

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

**FORM 8-K**

**CURRENT REPORT**  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

**December 3, 2018**  
Date of Report (Date of earliest event reported)

**PARATEK PHARMACEUTICALS, INC.**  
(Exact name of Registrant as specified in its charter)

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

**001-36066**  
(Commission  
File Number)

**33-0960223**  
(I.R.S. Employer  
Identification No.)

**75 Park Plaza**  
**Boston, MA**  
(Address of principal executive offices)

**(617) 807-6600**  
(Registrant's telephone number, including area code)

**02116**  
(Zip Code)

**Not applicable**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging Growth Company

If an emerging growth company, indicate by a 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.

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**Item 7.01 Regulation FD Disclosure.**

On December 3, 2018, Paratek Pharmaceuticals, Inc. issued a press release announcing that it filed two patent term extension requests with the U.S. Patent and Trademark Office for patents covering NUZYRA™ (omadacycline), including for U.S. Patent No. 7,553,828, directed to composition of matter, and U.S. Patent No. 9,265,740, directed to a method of treatment.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this report (including Exhibit 99.1) is being furnished pursuant to Item 7.01 and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor will it be incorporated by reference in any filing under the Securities Act of 1933, as amended, or in any filing under the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Number</u>	<u>Description</u>
99.1	<a href="#">Paratek Pharmaceuticals, Inc. Press Release dated December 3, 2018</a>

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 3, 2018

**PARATEK PHARMACEUTICALS, INC.**

By: /s/ William M. Haskel  
Name: William M. Haskel  
Title: Senior Vice President, General Counsel and Corporate Secretary



## **Paratek Pharmaceuticals Files Two Patent Term Extensions in the United States; Expects NUZYRA™ Patent Protection Exclusivity Until at Least October 2030**

**BOSTON, December 3, 2018** -- Paratek Pharmaceuticals, Inc. (Nasdaq: PRTK), a commercial-stage biopharmaceutical company focused on the development and commercialization of innovative therapeutics, today announced the Company filed two Patent Term Extension Requests with the U.S. Patent and Trademark Office. U.S. Patent No. 7,553,828, directed to composition of matter, is anticipated to be extended until May 2028, and U.S. Patent No. 9,265,740, directed to a method of treatment, is expected to be extended until October 2030.

"Significantly lengthening NUZYRA's exclusive commercial rights into at least 2030 in the United States will have substantial positive long-term impact on its commercial opportunity and builds on our broad and comprehensive protection for NUZYRA," said Michael Bigham, Chairman and Chief Executive Officer, Paratek. "Our commercial team is actively preparing for a NUZYRA launch in the U.S. in February, and we are looking forward to bringing a compelling new option for the treatment on community-acquired pneumonia and skin infections."

NUZYRA was approved in October 2018 by the United States Food and Drug Administration for the treatment of adult patients with community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI).

### **About Paratek Pharmaceuticals, Inc.**

Paratek Pharmaceuticals, Inc. is a commercial-stage biopharmaceutical company focused on the development and commercialization of innovative therapeutics. The company's lead commercial product, NUZYRA™ (omadacycline) is a once-daily intravenous and oral antibiotic for the treatment of adult patients with CABP and ABSSSI. Paratek is also studying NUZYRA for the treatment of urinary tract infections (UTI).

Paratek has submitted a marketing authorization application for omadacycline in the European Union. Paratek has entered into a collaboration agreement with Zai Lab for the development and commercialization of omadacycline in the greater China region and retains all remaining global rights.

Under a research agreement with the U.S. Department of Defense, omadacycline also is being studied against pathogenic agents causing infectious diseases of public health and biodefense importance, including plague and anthrax.

Paratek's second FDA approved product, SEYSARA™ (sarecycline), will be marketed by Almirall, LLC in the U.S. as a new once-daily oral therapy for the treatment of moderate to severe acne vulgaris. Paratek retains development and commercialization rights to sarecycline in the rest of the world.

Recognizing the serious threat of bacterial infections, Paratek is dedicated to providing solutions that enable positive outcomes and lead to better patient stories.

For more information, visit [www.ParatekPharma.com](http://www.ParatekPharma.com) or follow @ParatekPharma on Twitter.

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## About NUZYRA

NUZYRA (omadacycline) is a novel antibiotic with both once-daily intravenous (IV) and oral formulations for the treatment of community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI). A modernized tetracycline, NUZYRA is specifically designed to overcome tetracycline resistance and exhibits activity across a spectrum of bacteria, including Gram-positive, Gram-negative, atypicals, and other drug-resistant strains.

