interest rate	1.8%
Expected dividend yield	0.0%
Expected term	5 years

The Hercules Warrants, Loan Amendment Warrants and Additional 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 from the date of issuance or the consummation of certain acquisitions of the Company as set forth in the various agreements for the Warrants.

## 11. Preferred Stock

Following the Merger, 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 10, *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.

As a result of the Merger and concurrent recapitalization, there are no shares of preferred stock issued or outstanding as of December 31, 2017, 2016 and 2015.

## 12. Fair Value Measurements

Financial instruments, including cash, restricted cash, accounts receivable, accounts payable, accrued expenses and the Intermezzo reserve 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 carrying value of the long-term debt approximates its fair value as the interest rate is near current market rates. The fair value of the Company's long-term 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, 2017 and December 31, 2016, 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):

<u>Description</u>	<u>Quoted Prices in Active Markets (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Significant Unobservable Inputs (Level 3)</u>	<u>December 31, 2017</u>
<b>Assets:</b>				
U.S. treasury securities	\$ 114,508	\$ —	\$ —	\$ 114,508
Government agencies	—	1,799	—	\$ 1,799
Total Assets	<u>\$ 114,508</u>	<u>\$ 1,799</u>	<u>\$ —</u>	<u>\$ 116,307</u>
<b>Liabilities:</b>				
Contingent obligations	\$ —	\$ —	\$ 71	\$ 71
Total Liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 71</u>	<u>\$ 71</u>

<u>Description</u>	<u>Quoted Prices in Active Markets (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Significant Unobservable Inputs (Level 3)</u>	<u>December 31, 2016</u>
<b>Assets:</b>				
U.S. treasury securities	\$ 62,556	\$ —	\$ —	\$ 62,556
Government agencies	—	12,520	—	\$ 12,520
Total Assets	\$ 62,556	\$ 12,520	\$ —	\$ 75,076
<b>Liabilities:</b>				
Contingent obligations	\$ —	\$ —	\$ 655	\$ 655
Total Liabilities	\$ —	\$ —	\$ 655	\$ 655

### **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. The pricing on government agency securities was primarily sourced from independent third party pricing services, overseen by management, and is based on valuation models that consider standard input factor such as deal quotes, market spreads, cash flows, the U.S. Treasury yield curve, live trading levels, trade execution data, market consensus prepayment spreads, credit information and the bond's terms and conditions, among other things, and are therefore classified as Level 2.

### **Contingent Consideration**

Prior to the second anniversary of the Merger, contingent obligations represented the right for former Transcept stockholders to receive certain contingent amounts, in the future, which consisted of:

- i. one hundred percent of any royalty income received by the Company prior to October 30, 2016, pursuant to the United States License and Collaboration Agreement, dated July 31, 2009, as amended November 1, 2011, by and between Transcept and Purdue Pharmaceutical Products L.P.;
- ii. one hundred percent of any payments received by the Company pursuant to the termination of a License Agreement with Shin Nippon Biomedical Laboratories, or SNBL, which granted the Company an exclusive worldwide license to commercialize SNBL's proprietary nasal drug delivery technology for development of TO-2070, a proprietary nasal powder drug delivery system;
- iii. ninety percent of any cash proceeds from a sale or disposition of Intermezzo (less all fees and expenses incurred by the Company in connection with such sale or disposition following the closing date); provided such sale or disposition occurs prior to October 30, 2016;
- iv. the amount, if any, of the \$3.0 million Intermezzo Reserve deposited at closing which is remaining at October 30, 2016.

The contingent obligations to former Transcept stockholders as described above were recognized at fair value as of the acquisition date and subsequently remeasured through the second anniversary of the Merger. The change in fair value was recognized in our consolidated statements of operations. Through the third quarter of 2016, the fair value of the contingent obligations to former Transcept stockholders was determined using probability-weighted scenario methodologies, employing cash-flow and sale proceeds income approaches with consideration to the potential timing of possible payments to former Transcept stockholders.

On October 28, 2016, in satisfaction of the Company's payment obligation of the proceeds of sale or disposition of the Intermezzo product rights to the former Transcept stockholders under the Merger Agreement, the Company executed the Royalty Sharing Agreement with the Special Committee. Under the Royalty Sharing Agreement, the Company agreed to pay to the former Transcept stockholders fifty percent 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 former Transcept stockholders. The Company determined that the Royalty Sharing Agreement represents a modification to the original contingent obligations established under the Merger Agreement in accordance with ASC 805, *Business Combinations*.

The significant unobservable inputs used in the fair value measurement of the contingent obligation to former Transcept stockholders with respect to the Intermezzo product rights as of December 31, 2017 and December 31, 2016 were estimated future Intermezzo product revenues and associated royalties due to the Company as well as the appropriate discount rate given consideration to the market and forecast risk involved. The results of this valuation yielded a decrease in the contingent obligation to former Transcept stockholders of \$0.6 and \$0.3 million during the years ended December 31, 2017 and 2016, respectively. Significant increases or decreases in any of those inputs would result in a substantially lower or higher fair value measurement.

The contingent obligation associated with the TO-2070 license rights no longer exists as of December 31, 2017 since there were no payments received by the Company pursuant to the termination of the SNBL License Agreement prior to the second anniversary of the Merger. This yielded a decrease in the contingent obligation of \$0.1 million during the twelve months ended December 31, 2016.

The following table provides a roll forward of the fair value of contingent obligations categorized as Level 3 instruments for the years ended December 31, 2017 and 2016 (in thousands):

	<b>Contingent liability— former Transcept stockholders</b>
<b>Balances at December 31, 2015</b>	\$ 1,000
Decrease in fair value	(345)
<b>Balances at December 31, 2016</b>	\$ 655
Decrease in fair value	(584)
<b>Balances at December 31, 2017</b>	\$ 71

### 13. Stock-Based Compensation

Certain employees, officers, directors and consultants have been granted options and other equity instruments to purchase common shares under plans adopted in 1996, 2001, 2002, 2005, 2006, 2014 and 2015, or the 1996 Plan, the 2001 Plan, the 2002 Plan, the 2005 Plan, the 2006 Plan, the 2014 Plan, the 2015 Plan, respectively, the 2015 Inducement Plan and the 2017 Inducement Plan. The 2001 Plan, 2002 Plan, and 2006 Plan were former Transcept plans that carried forward to the date of the Merger. The 1996 Plan, 2001 Plan, 2002 Plan, and 2005 Plan were cancelled at the effective time of the Merger. The 2006 Plan and 2014 Plan survived the Merger. 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 the 2001 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 2001 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, 2017 and 2016, no additional shares remained available for issuance the 2006 Plan. All shares cancelled or forfeited during the years ended December 31, 2017 and 2016 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.

Certain of the options to purchase common stock issued in June 2014 were subsequently modified in 2014 in connection with the termination of the employment of employees holding such options to provide for, among other changes, accelerated vesting terms.

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, 2017 and 2016, no additional shares remained available for issuance the 2014 Plan. All shares cancelled or forfeited during the years ended December 31, 2017 and 2016 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, 73,167 shares remain available for grant under that plan, as well as any shares underlying outstanding 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. 1,397,050, 1,167,931 and 880,430 shares of common stock were automatically added to the shares authorized for issuance under the 2015 Plan on January 1, 2018, January 1, 2017 and January 1, 2016, 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 869,000 restricted stock unit, or RSU, awards to executives and employees of the Company and 746,200 stock options to directors, officers, employees and consultants of the Company under the 2015 Plan. The stock option awards are subject to time-based vesting over a period of one to four years. The RSU awards made to directors of the Company are subject to time-based vesting, with 100% of the shares of common stock subject to the RSUs vesting one year from the grant date. The grants also included performance-based RSU, or PRSU, awards to certain executives and employees of the Company. The PRSU awards issued in February 2017 have vested or will vest as follows: 20% of the PRSUs vested upon achievement of data lock for Study 16301 (oral only ABSSSI), which occurred in July 2017, or the First Milestone; 30% of the PRSUs shall vest upon achievement of IV and oral NDA filing acceptances, or the Second Milestone; and 50% of the PRSUs shall vest upon FDA approval of omadacycline, or the Third Milestone, provided, that, each of the First Milestone, the Second Milestone and the Third Milestone must occur no later than the fifth anniversary of the date of grant for the applicable portion of the PRSUs to vest. The PRSU awards issued in August 2017 shall become earned upon FDA approval of omadacycline, or the Milestone, and shall, upon achievement of the Milestone, be eligible to vest as to 100% of the PRSUs subject to the award on the first anniversary of the Milestone achievement date.

10,700 RSUs and 68,319 stock options granted under the 2015 Plan were cancelled or forfeited during the year ended December 31, 2017.

#### ***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.

During the year ended December 31, 2017, the Company's Board of Directors granted 222,800 stock options and 39,200 RSUs to employees of the Company under the 2017 Inducement Plan. The stock option awards are subject to time-based vesting over a period of one to four years. The RSU awards are time-based with 100% of the shares of common stock subject to the RSUs vesting three years from the grant date. 2,000 stock options granted under the 2017 Inducement Plan were forfeited during the year ended December 31, 2017.

Total shares available for future issuance under the 2015 Plan, 2015 Inducement Plan and 2017 Inducement Plan are 14,214, 73,167 shares and 290,000 shares, respectively, as of December 31, 2017.

A summary of stock option activity and related information through December 31, 2017 follows:

	Number of Shares	Weighted Average Exercise Price	Weighted- Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
<b>Outstanding</b>				
Balances at December 31, 2016	2,780,791	\$ 16.63	8.27	\$ 8,809
Granted	969,000	17.25		
Exercised	(66,455)	4.83		
Cancelled or forfeited	(74,429)	16.97		
Balances at December 31, 2017	<u>3,608,907</u>	<u>\$ 17.01</u>	7.78	\$ 13,311
<b>Exercisable</b>				
December 31, 2017	<u>2,173,767</u>	<u>\$ 16.28</u>	7.29	\$ 10,119

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, 2017 and 2016.

During the years ended December 31, 2017, 2016 and 2015, the Company granted stock options to purchase an aggregate of 969,000 shares, 723,500 shares and 1,522,269 shares of its common stock, under the equity plans described above, respectively, with weighted-average grant date fair values of options granted of \$11.34, \$9.14 and \$13.45, respectively.

The total intrinsic value of stock options exercised was \$1.4 million, \$0.0 million and \$1.4 million for the years ended December 31, 2017, 2016 and 2015, respectively.

#### **Restricted Stock Units**

The following is a summary of restricted stock unit activity for the year ended December 31, 2017:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Unvested balance at December 31, 2016	454,000	\$ 19.67
Granted	908,200	\$ 16.98
Released	(183,797)	\$ 14.60
Forfeited	(10,700)	\$ 14.14
Unvested balance at December 31, 2017	<u>1,167,703</u>	<u>\$ 18.43</u>

During the year ended December 31, 2017 the Company granted 908,200 restricted stock units with a weighted-average grant date fair value per share of \$16.98. During the year ended December 31, 2016 the Company granted 236,000 restricted stock units with a weighted-average grant date fair value per share of \$14.07. During the year ended December 31, 2015, the Company granted 275,500 restricted stock units with a weighted-average grant date fair value per share of \$24.43. The total fair value of restricted stock units vested during the year ended December 31, 2017 was \$4.0 million.

#### **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,		
	2017	2016	2015
Volatility	75.5%	73.6%	60.2%
Weighted average risk-free interest rate	2.0%	1.4%	1.7%
Expected dividend yield	0.0%	0.0%	0.0%
Expected life of options (in years)	5.8	5.8	6.0

As of January 1, 2017, the Company adopted ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, or ASU 2016-09. In connection with the adoption, the Company made an accounting policy change. Prior to adoption, the Company estimated forfeitures at the time of grant and revised those estimates in subsequent periods if actual forfeitures differed from the estimates. The Company used historical data to estimate pre-vesting option forfeitures to the extent that actual forfeitures differed from our estimates, the difference was recorded as a cumulative adjustment in the period the estimates were revised. Upon adoption, the Company recognize the effect of forfeitures in compensation cost when they occur. The Company recorded a cumulative-effect catch-up adjustment to equity of \$0.7 million upon adoption.

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

	Year Ended December 31,		
	2017	2016	2015
Research and development expense	\$ 5,513	\$ 3,262	\$ 1,233
General and administrative expense	11,389	7,530	3,829
Total stock-based compensation expense	<u>\$ 16,902</u>	<u>\$ 10,792</u>	<u>\$ 5,062</u>

Total unrecognized stock-based compensation expense for all stock-based awards was \$19.0 million at December 31, 2017. This amount will be recognized over a weighted-average period of 1.99 years.

#### **Employee Stock Purchase Plan**

The Company's 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 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, 2017 and 2016, 36,539 shares were available for issuance under the ESPP. Since the Merger, the Company has not made the ESPP available to employees.

#### **Reserved Shares**

At December 31, 2017, the Company has reserved shares of common stock for future issuance as follows:

	Number of Shares
Equity plans:	
Subject to outstanding options and restricted stock units	4,776,610
Available for future grants	377,381
Warrants	84,828
Employee stock purchase plan	36,539
Total	<u>5,275,358</u>

#### 14. Long-Term Debt

On September 30, 2015, the Company entered into the Loan Agreement with Hercules and certain other lenders, and Hercules Technology Growth Capital, Inc. (as agent). Under the Loan Agreement, Hercules provided the Company with access to term loans with an aggregate principal amount of up to \$40.0 million, or collectively, the Term Loan. The Company initially drew a principal amount of \$20.0 million, which was funded on September 30, 2015. The remaining \$20.0 million under the Loan Agreement was available to be drawn at the Company's option in minimum increments of \$10.0 million through December 31, 2016, or the Draw Period. The Term Loan was repayable in monthly installments commencing on April 1, 2018 through maturity on September 1, 2020. The interest rate was equal to the greater of (i) 8.5%, or (ii) the sum of 8.5%, plus the "prime rate" as reported in The Wall Street Journal minus 5.75% per annum. An end of term charge equal to 4.5% of the issued principal balance of the Term Loan was payable at maturity, including in the event of any prepayment, and was being accrued as interest expense over the term of the loan using the effective interest method. Borrowings under the Loan Agreement were 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 loan together with the prepayment and end of term charges. An Event of Default is defined in the 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 Loan Agreement; (v) insolvency, as described in the 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 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 Loan, which was not due within 12 months of December 31, 2017, has been classified as long-term as the Company determined that a material adverse effect resulting in Hercules exercising its rights under the subjective acceleration clause is remote.

Subject to certain terms, pursuant to the Loan Agreement, Hercules was also granted the right to participate in an amount of up to \$2.0 million in subsequent sales and issuances of the Company's equity securities to one or more investors for cash for financing purposes in an offering that is broadly marketed to multiple investors and at the same terms as the other investors. On September 30, 2015, Hercules Technology Growth Capital, Inc. entered into a Stock Purchase Agreement with the Company to purchase 44,782 shares of common stock resulting in proceeds to the Company of approximately \$1.0 million. The excess of proceeds received by the Company over the fair value of the common stock issued was allocated as a reduction of the fees paid to Hercules in conjunction with obtaining the initial \$20.0 million draw of the Term Loan.

Debt issuance costs of \$511,000 were ratably allocated to the initial \$20.0 million draw and the remaining unfunded \$20.0 million. Debt issuance costs related to the initial \$20.0 million draw were presented on the consolidated balance sheet as a direct deduction from the related debt liability. Issuance costs related to the unfunded amount were capitalized as prepaid asset and were to be amortized ratably through the end of the Draw Period.

In connection with the Loan Agreement, 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 the Company's common stock (32,692 shares of common stock in total) at an exercise price of \$24.47 per share. The Hercules Warrants' total relative fair value of \$288,000 at September 30, 2015 was determined using a Black-Scholes option-pricing model. The relative fair value of the Hercules Warrants was included as a discount to the Term Loan and also as a component of additional paid-in capital. See Note 10, *Common Stock*, for further description of the Hercules Warrants.

In addition to the Hercules Warrants, the Company paid fees to Hercules in conjunction with obtaining the Term Loan. The Hercules Warrants fair value and fees paid to Hercules, an aggregate of \$572,000, were ratably allocated to the initial \$20.0 million draw and the remaining unfunded \$20.0 million. The \$208,000 of costs allocated to the initial \$20.0 million draw were recorded as a debt discount and are being amortized as additional interest expense over the term of the loan using the effective interest method. The \$364,000 of costs allocated to the unfunded \$20.0 million was recorded as prepaid expenses and were being amortized ratably through the end of the Draw Period. In the event the Company exercised its option to borrow additional funds, the remaining unamortized prepaid asset balance related would be reclassified and recorded as debt discount based upon a ratable allocation of the amount drawn compared to the remaining unfunded amount available to the Company and would amortize over the remaining life of the term loan using the effective interest method.

On December 12, 2016, the Company and Hercules entered into a second amendment to the Loan Agreement, or the Second Amendment, which extended the date on which the Company must begin making amortization payments under the Loan Agreement from April 1, 2018 to January 1, 2019, or the Amortization Date. Upon commencement of the Amortization Date, the Company will make amortization payments based upon an amortization schedule equal to thirty consecutive months, with the balance of outstanding loans due on the original maturity date of the Loan Agreement. The Second Amendment also increased the amount that the Company may borrow by \$10.0 million, from up to \$40.0 million to up to \$50.0 million in multiple tranches. In connection with the Second Amendment the Company paid Hercules a \$0.4 million amendment fee. In connection with the Second Amendment, the Company issued to each one 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.

Under the Second Amendment, discussed above, the end of term charge was equal to 4.5% of the issued principal balance of the Loan Agreement, and was payable at maturity, including in the event of any prepayment, and is being accrued as interest expense over the term of the loan using the effective interest method. Borrowings under the Loan Agreement, as amended, are still collateralized by substantially all of the assets of the Company.

On June 27, 2017, the Company and Hercules entered into a third amendment to the Loan Agreement, or the Third Amendment. The Third Amendment increased the amount that the Company may borrow by \$10.0 million, from up to \$50.0 million to up to \$60.0 million, in multiple tranches. The additional \$10.0 million tranche, or the Fourth Tranche, was available at the Company's option through December 15, 2017. The Fourth Tranche shall bear interest and have the same maturity as all other loans outstanding under the Loan Agreement.

The Company borrowed the first tranche of \$20.0 million upon the closing of the Loan Agreement on September 30, 2015, and the second tranche of \$20.0 million on December 12, 2016, or collectively, the Initial Tranches. Concurrently with the closing of the Third Amendment, the Company borrowed a third tranche of \$10.0 million, or the Third Tranche. The Third Amendment extended the date on which the Company is required to begin making monthly principal installments under the Loan Agreement from January 1, 2019 to January 1, 2020, subject to the Company's receipt of marketing approval for the Company's lead product candidate, omadacycline, or the Interest Only Period Extension Event. Beginning on January 1, 2019, or, if the Company achieves the Interest Only Period Extension Event, beginning on January 1, 2020, the Company will make payments in equal monthly installments of principal and interest, with the balance of outstanding loans due on the original maturity date of the Loan Agreement. In connection with the Third Amendment, the Company paid Hercules a \$0.1 million amendment fee.

The Third Amendment reduced the end of term charge due with respect to the Third Tranche from 4.5% to 2.25% if the obligations under the Loan Agreement are repaid in full on or prior to September 30, 2017, following Hercules' election not to consent to a proposed third-party, non-equity financing arrangement (excluding any stock issuance). The end of term charge with respect to the Fourth Tranche is 2.25%.

If the Company prepays the loan prior to maturity, it will pay a prepayment charge, based on a percentage of the then outstanding principal balance, equal to (i) 1% with respect to the Third Tranche and the Fourth Tranche or (ii) 2% with respect to the Initial Tranches if the prepayment occurs prior to April 1, 2019, or equal to 0% if the prepayment occurs on or after April 1, 2019.

