

# TETRAPHASE PHARMACEUTICALS INC

## **FORM 8-K** (Current report filing)

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

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**FORM 8-K**

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**CURRENT REPORT  
PURSUANT TO SECTION 13 OR 15(D)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

**Date of Report (Date of earliest event reported): April 3, 2017**

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**Tetraphase Pharmaceuticals, Inc.**  
(Exact name of registrant as specified in charter)

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

**001-35837**  
(Commission  
File Number)

**20-5276217**  
(IRS Employer  
Identification No.)

**480 Arsenal Way**  
**Watertown, Massachusetts**  
(Address of principal executive offices)

**02472**  
(Zip Code)

**Registrant's telephone number, including area code: (617) 715-3600**

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

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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 ( *see* General Instruction A.2. below):

- 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))
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**Item 8.01. Other Events.**

On April 3, 2017, Tetrphase Pharmaceuticals, Inc. (the “Company”), issued a press release announcing completion of enrollment in IGNITE4, its ongoing phase 3 clinical trial evaluating the efficacy and safety of intravenous eravacycline compared to meropenem in complicated intra-abdominal infections. The Company expects to report top-line data from this trial in the third quarter of 2017.

A copy of the press release announcing these events has been filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

- (d) Exhibits

See Exhibit Index attached hereto.

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**SIGNATURE**

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: April 3, 2017

By: /s/ Maria D. Stahl  
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Maria D. Stahl  
Senior Vice President, General Counsel

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**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Tetrphase Pharmaceuticals, Inc., dated April 3, 2017.



## **Tetraphase Pharmaceuticals Completes Enrollment of IGNITE4 Phase 3 Clinical Trial of Eravacycline in Complicated Intra-abdominal Infections**

*- Accelerated Timelines for Both Top-line IGNITE4 Eravacycline Data and MAA filing in Europe; Both Now Expected in 3Q 2017 -*

*- IGNITE4 Results to Support U.S. NDA Filing for IV Eravacycline in cIAI –*

**WATERTOWN, Mass., April 3, 2017** – Tetraphase Pharmaceuticals, Inc. (NASDAQ:TPPH), a clinical stage biopharmaceutical company developing novel antibiotics to treat life-threatening multidrug-resistant (MDR) infections, today announced completion of enrollment in IGNITE4, its ongoing phase 3 clinical trial evaluating the efficacy and safety of intravenous (IV) eravacycline compared to meropenem in complicated intra-abdominal infections (cIAI). The Company expects to report top-line data from this trial in the third quarter of 2017.

“Completing IGNITE4 enrollment ahead of schedule speaks to the strong investigator support for this study, along with the dedication and hard work by our internal team and collaborating clinical research organization,” said Guy Macdonald, President and CEO of Tetraphase. “Following the protocol-specified follow-up period, requisite data validation and subsequent database lock activities, we now expect top-line data from IGNITE4 to be available during the third quarter of 2017. Assuming a positive outcome, we believe the data from IGNITE4, along with data from the successfully completed IGNITE1 trial, will form the basis of a U.S. NDA filing for IV eravacycline in cIAI.”

Tetraphase also updated its guidance today regarding the planned submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for IV eravacycline for the treatment of cIAI which will be supported by data from the IGNITE1 trial. The Company expects to file the MAA during the third quarter of 2017.

“With respect to eravacycline in Europe, we are updating our prior guidance to reflect submission of a MAA to the EMA, the first regulatory filing for IV eravacycline as a potential new treatment for cIAI, also during the third quarter of 2017. We are well positioned to execute on these critical milestones with the goal of bringing eravacycline to the physicians and patients who need it,” Mr. Macdonald concluded.

### **About IGNITE4**

IGNITE4 is a phase 3 randomized, double-blind, double-dummy, multicenter, prospective study that is designed to assess the efficacy, safety and pharmacokinetics of twice-daily eravacycline (1.0 mg/kg every 12 hours) compared with meropenem (1g every 8 hours) for the treatment of cIAI. The study is expected to enroll approximately 450 adult patients at 75 centers worldwide. The primary endpoint of IGNITE4 is clinical response at the test-of-cure (TOC) visit, which occurs 25 to 31 days after the initial dose of the study drug. The primary efficacy analysis will be conducted using a 12.5% non-inferiority margin in the microbiological intent-to-treat (micro-ITT) population.

