TETRAPHASE PHARMACEUTICALS INC
Form 8-K
July 25, 2017

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

Date of Report (Date of earliest event reported): July 25, 2017

Tetraphase Pharmaceuticals, Inc.

(Exact name of registrant as specified in charter)

Delaware	**001-35837**	**20-5276217**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

480 Arsenal Way

Watertown, Massachusetts	**02472**
(Address of principal executive offices)	**(Zip Code)**

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

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 (*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))
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 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.

Item 8.01. Other Events.

On July 25, 2017, Tetraphase Pharmaceuticals, Inc. (the Company), issued a press release announcing positive top-line results from IGNITE4, the Company s phase 3 clinical trial evaluating the efficacy and safety of twice-daily intravenous (IV) eravacycline compared to meropenem for the treatment of patients with complicated intra-abdominal infections (cIAI). The results of IGNITE4, which enrolled 500 patients, demonstrated statistical non-inferiority of eravacycline to meropenem for the primary efficacy endpoint of clinical response at the test-of-cure visit.

A summary of the IGNITE4 efficacy data is outlined in the following table and described below:

	Eravacycline	**Meropenem**	**95% Confidence Interval**
	n/N (%)	**n/N (%)**	**(CI)**
Microbiological intent-to-treat (micro-ITT) population; 12.5% non-inferiority margin according to the U.S. Food and Drug Administration (the FDA) guidance	177/195 (90.8%)	187/205 (91.2%)	-6.3, 5.3
Modified intent-to-treat (MITT); 12.5% non-inferiority margin according to European Medicines Agency guidance (the EMA)	231/250 (92.4%)	228/249 (91.6%)	-4.1, 5.8
Clinically evaluable (CE); 12.5% non-inferiority margin according to EMA guidance	218/225 (96.9%)	222/231 (96.1%)	2.9, 4.5

Eravacycline achieved high clinical cure rates in patients with complicated intra-abdominal infections, comparable to patients in the meropenem group. The primary efficacy analysis under the FDA guidance was conducted using a 12.5% non-inferiority margin in the micro-ITT population. Clinical cure rates in the micro-ITT population were 90.8% and 91.2% for eravacycline (n=195) and meropenem (n=205), respectively (95% CI: -6.3%,5.3%). Under the EMA guidance, the primary analysis was conducted using a 12.5% non-inferiority margin of the MITT and CE patient populations. Clinical cure rates in the MITT population were 92.4% and 91.6% for eravacycline (n=250) and meropenem (n=249), respectively (95% CI: -4.1%,5.8%). Clinical cure rates in the CE population were 96.9% and 96.1% for eravacycline (n=225) and meropenem (n=231), respectively (95% CI: -2.9%,4.5%). The secondary analyses were consistent with, and supportive of, the primary outcome.

There were no treatment-related serious adverse events in the trial. Treatment-emergent adverse event rates were similar in both treatment groups. The most commonly reported drug-related adverse events (AEs) for eravacycline were infusion site reactions, nausea and vomiting, each occurring at a rate of less than 5%. The AE profile for IV eravacycline in IGNITE4 was consistent with that seen in the previously completed phase 3 IGNITE1 and phase 2 clinical trials in cIAI.

The spectrum of pathogens in this trial was similar to that seen in previously completed clinical trials in this patient population. The most common Gram-negative pathogens in the study included *Escherichia coli, Klebsiella pneumonia, Pseudomonas* and *Bacteroides*.

The Company plans to submit a New Drug Application, which will be supported by data from the IGNITE1 and IGNITE4 clinical trials, to the FDA in the first quarter of 2018. The Company also remains on track to submit a Marketing Authorization Application to the EMA during the third quarter of 2017. In addition, the Company plans to submit detailed results from the phase 3 IGNITE4 clinical trial for presentation at a future scientific meeting.

Any statements in this Current Report on Form 8-K about the Company s future expectations, plans and prospects, including statements regarding the Company s strategy, future operations, prospects, plans and objectives, and other statements containing the words anticipates, believes, expects, plans, will and similar 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 eravacycline or any other 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 FDA 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 the Company s quarterly report on Form 10-Q, filed with the Securities and Exchange Commission on May 8, 2017. In addition, the forward-looking statements included in this Current Report on Form 8-K represent the Company s views as of July 25, 2017. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaim any obligation to do so.

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: July 25, 2017

By: /s/ Maria D. Stahl
Maria D. Stahl

Senior Vice President, General Counsel