In connection with the borrowing of the Third Tranche, on June 27, 2017, the Company issued the Additional Warrant to Hercules Capital, Inc. that is exercisable for an aggregate of 5,374 shares of Common Stock at an exercise price of \$23.26 per share. The Additional Warrant may be exercised on a cashless basis. The Additional Warrant is exercisable for a term beginning on the date of issuance and ending on the earlier to occur of five years from the date of issuance or the consummation of certain acquisitions of the Company as set forth in the Additional Warrant.

The modified terms under the Second Amendment and Third Amendment were not considered substantially different as compared to the terms of the Loan Agreement immediately prior to each of the Second Amendment and Third Amendment, pursuant to ASC 470-50, *Modification and Extinguishment*. As such, the Second Amendment and Third Amendment were accounted for as a debt modification. The \$0.4 million amendment fee paid to Hercules in connection with the Second Amendment was recorded as debt discount and will be amortized as part of the effective yield. In addition, the unamortized discount on the original loan agreement will be amortized as an adjustment of interest expense over the remaining term of the modified debt using an updated effective interest rate. All costs incurred with third parties were expensed as incurred.

As of December 31, 2017 and 2016, the Company recorded a long-term debt obligation of \$59.2 million, net of debt discount of \$0.8 million and \$39.0 million, net of debt discount of \$1.1 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*, or ASU 2015-03.

Future principal payments, which exclude the end of term charge, in connection with the Loan Agreement, as amended, as of December 31, 2017 are as follows (in thousands):

2018	\$	—
2019		33,140
2020		26,860
2021		—
2022 and thereafter		—
<b>Total</b>	<b>\$</b>	<b>60,000</b>

## 15. Income Taxes

(Loss) income before income taxes consists of the following:

(in thousands)	Year Ended December 31,		
	2017	2016	2015
United States	\$ (83,762)	\$ (98,465)	\$ (70,860)
Foreign	(4,554)	(13,171)	—
<b>Total</b>	<b>\$ (88,316)</b>	<b>\$ (111,636)</b>	<b>\$ (70,860)</b>

The components of income tax (benefit) expense consist of the following:

(in thousands)	Year Ended December 31,		
	2017	2016	2015
Foreign	753	—	—
<b>Total</b>	<b>\$ 753</b>	<b>\$ —</b>	<b>\$ —</b>

There is no provision for income taxes in the United States 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 the Zai territory. 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.

On December 22, 2017, the new tax reform law, which is commonly referred to as the “Tax Cuts and Jobs Act”, or The Act, was signed into law by President Trump. The Act includes a number of provisions, including the lowering of the U.S. corporate tax rate from 35 percent to 21 percent, effective January 1, 2018 and the establishment of a territorial-style system for taxing foreign-source income of domestic multinational corporations. The Company is in the process of quantifying the tax impacts of The Act. Due to the Company's full valuation allowance, no provisional tax expense or benefit associated with the re-measurement was recognized in the Company's consolidated statement of operations and comprehensive loss for the year ended December 31, 2017. However, the reduction of the U.S. federal corporate tax rate from 35 percent to 21 percent resulted in increases to the amounts reflected in the “Change in valuation allowance” and “Impact of Tax Law Change” captions for the year ended December 31, 2017 in the Company's tax reconciliation table compared to those amounts disclosed for the years ended December 31, 2016 and 2015. The change in the U.S. federal corporate tax rate, which is effective January 1, 2018, is also reflected in the Company's deferred tax table. The Company is still in the process of analyzing the impact to the Company of the Tax Act. On December 22, 2017, the SEC staff issued SAB 118 to address the application of GAAP in situations when a registrant does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. The Company has recognized the provisional tax impacts related to the revaluation of the deferred tax assets and liabilities and included these amounts in its consolidated financial statements for the year ended December 31, 2017. The ultimate impact may differ from these provisional amounts due to, among other things, additional analysis, changes in interpretations and assumptions the Company has made, additional regulatory guidance that may be issued, and actions the Company may take as a result of The Act, which could result in changes to the provisional tax impacts during 2018.

A reconciliation of the Company's effective tax rate to the statutory federal income tax rate is as follows:

	Year Ended December 31,		
	2017	2016	2015
Federal statutory rate	35.00%	35.00%	35.00%
Change in valuation allowance	17.61	(37.31)	(46.61)
Permanent differences	0.66	0.17	1.67
State taxes, net of federal benefits	5.57	4.61	6.13
Withholding Tax	(0.85)	—	—
Impact of Tax Law Change	(59.79)	—	—
Foreign Rate Differential	(1.80)	(4.13)	—
Other	2.74	1.66	3.81
	<u>(0.86)%</u>	<u>0.00%</u>	<u>0.00%</u>

Significant components of the Company's net deferred tax assets at December 31, 2017 and 2016 are as follows:

(in thousands)	Year Ended December 31,	
	2017	2016
<b>Non-current deferred tax assets</b>		
Net operating losses	\$ 69,977	\$ 83,480
Accrued expenses	228	2,774
Capitalized research and development	24,904	29,882
Tax credit carryforwards	12,843	9,478
Other	47	100
Stock compensation and other	8,218	6,425
Total non-current deferred tax assets	<u>116,217</u>	<u>132,139</u>
<b>Non-current deferred tax liabilities</b>		
Intangible assets	(39)	(408)
Total non-current deferred tax liabilities	<u>(39)</u>	<u>(408)</u>
Net non-current deferred tax asset	116,178	131,731
Less: valuation allowance	<u>(116,178)</u>	<u>(131,731)</u>
Net deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2017, the Company had federal and state net operating loss carryforwards of \$283.0 million and \$168.0 million, respectively, which begin to expire in 2018.

As of December 31, 2017, the Company had federal and state research and development tax credits carryforwards of \$9.0 million and \$4.4 million, respectively, which began to expire in 2018.

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised 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 \$116.2 million and \$131.7 million, respectively, was established as of December 31, 2017 and 2016. A change in the Company's valuation allowance was recorded in 2017, in the amount of \$(15.5) million due primarily to the adjustment in the corporate tax rate from 35 percent to 21 percent enacted for 2018 partially offset by 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.

During 2016, the Company performed a formal study to determine if any of its remaining net operating loss and credit attributes might be further limited due to the ownership change rules of Section 382 or Section 383 of the Internal Revenue Code of 1986, as amended. 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 or 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 is in the process of conducting a study of its research and development credit carryforwards. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until the study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. 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 2014 for both federal and Massachusetts. However, to the extent the Company utilizes net operating losses from years prior to 2014, 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 2017 or 2016.

## **16. 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. The total revised lease commitment of \$3.4 million is over a remaining four-year lease term. In accordance with the amended lease agreement, the Company paid a security deposit of \$0.1 million. The Company is required to make additional payments under the facility operating leases for taxes, insurance, and other operating expenses incurred during the lease period. In addition, the lease provided an incentive from the landlord of up to \$0.2 million in tenant improvements. The Company capitalized all leasehold improvements as fixed assets. Accordingly, the Company also recorded a related financing obligation in "other long-term liabilities" on the Company's consolidated balance sheet. These amounts will be treated as a reduction to rent expense over the lease term. Subsequent to the amended lease agreement, the Company records monthly rent expense of approximately \$54,000 for the Boston office space.

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, for a total commitment of \$3.3 million with respect to which lease payments became due beginning once the Company 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. The Company is required to make additional payments under the facility operating leases for taxes, insurance, and other operating expenses incurred during the operating lease period.

Deferred rent of \$0.5 million and \$0.2 million is included in other liabilities and accounts payable and other accrued expenses, respectively, in the consolidated balance sheet as of December 31, 2017 and 2016.

Rent expense, exclusive of related taxes, insurance, and maintenance costs, for continuing operations totaled approximately \$1.0 million, \$0.7 million and \$0.3 million for the years ended December 31, 2017, 2016 and 2015, respectively, and is reflected in operating expenses.

Future minimum operating lease obligations under non-cancelable leases with initial terms of more than one-year are as follows (in thousands):

<b>Years Ended December 31,</b>	<b>Minimum Lease Obligation</b>
2018	1,084
2019	1,156
2020	1,178
2021	964
2022	508
2023 and thereafter	914
Total	<u>\$ 5,804</u>

### ***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 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 our products that contain omadacycline as the active pharmaceutical ingredient. Under this agreement, the Company is obligated to pay a CIPAN Product price in the high three-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 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 an outsourcing agreement with CARBOGEN AMCIS AG, or Carbogen. The agreement provides for the terms and conditions under which Carbogen will manufacture and supply to the Company the active pharmaceutical ingredient for our omadacycline product 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 initially pay Carbogen an amount in the low 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 both parties are obligated to use diligent efforts to come to a subsequent long-term agreement to replace this agreement no later than the end of such initial term. If the Company has not executed a replacement agreement with Carbogen by such time, this agreement will automatically be extended for a fixed period of time. The Company may terminate this agreement by delivering notice of termination to Carbogen prior to the expiration of the initial or subsequent 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.

### *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. 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.

The Company's agreement with Almac will remain in effect for a fixed initial term, after which the 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 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 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. If the Company's omadacycline product is approved, the Company will also be subject to an annual minimum purchase requirement in the six-digit euro 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.

#### **Intermezzo Patent Litigation**

In July 2012, the Company received notifications from three companies, Actavis Elizabeth LLC, or Actavis Elizabeth, Watson Laboratories, Inc.—Florida, or Watson, and Novel Laboratories, Inc., or Novel, in September 2012, from each of Par Pharmaceutical, Inc. and Par Formulations Private Ltd., together, the Par Entities, in February 2013 from Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd., together, Dr. Reddy's, and in July 2013 from TWi Pharmaceuticals, Inc., or Twi, stating that each has filed with the FDA an ANDA, that references Intermezzo. Refer to Item 3, "Legal Proceedings", of the Company's Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC on March 9, 2016, for a full description of the history of this litigation.

The United States District Court for the District of New Jersey, or the New Jersey District Court, held a consolidated trial between December 1, 2014 and December 15, 2014 involving Paratek, Purdue Pharma, and their patent infringement claims against Actavis Elizabeth, Novel, and Dr. Reddy's. The New Jersey District Court then received post-trial briefing and held a February 13, 2015 post-trial hearing. On March 27, 2015, the New Jersey District Court issued an order and accompanying opinion finding that: (a) the asserted claims of U.S. Patent Nos. 7,682,628, 8,242,131, and 8,252,809, are invalid as obvious; (b) Actavis Elizabeth, Novel, and Dr. Reddy's infringe the '131 patent; (c) Novel infringes the '628 patent; and (d) Novel and Dr. Reddy's infringe the '809 patent. On April 9, 2015, the New Jersey District Court entered final judgment consistent with the March 27, 2015 opinion and order referenced above.

The Company and Purdue Pharma jointly appealed the New Jersey District Court's final judgment as to the '131 patent to the United States Court of Appeals for the Federal Circuit on May 6, 2015. On January 8, 2016, the United States Court of Appeals for the Federal Circuit affirmed the decision of the New Jersey District Court, and no opinion accompanied the judgment. On September 14, 2016, the defendants filed a warrant of satisfaction of judgment in the New Jersey District Court for the costs having been fully paid to the defendants.



## Patent Term Adjustment Suit

In January 2013, the Company filed suit in the Eastern District of Virginia against the United States 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, 2017.

## 17. 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 \$0.4 million, \$0.3 million and \$0.2 million for the years ended December 31, 2017, 2016, and 2015, respectively, and have been recorded in the consolidated statements of operations.

## 18. Quarterly Results (Unaudited)

	Three Months Ended			
	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
	(in thousands, except per share data) (unaudited)			
Revenue	\$ 18	\$ 7,514	\$ 12	\$ 5,072
Operating expenses	26,789	24,159	20,309	25,939
Loss from operations	(26,771)	(16,645)	(20,297)	(20,867)
Other expense, net	(899)	(785)	(1,027)	(1,025)
Provision for income tax	—	753	—	—
Net loss	\$ (27,670)	\$ (18,183)	\$ (21,324)	\$ (21,892)
Net loss per share - basic and diluted	\$ (1.14)	\$ (0.66)	\$ (0.77)	\$ (0.78)

	Three Months Ended			
	March 31, 2016	June 30, 2016	September 30, 2016	December 31, 2016
	(in thousands, except per share data) (unaudited)			
Revenue	\$ —	\$ —	\$ —	\$ 29
Operating expenses	30,732	29,752	23,113	25,918
Loss from operations	(30,732)	(29,752)	(23,113)	(25,889)
Other expense, net	(539)	(531)	(515)	(565)
Net loss	\$ (31,271)	\$ (30,283)	\$ (23,628)	\$ (26,454)
Net loss per share - basic and diluted	\$ (1.78)	\$ (1.69)	\$ (1.04)	\$ (1.16)

## **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

On May 13, 2016, we dismissed CohnReznick LLP as our independent registered public accounting firm. The Audit Committee approved the dismissal of CohnReznick LLP. The reports of CohnReznick LLP on our consolidated financial statements for the fiscal years ended December 31, 2015, 2014 and 2013, and on the effectiveness of the Company's internal control over financial reporting as of December 31, 2015 did not contain an adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope, or accounting principles. During the fiscal years ended December 31, 2015, 2014 and 2013, and the subsequent interim period through May 13, 2016 there were no: (1) disagreements, as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions, with CohnReznick LLP on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreement if not resolved to the satisfaction of CohnReznick LLP would have caused CohnReznick LLP to make reference thereto in its reports on the consolidated financial statements for such years, or (2) reportable events, as described in Item 304(a)(1)(v) of Regulation S-K.

We have furnished the foregoing disclosure to CohnReznick LLP and requested that it furnish us with a letter addressed to the SEC stating whether it agrees with the above statements, and if not, stating the respects with which it does not agree. A copy of the letter dated May 16, 2016 is filed as Exhibit 16.1 to our Current Report on Form 8-K filed on May 16, 2016.

Effective May 13, 2016, we engaged Ernst & Young LLP as our independent registered public accounting firm. The Board of Directors approved the engagement of Ernst & Young LLP. During the two most recent fiscal years ended prior to CohnReznick LLP's dismissal, December 31, 2015 and 2014, and through the subsequent interim period through May 13, 2016, we did not consult with Ernst & Young LLP, regarding either (i) the application of accounting principles to a specific transaction, completed or proposed, or the type of audit opinion that might be rendered on our financial statements, and neither a written report nor oral advice was provided to us that was an important factor considered in reaching a decision as to accounting, auditing or financial reporting issues; or (ii) any matter that was either the subject of a disagreement, as that term is defined in Regulation S-K 304(a)(1)(iv) and the related instructions to Regulation S-K 304, or a reportable event, as that term is defined in Regulation S-K 304(a)(1)(v).

## **Item 9A. Controls and Procedures**

### **Evaluation of Disclosure Controls and Procedures**

As of December 31, 2017, management, with the participation of our Chief Executive Officer and Chief Financial 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 Chief Financial 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 Chief Financial Officer concluded that, as of December 31, 2017, 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 Chief Financial 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 Chief Financial Officer, management has conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2017 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 Chief Financial Officer, has concluded that our internal control over financial reporting was effective as of December 31, 2017.

The effectiveness of our internal control over financial reporting as of December 31, 2017 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

The Stockholders and Board of Directors of Paratek Pharmaceuticals, Inc.

We have audited Paratek Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2017, 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, 2017, 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, 2017 and 2016, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2017, and the related notes and our report dated March 6, 2018 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 6, 2018

### (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, 2017, 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 2017 fiscal year pursuant to Regulation 14A for our 2018 Annual Meeting of Stockholders, or the 2018 Proxy Statement, and the information to be included in the 2017 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 2018 Proxy Statement and is hereby incorporated by reference.

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

The information required by this item will be contained in the 2018 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 2018 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 2018 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 2018 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 2018 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	
1.1	<a href="#">Controlled Equity Offering<sup>SM</sup> Sales Agreement between Paratek Pharmaceuticals, Inc. and Cantor Fitzgerald &amp; Co., dated February 28, 2017.</a>	Form 10-K	001-36066	1.1	March 2, 2017
2.1	<a href="#">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.</a>	Form 8-K	001-36066	2.1	July 1, 2014
3.1	<a href="#">Amended and Restated Certificate of Incorporation.</a>	Form 8-K	001-36066	3.1	October 31, 2014
3.2	<a href="#">Certificate of Amendment to the Amended and Restated Certificate of Incorporation.</a>	Form 8-K	001-36066	3.2	October 31, 2014
3.3	<a href="#">Certificate of Elimination of Series A Junior Participating Preferred Stock.</a>	Form 8-K	001-36066	3.1	July 24, 2015
3.4	<a href="#">Amended and Restated Bylaws.</a>	Form 8-K	001-36066	3.1	April 16, 2015
4.1	<a href="#">Specimen Common Stock Certificate.</a>	Form S-3	333-201458	4.2	January 12, 2015
4.2	<a href="#">Form of Warrant Agreement issued to Hercules Technology II, L.P. and Hercules Technology III, L.P.</a>	Form 8-K	001-36066	4.1	October 5, 2015
4.3	<a href="#">Form of Warrant Agreement issued to Hercules Technology II, L.P. and Hercules Technology III, L.P.</a>	Form 8-K	001-36066	4.1	December 13, 2016
4.4	<a href="#">Form of Warrant Agreement issued to Hercules Capital, Inc.</a>	Form 8-K	001-36066	4.1	June 29, 2017
4.5	<a href="#">Warrant, dated as of April 7, 2014, issued to HBM Healthcare Investments (Cayman) Ltd.</a>	Form 10-K	001-36066	10.22	April 2, 2015
4.6	<a href="#">Warrant, dated as of April 18, 2014 issued to K/S Danish BioVenture.</a>	Form 10-K	001-36066	10.23	April 2, 2015
4.7	<a href="#">Warrant, dated as of April 7, 2014 issued to Omega Fund III, L.P.</a>	Form 10-K	001-36066	10.24	April 2, 2015
10.1A+	<a href="#">2006 Incentive Award Plan, as amended and restated.</a>	Form 10-K	001-36066	10.1A	March 9, 2016
10.1B+	<a href="#">Form of Stock Option Grant Notice and Stock Option Agreement under 2006 Incentive Award Plan.</a>	Form S-8	333-172041	99.2	February 3, 2011
10.1C+	<a href="#">Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2006 Incentive Award Plan, as amended.</a>	Form 8-K	001-36066	10.1	February 10, 2015
10.2+	<a href="#">2009 Employee Stock Purchase Plan.</a>	Form 8-K	000-51967	10.1	June 9, 2009
10.3A+	<a href="#">2014 Equity Incentive Plan, as amended.</a>	Form S-8	333-201204	4.1	December 22, 2014
10.3B+	<a href="#">Form of Option Agreement under the 2014 Equity Incentive Plan, as amended.</a>	Form S-8	333-201204	4.2	December 22, 2014
10.4A+	<a href="#">2015 Inducement Plan.</a>	Form 8-K	001-36066	10.2	February 10, 2015
10.4B+	<a href="#">Form of Stock Option Grant Notice and Option Agreement under the 2015 Inducement Plan.</a>	Form 8-K	001-36066	10.3	February 10, 2015
10.5A+	<a href="#">2017 Inducement Plan.</a>	Form 8-K	001-36066	10.1	June 16, 2017
10.5B+	<a href="#">Form of Stock Option Grant Notice and Option Agreement under the 2017 Inducement Plan.</a>	Form 8-K	001-36066	10.2	June 16, 2017