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## About Eravacycline

Eravacycline is a novel, fully-synthetic fluorocycline antibiotic being developed for the treatment of serious infections, including those caused by multidrug-resistant (MDR) pathogens that have been highlighted as urgent public health threats by both the World Health Organization and the U.S. Centers for Disease Control (CDC). Eravacycline has demonstrated potent activity against multidrug-resistant (MDR) pathogens, including carbapenem-resistant *enterobacteriaceae* (CRE), *Acinetobacter baumannii*, and colistin-resistant bacteria carrying the *mcr-1* gene, and is being developed for the treatment of serious and life-threatening bacterial infections. Eravacycline is in phase 3 clinical development for the treatment of complicated intra-abdominal infections (cIAI) and complicated urinary tract infections (cUTI).

Eravacycline is currently being investigated in the Company's phase 3 IGNITE ( **I**nvestigating **G**ram- **n**egative **I**nfections **T**reated with **E**ravacycline) program. To date, eravacycline has been tested in over 1,300 patients and in two completed phase 3 trials – IGNITE1 in patients with cIAI and IGNITE2 in patients with cUTI. In IGNITE1, twice-daily IV eravacycline met the primary endpoint by demonstrating statistical non-inferiority of clinical response compared to ertapenem, was well tolerated, and achieved high cure rates in patients with Gram-negative pathogens, including resistant isolates. The IGNITE1 data will support an MAA submission to the EMA for IV eravacycline for the treatment of patients with cIAI. Tetrphase is currently evaluating eravacycline in a second phase 3 clinical trial in patients with cIAI (IGNITE4) comparing twice-daily IV eravacycline to meropenem. Assuming a positive outcome in IGNITE4, the Company plans to use the results from IGNITE1 and IGNITE4 to support an NDA submission for IV eravacycline in cIAI. Tetrphase is also currently conducting IGNITE3, an additional phase 3 trial evaluating once-daily IV eravacycline in patients with cUTI and, assuming a positive outcome, the Company plans to use the results from IGNITE3 to support a supplemental NDA submission for eravacycline in cUTI. In parallel, Tetrphase is continuing its efforts to develop an oral dose formulation of eravacycline. A phase 1 clinical program is ongoing which is designed to evaluate and optimize the oral dosing regimen for eravacycline.

## About Tetrphase Pharmaceuticals, Inc.

Tetrphase is a clinical-stage biopharmaceutical company using its proprietary chemistry technology to create novel antibiotics for serious and life-threatening bacterial infections, including those caused by many of the multidrug-resistant (MDR) bacteria highlighted as urgent public health threats by the CDC. Tetrphase has created more than 3,000 novel tetracycline analogs using its proprietary technology platform. Tetrphase's pipeline includes three antibiotic clinical candidates: eravacycline, which is in phase 3 clinical trials, and TP-271 and TP-6076, which are in phase 1 clinical trials. Please visit [www.tphase.com](http://www.tphase.com) for more company information.

## Forward-Looking Statements

*Any statements in this press release about our future expectations, plans and prospects, including statements regarding our strategy, future operations, prospects, plans and objectives, and other statements containing the words "anticipates," "believes," "expects," "plans," "will" and similar*

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*expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: whether results obtained in previous clinical trials will be indicative of results obtained in future clinical trials; whether any clinical candidate will advance through the clinical trial process on a timely basis or at all; whether the results of the Company's development efforts will warrant regulatory submission and whether any such submissions will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether, if any clinical candidate obtains approval, it will be successfully distributed and marketed; and other factors discussed in the "Risk Factors" section of our quarterly report on Form 10-K, filed with the Securities and Exchange Commission on March 13, 2017. In addition, the forward-looking statements included in this press release represent our views as of April 3, 2017. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so.*

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