TETRAPHASE PHARMACEUTICALS INC
Form 8-K
October 15, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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): October 6, 2014

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 Street, Suite 110, Watertown,

Massachusetts	**02472**
(Address of Principal Executive Offices)	**(Zip Code)**

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

(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))

Item 8.01. Other Events

On October 6, 2014, Tetraphase Pharmaceuticals, Inc. (the Company) announced that it had initiated patient enrollment in the pivotal portion of its IGNITE 2 Phase 3 clinical trial, a two-part trial studying the efficacy and safety of intravenous (IV) and oral formulations of its lead product candidate, eravacycline, for the treatment of complicated urinary tract infections (cUTI).

The lead-in portion of the trial was designed to determine the dose regimen to be carried forward into the pivotal portion of the trial. On October 6, 2014, the Company also announced that, after evaluating the results of the lead-in portion of the trial, the Company had determined to study in the pivotal portion of the trial an IV-to-oral eravacycline dosing regimen of 1.5 mg/kg IV followed by 200 mg orally.

In the lead-in portion of the trial, approximately 120 patients, randomized 1:1:1, received eravacycline in one of two IV-to-oral switch dosing cohorts (1.5 mg/kg IV every 24 hours followed by 200 mg or 250 mg orally every 12 hours) or levofloxacin (750 mg IV every 24 hours followed by 750 mg orally every 24 hours). Data from the lead-in portion of the trial demonstrated that both IV-to-oral dosing regimens of eravacycline compared favorably to levofloxacin. The responder outcome (the primary endpoint of the pivotal portion of the trial for the FDA) for the IV-to-oral 200 mg, IV-to-oral 250 mg and levofloxacin groups were 70.8%, 64.3% and 52.2%, respectively. The microbiological response (the primary endpoint of the pivotal portion of the trial for the European Medicines Agency) were 75.0%, 64.3% and 56.5%, respectively. The pharmacokinetics of both oral doses of eravacycline were comparable to the IV formulation. Overall, treatment was generally well tolerated in all three groups with the most common adverse events reported being nausea and emesis. Only two patients discontinued treatment as a result of drug related adverse events. The Company plans to present the full data from the lead-in portion of the IGNITE 2 Phase 3 trial at an upcoming scientific meeting.

The Company expects to enroll approximately 720 patients in the pivotal portion of the trial. These patients will be randomized 1:1 to receive the selected dose regimen of eravacycline or levofloxacin. The pivotal portion of the trial is designed to be a non-inferiority (10% margin) study. Consistent with the draft guidance of the FDA for the development of drugs for the treatment of cUTI, the primary endpoint for the trial is the responder outcome (a combination of clinical cure rate and microbiological response) in the microbiological intent-to-treat population at the post-treatment visit (defined as six to eight days after the completion of therapy). Under the protocol, the primary endpoint for the European Medicines Agency is the microbiological response in the micro-MITT and microbiologically evaluable populations at the post-treatment visit.

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.

TETRAPHASE PHARMACEUTICALS, INC.

Date: October 15, 2014

By: /s/ David C. Lubner

David C. Lubner

Senior Vice President and Chief Financial Officer