Exhibit No.	Exhibit Description	Incorporated by Reference			Filing Date
		Schedule/Form	File Number	Exhibit	
10.5C+	<a href="#">Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2017 Inducement Plan.</a>	Form 8-K	001-36066	10.3	June 16, 2017
10.6A+	<a href="#">2015 Equity Incentive Plan</a>	Form S-8	333-205482	99.5	July 2, 2015
10.6B+	<a href="#">Form of Stock Option Grant Notice and Option Agreement under the 2015 Equity Incentive Plan</a>	Form S-8	333-205482	99.6	July 2, 2015
10.6C+	<a href="#">Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2015 Equity Incentive Plan.</a>	Form S-8	333-205482	99.7	July 2, 2015
10.6D+	<a href="#">Form of Leadership Team Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2015 Equity Incentive Plan.</a>	Form 8-K	001-36066	10.1	August 4, 2017
10.6E*+	<a href="#">Form of Director Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2015 Equity Incentive Plan.</a>				
10.6F*+	<a href="#">Form of Director Stock Option Grant Notice and Option Agreement under the 2015 Equity Incentive Plan.</a>				
10.7+	<a href="#">Paratek Pharmaceuticals, Inc. Annual Incentive Plan.</a>	Form 8-K	001-36066	10.4	June 16, 2017
10.8*+	<a href="#">Non-Employee Director Compensation Policy.</a>				
10.9+	<a href="#">Form of Indemnification Agreement between the Company, its executive officers and directors.</a>	Form 10-K	001-36066	10.8	March 9, 2016
10.10†	<a href="#">United States License and Collaboration Agreement by and between the Company and Purdue Pharmaceutical Products L.P., dated as of July 31, 2009.</a>	Form 10-Q	000-51967	10.1	November 16, 2009
10.11†	<a href="#">First Amendment to the United States License and Collaboration Agreement by and between the Company and Purdue Pharmaceutical Products L.P., dated as of November 1, 2011.</a>	Form 10-K	000-51967	10.30	March 30, 2012
10.12†	<a href="#">Letter Agreement by and between the Company and Purdue Pharmaceutical Products L.P., dated as of July 31, 2009.</a>	Form 10-Q	000-51967	10.2	November 16, 2009
10.13†	<a href="#">License Agreement by and between the Company and Shin Nippon Biomedical Laboratories, Ltd., dated as of September 24, 2013.</a>	Form 10-Q	001-36066	10.6	November 7, 2013
10.14	<a href="#">Termination Agreement and Release, between the Company and Shin Nippon Biomedical Laboratories, dated as of September 19, 2014.</a>	Form 10-Q	001-36066	10.1	October 28, 2014
10.15†	<a href="#">Collaborative Research and License Agreement by and between the Company and Warner Chilcott, dated as of July 2, 2007.</a>	Form 10-K	001-36066	10.16	April 2, 2015
10.16†	<a href="#">License and Collaboration Agreement by and between Paratek Bermuda Ltd. and Zai Lab (Shanghai) Co., Ltd., dated April 21, 2017.</a>	Form 10-Q	001-36066	10.11	August 2, 2017
10.17*^	<a href="#">License Agreement by and between the Company and Tufts University dated as of February 1, 1997, as amended.</a>				

Exhibit No.	Exhibit Description	Incorporated by Reference			Filing Date
		Schedule/Form	File Number	Exhibit	
10.18	<a href="#">Amendment No. 10, dated as of March 21, 2017, to the License Agreement by and between the Company and Tufts University</a>	Form 10-Q	001-36066	10.1	May 4, 2017
10.19*^	<a href="#">Amendment No. 11, dated as of November 15, 2017, to the License Agreement by and between the Company and Tufts University</a>				
10.20+	<a href="#">Amended and Restated Employment Agreement by and between the Company and Douglas W. Pagán, dated as of August 4, 2017.</a>	Form 10-Q	001-36066	10.4	November 8, 2017
10.21+	<a href="#">Amended and Restated Employment Agreement, by and between the Company and Michael F. Bigham, dated as of August 4, 2017.</a>	Form 10-Q	001-36066	10.1	November 8, 2017
10.22+	<a href="#">Amended and Restated Employment Agreement, by and between the Company and Evan Loh, M.D., dated as of August 4, 2017.</a>	Form 10-Q	001-36066	10.3	November 8, 2017
10.23+	<a href="#">Amended and Restated Employment Agreement, by and between the Company and Adam Woodrow, dated as of August 4, 2017.</a>	Form 10-Q	001-36066	10.5	November 8, 2017
10.24+	<a href="#">Amended and Restated Employment Agreement, by and between the Company and William M. Haskel, dated as of August 4, 2017.</a>	Form 10-Q	001-36066	10.2	November 8, 2017
10.25	<a href="#">Stock Purchase Agreement dated October 1, 2015, by and between Paratek Pharmaceuticals, Inc. and Hercules Technology Growth Capital, Inc.</a>	Form 8-K	001-36066	10.1	October 5, 2015
10.26†	<a href="#">Loan and Security Agreement, dated September 30, 2015, between the Company and Hercules Technology II, L.P., Hercules Technology III, L.P., certain other lenders and Hercules Technology Growth Capital, Inc.</a>	Form 10-Q/A	001-36066	10.5	December 3, 2015
10.27	<a href="#">Amendment No. 1 to Loan and Security Agreement dated November 10, 2015, by and between Paratek Pharmaceuticals, Inc., Paratek Pharma, LLC, Hercules Technology II, L.P., Hercules Technology III, L.P., certain other lenders and Hercules Technology Growth Capital, Inc.</a>	Form 10-K	001-36066	10.23	March 2, 2017
10.28	<a href="#">Amendment No. 2 to Loan and Security Agreement dated December 12, 2016, by and between Paratek Pharmaceuticals, Inc., Paratek Pharma, LLC, Hercules Technology II, L.P., Hercules Technology III, L.P., certain other lenders and Hercules Technology Growth Capital, Inc.</a>	Form 8-K	001-36066	10.1	December 13, 2016
10.29	<a href="#">Amendment No. 3 to Loan and Security Agreement dated June 27, 2017, by and between Paratek Pharmaceuticals, Inc., Paratek Pharma, LLC, Hercules Technology II, L.P., Hercules Technology III, L.P., and Hercules Capital, Inc.</a>	Form 8-K	001-36066	10.1	June 29, 2017
10.30	<a href="#">Boston Lease Agreement between Paratek Pharma LLC and TDC Heritage LLC, dated as of April 24, 2015, as amended.</a>	Form 10-Q	001-36066	10.3	May 4, 2017



Exhibit No.	Exhibit Description	Incorporated by Reference			Filing Date
		Schedule/Form	File Number	Exhibit	
10.31	<a href="#">King of Prussia Lease Agreement between Paratek Pharma LLC and Atlantic American Properties Trust, dated as of January 23, 2015, as amended.</a>	Form 10-Q	001-36066	10.2	May 4, 2017
10.32†	<a href="#">Manufacturing and Services Agreement by and between the Company and Almac Pharma Services Limited, dated as of December 30, 2016.</a>	Form 10-K/A	001-36066	10.27	May 5, 2017
10.33†	<a href="#">Manufacturing and Services Agreement by and between the Company and CIPAN – Companhia Industrial Produtora de Antibióticos, S.A., dated as of November 2, 2016.</a>	Form 10-K/A	001-36066	10.28	May 5, 2017
10.34†	<a href="#">Outsourcing Agreement by and between the Company and CARBOGEN AMCIS AG, dated as of December 30, 2016.</a>	Form 10-K/A	001-36066	10.29	May 5, 2017
10.35†	<a href="#">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.</a>	Form 10-Q/A	001-36066	10.12	November 6, 2017
16.1	<a href="#">Letter from CohnReznick to the Securities and Exchange Commission dated as of May 16, 2016.</a>	Form 8-K	001-36066	16.1	May 16, 2016
21.1*	<a href="#">Subsidiaries of the Company.</a>				
23.1*	<a href="#">Consent of Emst &amp; Young LLP, Independent Registered Public Accounting Firm.</a>				
23.2*	<a href="#">Consent of CohnReznick LLP, Independent Registered Public Accounting Firm.</a>				
24.1	<a href="#">Power of Attorney (included on signature page)</a>				
31.1*	<a href="#">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.</a>				
31.2*	<a href="#">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.</a>				
32.1*	<a href="#">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.</a>				
32.2*	<a href="#">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.</a>				

Exhibit No.	Exhibit Description	Incorporated by Reference			Filing Date
		Schedule/Form	File Number	Exhibit	
101.INS*	XBRL Instance Document.				
101.SCH*	XBRL Taxonomy Extension Schema Document.				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.				
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.				
^	Confidential treatment has been requested as to certain portions, which portions have been omitted and submitted separately to the Securities and Exchange Commission.				
+	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 6<sup>th</sup> day of March, 2018.

**Paratek Pharmaceuticals, Inc.**

By:                                 /s/ Michael F. Bigham                                  
**Michael F. Bigham**  
*Chairman and Chief Executive Officer*

## POWER OF ATTORNEY

**KNOW ALL PERSONS BY THESE PRESENTS**, that each person whose signature appears below constitutes and appoints each of William M. Haskell and Douglas W. Pagán his true and lawful attorney-in-fact and agent, with full power of substitution, for him and in his 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 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Michael F. Bigham</u> <b>Michael F. Bigham</b>	Chairman of the Board of Directors and Chief Executive Officer <i>(Principal Executive Officer)</i>	March 6, 2018
<u>/s/ Douglas W. Pagán</u> <b>Douglas W. Pagán</b>	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	March 6, 2018
<u>/s/ Evan Loh, M.D.</u> <b>Evan Loh, M.D.</b>	President, Chief Operating Officer, Chief Medical Officer and Director	March 6, 2018
<u>/s/ Thomas J. Dietz, Ph.D.</u> <b>Thomas J. Dietz, Ph.D.</b>	Director	March 6, 2018
<u>/s/ Timothy R. Franson, M.D.</u> <b>Timothy R. Franson, M.D.</b>	Director	March 6, 2018
<u>/s/ Richard J. Lim</u> <b>Richard J. Lim</b>	Director	March 6, 2018
<u>/s/ Kristine Peterson</u> <b>Kristine Peterson</b>	Director	March 6, 2018
<u>/s/ Robert S. Radie</u> <b>Robert S. Radie</b>	Director	March 6, 2018
<u>/s/ Jeffrey Stein, Ph.D.</u> <b>Jeffrey Stein, Ph.D.</b>	Director	March 6, 2018

**PARATEK PHARMACEUTICALS, INC.  
DIRECTOR RESTRICTED STOCK UNIT GRANT NOTICE  
(2015 EQUITY INCENTIVE PLAN)**

Paratek Pharmaceuticals, Inc. (the “*Company*”), pursuant to Section 6(b) of the Company’s 2015 Equity Incentive Plan (the “*Plan*”), hereby awards to Participant a Restricted Stock Unit Award for the number of shares of the Company’s Common Stock (“*Restricted Stock Units*”) set forth below (the “*Award*”). The Award is subject to all of the terms and conditions as set forth in this notice of grant (this “*Restricted Stock Unit Grant Notice*”) and in the Plan and the Director Restricted Stock Unit Award Agreement (the “*Award Agreement*”), both of which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein shall have the meanings set forth in the Plan or the Award Agreement. In the event of any conflict between the terms in the Award and the Plan, the terms of the Plan shall control.

Participant: \_\_\_\_\_  
 Date of Grant: \_\_\_\_\_  
 Vesting Commencement Date: \_\_\_\_\_  
 Number of Restricted Stock Units/Shares: \_\_\_\_\_

**Vesting Schedule:**             [ ]

[If a Change in Control or Corporate Transaction occurs, then, as of immediately prior to such Change in Control or Corporate Transaction, as applicable, the vesting of the Award shall be accelerated to the extent of one-hundred percent (100%) of the unvested portion of the then outstanding Restricted Stock Units, provided that Participant has remained in Continuous Service from the Vesting Commencement Date until the effective date of such Change in Control or Corporate Transaction.]

**Issuance Schedule:**            Subject to any change on a Capitalization Adjustment, one share of Common Stock will be issued for each Restricted Stock Unit that vests at the time set forth in Section 6 of the Award Agreement.

**Additional Terms/Acknowledgements:** Participant acknowledges receipt of, and understands and agrees to, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the acquisition of the Common Stock pursuant to the Award specified above and supersede all prior oral and written agreements on the terms of this Award with the exception, if applicable, of any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law.

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By accepting this Award, Participant acknowledges having received and read this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan and agrees to all of the terms and conditions set forth in these documents. Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

**PARATEK PHARMACEUTICALS, INC.**

**PARTICIPANT**

By: \_\_\_\_\_  
Signature

Title: \_\_\_\_\_

Date: \_\_\_\_\_

\_\_\_\_\_  
Signature

Date: \_\_\_\_\_

**ATTACHMENTS:** Director Restricted Stock Unit Award Agreement and 2015 Equity Incentive Plan

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**ATTACHMENT I**

**DIRECTOR RESTRICTED STOCK UNIT AWARD AGREEMENT**

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**Paratek Pharmaceuticals, Inc.**  
**Director Restricted Stock Unit Award Agreement**  
**(2015 Equity Incentive Plan)**

Pursuant to the Director Restricted Stock Unit Grant Notice (the “*Grant Notice*”) and this Director Restricted Stock Unit Award Agreement (the “*Agreement*”), Paratek Pharmaceuticals, Inc. (the “*Company*”) has awarded you (“*Participant*”) a Restricted Stock Unit Award (the “*Award*”) pursuant to Section 6(b) of the Company’s 2015 Equity Incentive Plan (the “*Plan*”) for the number of Restricted Stock Units/shares indicated in the Grant Notice. Capitalized terms not explicitly defined in this Agreement or the Grant Notice shall have the same meanings given to them in the Plan. The terms of your Award, in addition to those set forth in the Grant Notice, are as follows.

**1. Grant of the Award.** This Award represents the right to be issued on a future date one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 below) as indicated in the Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the “*Account*”) the number of Restricted Stock Units/shares of Common Stock subject to the Award. This Award was granted in consideration of your services to the Company.

**2. Vesting.** Subject to the limitations contained herein, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice, provided that vesting will cease upon the termination of your Continuous Service. Upon such termination of your Continuous Service, the Restricted Stock Units/shares of Common Stock credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in or to such underlying shares of Common Stock.

**3. Number of Shares.** The number of Restricted Stock Units/shares subject to your Award may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan. Any additional Restricted Stock Units, shares, cash or other property that becomes subject to the Award pursuant to this Section 3, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Restricted Stock Units and shares covered by your Award. Notwithstanding the provisions of this Section 3, no fractional shares or rights for fractional shares of Common Stock shall be created pursuant to this Section 3. Any fraction of a share will be rounded down to the nearest whole share.

**4. Securities Law Compliance.** You may not be issued any Common Stock under your Award unless the shares of Common Stock underlying the Restricted Stock Units are either (i) then registered under the Securities Act, or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award must also comply with other applicable laws and regulations governing the Award, and you shall not receive such Common Stock if the Company determines that such receipt would not be in material compliance with such laws and regulations.

**5. Transfer Restrictions.** Prior to the time that shares of Common Stock have been delivered to you, you may not transfer, pledge, sell or otherwise dispose of this Award or the shares issuable in respect of your Award, except as expressly provided in this Section 5. For example, you may not use shares that may be issued in respect of your Restricted Stock Units as security for a loan. The restrictions on transfer set forth herein will lapse upon delivery to you of shares in respect of your vested Restricted Stock Units.

**(a) Death.** Your Award is transferable by will and by the laws of descent and distribution. At your death, vesting of your Award will cease and your executor or administrator of your estate shall be entitled to receive, on behalf of your estate, any Common Stock or other consideration that vested but was not issued before your death.

**(b) Domestic Relations Orders.** Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your right to receive the distribution of Common Stock or other consideration hereunder, pursuant to a domestic relations order or marital settlement agreement that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this Award with the Company General Counsel prior to finalizing the domestic relations order or marital settlement agreement to verify that you may make such transfer, and if so, to help ensure the required information is contained within the domestic relations order or marital settlement agreement.

**6. Date of Issuance.**

**(a)** The issuance of shares in respect of the Restricted Stock Units is intended to comply with Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such a manner. In the event one or more Restricted Stock Units vests, the Company shall issue to you one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 above). The issuance date determined by this paragraph is referred to as the “*Original Issuance Date*”.

**(b)** If the Original Issuance Date falls on a date that is not a business day, delivery shall instead occur on the next following business day.

**(c)** The form of delivery (e.g., a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

**7. Dividends.** You shall receive no benefit or adjustment to your Award with respect to any cash dividend, stock dividend or other distribution that does not result from a Capitalization Adjustment.

**8. Restrictive Legends.** The shares of Common Stock issued under your Award shall be endorsed with appropriate legends as determined by the Company.



**9. Execution of Documents.** You hereby acknowledge and agree that the manner selected by the Company by which you indicate your consent to your Grant Notice is also deemed to be your execution of your Grant Notice and of this Agreement. You further agree that such manner of indicating consent may be relied upon as your signature for establishing your execution of any documents to be executed in the future in connection with your Award.

**10. Award not a Service Contract.**

(a) Nothing in this Agreement (including, but not limited to, the vesting of your Award or the issuance of the shares subject to your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

(b) The Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a “*reorganization*”). Such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. This Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with the Company’s right to conduct a reorganization.

**11. Withholding Obligations.** You expressly acknowledge and agree that you shall be responsible for satisfying and paying all taxes arising from or due in connection with the grant or vesting of the Restricted Stock Units and/or the delivery of any Common Stock hereunder. The Company shall have no liability or obligation relating to the foregoing.

**12. Tax Consequences.** The Company has no duty or obligation to minimize the tax consequences to you of this Award and shall not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by signing the Grant Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so. You understand that you (and not the Company) shall be responsible for your own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

**13. Unsecured Obligation.** Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue shares or other property pursuant to this Agreement. You shall not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this Agreement until such shares are issued to you pursuant to Section 6 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

**14. Notices.** Any notice or request required or permitted hereunder shall be given in writing to each of the other parties hereto and shall be deemed effectively given on the earlier of (i) the date of personal delivery, including delivery by express courier, or delivery via electronic means, or (ii) the date that is five (5) days after deposit in the United States Post Office (whether or not actually received by the addressee), by registered or certified mail with postage and fees prepaid, addressed at the following addresses, or at such other address(es) as a party may designate by ten (10) days' advance written notice to each of the other parties hereto:

**Company:** Paratek Pharmaceuticals, Inc.  
Attn: Stock Administrator  
75 Park Plaza, Fourth Floor  
Boston, MA 02116 USA

**Participant:** Your address as on file with the Company  
at the time notice is given

**15. Headings.** The headings of the Sections in this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement or to affect the meaning of this Agreement.

**16. Miscellaneous.**

**(a)** The rights and obligations of the Company under your Award shall be transferable by the Company to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by, the Company's successors and assigns.

**(b)** You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

**(c)** You agree that you will not sell, dispose of, transfer, make any short sale of, grant any option for the purchase of, or enter into any hedging or similar transaction with the same economic effect as a sale with respect to any shares of Common Stock or other securities of the Company held by you, for a period of 180 days following the effective date of a registration statement of the Company filed under the Securities Act or such longer period as the underwriters or the Company will request to facilitate compliance with FINRA Rule 2711 or

NYSE Member Rule 472 or any successor or similar rules or regulation (the “*Lock-Up Period*”). You further agree to execute and deliver such other agreements as may be reasonably requested by the Company or the underwriters that are consistent with the foregoing or that are necessary to give further effect thereto. In order to enforce the foregoing covenant, the Company may impose stop-transfer instructions with respect to your shares of Common Stock until the end of such period. You also agree that any transferee of any shares of Common Stock (or other securities) of the Company held by you will be bound by this Section 16(c). The underwriters of the Company’s stock are intended third party beneficiaries of this Section 16(c) and will have the right, power and authority to enforce the provisions hereof as though they were a party hereto.

(d) You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award and fully understand all provisions of your Award.

(e) This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(f) All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

**17. Governing Plan Document.** Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Your Award (and any compensation paid or shares issued under your Award) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to voluntarily terminate employment upon a resignation for “good reason,” or for a “constructive termination” or any similar term under any plan of or agreement with the Company.

**18. Effect on Other Employee Benefit Plans.** The value of the Award subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating benefits under any employee benefit plan (other than the Plan) sponsored by the Company or any Affiliate except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any or all of the employee benefit plans of the Company or any Affiliate.

