TETRAPHASE PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

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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): March 8, 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))

Item 2.02. Results of Operations and Financial Condition.

On March 8, 2017, Tetraphase Pharmaceuticals, Inc. announced its financial results for the fourth quarter and fiscal year ended December 31, 2016. 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: March 8, 2017

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by Tetraphase Pharmaceuticals, Inc., dated March 8, 2017.

Exhibit 99.1

Tetraphase Pharmaceuticals Reports Fourth Quarter and Full-Year 2016 Financial Results and Highlights Key 2017 Milestones

–Event-Driven 2017 Includes MAA Filing for IV Eravacycline in Europe and Top-Line Data Readout from IGNITE4 in cIAI –

– Company to Host Conference Call Today, March 8, 2017 at 4:30 p.m. ET –

WATERTOWN, Mass., March 8, 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 fourth quarter and year-ended December 31, 2016, highlighted key milestones for 2017 and provided an overview of recent achievements.

"2016 marked a year of important progress for Tetraphase as we advanced our phase 3 global development program for IV eravacycline with initiation of IGNITE4 in complicated intra-abdominal infections (cIAI), in which enrollment is proceeding well, and the recent commencement of IGNITE3 in complicated urinary tract infections (cUTI)," said Guy Macdonald, President and Chief Executive Officer of Tetraphase. "We have laid the groundwork for an event-driven 2017 and look forward to several important IV eravacycline milestones, including the submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for the treatment of cIAI during the second half of the year and top-line data from IGNITE4 during the fourth quarter, which would support a subsequent NDA filing."

Mr. Macdonald continued, "Beyond IV eravacycline, we are also focused on completing the phase 1 clinical development of oral eravacycline and expect to provide an update during the third quarter of 2017, including next steps toward our goal of delivering the first and only IV-to-oral antibiotic transition therapy for the treatment of MDR gram-negative infections."

Key Milestones for 2017

- Submit MAA for IV eravacycline to EMA for the treatment of cIAI – 2H 2017
- Report top-line data from phase 3 IGNITE4 trial evaluating IV eravacycline in cIAI – 4Q 2017
- Provide oral eravacycline development program update – 3Q 2017
- Report phase 1 single-ascending dose data for TP-271 – mid-2017
- Report phase 1 single-ascending dose data for TP-6076 – mid-2017
- Initiate phase 1 multiple-ascending dose trials for IV TP-271 and IV TP-6076 – 2017

Fourth Quarter and Recent Highlights

- Initiated 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 fourth 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 New Drug Application (sNDA) submission for IV eravacycline in cUTI.
- Published results from IGNITE1 in the *Journal of the American Medical Association (JAMA) Surgery* . In the phase 3 IGNITE1 trial, eravacycline was well tolerated and demonstrated statistical non-inferiority to ertapenem in patients with cIAI.
- Presented data at IDWeek 2016, including *in vitro* data for eravacycline demonstrating consistent and potent activity against drug-resistant bacteria, including carbapenem-resistant *Enterobacteriaceae* (CRE), *Acinetobacter baumannii* , vancomycin-resistant enterococci (VRE) and methicillin-resistant *Staphylococcus aureus* (MRSA), isolated from recent patients.
- Published data in *Antimicrobial Agents and Chemotherapy (AAC)* demonstrating that eravacycline retained potency against *E. coli* clinical isolates containing a plasmid expressing *mcr-1* (ERV MIC $_{90}$ =0.5 µg/mL; colistin MIC $_{90}$ =16 µg/mL).
- Continued clinical testing designed to advance the development of an oral dose formulation of eravacycline. Additional clinical testing is ongoing to evaluate variables associated with increasing drug exposure and optimizing the oral eravacycline dosing regimen.
- Continued to advance pipeline candidates, TP-271 and TP-6076, with the completion of phase 1 single-ascending dose studies for the IV formulations of both compounds.
- Received Qualified Infectious Disease Product and Fast Track designation from the FDA for the oral formulation of TP-271 and initiated a single-ascending dose phase 1 study of oral TP-271.
- Promoted Larry Edwards to Chief Commercial Officer in January 2017. Larry joined Tetraphase as Vice President, Marketing in 2015 and this promotion recognizes Larry’s contributions in providing strong leadership and direction in the commercial and business development functions. Larry has exceptional commercialization experience for early and late-stage hospital infectious disease products. Prior to Tetraphase, he served as Senior Director of Marketing, Gram Negative Franchise for Cubist Pharmaceuticals from April 2014 through the Merck acquisition, and previously at Merck & Company in infectious disease global marketing leadership roles from 2007 to 2014 and various sales positions of increasing responsibility from 1999 to 2007. Larry has a Masters of Business Administration from St. Joseph’s University and a Bachelors of Science in Business & Healthcare Administration from Ohio University.