## Indications and Usage

NUZYRA™ is a tetracycline class antibacterial indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms:

**Community-Acquired Bacterial Pneumonia (CABP) caused by the following:** *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydia pneumoniae*.

**Acute Bacterial Skin and Skin Structure Infections (ABSSSI) caused by the following:** *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae*, and *Klebsiella pneumoniae*.

## Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of NUZYRA and other antibacterial drugs, NUZYRA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

## Important Safety Information

### Contraindications

NUZYRA is contraindicated in patients with known hypersensitivity to omadacycline or tetracycline class antibacterial drugs, or to any of the excipients.

### Warnings and Precautions

Mortality imbalance was observed in the CABP clinical trial with eight deaths (2%) occurring in patients treated with NUZYRA compared to four deaths (1%) in patients treated with moxifloxacin. The cause of the mortality imbalance has not been established. All deaths, in both treatment arms, occurred in patients > 65 years of age; most patients had multiple comorbidities. The causes of death varied and included worsening and/or complications of infection and underlying conditions. Closely monitor clinical response to therapy in CABP patients, particularly in those at higher risk for mortality.

The use of NUZYRA during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown) and enamel hypoplasia.

The use of NUZYRA during the second and third trimester of pregnancy, infancy and childhood up to the age of 8 years may cause reversible inhibition of bone growth.

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Hypersensitivity reactions have been reported with NUZYRA. Life-threatening hypersensitivity (anaphylactic) reactions have been reported with other tetracycline-class antibacterial drugs. NUZYRA is structurally similar to other tetracycline-class antibacterial drugs and is contraindicated in patients with known hypersensitivity to tetracycline-class antibacterial drugs. Discontinue NUZYRA if an allergic reaction occurs.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.

NUZYRA is structurally similar to tetracycline-class of antibacterial drugs and may have similar adverse reactions. Adverse reactions including photosensitivity, pseudotumor cerebri, and anti-anabolic action which has led to increased BUN, azotemia, acidosis, hyperphosphatemia, pancreatitis, and abnormal liver function tests, have been reported for other tetracycline-class antibacterial drugs, and may occur with NUZYRA. Discontinue NUZYRA if any of these adverse reactions are suspected.

Prescribing NUZYRA in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

### **Adverse Reactions**

The most common adverse reactions (incidence  $\geq 2\%$ ) are nausea, vomiting, infusion site reactions, alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyl transferase increased, hypertension, headache, diarrhea, insomnia, and constipation.

### **Drug Interactions**

Patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage while taking NUZYRA.

Absorption of tetracyclines, including NUZYRA is impaired by antacids containing aluminum, calcium, or magnesium, bismuth subsalicylate and iron containing preparations.

### **Use in Specific Populations**

Lactation: Breastfeeding is not recommended during treatment with NUZYRA.

**To report SUSPECTED ADVERSE REACTIONS, contact Paratek Pharmaceuticals, Inc. at 1-833-727-2835 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

Please see full Prescribing Information for NUZYRA at [www.NUZYRA.com](http://www.NUZYRA.com).

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## **Forward Looking Statements**

This press release contains forward-looking statements including statements related to our overall strategy, product candidates, clinical studies, prospects, potential and expected results, including statements about the timing of commercializing NUZYRA, periods of expected exclusivity of NUZYRA, advancing omadacycline and otherwise preparing for clinical studies, the timing of enrollment in our clinical studies and our reporting of the results of such studies, the potential for omadacycline to serve as an empiric monotherapy treatment option for patients suffering from ABSSSI, CABP, UTI, and other bacterial infections when resistance is of concern, the prospect of omadacycline providing broad-spectrum activity, and our ability to make and sell NUZYRA, obtain certain regulatory approvals of omadacycline. All statements, other than statements of historical facts, included in this press release are forward-looking statements, and are identified by words such as "advancing," "believe," "expect," "well positioned," "look forward," "anticipated," "continued," and other words and terms of similar meaning. These forward-looking statements are based upon our current expectations and involve substantial risks and uncertainties. We may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in our forward-looking statements and you should not place undue reliance on these forward-looking statements. Our actual results and the timing of events could differ materially from those included in such forward-looking statements as a result of these risks and uncertainties. These and other risk factors are discussed under "Risk Factors" and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2017, our Form 10-Q filed for the quarter ended September 30, 2018 and our other filings with the Securities and Exchange Commission. We expressly disclaim any obligation or undertaking to update or revise any forward-looking statements contained herein.

## **CONTACT:**

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