**19. Choice of Law.** The interpretation, performance and enforcement of this Agreement shall be governed by the law of the State of Delaware without regard to that state’s conflicts of laws rules.

**20. Severability.** If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

**21. Other Documents.** You acknowledge receipt of and the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company's Insider Trading Policy.

**22. Amendment.** This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that, except as otherwise expressly provided in the Plan, no such amendment materially adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the Award as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Award which is then subject to restrictions as provided herein.

**23. Compliance with Section 409A of the Code.** This Award is intended to comply with the "short-term deferral" rule set forth in Treasury Regulation Section 1.409A-1(b)(4). Notwithstanding the foregoing, if it is determined that the Award fails to satisfy the requirements of the short-term deferral rule and is otherwise deferred compensation subject to Section 409A, and if you are a "Specified Employee" (within the meaning set forth in Section 409A(a)(2)(B)(i) of the Code) as of the date of your "separation from service" (within the meaning of Treasury Regulation Section 1.409A-1(h) and without regard to any alternative definition thereunder), then the issuance of any shares that would otherwise be made upon the date of the separation from service or within the first six (6) months thereafter will not be made on the originally scheduled date(s) and will instead be issued in a lump sum on the date that is six (6) months and one day after the date of the separation from service, with the balance of the shares issued thereafter in accordance with the original vesting and issuance schedule set forth above, but if and only if such delay in the issuance of the shares is necessary to avoid the imposition of adverse taxation on you in respect of the shares under Section 409A of the Code. Each installment of shares that vests is intended to constitute a "separate payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2).

\* \* \* \* \*

This Restricted Stock Unit Award Agreement shall be deemed to be signed by the Company and the Participant upon the signing by the Participant of the Restricted Stock Unit Grant Notice to which it is attached.

**ATTACHMENT II**

**2015 EQUITY INCENTIVE PLAN**

7.

**Paratek Pharmaceuticals, Inc.  
Director Stock Option Grant Notice  
(2015 Equity Incentive Plan)**

Paratek Pharmaceuticals, Inc. (the “*Company*”), pursuant to its 2015 Equity Incentive Plan (the “*Plan*”), hereby grants to Optionholder an option to purchase the number of shares of the Company’s Common Stock set forth below (the “*Option*”). This Option is subject to all of the terms and conditions as set forth in this notice of grant (this “*Stock Option Grant Notice*”) and in the Director Option Agreement, the Plan and the Notice of Exercise, all of which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein shall have the meanings set forth in the Plan or the Director Option Agreement. In the event of a conflict between the terms in this Stock Option Grant Notice and the Plan, the terms of the Plan will control.

Optionholder:	_____
Date of Grant:	_____
Vesting Commencement Date:	_____
Number of Shares Subject to Option:	_____
Exercise Price (Per Share):	_____
Total Exercise Price:	_____
Expiration Date:	_____

**Type of Grant:** Nonstatutory Stock Option

**Exercise Schedule:** Same as Vesting Schedule

**Vesting Schedule:** [ ]

[If a Change in Control or Corporate Transaction occurs, then, as of immediately prior to such Change in Control or Corporate Transaction, as applicable, the vesting of the Options shall be accelerated to the extent of one-hundred percent (100%) of the unvested portion of the then outstanding Options, provided that Optionholder has remained in Continuous Service from the Vesting Commencement Date until the effective date of such Change in Control or Corporate Transaction.]

**Payment:** By one or a combination of the following items (described in the Option Agreement):

- By cash, check, bank draft or money order payable to the Company
- Pursuant to a Regulation T Program
- By delivery of already-owned shares
- If and only to the extent this option is a Nonstatutory Stock Option, and subject to the Company’s consent at the time of exercise, by a “net exercise” arrangement

**Additional Terms/Acknowledgements:** Optionholder acknowledges receipt of, and understands and agrees to, this Stock Option Grant Notice, the Option Agreement and the Plan. Optionholder acknowledges and agrees that this Stock Option Grant Notice and the Option Agreement may not be modified, amended or revised except as provided in the Plan. Optionholder further acknowledges that as of the Date of Grant, this Stock Option Grant Notice, the Option Agreement, and the Plan set forth the entire understanding between Optionholder and the Company regarding this option award and supersede

all prior oral and written agreements, promises and/or representations on that subject with the exception of (i) options previously granted and delivered to Optionholder and (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law.

By accepting this option, Optionholder acknowledges having received and read the Stock Option Grant Notice, the Option Agreement and the Plan and agrees to all of the terms and conditions set forth in these documents. Optionholder consents to receive such documents by electronic delivery and to participate in the Plan through an online or electronic system established and maintained by the Company or another third party designated by the Company.

**Paratek Pharmaceuticals, Inc.**

**Optionholder:**

By: \_\_\_\_\_  
Signature

\_\_\_\_\_  
Signature

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

**Attachments:** Director Option Agreement, 2015 Equity Incentive Plan and Notice of Exercise

**Attachment I**

**Director Option Agreement**

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**Paratek Pharmaceuticals, Inc.**  
**Director Option Agreement**  
**(2015 Equity Incentive Plan)**

Pursuant to your Stock Option Grant Notice (“**Grant Notice**”) and this Director Option Agreement, Paratek Pharmaceuticals, Inc. (the “**Company**”) has granted you an option under its 2015 Equity Incentive Plan (the “**Plan**”) to purchase the number of shares of the Company’s Common Stock indicated in your Grant Notice at the exercise price indicated in your Grant Notice. The option is granted to you effective as of the date of grant set forth in the Grant Notice (the “**Date of Grant**”). If there is any conflict between the terms in this Option Agreement and the Plan, the terms of the Plan will control. Capitalized terms not explicitly defined in this Option Agreement or in the Grant Notice but defined in the Plan will have the same definitions as in the Plan.

The details of your option, in addition to those set forth in the Grant Notice and the Plan, are as follows:

**1. Vesting.** Subject to the provisions contained herein, your option will vest as provided in your Grant Notice. Vesting will cease upon the termination of your Continuous Service.

**2. Number of Shares and Exercise Price.** The number of shares of Common Stock subject to your option and your exercise price per share in your Grant Notice will be adjusted for Capitalization Adjustments.

**3. Method of Payment.** You must pay the full amount of the exercise price for the shares you wish to exercise. You may pay the exercise price in cash or by check, bank draft or money order payable to the Company or in any other manner permitted by your Grant Notice, which may include one or more of the following:

**(a)** Pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds. This manner of payment is also known as a “broker-assisted exercise”, “same day sale”, or “sell to cover”.

**(b)** By delivery to the Company (either by actual delivery or attestation) of already-owned shares of Common Stock that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. “Delivery” for these purposes, in the sole discretion of the Company at the time you exercise your option, will include delivery to the Company of your attestation of ownership of such shares of Common Stock in a form approved by the Company. You may not exercise your option by delivery to the Company of Common Stock if doing so would violate the provisions of any law, regulation or agreement restricting the redemption of the Company’s stock.

**(c)** If this option is a Nonstatutory Stock Option, subject to the consent of the Company at the time of exercise, by a “net exercise” arrangement pursuant to which the Company will reduce the number of shares of Common Stock issued upon exercise of your option by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price. You must pay any remaining balance of the aggregate exercise price not satisfied by the “net exercise” in cash or other permitted form of payment. Shares of Common Stock will no longer be outstanding under your

option and will not be exercisable thereafter if those shares (i) are used to pay the exercise price pursuant to the “net exercise,” (ii) are delivered to you as a result of such exercise, and (iii) are withheld to satisfy your tax withholding obligations.

**4. Whole Shares.** You may exercise your option only for whole shares of Common Stock.

**5. Securities Law Compliance.** In no event may you exercise your option unless the shares of Common Stock issuable upon exercise are then registered under the Securities Act or, if not registered, the Company has determined that your exercise and the issuance of the shares would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with all other applicable laws and regulations governing your option, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations (including any restrictions on exercise required for compliance with Treas. Reg. 1.401(k)-1(d)(3), if applicable).

**6. Term.** You may not exercise your option before the Date of Grant or after the expiration of the option’s term. The term of your option expires, subject to the provisions of Section 5(h) of the Plan, upon the earliest of the following:

**(a)** immediately upon the date on which the event giving rise to your termination of Continuous Service for Cause occurs (or, if required by law, the date of termination of Continuous Service for Cause);

**(b)** three (3) months after the termination of your Continuous Service for any reason other than Cause, your Disability or your death (except as otherwise provided in Section 7(d) below); *provided, however*, that if during any part of such three (3) month period your option is not exercisable solely because of the condition set forth in the section above relating to “Securities Law Compliance,” your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service; *provided further*, if during any part of such three (3) month period, the sale of any Common Stock received upon exercise of your option would violate the Company’s insider trading policy, then your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service during which the sale of the Common Stock received upon exercise of your option would not be in violation of the Company’s insider trading policy ;

**(c)** twelve (12) months after the termination of your Continuous Service due to your Disability (except as otherwise provided in Section 7(d)) below;

**(d)** eighteen (18) months after your death if you die either during your Continuous Service or within three (3) months after your Continuous Service terminates for any reason other than Cause;

**(e)** the Expiration Date indicated in your Grant Notice; or

**(f)** the day before the tenth (10th) anniversary of the Date of Grant.

**7. Exercise.** You may exercise the vested portion of your option during its term by (i) delivering a Notice of Exercise (in a form designated by the Company) or completing such other documents and/or procedures designated by the Company for exercise and (ii) paying the exercise price to the Company's Secretary, stock plan administrator, or such other person as the Company may designate, together with such additional documents as the Company may then require.

**8. Transferability.** Except as otherwise provided in this Section 9, your option is not transferable, except by will or by the laws of descent and distribution, and is exercisable during your life only by you.

**(a) Certain Trusts.** Upon receiving written permission from the Board or its duly authorized designee, you may transfer your option to a trust if you are considered to be the sole beneficial owner (determined under Section 671 of the Code and applicable state law) while the option is held in the trust. You and the trustee must enter into transfer and other agreements required by the Company.

**(b) Domestic Relations Orders.** Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your option pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument as permitted by Treasury Regulation 1.421-1(b)(2) that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this option with the Company prior to finalizing the domestic relations order or marital settlement agreement to help ensure the required information is contained within the domestic relations order or marital settlement agreement.

**(c) Beneficiary Designation.** Upon receiving written permission from the Board or its duly authorized designee, you may, by delivering written notice to the Company, in a form approved by the Company and any broker designated by the Company to handle option exercises, designate a third party who, on your death, will thereafter be entitled to exercise this option and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, your executor or administrator of your estate will be entitled to exercise this option and receive, on behalf of your estate, the Common Stock or other consideration resulting from such exercise.

**9. Option not a Service Contract.** Your option is not an employment or service contract, and nothing in your option will be deemed to create in any way whatsoever any obligation on your part to continue in the employ of the Company or an Affiliate, or of the Company or an Affiliate to continue your employment. In addition, nothing in your option will obligate the Company or an Affiliate, their respective stockholders, boards of directors, officers or employees to continue any relationship that you might have as a Director or Consultant for the Company or an Affiliate.

**10. Withholding Obligations.** You expressly acknowledge and agree that you shall be responsible for satisfying and paying all taxes arising from or due in connection with the vesting or exercise of the options and/or the delivery of any Common Stock hereunder. The Company shall have no liability or obligation relating to the foregoing.

**11. Tax Consequences.** You hereby agree that the Company does not have a duty to design or administer the Plan or its other compensation programs in a manner that minimizes your tax liabilities. You will not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from your option or your other compensation. In particular, you acknowledge that this option is exempt from Section 409A of the Code only if the exercise price per

share specified in the Grant Notice is at least equal to the “fair market value” per share of the Common Stock on the Date of Grant and there is no other impermissible deferral of compensation associated with the option.

**12. Notices.** Any notices provided for in your option or the Plan will be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this option by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this option, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

**13. Governing Plan Document.** Your option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. If there is any conflict between the provisions of your option and those of the Plan, the provisions of the Plan will control. In addition, your option (and any compensation paid or shares issued under your option) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

**14. Other Documents.** You hereby acknowledge receipt of and the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company’s policy permitting certain individuals to sell shares only during certain “window” periods and the Company’s insider trading policy, in effect from time to time.

**15. Effect on Other Employee Benefit Plans.** The value of this option will not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company’s or any Affiliate’s employee benefit plans.

**16. Voting Rights.** You will not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this option until such shares are issued to you. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this option, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

**17. Severability.** If all or any part of this Option Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Option Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Option Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

**18.**

**Miscellaneous.**

**(a)** The rights and obligations of the Company under your option will be transferable to any one or more persons or entities, and all covenants and agreements hereunder will inure to the benefit of, and be enforceable by the Company's successors and assigns.

**(b)** You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your option.

**(c)** You acknowledge and agree that you have reviewed your option in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your option, and fully understand all provisions of your option.

**(d)** This Option Agreement will be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

**(e)** All obligations of the Company under the Plan and this Option Agreement will be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

\* \* \*

This Option Agreement will be deemed to be signed by you upon the signing by you of the Grant Notice to which it is attached.

**Attachment II**

**2015 Equity Incentive Plan**

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**Attachment III**  
**Notice of Exercise**

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**Notice Of Exercise**  
**Under the Paratek Pharmaceuticals, Inc.**  
**2015 Equity Incentive Plan**

Paratek Pharmaceuticals, Inc.  
Attention: Stock Plan Administrator  
75 Park Plaza, Fourth Floor  
Boston, MA 02116, USA

Date of Exercise: \_\_\_\_\_

This constitutes notice to Paratek Pharmaceuticals, Inc. (the "**Company**") under my stock option that I elect to purchase the below number of shares of Common Stock of the Company (the "**Shares**") for the price set forth below.

Type of option (check one):	Incentive <input type="checkbox"/>	Nonstatutory <input type="checkbox"/>
Stock option dated:	_____	_____
Number of Shares as to which option is exercised:	_____	_____
Certificates to be issued in name of:	_____	_____
Total exercise price:	\$ _____	\$ _____
Cash payment delivered herewith:	\$ _____	\$ _____
Value of _____ Shares delivered herewith:	\$ _____	\$ _____
Value of _____ Shares pursuant to net exercise:	\$ _____	\$ _____
Regulation T Program (cashless exercise):	\$ _____	\$ _____

By this exercise, I agree (i) to provide such additional documents as you may require pursuant to the terms of the Paratek Pharmaceuticals, Inc. 2015 Equity Incentive Plan, (ii) to provide for the payment by me to you (in the manner designated by you) of your withholding obligation, if any, relating to the exercise of this option, and (iii) if this exercise relates to an Incentive Stock Option, to notify you in writing within fifteen (15) days after the date of any disposition of any of the Shares issued upon exercise of this option that occurs within two (2) years after the date of grant of this option or within one (1) year after such Shares are issued upon exercise of this option.

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Very truly yours,

---

Signature

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Print Name

## PARATEK PHARMACEUTICALS, INC.

## NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Each member of the Board of Directors (the "*Board*") who is not also serving as an employee of Paratek Pharmaceuticals, Inc. (the "*Company*") or any of its subsidiaries (each such member, an "*Eligible Director*") will receive the compensation described in this Non-Employee Director Compensation Policy for his or her Board service. This Non-Employee Director Compensation Policy is effective on January 1, 2018 (the "*Effective Date*"). An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date for which service begins for a cash payment, or the date of grant for an equity award, as the case may be (*e.g.*, an election to decline the cash payment to be made for a quarter must be made prior to the date the quarter begins). This policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board, and supersedes any prior policies related to compensation of Eligible Directors.

**Annual Cash Compensation**

The annual cash compensation amount set forth below is payable in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with a pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service, and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
  - a. All Eligible Directors: \$45,000
  
2. Annual Committee Chair Service Retainer:
  - a. Chairman of the Audit Committee: \$20,000
  - b. Chairman of the Compensation Committee: \$15,000
  - c. Chairman of the Nominating and Corporate Governance Committee: \$10,000
  
3. Annual Committee Member Service Retainer (other than Chairman):
  - a. Member of the Audit Committee: \$7,750
  - b. Member of the Compensation Committee: \$6,000
  - c. Member of the Nominating and Corporate Governance Committee: \$4,500

**Equity Compensation**

The stock options and restricted stock units set forth below will be granted under the Company's 2015 Equity Incentive Plan (the "*Plan*"). All stock options granted under this policy will be non-statutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying Common Stock on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan). In addition to the vesting schedules described below, in the event of a Change in Control or a Corporate Transaction (each, as defined in the Plan), any unvested portion of the stock options and restricted stock units described below will fully vest and become exercisable as of immediately prior to the effective time of such Change in Control or Corporate Transaction, subject to the Eligible Director's Continuous Service (as defined in the Plan) on the effective date of such transaction.

1. Initial Grant: On the last trading day of the month in which an Eligible Director is initially elected or appointed to the Board (or if there is no trading day in that month on or after the date of election or appointment of the Eligible Director, then on the last trading day of the month following the month in which an Eligible Director is initially elected or appointed to the Board), the Eligible Director will be granted automatically, without further action by the Board or Compensation Committee of the Board, (i) stock options to purchase 10,000 shares of the Company's Common Stock and (ii) Restricted Stock Units (RSUs) representing 15,000 shares of the Company's Common Stock. The shares subject to each such (i) stock option will vest as to 1/36 of the shares on the last day of the month following the month of the date of grant, and on the last day of each successive month thereafter until fully vested, and (ii) 1/3 of the RSUs will vest on each successive one-year anniversary following the grant date over a three-year period, in either case, subject to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting dates. No Initial Grant will be granted to an Eligible Director who is already serving as a director on the Effective Date.
2. Annual Grant: At the Compensation Committee meeting held in January or February of each year for the purpose of granting executives annual equity incentive awards following the Effective Date or, if a Compensation Committee meeting is not held by the end of February of any year, on the last trading date in February of such year following the Effective Date, each Eligible Director who continues to serve as a non-employee member of the Board on such date will be granted automatically, without further action by the Board or Compensation Committee of the Board, a stock option to purchase 5,000 shares of the Company's Common Stock and Restricted Stock Units (RSUs) representing 7,500 shares of the Company's Common Stock. The shares subject to each such (i) stock option will vest as to 1/12 of the shares on the one-month anniversary following the vesting commencement date, and on the same calendar date of each successive month thereafter until fully vested, and (ii) RSUs on the one-year anniversary following the grant date, subject, in either case, to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting date.

#### **Expenses**

The Company will reimburse Eligible Directors for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at and participation in Board and/or Committee meetings.

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

[Execution Copy]

### TUFTS UNIVERSITY LICENSE AGREEMENT

This Agreement is made and entered into as of February 1, 1997 ("the Effective Date"), by and between Paratek Pharmaceuticals, Inc., a Delaware corporation having an address of P.O. Box 1525, Boston, Massachusetts 02117-1525 ("Licensee") and Tufts University, a/k/a Trustees of Tufts College, a corporation duly organized and existing under the laws of the Commonwealth of Massachusetts and having a principal office at Medford, Massachusetts 02155 ("Tufts").

WHEREAS, Tufts possesses certain know-how, inventions and intellectual property in the field of drug resistance;

WHEREAS, Tufts, acting through Dr. Stuart Levy, (the "Principal Investigator") wishes to and is prepared to conduct additional research in this field under a Sponsored Research Agreement of even date herewith;

WHEREAS, Licensee is prepared to provide support to Tufts for such research by the Principal Investigator, providing it receives certain license rights under inventions, biological materials, and/or know-how developed in the research under the terms of this License Agreement; and

WHEREAS, Tufts wishes to have such inventions, biological materials, and/or know-how perfected and marketed in order that products resulting therefrom might be available for public use and benefit.

