TETRAPHASE PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

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Address	480 ARSENAL STREET SUITE 110 WATERTOWN, MA 02472
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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): May 4, 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 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 2.02. Results of Operations and Financial Condition.

On May 4, 2017, Tetraphase Pharmaceuticals, Inc. announced its financial results for the first quarter ended March 31, 2017. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Current Report on Form 8-K, including Exhibit 99.1, 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 shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

See Exhibit Index attached hereto.

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.

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

Date: May 5, 2017

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by Tetraphase Pharmaceuticals, Inc., dated May 4, 2017.

Exhibit 99.1

Tetraphase Pharmaceuticals Reports First Quarter 2017 Financial Results and Reviews Recent Highlights

WATERTOWN, Mass., May 4, 2017 – Tetraphase Pharmaceuticals, Inc. (NASDAQ:TTPH), a clinical-stage biopharmaceutical company developing novel antibiotics to treat life-threatening multidrug-resistant (MDR) infections, today reported financial results for the first quarter ended March 31, 2017 and provided an overview of recent achievements.

"We have continued to make significant advancements across all of our development programs, particularly for IV eravacycline with the early completion of enrollment of IGNITE4 in complicated intra-abdominal infections (cIAI), and the initiation of IGNITE3 in complicated urinary tract infections (cUTI), for which enrollment is progressing well," said Guy Macdonald, President and Chief Executive Officer of Tetraphase. "Preparations are ongoing for the submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for the treatment of cIAI in the third quarter of this year and we look forward to top-line data from IGNITE4 also in the third quarter, which would support a subsequent U.S. New Drug Application (NDA) filing."

Mr. Macdonald added, "We also look forward to data from the ongoing phase 1 clinical trials for oral eravacycline which are designed to optimize the oral dosing regimen, and we continue to anticipate providing an update on that program during the third quarter of 2017."

First Quarter and Recent Highlights

- Completed enrollment for the phase 3 IGNITE4 clinical trial of IV eravacycline in patients with cIAI. IGNITE4 is designed to evaluate IV eravacycline compared to meropenem and is expected to enroll approximately 450 patients. The primary analysis will be conducted using a 12.5% non-inferiority margin. Tetraphase expects to report top-line results in the third quarter of 2017. Assuming a successful outcome, this study, along with data from IGNITE1, would support an NDA filing for IV eravacycline for cIAI.
- Initiated the phase 3 IGNITE3 clinical trial of IV eravacycline in patients with cUTI. IGNITE3 is designed to evaluate IV eravacycline compared to ertapenem and is expected to enroll approximately 1,000 patients. The primary analysis will be conducted using a 10% non-inferiority margin. Assuming a positive outcome, the IGNITE3 clinical data are expected to support a supplemental NDA (sNDA) submission for IV eravacycline in cUTI.
- Presented data at ECCMID 2017, including *in vitro* data for eravacycline demonstrating potent activity against drug-resistant bacteria, specifically Gram-negative bacteria *Acinetobacter baumannii* and *Enterobacteriaceae* , including carbapenem-resistant or extended beta-lactamase producing phenotypes, as well as Gram-positive bacteria *Staphylococcus aureus* and enterococci, including

methicillin- or vancomycin-resistant phenotypes. Additionally, data presentations for TP-6076 highlighted its potency against multidrug-resistant *Acinetobacter baumannii* and carbapenem-resistant *Enterobacteriaceae,* with activity demonstrated in clinical isolates that were pan-resistant to multiple antibiotic classes.

- Awarded up to $4 million in research funding from the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), an international, public-private partnership focused on the discovery and development of new antimicrobial products to address the threat of antibiotic resistance, for its pipeline candidate TP-6076.
- Initiated a multiple-ascending dose study evaluating a 7-day dose regimen of IV TP-6076 in healthy volunteers.
- Received Qualified Infectious Disease Product and Fast Track designation from the FDA and initiated a single-ascending dose study for the oral formulation of TP-271.

First-Quarter 2017 Financial Results

As of March 31, 2017, Tetraphase had cash and cash equivalents of $128.2 million and 37.7 million shares outstanding. The company expects that its cash and cash equivalents, as well as expected revenue from its U.S. government awards, will be sufficient to fund operations into the second half of 2018.

Revenues during the first quarter of 2017 were $1.5 million compared to $2.0 million for the same period in 2016. Revenues for each period consisted of contract and grant revenue under the Company's U.S. government awards for the development of Tetraphase compounds for the treatment of diseases caused by bacterial biothreat pathogens and for certain infections caused by life-threatening multidrug-resistant bacteria. This decrease was primarily due to the scope and timing of activities related to our BARDA subcontract conducted during the quarter ended March 31, 2017, offset in part by an increase in clinical development activities under our NIAID subcontract.

Research and development (R&D) expenses for the first quarter of 2017 were $25.9 million compared to $13.5 million for the same period in 2016. The increase in R&D expenses was primarily due to increased costs related to our IGNITE3 and IGNITE4 phase 3 clinical studies for eravacycline.

General and administrative (G&A) expenses for the first quarter of 2017 were $5.1 million compared to $5.3 million for the same period in 2016.

For the first quarter of 2017, Tetraphase reported a net loss of $29.5 million, or $0.79 per share, compared to a net loss of $16.7 million, or $0.46 per share, for the same period in 2016.

About Tetraphase Pharmaceuticals, Inc.

Tetraphase 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. Tetraphase has created more than 3,000 novel tetracycline analogs using its proprietary technology platform. Tetraphase'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 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 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 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 May 4, 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.

Tetraphase Pharmaceuticals, Inc.
Condensed Consolidated Statement of Operations (Unaudited)
(In thousands, except per share data)

	Three Months Ended March 31,	
	2017	2016
Revenues	$ 1,485	$ 1,962
Operating expenses		
Research and development	25,947	13,523
General and administrative	5,133	5,253
Total operating expenses	31,080	18,776
Loss from operations	(29,595)	(16,814)
Other income (expense)		
Other income (expense), net	137	73
Net loss	$(29,458)	$(16,741)
Net loss per share-basic and diluted	$ (0.79)	$ (0.46)
Weighted-average number of common shares used in net loss per share applicable to common stockholders-basic and diluted	37,093	36,598

Tetraphase Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets (unaudited)
(In thousands)

	March 31, 2017	December 31, 2016
Assets		
Cash and cash equivalents	$128,159	$ 142,086
Accounts receivable	1,703	1,789
Prepaid expenses and other current assets	3,829	6,582
Property and equipment, net	1,467	1,054
Other assets, noncurrent	199	199
Total assets	$135,357	$ 151,710
Liabilities and Stockholders' equity		
Accounts payable and accrued expenses	$ 15,366	$ 10,240
Total deferred revenue	851	1,255
Other liabilities, noncurrent	148	162
Total stockholders' equity	118,992	140,053
Total liabilities and stockholders' equity	$135,357	$ 151,710

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