Fourth-Quarter and Full-Year 2016 Financial Results

As of December 31, 2016, Tetraphase had cash and cash equivalents of $142.1 million and 36.9 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 at least the second half of 2018.

For the fourth quarter of 2016, Tetraphase reported a net loss of $22.5 million, or $0.61 per share, compared to a net loss of $18.1 million, or $0.50 per share, for the same period in 2015. Revenues were $1.1 million compared to $2.5 million for the same period in 2015. 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. The decrease in revenues was primarily due to the scope and timing of activities related to our BARDA Contract conducted during the fourth quarter of 2016. Research and development (R&D) expenses for the fourth quarter of 2016 were $19.3 million compared to $15.0 million for the same period in 2015. The increase in R&D expenses was primarily due to higher clinical trial costs for eravacycline driven by the start-up activities of our IGNITE3 and IGNITE4 clinical trials, and an increase in manufacturing activity. General and administrative (G&A) expenses for the fourth quarter of 2016 were $4.3 million compared to $5.6 million for the same period in 2015. The decrease in G&A expenses was primarily due to lower headcount-related costs.

For the year ended December 31, 2016, Tetraphase reported a net loss of $77.5 million, or $2.11 per share, compared to a net loss of $83.2 million, or $2.36 per share, for the same period in 2015. Revenues were $5.1 million for the year ended December 31, 2016 compared to $11.7 million for the same period in 2015. As stated above, 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. The decrease in revenues was primarily due to the scope and timing of activities related to our BARDA Contract conducted during 2016. R&D expenses were $63.8 million for the year ended December 31, 2016 compared to $73.8 million for the same period in 2015. The decrease in R&D expenses was primarily due to a net decrease in development spending on the eravacycline program. G&A expenses were $19.2 million for the year ended December 31, 2016 compared to $20.9 million for the same period in 2015. The decrease in G&A expenses was primarily due to lower spending related to pre-commercialization activities for eravacycline.

Conference Call Information

Tetraphase will host a conference call today at 4:30 pm Eastern Time. The call can be accessed by dialing (844) 831-4023 (U.S. and Canada) or (731) 256-5215 (international) and entering passcode: 82825167. To access the live audio webcast, or the subsequent archived recording, visit the "Investor Relations — Events & Presentations" section of the Tetraphase website at www.tphase.com. The webcast will be recorded and available for replay on the Tetraphase website for 30 days following the call.

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-Q, filed with the Securities and Exchange Commission on November 3, 2016. In addition, the forward-looking statements included in this press release represent our views as of March 8, 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 December 31,		Year Ended December 31,	
	2016	2015	2016	2015
Revenues	$ 1,090	$ 2,471	$ 5,145	$ 11,686
Operating expenses				
Research and development	19,305	15,016	63,764	73,768
General and administrative	4,341	5,587	19,211	20,916
Total operating expenses	23,646	20,603	82,975	94,684
Loss from operations	(22,556)	(18,132)	(77,830)	(82,998)
Other income (expense)				
Other income (expense), net	95	16	350	(191)
Net loss	$(22,461)	$(18,116)	$(77,480)	$(83,189)
Net loss per share-basic and diluted	$ 0.61	$ (0.50)	$ (2.11)	$ (2.36)
Weighted-average number of common shares used in net loss per share applicable to common stockholders-basic and diluted	36,894	36,559	36,704	35,261

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

	December 31, 2016	December 31, 2015
Assets		
Cash and cash equivalents	$ 142,086	$ 205,912
Accounts receivable	1,789	4,151
Prepaid expenses and other current assets	6,582	3,705
Property and equipment, net	1,054	943
Other assets, noncurrent	199	206
Total assets	$ 151,710	$ 214,917
Liabilities and Stockholders' equity		
Accounts payable and accrued expenses	$ 10,240	$ 9,788
Total deferred revenue	1,255	909
Other liabilities, noncurrent	162	165
Total stockholders' equity	140,053	204,055
Total liabilities and stockholders' equity	$ 151,710	$ 214,917

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