NOW THEREFORE, for valuable consideration, the receipt and adequacy of which are hereby acknowledged, and intending to be legally bound, the parties hereto mutually agree as follows:

#### ARTICLE I - DEFINITIONS.

1.1. "Patent Rights" shall mean rights owned or controlled by Tufts which arise under United States or foreign patents or patent applications as described in Exhibit A or any patents issuing from said applications that cover inventions which were discovered or developed at Tufts by Dr. Stuart Levy, alone or in conjunction with others, or which are discovered or developed in the Field of Use pursuant to the Sponsored Research Agreement of even date herewith (the "Research Agreement"), including any divisions, continuations, continuations-in-part, re-examinations, extensions, renewals, or reissues thereof.

1.2. "Technology" shall mean the trade secret, know-how, and other proprietary, non-public information relating to the "Field of Use" and necessary or useful for practicing the Patent Rights that was discovered or developed at Tufts by Dr. Stuart Levy, alone or in conjunction with others, or is discovered or developed pursuant to the Research Agreement and that has been revealed to Licensee pursuant to the Research Agreement or that may hereafter be revealed to Licensee pursuant to the requirements of this Agreement or the Research Agreement. The

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**THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.**

Technology shall not include the Patent Rights but shall include any non-public information included in patent applications if and when it is subsequently deleted therefrom before the patent is issued.

1.3. "Confidential Technology" shall mean all Technology, and all information in or concerning patent applications included in the Patents, provided, however, that Licensee need not keep confidential any information that:

(a) at the date of its disclosure by Tufts to Licensee was known to Licensee as documented in Licensee's files and is revealed to Tufts within thirty (30) days after Tufts' disclosure to Licensee; or

(b) at the date of disclosure by Tufts to Licensee was, or thereafter becomes, through no fault of Licensee, publicly known through publication or so widely known and used that it can be said to be generally available to the public.

1.4. "Field of Use" shall mean the prophylaxis, treatment or prevention of bacterial or microbial diseases or medical conditions in humans or animals or agriculture using (i) tetracycline derivatives or other compounds which affect tetracycline resistance or (ii) compounds based on knowledge of the MAR operon or (iii) compounds involving novel genes which affect antibiotic resistance or microbial infectivity and which are derived from studies of the MAR operon or (iv) compounds that affect any such genes.

1.5. "License Period" shall mean collectively the respective periods commencing on the Effective Date and ending (unless sooner terminated) upon the later of the expiration of the last to expire of the Patent Rights (treating pending applications as issued patents for so long as they are pending) and fifteen (15) years from the Effective Date.

1.6. "Licensed Products" shall mean all products that are within or made by a process within the Field of Use and that embody or are made in accordance with or using or are based upon or derived from any aspect of the Patent Rights or the Technology.

1.7 "Gross Sales" shall mean the gross sales of Licensed Products subject to royalty under this Agreement billed to customers by Licensee and its Subsidiaries, less the following:

- (a) [\*\*\*];
- (b) [\*\*\*]; and
- (c) [\*\*\*].

Gross Sales shall also include and be deemed to have been made with respect to any Licensed Products used by Licensee or any Subsidiary, for its own commercial purposes, or transferred to any third-party for less than the transferee is then charging in normal arms-length sales transactions; and Gross Sales in all such cases shall be deemed to have been made at the prices therefor at which such Licensed Products are then being sold to the customers of such user or transferor (or of Licensee, if a Subsidiary is a user but not a seller) in arms-length sales transactions.

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In the event that a Licensed Product under this Agreement is sold in combination with another active ingredient or component having independent therapeutic effect or diagnostic utility, then "Gross Sales," for purposes of determining royalty payments on the combination, shall be calculated using one of the following methods:

- (e) By multiplying the Gross Sales of the combination by the fraction  $A/A+B$ , where A is the gross selling price, during the royalty paying period in question, of the Licensed Product sold separately, and B is the gross selling price, during the royalty period in question, of the other active ingredients or components sold separately; or
- (f) In the event that no such separate sales are made of the Licensed Product or any of the active ingredients or components in such combination package during the royalty paying period in question, Gross Sales, for the purposes of determining royalty payments, shall be calculated using the above formula where A is the reasonably estimated commercial value of the Licensed Product sold separately and B is the reasonably estimated commercial value of the other active ingredients or components sold separately. Any such estimates shall be made in good faith by Licensee and reported to Tufts with the reports to be provided to Tufts pursuant to Section 3.7 hereof.

1.8. "Subsidiary" shall mean any corporation, partnership, or other business organization that directly or indirectly controls, is controlled by, or is under common control with Licensee. For the purpose of this Agreement, "control" shall mean the holding directly or indirectly of fifty percent (50%) or more of the voting stock or other ownership interest of the corporation or other business organization invoiced.

1.9. "Territory" shall mean the world.

## ARTICLE II - GRANT; SUBLICENSES.

2.1. Grant. Subject to the terms and conditions hereinafter set forth, Tufts hereby grants to Licensee, to the extent that it lawfully may, a royalty-bearing, exclusive license to practice the Patent Rights and use the Technology in the Territory, only for the purpose of developing, making, using, and selling Licensed Products (the "License"). The License shall exist as such an exclusive, royalty-bearing license during and will terminate as such at the end of the License Period, unless sooner terminated as hereinafter provided. If the License does not terminate before the end of the License Period, then the License to use the Technology shall continue in effect thereafter without limitation of time as an exclusive, fully-paid-up license subject to termination only as provided in Article IX.

2.2. Reserved Rights. During the License Period, Tufts shall have no right to use the Patent Rights or Technology to make, use, or sell Licensed Products for commercial purposes, but Tufts reserves to itself (a) the right at all times to practice the Patent Rights and to use the Technology, and to make and use Licensed Products for research purposes within Tufts, and (b) all other rights not granted to Licensee, including the rights to use and permit the use of Patent Rights and Technology for any purpose not in conflict with the provisions of the License.

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2.3. Sublicenses. Licensee shall also have the right to grant to its Subsidiaries or other sublicensees, exclusive or non-exclusive sublicenses under the License during the License Period; provided, however, and Licensee agrees that:

(a) the terms and conditions of each sublicense shall be consistent with the terms and conditions of this Agreement and shall contain, among other things (by way of example but not limitation), provisions substantially similar to and consistent with: the "Gross Sales" definition; Article III (providing, among other things, that royalties shall be paid to Licensee in amounts at least equal to those of Article III hereof, so that Licensee may in turn pay those royalties to Tufts); Article V; Section 7.1 (so that no representations or warranties inconsistent with that Article shall be extended to or by any sublicensee); Article IX, but the sublicense must terminate not later than the end of the License Period, or earlier if the License terminates earlier for any reason; Article XI; and Article XII.

(b) each sublicense shall provide that the obligations to Tufts of Sections 3.8, 3.9, 3.10, 7.1, 8.1, 8.5, and 9.2, and Articles V, XI, and XII of this Agreement shall be binding on the sublicensee and be enforceable both by Tufts and the Licensee.

(c) if a proposed sublicensee is either (i) a Subsidiary or (ii) a company engaged in the development, manufacture or distribution of health care products with a net worth or market capitalization of at least \$50 million, no approval of Tufts shall be required for the proposed sublicense: in all other cases, the sublicense may not be granted without Tufts' prior written approval (which may not be unreasonably withheld or delayed);

(d) Licensee shall furnish to Tufts a true and complete copy of each sublicense agreement and each amendment thereto, promptly after the sublicense or amendment has been agreed upon;

(e) no Subsidiary or other sublicensee shall have the right to further license, sublicense, or assign its rights without the prior approval of Licensee; and

(f) no sublicense shall relieve Licensee of any of its obligations hereunder, and Licensee shall be responsible for the acts or omissions of its Subsidiaries and sublicensees and for compliance by them with their obligations, and Licensee shall take all steps necessary to enforce that compliance to the extent required to allow Licensee to fully comply with all of its obligations under this agreement.

2.4 During the term of this Agreement and so long as neither Licensee nor any Subsidiary or sublicensee is in default with respect to any payment due to Tufts hereunder, Tufts will not assert its rights under any Patent Rights to prevent any party from using or selling any quantity of Licensed Product on which a royalty has been paid hereunder.

#### ARTICLE III - PAYMENTS; RECORDS.

3.1. License Fee. As partial consideration for the licenses granted hereunder, Licensee agrees to issue to Tufts and its designees, within thirty (30) days of the Effective Date, 500,000 shares of Licensee's Common Stock, par value \$0.001 per share, pursuant to the terms of a Stock Subscription and Right of First Refusal Agreement.

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3.2. Milestone Payments. Licensee agrees to pay to Tufts the following non- refundable milestone payments:

<u>Milestone</u>	<u>Payment Amount</u>
Commencement of First Phase III Clinical Trials in The United States	50,000
First marketing application (NDA) submitted in the United States	100,000
[***]	[***]

3.3 Minimum Royalties. Licensee agrees to pay to Tufts a minimum royalty payment of Twenty-Five Thousand Dollars (\$25,000) in each twelve-month period commencing on each anniversary of the Effective Date if during such period Licensee is not sponsoring at least One Hundred Thousand Dollars (\$100,000) in research at Tufts. Minimum royalty payments shall be creditable against royalties due under Section 3.4 during the same twelve-month period.

3.4. Running Royalties. Licensee agrees to pay to Tufts royalties of:

(a) [\*\*\*] percent ([\*\*\*]%) of the Gross Sales of Licensed Products, the making, using, or selling of which infringes (were it not for the License) at least one claim in an issued, unexpired and non-lapsed patent included in the Patent Rights; or

(b) [\*\*\*] percent ([\*\*\*]%) of the Gross Sales of Licensed Products that do not fall within the clause (a), above, but the manufacture, use or sale of which would infringe (were it not for the License) at least one claim in a pending application included in the Patent Rights, if such claim were to issue.

3.5 Sublicense Royalties. For each sublicense granted by Licensee, Licensee shall pay to Tufts (a) fourteen percent (14%) of that portion of any sublicense issue fees or license maintenance fees received by Licensee which are reasonably attributable to sublicenses of rights granted to Licensee hereunder, and (b) the lesser of (i) [\*\*\*] percent ([\*\*\*]%) of any royalty payments received under such sublicense with respect to the Gross Sales by the sublicensee of Licensed Products covered by a claim contained in an issued Patent Right or a claim included in a pending application covering a Patent Right on a country-by-country basis or (ii) the royalty which would be due if Licensee, rather than the sublicensee, had sold the Licensed Product. Funds received by Licensee from a sublicensee for research conducted by Licensee, achievement of product development-related performance milestones, or for equity investments in Licensee will not be subject to any royalties hereunder.

3.6 Royalty Reductions. In the event Licensee or a sublicensee of Licensee incurs expenses in judicial or administrative proceedings based upon allegations of infringement by Licensee or sublicensee of third-party patents or know-how solely or primarily as a result of the sale of Licensed Products, Licensee may withhold up to [\*\*\*] percent ([\*\*\*]%) of the royalties due hereunder for the calendar year in which the expenses are incurred, and apply the same toward reimbursement of its expenses in connection therewith.

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3.7. Statements; Payments. After the first commercial sale of a Licensed Product, Licensee shall, within sixty (60) days after the last days of March, June, September, and December in each year or portion thereof during the License Period, and within sixty (60) days after the end of the License Period, provide Tufts with a statement accounting for the Gross Sales of Licensed Products by Licensee, its Subsidiaries, and its sublicensees and all amounts described in Section 3.5, all for the immediately preceding three (3) month period or portion thereof, accompanied by payment for the full amount of royalties due under this Article III for that period or portion thereof. Each such statement shall be certified by the Chief Financial Officer of Licensee as being true, correct, and complete.

3.8. Currencies. All payments to be paid to Tufts shall be computed and made in United States Dollars, and Licensee shall use best efforts to convert royalty payments payable on Gross Sales in any country to United States Dollars; provided, however, that if conversion to and transfer of such Dollars cannot be made by Licensee, its Subsidiaries, or its sublicensees in any country for any reason, Licensee may pay such sums in the currency of the country in which such Gross Sales are made, deposited in Tufts' name in a bank designated by Tufts in any such country. The rate of exchange of local currencies to U.S. Dollars shall be at the rate of exchange prevailing at the Bank of Boston (or such other bank in Boston, Massachusetts or New York, New York as Tufts may designate in writing from time to time), for currencies of the amounts involved, as such rate is stated for the first business day after the end of the period with respect to which the royalties are due.

3.9. Records; Audits. Licensee shall keep (and cause to be kept) and maintain complete and accurate records of Gross Sales of the Licensed Products by Licensee, its Subsidiaries, and its sublicensees, in accordance with generally accepted accounting procedures. Such records shall be accessible to independent certified public accountants selected by Tufts and reasonably acceptable to Licensee, by audits conducted not more than once a year during the License Period and for one year after the termination thereof, at any reasonable times during business hours, for the purpose of verifying Gross Sales and any royalties due thereon. Such accountants shall disclose to Tufts only information relating to the accuracy of the records kept and the payments made, and shall be under a duty to keep confidential any other information obtained from such records. Licensee, its Subsidiaries, and its sublicensees shall not be required to retain such records for more than three (3) years after the close of any calendar quarter-year. No period shall be subject to audit under this Section more than once as to any entity being audited.

3.10. Substantial Underpayment. If any such audit reveals that the aggregate of royalties paid during any four consecutive calendar quarters was more than five percent (5%) less than the amount that should have been paid, then the reasonable expenses of the audit shall be borne by Licensee, which shall pay those expenses within thirty (30) days after demand therefore by Tufts accompanied by the accountants' statement therefor.

#### ARTICLE IV - TECHNOLOGY DISCLOSURE; PATENT PROSECUTION.

4.1. Demonstration. Within ninety (90) days of the Effective Date, Tufts representative(s) having knowledge of the Technology and Patent Rights will disclose them to Licensee personnel generally competent in the Field of Use, at the premises of Tufts, or, if mutually agreed, at the premises of Licensee. Such disclosure shall be scheduled at the mutual convenience of Tufts and Licensee and shall be made in such ways as the parties mutually agree seems most likely to enable those Licensee personnel to learn the Technology and Patent Rights.

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4.2. Written Disclosure. Tufts may elect to prepare and furnish to Licensee one or more written descriptions of the Technology and Patent Rights or portions thereof. Licensee agrees to review the written descriptions promptly after receiving them and indicate in writing to Tufts whether there are any details or aspects with which Licensee does not concur. Absent a sufficiently detailed objection by Licensee, those written descriptions will be deemed binding on the parties for all purposes under this Agreement as to the description of the Technology and Patent Rights so described.

4.3. Availability. Tufts shall perform its obligations under Sections 4.1 and 4.2 for no additional consideration. Tufts shall not be obligated to devote any particular amount of time to the performance of those obligations as long as Tufts makes its knowledgeable personnel available to competent Licensee personnel as stated above, and devotes the amount of time reasonably required to teach the necessary Technology to those Licensee personnel. Licensee agrees to make those personnel available for instruction within the time period and otherwise as stated in Section 4.1.

4.4. Patent Prosecution. Commencing on the Effective Date, Licensee shall have the responsibility to apply for, seek prompt issuance of, and maintain while the License is in effect, the Patent Rights in the United States, in the foreign countries listed on Exhibit B hereto and in the foreign countries selected by Licensee and Licensee will keep Tufts informed of the foregoing on a current basis. Upon Tufts' request, Licensee will file and prosecute patent applications corresponding to the Patent Rights in any one or more other countries, to the extent commercially reasonable. Tufts shall cooperate fully with Licensee and provide all such information and data and execute any documents reasonably required in order to allow Licensee to conduct such prosecution and Tufts shall have the opportunity to provide substantive review and comment on any such filing or prosecution. The choice of patent counsel shall be reasonably acceptable to Tufts.

4.5. Patent Expenses. Licensee shall pay all costs associated with the preparation, filing, prosecution, and maintenance of all patent applications filed and patents obtained, which are included in the Patent Rights.

4.6 Abandonment. In the event that Licensee desires to abandon any patent or patent application within the Patent Rights in any country, Licensee shall provide Tufts with reasonable prior written notice of such intended abandonment or decline of responsibility, and Tufts shall have the right, at its expense, to prepare, file, prosecute, and maintain the relevant Patent Rights. If Licensee decides to abandon an issued patent (and all filed applications therefor) throughout the world, or if Licensee determines not to file and prosecute in at least one country a patent application that Tufts has requested Licensee to file, then in any such event such patent and patent applications shall not thereafter be included in "Patent Rights", and the non-public information included in (or that would be included in) such patent and applications shall not thereafter be included in "Technology". If Licensee decides to abandon an issued patent (or a filed application therefor) in any country, or if Licensee declines to file and prosecute a patent application in a country as requested by Tufts herein, then in any such event each such country shall no longer be included in the "Territory" for purposes of the claims covered by the relevant patent or patent application or for purposes of the non-public information included in (or that would be included in) such patent or application.

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ARTICLE V - CONFIDENTIALITY.

5.1. Limitations on Use, Disclosure. Licensee agrees to treat as confidential, and to use and disclose only in furtherance of this Agreement, all Confidential Technology disclosed to it by Tufts. Licensee agrees that it will exercise every reasonable precaution to prevent the unauthorized disclosure of Confidential Technology by any of its directors, officers, employees, or agents to other parties, other than to Subsidiaries and to Licensee sublicensees. Any Confidential Technology disclosed to Subsidiaries or sublicensees shall be disclosed on the basis of and subject to the confidentiality provisions of this Agreement.

5.2. Cessation. Any information which is Confidential Technology at the date of disclosure thereof to Licensee shall cease to be Technology, and Licensee, its Subsidiaries, and its sublicensees shall be released from the provisions of Section 5.1 as to such information on the date when, through no act or omission on the part of Licensee, its Subsidiaries, or its sublicensees, such information becomes (a) publicly known by way of a single publication in which such Confidential Technology is disclosed in reasonable detail, (b) so widely known and used in combination that it can be said to be generally available to the public or (c) is subsequently rightfully obtained without restriction on use or disclosure from sources other than Tufts having no confidential obligation in favor of Tufts.

5.3. Time Limit. The provisions of this Article V shall continue to apply to any information which is Confidential Technology for so long as it shall remain such, notwithstanding any termination of this Agreement or the License or expiration of the License Period, provided, however, that the obligations of confidentiality under this Article shall in any event expire and cease to exist ten years from the Effective Date.

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ARTICLE VI - DILIGENCE.

Licensee agrees to use its best efforts to effect introduction of Licensed Products into the United States commercial market as soon as practical, consistent with sound and reasonable business practices and judgments. Prior to the first commercial sale of a Licensed Product, Licensee shall provide annual reports of such efforts to Tufts within sixty (60) days of each anniversary of the Effective Date. Tufts shall have the right, at any time after eighteen (18) months from the Effective Date, to terminate the License and Tufts' obligations under this Agreement if Licensee, within ninety (90) days after written notice from Tufts of such intended termination, fails to provide written evidence that Licensee has commercialized or is actively attempting to commercialize Licensed Products. Evidence that Licensee has, within eighteen months after the Effective Date, (i) delivered to Tufts a business plan, (ii) taken all reasonable steps to prosecute and maintain the Patent Rights in accordance with the provisions of Section 4.4 hereof, (iii) made payment of all research support under the Sponsored Research Agreement between the parties of even date herewith and (iv) raised a total of \$2 million through venture capital investors or strategic partners shall be deemed, in and of itself, a sufficient showing of such active attempts to commercialize Licensed Products during such period. Thereafter, evidence that Licensee has achieved the following milestones as scheduled below shall be deemed, in and of itself, a sufficient showing of such active attempts to commercialize Licensed Products through such date:

- (i) raised a total of \$5 million through venture capital investors or strategic partners within three (3) years of the Effective Date; and
- (ii) filed an IND for a Licensed Product in the United States within five (5) years of the Effective Date.

Tufts shall not unreasonably withhold its assent to any revision of such milestones whenever requested in writing by Licensee and supported by evidence of technical difficulties or delays that the parties could not have reasonably avoided.

Notwithstanding the foregoing, Tufts shall have the right at any time after ten (10) years from the Effective Date to convert the License hereunder to non-exclusive if Licensee, its Subsidiaries, or its sublicensees have not by the time of such conversion sold Licensed Products into the United States market.

If at any time Licensee decides to discontinue all programs relating to the MAR operon or all programs relating to tetracycline derivatives, Licensee shall give notice of such intent to Tufts and Tufts shall have the option to terminate the License granted hereunder solely with respect to such discontinued programs on thirty days notice to Licensee. Upon any such termination, responsibility for the prosecution and maintenance of any Patent Rights on the discontinued programs shall revert to Tufts.

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ARTICLE VII - REPRESENTATIONS, WARRANTIES, AND LIMITATIONS.

7.1 Tufts Disclaimer. TUFTS MAKES NO REPRESENTATIONS, EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED (INCLUDING, WITHOUT LIMITATION, ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR PURPOSE), AND ASSUMES NO RESPONSIBILITIES WHATSOEVER, WITH RESPECT TO THE PATENTS OR TECHNOLOGY OR THE USE THEREOF, OR THE MANUFACTURE, POSSESSION, USE, MARKETING, SALE, OR OTHER DISPOSITION BY TUFTS, LICENSEE, OR ANYONE ELSE, OF LICENSED PRODUCT(S) OR ANY OTHER PRODUCTS OF SERVICES (INCLUDING, WITHOUT LIMITATION, PRODUCTS MADE BY TUFTS, AND TUFTS SERVICES, THAT ARE OR WERE FURNISHED TO LICENSEE AT ANY TIME BEFORE, ON, OR AFTER THE Effective Date), EXCEPT ONLY AS EXPRESSLY STATED BELOW IN THIS ARTICLE VII. Without limitation of the foregoing generality, nothing contained herein or in any disclosure of the Patents or Technology made by or on behalf of Tufts shall be construed as extending any representation or warranty with respect to the Patents or Technology or Licensed Products or the results to be obtained by the use of the Patents or Technology or any Licensed Products, or that anything made, used, or sold by use of the Patents or Technology or any part thereof, alone or in combination, will be free from infringement of patents of third parties. TUFTS SHALL NOT BE LIABLE TO LICENSEE, ITS SUBSIDIARIES, ITS SUBLICENSEES, OR ANY OTHER PARTY, REGARDLESS OF THE FORM OR THEORY OF ACTION (WHETHER CONTRACT, TORT, INCLUDING NEGLIGENCE, STRICT LIABILITY, OR OTHERWISE), FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, PUNITIVE, OR OTHER EXTRAORDINARY DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT, PATENTS, THE TECHNOLOGY, THE LICENSED PRODUCTS, OR ANY PRODUCTS OR SERVICES FURNISHED OR NOT FURNISHED BY TUFTS, EVEN IF TUFTS HAS BEEN ADVISED OF THE POSSIBILITY THEREOF.

Licensee agrees that all warranties, if any, in connection with the sale or other disposition of any Licensed Products (or any products made by Tufts and furnished at any time to Licensee) by Licensee, its Subsidiaries, or its sublicensees will be made by them and will not directly or impliedly obligate Tufts.

7.2 Tufts Representations. Notwithstanding the first sentence of Section 7.1, Tufts:

- (a) Represents that Tufts is a corporation organized and existing under the laws of the Commonwealth of Massachusetts and has the power and authority to enter into this Agreement.
  - (b) Represents that Tufts has taken all necessary action to authorize its execution and delivery of this Agreement by the representatives of Tufts who carried out such execution and delivery, and to authorize the performance by Tufts of its obligations hereunder.
  - (c) Represents that execution and delivery of this Agreement and its performance by Tufts will not result in any breach or violation of, or constitute a default under, any agreement, instrument, judgment, or order to which Tufts is a party or by which it is bound.
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7.3. Licensee Representations. Licensee represents and warrants to Tufts that:

- (a) Licensee is a corporation organized and existing under the laws of Delaware and has the power and authority to enter into this Agreement.
- (b) Licensee has taken all necessary action to authorize its execution and delivery of this Agreement by the representatives of Licensee who carried out such execution and delivery, and to authorize the performance by Licensee of its obligations hereunder.
- (c) Execution and delivery of this Agreement and its performance by Licensee will not result in any breach or violation of, or constitute a default under, any agreement, instrument, judgment, or order to which Licensee is a party or by which it is bound.

ARTICLE VIII - INDEMNITY; INSURANCE; INFRINGERS.

8.1. Indemnity. Licensee agrees to exonerate, indemnify, and hold harmless Tufts, its trustees, officers, employees, and agents, from all costs, expenses (including attorneys' fees), interest, losses, obligations, liabilities, and damages paid or liability for which is incurred by any of said parties ("Losses"), and which arise out of or are in connection with or are for the purpose of avoiding any and all claims, demands, actions, causes of action, suits, appeals, and proceedings ("Claims"), all whether groundless or not, or the settlement thereof, based on any actual or alleged injuries, damages, or liability of any kind whatsoever (including, without limitation, personal injury, death, property damage, breach of warranty, or breach of contract) arising, directly or indirectly, out of any one or more of: any breach of Licensee of its representations, warranties, or agreements hereunder; or out of any manufacture, marketing, possession, use, sale, or other disposition of Licensed Products or products furnished by Tufts to Licensee in connection herewith or in connection with the Research Agreement (whether same occurs during or after the License or during or after the License Period) by Licensee, its Subsidiaries, its sublicensees, or anyone claiming by, through, or under any of them; or any acquisition, possession, disclosure, or use of the Patents or Technology, or any thereof, by Licensee, its Subsidiaries, its sublicensees, or anyone claiming by, through, or under any of them or the presence of Licensee's or its Subsidiaries' or sublicensee's officers, agents, employees, invitees or property on Tufts' premises.

8.2. Defense; Settlement. Licensee shall defend and control negotiation of settlement of any Claim, with counsel of Licensee's choosing approved in advance by Tufts, which approval shall not be unreasonably withheld. Tufts agrees to cooperate fully in the defense of any Claim and may participate in the defense with counsel of Tufts' choosing, such separate counsel to be at Tufts' expense unless a conflict of interest exists between Licensee and Tufts with respect to the defense, in which case Tufts' separate counsel shall be at Licensee's expense. Any settlement by which Tufts would incur any obligation or liability, whether for the payment of money, the taking of any action, the refraining from any action, or otherwise, shall require the advance written consent of Tufts, which may be withheld in the sole discretion of Tufts without relieving Licensee of any of its indemnification or other obligations hereunder.

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8.3. Insurance. Not later than thirty (30) days before the time when Licensee, any Subsidiary, or any Licensee sublicensee shall, on a commercial basis, make, use, or sell any Licensed Products or any products furnished to Licensee by Tufts at any time (before, on or after the Effective Date) in connection herewith or in connection with the Research Agreement, and at all times thereafter until the expiration of all applicable statutes of limitation pertaining to any such manufacture, marketing, possession, use, sale or other disposition of any Licensed Products or the aforesaid products furnished by Tufts (whether same occurs or exists during or after the existence of the License or during or after the License Period), Licensee will at Licensee's expense, obtain and maintain in full force and effect, comprehensive general liability insurance, including product liability insurance, protecting Tufts against all claims, suits, obligations, liabilities, and damages, based upon or arising out of actual or alleged bodily injury, personal injury, death, or any other damage to or loss of persons or property, caused by any such manufacture, marketing, possession, use, sale, or other disposition. Such insurance policy or policies shall be issued by companies rated by A. M. Best as A VIII or better (or other companies acceptable to Tufts), shall name Tufts as an additional named insured, shall have limits of at least one million dollars (\$1,000,000) per occurrence with an aggregate of three million dollars (\$3,000,000), shall be non-cancelable except upon thirty (30) days prior written notice to Tufts, and shall provide that as to any loss covered thereby and also by any policies obtained by Tufts itself, Licensee's policies shall provide primary coverage for Tufts and Tufts' policies shall be considered excess coverage for Tufts.

8.4. Certificates: Policies. Licensee will forthwith after the obtaining of such insurance required by Section 8.3, obtain and deliver to Tufts certificates of and copies of, and at all times thereafter deliver without further demand replacement certificates and copies of, all such insurance policies that are in force and effect. As requested by Tufts but in no event more than once per calendar year, Licensee will furnish to Tufts a complete list, statement, and description of all insurance called for in this Article, together with certificates and copies of policies for each insurance company issuing any thereof, that such insurance is in full force and effect, that all premiums have been paid, and that such insurance will not be canceled except upon thirty (30) days prior written notice to Tufts.

8.5. Infringers. Each party shall inform the other promptly in writing of any alleged infringement of the Patent Rights in the Field of Use by a third party, including all details then available. Licensee shall have the right, but shall not be obligated, to prosecute at its own expense any such infringements, and Tufts agrees that Licensee may join Tufts as a plaintiff at the expense of Licensee. In any infringement action commenced solely by Licensee, all expenses of Licensee shall first be reimbursed and all recovery for infringement shall be shared [\*\*\*]% to Tufts and [\*\*\*]% to Licensee. Licensee shall indemnify Tufts against any order for costs or other payments that may be made against Tufts in such proceedings.

If Licensee has not taken legal action or been successful in obtaining cessation of the infringement, within one-hundred eighty (180) days of written notification from Tufts of such infringement, or if Licensee elects not to continue prosecuting any legal action against an infringer, Tufts shall have the right, but shall not be obligated, to prosecute at its own expense any such infringement. Tufts may join Licensee as a plaintiff in any such infringement suit at Tufts' expense. In any such action by Tufts, all expenses of Tufts shall first be reimbursed and all recovery for infringement shall be shared [\*\*\*]% to Tufts and [\*\*\*]% to Licensee.

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**THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [ \* \* \* ] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.**

No settlement, consent judgment or other voluntary final disposition of any suit may be entered into without the consents of Tufts and Licensee, which consents shall not be unreasonably withheld or delayed.

In any infringement suit that either party brings to enforce the Patent Rights, the other party shall at the request and expense of the party bringing the suit, cooperate in all reasonable respects, including, to the extent possible, obtaining the testimony of its employees and making available physical evidence in the possession of that party.

Licensee shall have the exclusive right in accordance with the provisions of Section 2.2, to sublicense any alleged infringer in the Territory for the Field of Use, for future use of the Patent Rights.

8.6 Declaratory Judgment. If any declaratory judgment action alleging invalidity or non-infringement of any of the Patent Rights shall be brought against Licensee, Tufts shall have the right at its election made within sixty (60) days after commencement of that action, to intervene and take over the sole defense of the action at its expense.

#### ARTICLE IX - LICENSE TERMINATION.

9.1. Events. The License granted hereunder may be terminated by Tufts pursuant to Article VI or one of the following subsections:

(a) Material Default. If Licensee shall fail after thirty (30) days written notice from Tufts to pay to Tufts any royalties or other payments and payable hereunder, or shall fail in any material way to perform any other agreement required to be performed by Licensee under this Agreement, or if any Subsidiary or sublicensee shall be in material breach of any conditions or obligations affecting Tufts and compliance with which Licensee is responsible for hereunder, or if any representation or warranty of Licensee contained in this Agreement shall prove to have been inaccurate or misleading in any material way when made (referred to collectively and individually as a "material default"), then, without limitation of and in addition to any and all other rights and remedies available to Tufts with respect to such material default, Tufts may terminate the License and Tufts' obligations hereunder by written notice to Licensee at any time after the expiration of such thirty (30) day notice period if Licensee has not cured the material default and the effects thereof before Tufts gives such notice of termination to Licensee, unless Licensee commences arbitration proceedings hereunder to contest such material default, in which event Tufts' right to terminate the License shall be stayed until such arbitration proceedings shall have been completed.

(b) Cessation of Business. If Licensee shall have commenced to carry on the business of selling any Licensed Products (either directly or through any Subsidiary or sublicensee) and shall at any time thereafter cease for a consecutive period of ninety (90) days to carry on such business actively (either directly or through any Subsidiary or sublicensee), other than as a result of fire or other casualty or governmental action taken in the absence of Licensee's fault, Tufts may at any time thereafter while that state of affairs continues, terminate the License by written notice to Licensee.

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**THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.**

9.2 Licensee shall have the option at any time to terminate this License upon one- hundred and eighty (180) days' written notice to Tufts.

9.3. Effects. Upon termination of the License for any reason, nothing herein shall be construed to release Licensee from any obligations hereunder except those of Article VI, but all rights of Licensee and its Subsidiaries and its sublicensees to make, use, or sell Licensed Products, or to practice the Patents and use the Technology, shall cease immediately, except that Licensee, its Subsidiaries, and its sublicensees may after the effective date of such termination sell all Licensed Products that they may have on hand at the date of termination, and may complete manufacture of Licensed Products then in the process of manufacture, and sell them, provided that they pay all royalties due thereon with respect to Gross Sales, as provided in this Agreement.

#### ARTICLE X - NOTICE.

Any notice or communication required to be given hereunder in writing shall be given by registered or certified mail, return receipt requested, or delivered by courier, return receipt requested, charges and postage prepaid, addressed to the parties, respectively, at the following addresses:

In the case of Tufts to:

Joseph J. Byrne, Ph.D.  
Associate Provost for Research  
Tufts University  
136 Harrison Avenue  
Boston, MA 02111 with a copy to:

Mason (Skip) Irving, III  
Vice President, Commercial Development  
Massachusetts Biotechnology Research Institute  
One Innovation Drive  
Worcester, MA 01605

with a second copy to:

Mary Lee Jacobs, Esq.  
General Counsel  
Tufts University  
Ballou Hall  
Medford, MA 02155

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**THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.**

or in the case of Licensee to:

Walter Gilbert  
Acting Chief Executive Officer  
Paratek Pharmaceuticals, Inc.  
P.O. Box 1525  
Boston, MA 02117-1525

with a copy to:

Jeffrey M. Wiesen, Esq.  
Mintz, Levin, Cohn, Ferris,  
Glovsky & Popeo P.C.  
One Financial Center  
Boston, MA 02111

or at such other respective substitute addresses as the addressee may designate in writing to the other party.

#### ARTICLE XI - NON-USE OF NAMES.

Licensee, its subsidiaries and its sublicensees agree that it will not use the name "Tufts University," or any variant thereof, or identify Tufts or any portion of Tufts, or any inventor of any of the Patents or Technology, as a party to this Agreement, or as a participant in inventing the inventions of the Patents or creating the Technology, including, without limitation, in any advertising or promotional sales literature, without the prior express written consent of Tufts, which consent may be withheld or withdrawn by Tufts in its complete and uncontrolled discretion for any reason whatsoever and at any time or times. However, notwithstanding the foregoing, Tufts will make no objection to any proper reference by Licensee to published technical publications by such inventors or creators; and, subject to the confidentiality requirements hereof, Tufts will make no objection to Licensee's making such disclosures as in the reasonable opinion of legal counsel are required as a matter of law and such general disclosures of this Agreement as may be desired by Licensee for purposes of grant solicitations from governmental authorities or as reasonably necessary (as reasonably determined by Licensee) for the purposes of obtaining financing for Licensee or as reasonably necessary (as reasonably determined by Licensee) for the conduct of its business, other than advertising or sales promotion. Licensee shall impose and enforce the requirements of this Article on its Subsidiaries and sublicensees.

#### ARTICLE XII - COMPLIANCE WITH LAWS.

12.1. Export Controls. The Export Control Regulations of the U. S. Department of Commerce prohibit, except under special validated license, the exportation from the United States of technical data relating to certain commodities (listed in the Regulations), unless the exporter has received certain written assurance from the foreign importer. In order to facilitate the exchange of technical information under this Agreement, Licensee therefore hereby agrees and gives its assurance to Tufts that Licensee will not, unless any required prior authorization is obtained from the U. S. Office of Export Control, re-export directly or indirectly any technical data received from

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**THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.**

Tufts under this Agreement and will not export directly the Licensed Products or such technical data to any country listed on either the Commodity Control List or Militarily-Critical Technologies List. Tufts makes no representation as to whether any such license is required or, if one is required, as to whether it will be issued by the U. S. Department of Commerce.

12.2. Other Laws. In addition to the foregoing export control requirements, Licensee agrees that it, its Subsidiaries, and its sublicensees will comply with all applicable mandatory or permissive patent marking laws, rules, and regulations and comply with all other laws, rules, and regulations of all governmental authorities applicable to any of their activities contemplated by this Agreement, and will comply with all necessary and desirable practices in connection and compliance with safety recommendations of trade associations or governmental authorities.

#### ARTICLE XIII - MISCELLANEOUS PROVISIONS.

13.1. Assignment. Licensee shall not assign the License or this Agreement without the prior written consent of Tufts, which consent shall not be unreasonably withheld; provided, however, that Licensee, without such consent, may assign all of its rights hereunder to a wholly-owned Subsidiary or to the acquiring party in connection with the transfer of all or substantially all of its business and assets to an acquiring party or in the event of its merger or consolidation with that acquiring party, if and only if the assignee shall assume all obligations of Licensee under this Agreement. However, no assignment or other transfer by Licensee shall relieve Licensee of any obligations hereunder and Licensee shall continue to be primarily and jointly and severally liable (along with such assignee or other transferee) for the performance of all obligations of Licensee and such assignee or other transferee hereunder.

13.2. Independent Contractors. The parties hereto shall be independent contractors with respect to each other, and nothing contained herein shall be construed as constituting either of them as the agent, principal, employee, servant, joint venturer, or partner of the other for any purpose whatsoever.

13.3. Governing Law. This Agreement shall be governed by and construed in accordance with Massachusetts law, without regard to its conflict of laws principles.

13.4. Sole Agreement. This Agreement and any Exhibits annexed hereto (each of which is hereby made part hereof by this reference), and any other documents which may be expressly incorporated by reference herein, constitute the entire and only agreement between the parties concerning the subject matter hereof; and all prior negotiations, representations, warranties, agreements, and understandings related thereto are superseded hereby.

13.5. Severability. If any provision of this Agreement shall to any extent be found to be invalid or unenforceable, the remainder of this Agreement shall not be affected thereby, and any such invalid or unenforceable provision shall be reformed so as to be valid and enforceable to the fullest extent permitted by law.

13.6. Headings. Headings of Articles, Sections, and subsections included herein are for convenience of reference only and shall not be used to construe this Agreement.

13.7. Financial Confidentiality. Both parties agree to keep the financial terms of this Agreement confidential.

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ARTICLE XIV - ARBITRATION.

14.1. Arbitration. Subject to Section 14.2 below, all disputes, controversies, or differences which may arise between the parties out of or in relation to or in connection with this Agreement, or for the breach thereof, which cannot be resolved by mutual agreement, shall be finally settled by arbitration to be held in accordance with the Commercial Arbitration Rules (the "Rules") of the American Arbitration Association (the "Association") as the Rules then exist, in Boston, Massachusetts, with the following deviations from the Rules. The arbitrators shall consist of one Tufts nominee, one Licensee nominee, and a third person jointly selected by those two nominees. The party requesting arbitration shall designate its nominee in the request, which shall be addressed to the Association with a simultaneous copy to the other party. If the other party shall fail within thirty (30) days of the request for arbitration to nominate the second arbitrator or if the two arbitrators are unable to agree upon the third arbitrator within thirty (30) days after selection of the second arbitrator, then in either case the arbitration panel will be completed according to the Rules. Both legal and equitable remedies shall be available to the arbitrators. The award of a majority of the arbitration panel shall be final and binding on the parties hereto and shall be enforceable in any court having jurisdiction. Tufts and Licensee each irrevocably consent and submit to the jurisdiction of the courts of the Commonwealth of Massachusetts and the United States District Court for the District of Massachusetts.

14.2. Judicial Relief. Claims, disputes, or controversies concerning the validity, infringement, construction, or effect of any patent including, without limitation, any patent licensed hereunder, shall be resolved in any court having jurisdiction thereof, and the parties submit to the jurisdiction of the United States District Court for the District of Massachusetts. In the event that, in any arbitration proceeding, any issue shall arise concerning the validity, infringement, construction, or effect of any patent licensed hereunder, the arbitrators shall assume the validity of all claims as set forth in such patent. In any case, the arbitrators shall not delay the arbitration proceeding for the purpose of obtaining or permitting either party to obtain judicial resolution of such an issue, unless an order staying such arbitration proceeding shall be entered by a court of competent jurisdiction. Neither party shall raise any issue concerning the validity, infringement, construction, or effect of any patent licensed hereunder in any proceeding to enforce any arbitration award hereunder in any proceeding otherwise arising out of any such arbitration award. Nothing in Section 14.1 shall be construed to waive any rights or timely performance of any obligations existing under this Agreement. Moreover, each party acknowledges that appropriate cases (as determined by the courts of competent jurisdiction) of a violation by either party of any of the provisions of this Agreement may entitle the other party to equitable judicial relief, and this relief shall be available in addition to, and shall not be unavailable by reason of, the arbitration provisions of Section 14.1, above. Such equitable judicial relief may be by temporary restraining orders, preliminary and permanent injunctions, and such other equitable relief as any court of competent jurisdiction may deem just and proper.

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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

IN WITNESS WHEREOF, the parties hereto have duly executed and delivered this License Agreement to be effective as of the Effective Date.

TUFTS UNIVERSITY

PARATEK PHARMACEUTICALS, INC.

By: /s/ Steven S. Manos  
Signature

By: /s/ Walter Gilbert

Steven S. Manos  
Typed Name

Typed Name

Executive Vice President  
Title

Title

3/19/97  
Date

4/23/97  
Date

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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

EXHIBIT A  
TO  
LICENSE AGREEMENT  
BETWEEN  
TUFTS UNIVERSITY AND PARATEK PHARMACEUTICALS, INC.

Existing Patent Rights (Including Existing Applications)

I. Issued Patents: (See attached Patent Summary)

"Patent Rights" shall also include the patents to be applied for pursuant to the terms of the License Agreement after the Effective Date, after such applications are made.

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**EXHIBIT B**

List of Foreign Countries in which Patents are to be Filed.

United States

Canada

Japan

Europe (Germany, Belgium, France, Italy, Spain and United Kingdom)

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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [ \* \* \* ] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

TUFTS UNIVERSITY -- PARATEK PHARMACEUTICALS, INC.  
AMENDMENT NO. 1  
TO LICENSE AGREEMENT DATED FEBRUARY 1, 1997

Exhibit A is hereby amended to include:

- Provisional patent application "[\*\*\*]", Filed [\*\*\*]
- Patent application "[\*\*\*]", Filed [\*\*\*]

Section 1.4. "Field of Use" is hereby replaced by the following:

1.4. "Medical Field of Use" shall mean the prophylaxis, treatment or prevention of bacterial or microbial diseases or medical conditions in humans or animals or agriculture through the direct administration of (i) tetracycline derivatives or other compounds which affect tetracycline resistance or (ii) compounds based on knowledge of the MAR operon or (iii) compounds involving novel genes which affect antibiotic resistance or microbial infectivity and which are derived from studies of the MAR operon or (iv) compounds that affect any such genes.

"Disinfectant Field of Use" shall mean the use of compositions, including but not limited to disinfectants and soaps, in any manner other than the direct administration to humans or animals or agriculture, to kill or reduce the growth rate of microorganisms, where such compositions include (i) tetracycline derivatives or other compounds which affect tetracycline resistance or (ii) compounds based on knowledge of the MAR operon or (iii) compounds involving novel genes which affect antibiotic resistance or microbial infectivity and which are derived from studies of the MAR operon or (iv) compounds that affect any such genes.

"Field of Use" shall mean the Medical Field of Use and Disinfectant Field of Use, collectively.

Section 1.7. Third paragraph is hereby amended to read: "In the event that a Licensed Product in the Medical Field of Use under this Agreement is sold..."

Section 3.4 Running Royalties is hereby replaced by the following:

3.4. Running Royalties.

For the Medical Field of Use, Licensee agrees to pay to Tufts royalties of:

(a) [\*\*\*] percent ([\*\*\*]%) of the Gross Sales of Licensed Products, the making, using, or selling of which infringes (were it not for the License) at least one claim in an issued, unexpired and non-lapsed patent included in the Patent Rights; or

(b) [\*\*\*] percent ([\*\*\*]%) of the Gross Sales of Licensed Products that do not fall within the clause (a), above, but the manufacture, use or sale of which would infringe (were it not for the License) at least one claim in a pending application included in the Patent Rights, if such claim were to issue.

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**THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [ \* \* \* ] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.**

For the Disinfectant Field of Use, Licensee agrees to pay to Tufts royalties of:

[\*\*\*] percent ([\*\*\*]%) of the Gross Sales of Licensed Products, the making, using, or selling of which infringes (were it not for the License) at least one claim in an issued, unexpired and non-lapsed patent included in the Patent Rights or would infringe (were it not for the License) at least one claim in a pending application included in the Patent Rights, if such claim were to issue.

Section 3.5. Sublicense Royalties is hereby replaced by the following:

3.5. Sublicense Fees and Royalties. For each sublicense granted by Licensee, Licensee shall pay to Tufts fourteen percent (14%) of that portion of any sublicense issue fees or license maintenance fees received by Licensee which are reasonably attributable to sublicenses of rights granted to Licensee hereunder. Funds received by Licensee from a sublicensee for research conducted by Licensee, achievement of product development-related performance milestones, or for equity investments in Licensee will not be subject to any fees hereunder.

For the Medical Field of Use, for each sublicense granted by Licensee, Licensee shall pay to Tufts the lesser of (i) [\*\*\*] percent ([\*\*\*]%) of any royalty payments received under such sublicense with respect to the Gross Sales by the sublicensee of Licensed Products covered by a claim contained in an issued Patent Right or a claim included in a pending application covering a Patent Right on a country-by-country basis or (ii) the royalty which would be due, pursuant to Section 3.4, if Licensee, rather than the sublicensee, had sold the Licensed Product.

For the Disinfectant Field of Use, for each sublicense granted by Licensee, Licensee shall pay to Tufts the lesser of (i) [\*\*\*] percent ([\*\*\*]%) of any royalty payments received under such sublicense with respect to the Gross Sales by the sublicensee of Licensed Products covered by a claim contained in an issued Patent Right or a claim included in a pending application covering a Patent Right on a country-by-country basis or (ii) the royalty which would be due, pursuant to Section 3.4, if Licensee, rather than the sublicensee, had sold the Licensed Product.

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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [ \* \* \* ] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

All other provisions of the Agreement remain unchanged and in full force and effect.

TUFTS UNIVERSITY

PARATEK PHARMACEUTICALS, INC.

By: /s/ Philip G. Salem  
(signature)

By: /s/ George C. Hillman  
(signature)

Philip G. Salem  
Name

George C. Hillman  
Name

Senior Director, University Development  
Title

Executive Vice President  
Title

12/23/97  
Date

12/29/97  
Date

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TUFTS UNIVERSITY -- PARATEK PHARMACEUTICALS, INC.  
AMENDMENT NO. 2  
TO LICENSE AGREEMENT DATED FEBRUARY 1, 1997

Exhibit A is hereby amended to include:

- Patent application entitled: "[\*\*\*]" Continuation in Part of U.S. patent No.: [\*\*\*], Filed [\*\*\*], Notice of Allowance [\*\*\*].
- Provisional patent application entitled: "[\*\*\*]", Serial No.: [\*\*\*], Filed [\*\*\*]
- Patent application jointly owned with [\*\*\*], entitled: "[\*\*\*]", Serial No.: [\*\*\*], Filed [\*\*\*]
- Provisional patent application entitled: "[\*\*\*]", Serial No.: [\*\*\*], Filed [\*\*\*]
- Patent application entitled: "[\*\*\*]", Serial No.: [\*\*\*], Filed [\*\*\*]
- Patent application entitled: "[\*\*\*]", U.S. patent No. [\*\*\*], Issued [\*\*\*], Divisional Application of U.S. patent No. [\*\*\*]

All other provisions of the Agreement remain unchanged and in full force and effect.

TUFTS UNIVERSITY

PARATEK PHARMACEUTICALS, INC.

By: /s/ Margaret Newell  
(signature)

By: /s/ George C. Hillman  
(signature)

Margaret Newell  
Name

George C. Hillman  
Name

Executive Vice President and Associate Provost for Research  
Title

Chief Operating Officer  
Title

7/31/98  
Date

7/31/98  
Date

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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

**TUFTS UNIVERSITY - PARATEK PHARMACEUTICALS, INC**

**AMENDMENT NO. 3**

TO LICENSE AGREEMENT DATED FEBRUARY 1, 1997

Exhibit A and all amendments and modifications are deleted and replaced in their entirety by the attached Exhibit A. Tufts' ownership interests in all patents, patent applications and disclosures listed in the attached Exhibit A are hereby incorporated into the License Agreement dated February 1, 1997.

All other provisions of the Agreement as amended remain in full force and effect.

IN WITNESS WHEREOF, the parties hereto have duly executed and delivered this Amendment to be effective as of the last date of signature below.

TUFTS UNIVERSITY

PARATEK PHARMACEUTICALS, INC.

By: /s/ Margaret Newell

By: /s/ George C. Hillman

Margaret Newell, Associate Provost for Research

George Hillman, Executive Vice President

Date: 6/3/99

Date: 6/3/99

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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [ \* \* \* ] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

**Amendment #3 - Exhibit A**

*PATENT SUMMARY AS OF MAY 27, 1999*

Stuart B. Levy, M.D.

**TETRACYCLINE**

[ * * * ]	[ * * * ]
[ * * * ]	[ * * * ]
[ * * * ]	[ * * * ]

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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [ \* \* \* ] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

**Amendment #3 - Exhibit A**

*PATENT SUMMARY AS OF MAY 27, 1999*

Stuart B. Levy, M.D.

**COMPOSITIONS AND METHODS RELATED TO ANTIBIOTIC RESISTANCE  
DISCLOSURES**

[ * * * ]	
[ * * * ]	[ * * * ]

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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [ \* \* \* ] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

**Amendment #3 - Exhibit A**

***PATENT SUMMARY AS OF MAY 27, 1999***

Stuart B. Levy, M.D.

**TETRACYCLINE DISCLOSURES**

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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

TUFTS UNIVERSITY - PARATEK PHARMACEUTICALS, INC  
AMENDMENT NO. 4  
TO LICENSE AGREEMENT DATED FEBRUARY 1, 1997

Exhibit A and all amendments and modifications are deleted and replaced in their entirety by the attached Exhibit A. Tufts' ownership interests in all patents, patent applications and disclosures listed in the attached Exhibit A are hereby incorporated into the License Agreement dated February 1, 1997. Exhibit A shall hereafter be updated on an annual basis. Each new Exhibit A shall be dated and appended hereto and by such action replace all prior versions of Exhibit A.

All other provisions of the Agreement as amended remain in full force and effect.

IIN WITNESS WHEREOF, the parties hereto have duly executed and delivered this Amendment to be effective as of the last date of signature below.

TUFTS UNIVERSITY

PARATEK PHARMACEUTICALS, INC.

By: /s/ Margaret Newell  
Margaret Newell, Associate Provost for Research

By: /s/ George C. Hillman  
George Hillman, Executive Vice President

Date: 8/9/00

Date: 8/14/00

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Updated August 8, 2000

Exhibit A

CONFIDENTIAL  
ATTORNEY-CLIENT PRIVILEGED

***PARATEK PHARMACEUTICALS, INC.***

PATENT STATUS SHEET

<u>Docket No.</u> (Firm of Record)	<u>Serial No./</u> <u>Patent No.</u>	<u>Title and Description</u>	<u>Inventors</u> <u>and/or</u> <u>Contributors</u> (Owners)	<u>Filing date/</u> <u>Issue date</u>	<u>Status</u>
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CONFIDENTIAL  
ATTORNEY-CLIENT PRIVILEGED

*PARA TEK PHARMACEUTICALS, INC.*  
PATENT STATUS SHEET (FOREIGN)

<u>Docket No.</u> <u>(Firm of Record)</u>	<u>Region/</u> <u>Country</u>	<u>Appl. No./</u> <u>Patent No.</u>	<u>Title and Description</u>	<u>Appl. Date/</u> <u>Grant date</u>	<u>Status</u>
[***]	[***]	[***]	[***]	[***]	[***]
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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

TUFTS UNIVERSITY - PARATEK PHARMACEUTICALS, INC  
AMENDMENT NO. 5  
TO LICENSE AGREEMENT DATED FEBRUARY 1, 1997

Exhibit A and all amendments and modifications are deleted and replaced in their entirety by the attached Exhibit A. Tufts' ownership interests in all patents, patent applications and disclosures listed in the attached Exhibit A are hereby incorporated into the License Agreement dated February 1, 1997. Exhibit A shall hereafter be updated on an annual basis. Each new Exhibit A shall be dated and appended hereto and by such action replace all prior versions of Exhibit A.

All other provisions of the Agreement as amended remain in full force and effect.

IN WITNESS WHEREOF, the parties hereto have duly executed and delivered this Amendment to be effective as of the last date of signature below.

TUFTS UNIVERSITY  
INC.

PARATEK PHARMACEUTICALS,

By: /s/ Margaret Newell  
Margaret Newell, Associate Provost for Research

By: /s/ George Hillman  
George Hillman, Executive Vice President

Date: 9/10/01

Date: 9/10/01

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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

**TUFTS UNIVERSITY - PARATEK PHARMACEUTICALS, INC**  
**AMENDMENT NO. 6**  
TO LICENSE AGREEMENT DATED FEBRUARY 1, 1997

Exhibit A and all amendments and modifications are deleted and replaced in their entirety by the attached Exhibit A. Tufts' ownership interests in all patents, patent applications and disclosures listed in the attached Exhibit A are hereby incorporated into the License Agreement dated February 1, 1997. Exhibit A shall hereafter be updated on an annual basis. Each new Exhibit A shall be dated and appended hereto and by such action replace all prior versions of Exhibit A.

All other provisions of the Agreement as amended remain in full force and effect.

IN WITNESS WHEREOF, the parties hereto have duly executed and delivered this Amendment to be effective as of the last date of signature below.

TUFTS UNIVERSITY

PARATEK PHARMACEUTICALS, INC.

By: /s/ Margaret Newell

By: /s/ George Hillman  
George Hillman, Executive Vice President

Date: 12/11/02

Date: 12/11/02

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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

L&C Docket No.	Title	Application No.	Patent No.	Filing Date	Issue Date	Status
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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [ \* \* \* ] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

L&C Docket No.	Title	Application No.	Patent No.	Filing Date	Issue Date	Status
[***]	[***]	[***]		[***]	[***]	[***]
[***]	[***]	[***]		[***]	[***]	[***]

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**TUFTS UNIVERSITY — PARATEK PHARMACEUTICALS, INC.**  
**AMENDMENT NO. 7**  
TO LICENSE AGREEMENT DATED FEBRUARY 1, 1997

Section 3.4 Running Royalties is hereby replaced by the following:

3.4 Running Royalties.

For the Medical Field of Use, Licensee agrees to pay to Tufts royalties of:

- (a) [\*\*\*] percent ([\*\*\*]%) of the Gross Sales of Licensed Products, the making using, or selling of which infringes (were it not for the License) at least one claim in an issued, unexpired and non-lapsed patent included in the Patent Rights; or
- (b) [\*\*\*] percent ([\*\*\*]%) of the Gross Sales of Licensed Products that do not fall within clause (a), above, but the manufacture, use, or sale of which would infringe (were it not for the License) at least one claim in a pending patent application included in the Patent Rights, if such claim were to issue.

For the Disinfectant Field of Use, Licensee agrees to pay to Tufts royalties of:

[\*\*\*] percent ([\*\*\*]%) of the Gross Sales of Licensed Products, the making using, or selling of which infringes (were it not for the License) at least one claim in an issued, unexpired and non-lapsed patent included in the Patent Rights or would infringe (were it not for the License) at least one claim in a pending patent application included in the Patent Rights, if such claim were to issue.

Section 3.5 Sublicense Royalties is hereby replaced by the following:

3.5 Sublicense Fees and Royalties.

For the Medical Field of Use, Licensee agrees to make the following payments to Tufts:

(a) Sublicense Fees. For the Medical Field of Use, for each sublicense granted by Licensee, Licensee shall pay to Tufts ten percent (10%) of that portion of any sublicense issue fees or license maintenance fees received by Licensee that are reasonably attributable to sublicenses of rights granted to Licensee hereunder. Funds received by Licensee from a sublicensee for research conducted by Licensee, achievement of product development-related performance milestones, or for equity investments in Licensee will not be subject to any fees hereunder.

(b) Sublicense Royalties. For the Medical Field of Use, for each sublicense granted by Licensee, Licensee shall pay to Tufts the lesser of (i) [\*\*\*] percent ([\*\*\*]%) of any royalty payments received under such sublicense with respect to sales by the sublicensee of Licensed Products covered by a claim contained in an issued Patent Right or a claim included in a pending application covering a Patent Right on a country-by-country basis or (ii) the royalty which would be due, pursuant to Section 3.4, if Licensee, rather than the sublicensee, had sold the Licensed Product.

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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

For the Disinfectant Field of Use, Licensee agrees to make the following payments to Tufts:

(c) Sublicense Fees. For the Disinfectant Field of Use, for each sublicense granted by Licensee, Licensee shall pay to Tufts fourteen percent (14%) of that portion of any sublicense issue fees or license maintenance fees received by Licensee that are reasonably attributable to sublicenses of rights granted to Licensee hereunder. Funds received by Licensee from a sublicensee for research conducted by Licensee, achievement of product development- related performance milestones, or for equity investments in Licensee will not be subject to any fees hereunder.

(d) Sublicense Royalties. For the Disinfectant Field of Use, for each sublicense granted by Licensee, Licensee shall pay to Tufts the lesser of (i) [\*\*\*] percent ([\*\*\*]%) of any royalty payments received under such sublicense with respect to sales by the sublicensee of Licensed Products covered by a claim contained in an issued Patent Right or a claim included in a pending application covering a Patent Right on a country-by-country basis or (ii) the royalty which would be due, pursuant to Section 3.4, if Licensee, rather than the sublicensee, had sold the Licensed Product.

ARTICLE VI — DILIGENCE clause (ii) of the fifth sentence is hereby amended to read:

(ii) filed an IND for a Licensed Product in the United States within seven (7) years of the Effective Date.

ARTICLE VI — DILIGENCE Third paragraph is hereby amended to read: “Notwithstanding the forgoing, Tufts shall have the right at any time after twelve (12) years from the Effective Date to convert the License...”

Exhibit A and all amendments and modifications are deleted and replaced in their entirety by the attached Exhibit A. Tufts’ ownership interests in all patents, patent applications and disclosures listed in the attached Exhibit A are hereby incorporated into the License Agreement dated February 1, 1997. Exhibit A shall hereafter be updated on an annual basis. Each new Exhibit A shall be dated and appended hereto and by such action replace all prior versions of Exhibit A.

All other provisions of the Agreement as amended remain in full force and effect.

IN WITNESS WHEREOF, the parties hereto have duly executed and delivered this Amendment to be effective as of the last date of signature below.

TUFTS UNIVERSITY

PARATEK PHARMACEUTICALS

By: /s/ Margaret Newell  
Margaret Newell Associate Provost for Research

By: /s/ Thomas J. Bigger  
Thomas J. Bigger President and Chief Executive Officer

Date: 7/1/03

Date: 6/17/03

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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

*EXHIBIT A*  
**CONFIDENTIAL**  
*Patent Summary (TET)*

L&C Docket No.	Title	Application No.	Patent No.	Billing Date	Filing Date	Status
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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [ \* \* \* ] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

*EXHIBIT A*

*CONFIDENTIAL*  
*Patent Summary (TET)*

L&C Docket No.	Title	Application No.	Patent No.	Billing Date	Filing Date	Status
[***]	[***]	[***]		[***]		[***]
[***]	[***]	[***]		[***]		[***]
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**AMENDMENT NO. 8 TO THE  
TUFTS UNIVERSITY LICENSE AGREEMENT**

This Amendment No. 8 to the Tufts University License Agreement (this “**Amendment**”), dated as of November 20, 2012 (the “**Amendment Effective Date**”) is by and between Paratek Pharmaceuticals, Inc. (“**Licensee**”), and Tufts University, a/k/a Trustees of Tufts College (“**Tufts**”). Each of Licensee and Tufts is sometimes referred to individually herein as a “**Party**” and collectively as the “**Parties**”.

WHEREAS, the Parties entered into the Tufts University License Agreement, effective as of February 1, 1997 and entered into amendments thereto: Amendment No. 1 dated as of December 29, 1997, Amendment No. 2 dated July 31, 1998, Amendment No. 3 dated June 3, 1999, Amendment No. 4 dated August 14, 2000, Amendment No. 5 dated September 10, 2001, Amendment No. 6 dated December 11, 2002, Amendment No. 7 dated July 1, 2003 and the letter agreement dated September 17, 2009 (the “**Novartis Amendment**”), as so amended, the “**License Agreement**”; and

WHEREAS, the Parties now wish to further amend the License Agreement as set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereto, intending to be legally bound, hereby agree as follows:

1. Amendments to Agreement.

(a) The definition of Field of Use in Section 1.4 of the License Agreement is hereby deleted in its entirety and the following is hereby inserted in lieu thereof:

“Medical Field of Use” shall mean the prophylaxis, treatment or prevention of all diseases or medical conditions in humans, animals and/or agriculture, including bacterial or microbial diseases, through the direct administration of (a) tetracycline derivatives or (b) compounds which affect tetracycline resistance or (c) compounds based on knowledge of the MAR operon or (d) compounds involving novel genes which affect antibiotic resistance or microbial infectivity and which are derived from studies of the MAR operon or (e) compounds that affect any such genes.

“Disinfectant Field of Use” shall mean the use of compositions, including but not limited to disinfectants and soaps, in any manner other than the direct administration to humans or animals or agriculture, to kill or reduce the growth rate of microorganisms, where such compositions include (a) tetracycline derivatives or (b) compounds which affect tetracycline resistance or (c) compounds based on knowledge of the MAR operon or (d) compounds involving novel genes which affect antibiotic resistance or microbial infectivity and which are derived from studies of the MAR operon or (e) compounds that affect any such genes.

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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [ \* \* \* ] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

“Field of Use” shall mean the Medical Field of Use and Disinfectant Field of Use, collectively.

(b) The definition of Licensed Products in Section 1.6 of the License Agreement is hereby amended by adding the following at the end of the definition:

“For purposes of clarity, the Parties hereby agree that [\*\*\*] shall be treated as Licensed Products.”

(c) The first sentence of Section 3.3 of the License Agreement is hereby deleted in its entirety and the following is hereby inserted in lieu thereof:

“Licensee agrees to pay to Tufts a minimum royalty payment of Twenty Five Thousand Dollars (\$25,000) at the end of each twelve-month period commencing on each anniversary of the Effective Date.”

(d) Section 3.4 of the License Agreement is hereby deleted in its entirety and the following is hereby inserted in lieu thereof:

“3.4 Running Royalties.

For the Medical Field of Use, Licensee agrees to pay to Tufts royalties of:

[\*\*\*] percent ([\*\*\*]%) of the Gross Sales of Licensed Products, (a) that are comprised of or contain Licensed Compounds or (b) the making, using, or selling of which infringes (were it not for the License) at least one claim in an issued, unexpired and non-lapsed patent included in the Patent Rights or would infringe (were it not for the License) at least one claim in a pending patent application included in the Patent Rights, if such claim were to issue.

For the Disinfectant Field of Use, Licensee agrees to pay to Tufts royalties of:

[\*\*\*] percent ([\*\*\*]%) of the Gross Sales of Licensed Products, (a) that are comprised of or contain Licensed Compounds or (b) the making, using, or selling of which infringes (were it not for the License) at least one claim in an issued, unexpired and non-lapsed patent included in the Patent Rights or would infringe (were it not for the License) at least one claim in a pending patent application included in the Patent Rights, if such claim were to issue.”

(e) The following new Section 3.6A of the License Agreement is hereby inserted immediately before Section 3.6:

“3.6A Licensee Challenge. In the event Licensee, its affiliates or subsidiaries, directly or indirectly through a third party, initiates a Challenge or assists any party in doing so then, commencing on the date that such Challenge is initiated and continuing until such Challenge is irrevocably withdrawn: (a) the [\*\*\*] shall be [\*\*\*] and (b) Licensee’s right to withhold any royalty identified in Section 3.6 shall not be applicable, in the case of each of (a), (b) and (c) of Section 3.6 until such Challenge has been withdrawn irrevocably.

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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

As used herein, the term “Challenge” shall mean any challenge to the validity or enforceability of any patents or patent applications owned in whole or in part by Tufts by: (a) filing a declaratory judgment action in which any such patents or patent applications is alleged to be invalid or unenforceable; (b) filing a request for re-examination of any of such patents or patent applications pursuant to 35 U.S.C. §302 and/or §311, or provoking or becoming party to an interference with an application for any such patents or patent applications pursuant to 35 U.S.C. §135; or (c) filing or commencing any post grant review, *inter partes* review, third party observation, derivation, opposition, cancellation, nullity or similar proceedings against any of such patents or patent applications.”

(f) The fourth paragraph of Article VI of the License Agreement is hereby deleted in its entirety and the following is hereby inserted in lieu thereof:

“Notwithstanding the foregoing, Tufts shall have the right at any time after [\*\*\*] to convert the License hereunder to non-exclusive if Licensee, its Subsidiaries or its sublicensees have not by the time of such conversion met each of the following milestones by the applicable date:

	<u>Milestone</u>	<u>Due By</u>
	[***]	[***]
	[***]	[***]

(g) The Novartis Amendment is hereby terminated and of no further force and effect.

2. Payment of Minimum Royalty Fee. The \$25,000 Minimum Royalty Fee for the license period through the Amendment Effective Date shall be paid by Licensee to Tufts within [\*\*\*] days of the date that Licensee receives an invoice from Tufts on and after the Amendment Effective Date.

3. Further Clarification of Terms. Tufts hereby agrees to cooperate with Licensee, including by taking such actions reasonably requested by Licensee, to enforce, commercialize products under, protect and/or maintain foreign patents or patent applications included as Patent Rights under the License Agreement, as amended by the Amendment, in each case including any divisions, continuations, continuations-in-part, re-examinations, extensions, renewals, or reissues of such patents or patent applications. Licensee hereby agrees to cooperate with Tufts to properly reflect the rights of Tufts in any patents or patent applications covering any products that include or contain any compound identified as a lead by Paratek, in each case including any divisions, continuations, continuations-in-part, re-examinations, extensions, renewals, or reissues of such patents or patent applications. Licensee will file and prosecute patent applications or claims to pending patent applications corresponding to the Patent Rights as reasonably requested by Tufts. Licensee shall reimburse Tufts for its reasonable attorneys’ fees and out-of-pocket costs incurred on and after the Amendment Effective Date in so doing, up to a maximum amount equal to \$[\*\*\*] for the period commencing on the Amendment Effective Date and ending on January 31, 2014 and \$[\*\*\*] each twelve (12) month period thereafter, which shall be payable in arrears within [\*\*\*] days upon submission by Tufts to Licensee of an invoice evidencing such fees and costs.



THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

4. Covenant. The Parties hereby covenant and agree to use commercially reasonable efforts to reach a mutually satisfactory agreement on an amendment to Exhibit A to the License Agreement as soon as practicable after the Amendment Effective Date and before [\*\*\*].

5. Confirmation. Tufts hereby confirms to Licensee that Licensee, as of the date of the Amendment: (a) has provided to Tufts all annual and any other reports required pursuant to Article VI of the License Agreement; and (b) has made the payments required by Sections 3.1, and 3.3 (including but not limited to Sponsored Research Agreement payments) under the License Agreement.

6. Miscellaneous. The Parties hereby confirm and agree that the License Agreement, as amended hereby and as further provided in this Amendment, together shall constitute the entire amended License Agreement among the parties, remains in full force and effect and is a binding obligation of the Parties hereto. This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

**[Remainder of page intentionally left blank.]**

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**THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.**

IN WITNESS WHEREOF, the Parties hereto have executed this Amendment as of the Amendment Effective Date.

**PARATEK PHARMACEUTICALS, INC.**

By: /s/ Dennis Molnar  
Name: Dennis Molnar  
Title: President and Chief Executive Officer

**TUFTS UNIVERSITY A/K/A TRUSTEES OF TUFTS COLLEGE**

By: /s/ David R. Harris  
Name: David R. Harris  
Title: Provost & Senior Vice President

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**AMENDMENT NO.9 TO THE  
TUFTS UNIVERSITY LICENSE AGREEMENT**

This Amendment No. 9 to the Tufts University License Agreement (this “**Amendment**”), dated as of June 24th, 2014 (the “**Amendment Effective Date**”) is by and between Paratek Pharmaceuticals, Inc. (“**Licensee**”), and Tufts University, a/k/a Trustees of Tufts College (“**Tufts**”). Each of Licensee and Tufts is sometimes referred to individually herein as a “**Party**” and collectively as the “**Parties**”.

WHEREAS, the Parties entered into the Tufts University License Agreement, effective as of February 1, 1997 and entered into amendments thereto: Amendment No. 1 dated as of December 29, 1997, Amendment No. 2 dated July 31, 1998, Amendment No. 3 dated June 3, 1999, Amendment No. 4 dated August 14, 2000, Amendment No. 5 dated September 10, 2001, Amendment No. 6 dated December 11, 2002, Amendment No. 7 dated July 1, 2003 and Amendment No. 8 dated November 20, 2012, as so amended, the “**License Agreement**”; and

WHEREAS, the Parties now wish to further amend the License Agreement as set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereto, intending to be legally bound, hereby agree as follows:

1. Amendments to Agreement.

(a) The fourth paragraph of Article VI of the License Agreement is hereby deleted in its entirety and the following is hereby inserted in lieu thereof:

“Notwithstanding the foregoing, Tufts shall have the right at any time after [\*\*\*] to convert the License hereunder to non-exclusive if Licensee, its Subsidiaries or its sublicensees have not by the time of such conversion met each of the following milestones by the applicable date:

	<u>Milestone</u>	<u>Due By</u>
[***]		[***]
[***]		[***]

(b) The Covenant in Section 4 of Amendment No. 8 is hereby deleted in its entirety and the following is hereby inserted in lieu thereof:

“4. Covenant. The Parties hereby covenant and agree to use commercially reasonable efforts to reach a mutually satisfactory agreement on an amendment to Exhibit A to the License Agreement as soon as practicable after the Amendment Effective Date and before [\*\*\*].”

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**THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.**

2. Payment of outstanding Minimum Royalty Fees due under Section 2 of Amendment No. 8. The \$25,000 Minimum Royalty Fee described in the invoice dated [\*\*\*] and attached as Appendix A to this Amendment No. 9 shall be paid by Licensee to Tufts by [\*\*\*]. The \$25,000 Minimum Royalty Fee described in the invoice dated [\*\*\*] and attached as Appendix B to this Amendment No. 9 shall be paid by Licensee to Tufts within by [\*\*\*].

3. Miscellaneous. The Parties hereby confirm and agree that the License Agreement, as amended hereby and as further provided in this Amendment, together shall constitute the entire amended License Agreement among the parties, remains in full force and effect and is a binding obligation of the Parties hereto. This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

**[Remainder of page intentionally left blank.]**

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**THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.**

IN WITNESS WHEREOF, the Parties hereto have executed this Amendment as of the Amendment Effective Date.

**PARATEK PHARMACEUTICALS, INC.**

By: /s/ Dennis Molnar  
Name: Dennis Molnar  
Title: President and Chief Executive Officer

**TUFTS UNIVERSITY A/K/A TRUSTEES OF TUFTS COLLEGE**

By: /s/ Diane L. Souvaine  
Name: Diane L. Souvaine  
Title: Vice-Provost for Research

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TUFTS UNIVERSITY  
**Office for Technology Licensing and Industry Collaboration**  
136 Harrison Avenue, Suite 75K-950  
Boston, MA 02111  
FEIN 04 210 3634

[\*\*\*]

Tufts invoice 13/OTLIC/083 (revised)

By email to [dmolnar@Paratekpharm.com](mailto:dmolnar@Paratekpharm.com)

Dennis Molnar  
President, Chief Executive Officer  
Paratek Pharmaceuticals, Inc.  
75 Kneeland Street  
Boston, MA 02111

Re: Tufts University—Paratek Pharmaceuticals License Agreement  
effective February 1, 1997  
Amendment 8 of November 20, 2012  
Amendment to section 3.3

Minimum royalty payment of twenty five thousand dollars at the end of each twelve month period commencing on each anniversary of effective date

INVOICE

Fee due for license period through the amendment 8 effective date

February 1, 2012, through January 31, 2013      \$25,000.00

Please make your check payable to Tufts University and send it to

Thomas McVarish  
Tufts University  
Office of the Vice Provost  
Suite 75K-950  
136 Harrison Avenue  
Boston, MA 02111

Phone • [\*\*\*]      E-mail • [\*\*\*]

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TUFTS UNIVERSITY  
**Office for Technology Licensing and Industry Collaboration**  
136 Harrison Avenue, Suite 75K-950  
Boston, MA 02111  
FEIN 04 210 3634

[\*\*\*]

Tufts invoice 14/OTLIC/062

By email to [dmolnar@Paratekpharm.com](mailto:dmolnar@Paratekpharm.com)

Dennis Molnar  
President, Chief Executive Officer  
Paratek Pharmaceuticals, Inc.  
75 Kneeland Street  
Boston, MA 02111

Re: Tufts University—Paratek Pharmaceuticals License Agreement  
effective February 1, 1997  
Amendment 8 of November 20, 2012  
Amendment to section 3.3

Minimum royalty payment of twenty five thousand dollars at the end of each twelve month period commencing on each anniversary of effective date

INVOICE

Fee due for license period

February 1, 2013, through January 31, 2014      \$25,000.00

Please make your check payable to Tufts University and send it to

Thomas McVarish  
Tufts University  
Office of the Vice Provost  
Suite 75K-950  
136 Harrison Avenue  
Boston, MA 02111

Phone • [\*\*\*]      E-mail • [\*\*\*]

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

**AMENDMENT NO. 11 TO THE  
TUFTS UNIVERSITY LICENSE AGREEMENT**

**This Amendment No. 11 to the Tufts University License Agreement** (this “**Amendment**”) is made as of November 15, 2017 (the “**Amendment Effective Date**”) by and between Paratek Pharmaceuticals, Inc., a Delaware corporation with a principal business address at 75 Park Plaza, 4th Floor, Boston, MA 02116 (“**Licensee**”) and Tufts University a/k/a Trustees of Tufts College (“**Tufts**”). Each of Licensee and Tufts is sometimes referred to individually as a “**Party**” and collectively as the “**Parties**.”

**WHEREAS**, the Parties entered into the Tufts University License Agreement, effective as of February 1, 1997, and entered into amendments thereto: Amendment No. 1 dated December 29, 1997, Amendment No. 2 dated July 31, 1998, Amendment No. 3 dated June 3, 1999, Amendment No. 4 dated August 14, 2000, Amendment No. 5 dated September 10, 2001, Amendment No. 6 dated December 11, 2002, Amendment No. 7 dated July 1, 2003, Amendment No. 8 dated November 20, 2012, Amendment No. 9 dated June 24, 2014, and Amendment No. 10 dated March 21, 2017 (as so amended, the “**License Agreement**”);

**WHEREAS**, the Parties now wish to further amend the License Agreement as set forth herein;

**NOW THEREFORE**, the Parties agree as follows:

**1. Amendment to Agreement.**

Section 3.5(a) of the License Agreement is hereby replaced in its entirety with the paragraph below:

- (a) **Sublicense Fees.** For the Medical Field of Use, for each sublicense granted by Licensee for compounds other than omadacycline, Licensee shall pay to Tufts ten percent (10%) of that portion of any sublicense issue fees or license maintenance fees received by Licensee that are reasonably attributable to sublicenses of rights granted to Licensee hereunder. For the Medical Field of Use, for each sublicense granted by Licensee for the compound omadacycline, Licensee shall pay to Tufts [\*\*\*] percent ([\*\*\*]%) of any sublicense issue fees or license maintenance fees received by Licensee. Funds received by Licensee from a sublicensee for research conducted by Licensee, achievement of product-development related performance milestones, or for equity investments in Licensee will not be subject to any fees hereunder.

**2. Miscellaneous.**

The Parties hereby confirm and agree that the License Agreement, as amended hereby and as further provided in this Amendment, together shall constitute the entire amended License Agreement among the Parties, remains in full force and effect and is a binding obligation of the Parties hereto. This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

IN WITNESS WHEREOF, the Parties hereto have executed this Amendment as of the Amendment Effective Date.

**PARATEK PHARMACEUTICALS, INC.**

**TUFTS UNIVERSITY A/K/A TRUSTEES OF TUFTS COLLEGE**

By: /s/ William M. Haskel  
Name: William M. Haskel  
Title: Sr. VP

By: /s/ Larry R. Steranka  
Name: Larry R. Steranka  
Title: Director Technology Transfer

Paratek Pharmaceuticals, Inc.

Subsidiaries

Paratek Bermuda Ltd.

Paratek Ireland Limited

Paratek Pharma, LLC

Paratek Securities Corporation

Paratek UK Limited

Transcept Pharma, Inc.

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statements (Form S-3 Nos. 333-201458, 333-207441, 333-215123 and 333-221843) of Paratek Pharmaceuticals, Inc.,
- (2) Registration Statement (Form S-8 No. 333-135506) pertaining to the Novacea, Inc. 2006 Incentive Award Plan and the Amended 2001 Stock Option Plan of Novacea, Inc.,
- (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 and 333-217660) pertaining to the Paratek Pharmaceuticals, Inc. 2015 Equity Incentive Plan, and
- (9) Registration Statement (Form S-8 No. 333-218847) pertaining to the Paratek Pharmaceuticals, Inc. 2017 Inducement Plan,

of our reports dated March 6, 2018, 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, 2017.

/s/ Ernst & Young LLP

Boston, Massachusetts  
March 6, 2018

**Consent of Independent Registered  
Public Accounting Firm**

We consent to the incorporation by reference in Registration Statement Nos. 333-188171, 333-201458, 333-207441 and 333-215123 on Form S-3 and Registration Statement Nos. 333-135506, 333-150869, 333-157927, 333-157929, 333-160222, 333-164468, 333-172041, 333-180517, 333-187254, 333-194624, 333-201204, 333-205482 and 333-210053 on Form S-8 of our report dated March 9, 2016, on our audit of the consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows of Paratek Pharmaceuticals, Inc. for the year ended December 31, 2015, included in this Annual Report on Form 10-K of Paratek Pharmaceuticals, Inc. for the year ended December 31, 2017.

/s/ CohnReznick LLP  
Vienna, Virginia  
March 6, 2018

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael F. Bigham, 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/ MICHAEL F. BIGHAM

Michael F. Bigham  
Chief Executive Officer  
March 6, 2018

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Douglas W. Pagán, 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/ DOUGLAS W. PAGAN

Douglas W. Pagán  
Chief Financial Officer  
March 6, 2018



**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), Michael F. Bigham, 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, 2017 (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 6<sup>th</sup> day of March, 2018.

/s/ MICHAEL F. BIGHAM

Michael F. Bigham  
*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.

**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), Douglas W. Pagán, Chief Financial 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, 2017 (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 his hand hereto as of the 6<sup>th</sup> day of March, 2018.

/s/ DOUGLAS W. PAGAN

Douglas W. Pagán  
*Chief 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.

