Tetraphase Pharmaceuticals Reports Third Quarter 2017 Financial Results and Highlights Recent Clinical and Corporate Achievements

November 2, 2017

WATERTOWN, Mass., Nov. 02, 2017 (GLOBE NEWSWIRE) -- 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 third quarter ended September 30, 2017 and provided an overview of recent achievements.

“During the third quarter, Tetraphase achieved several key milestones that continue to set the stage for the potential approval and commercialization of intravenous (IV) eravacycline in 2018,” said Guy Macdonald, President and Chief Executive Officer of Tetraphase. “We submitted a Marketing Authorization Application (MAA) for IV eravacycline in complicated intra-abdominal infections (cIAI) to the European Medicines Agency (EMA) which is now under review, and we successfully completed our phase 3 IGNITE4 clinical trial, which, together with IGNITE1, will form the basis of our New Drug Application (NDA) to the FDA in the first quarter of 2018.”

Mr. Macdonald continued, “For IV eravacycline in complicated urinary tract infections (cUTI), we completed enrollment in the phase 3 IGNITE3 trial, and expect top-line data to be available in the first quarter of 2018. Assuming a positive IGNITE3 outcome and upon approval of IV eravacycline in cIAI, we plan to file a supplemental NDA (sNDA) for cUTI.”

“Lastly, we recently announced an update on our oral eravacycline development program, including positive phase 1 results in healthy volunteers, and look forward to moving our optimized IV-to-oral regimen into a phase 2 clinical trial in cUTI patients in the first half of 2018,” Mr. Macdonald added. “With a strengthened balance sheet following a successful public offering in the third quarter, we will be able to execute on these important objectives for the eravacycline program and through our anticipated commercial launch."

Key 2018 Milestones

- Submit NDA for IV eravacycline for the treatment of cIAI (1Q)
- Report top-line phase 3 IGNITE3 data for IV eravacycline in cUTI (1Q)
- Initiate phase 2 clinical trial in cUTI patients for IV-to-oral eravacycline (1H)
- Complete phase 1 multiple-ascending dose studies for TP-271 and TP-6076 (1H)
- Potential approval of IV eravacycline for cIAI in US and Europe (2H)
- Submit sNDA for IV eravacycline in cUTI (2H)

Third Quarter and Recent Highlights

- Announced positive top-line results from IGNITE4, the Company's phase 3 clinical trial evaluating the efficacy and safety of twice-daily IV eravacycline compared to meropenem for the treatment of patients with complicated intra-abdominal infections. 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 (TOC) visit.
- Announced that the MAA for IV eravacycline for the treatment of complicated intra-abdominal infections was submitted to and subsequently validated by the EMA. The MAA filing is based on data from the phase 3 IGNITE1 clinical trial in which eravacycline was well tolerated and demonstrated statistical non-inferiority to ertapenem using the primary endpoint of clinical response at the TOC visit.
- Announced completion of enrollment in IGNITE3, the Company’s ongoing phase 3 clinical trial evaluating the efficacy and safety of once-daily IV eravacycline compared to ertapenem in cUTI. The Company expects to report top-line data from this trial in the first quarter of 2018.
- Presented data at IDWeek 2017 from the first study of the Company’s recently completed phase 1 program designed to evaluate drug exposure of oral eravacycline in an IV-to-oral dosing regimen. These results, along with data from subsequent trials in this phase 1 program, have allowed for the identification of an optimized IV-to-oral dosing regimen using the current oral eravacycline formulation which the company plans to advance into a phase 2 clinical trial in patients with complicated urinary tract infections. This study is anticipated to begin in the first half of 2018.
- Successfully completed a public offering of shares of common stock with gross proceeds totaling approximately $65.7 million.
- Appointed Kamalam (Kam) Unninayar as Chief Financial Officer. Kam is an experienced financial executive with a track record of over two decades of financial leadership in the life sciences and consumer goods industries. Most recently, Kam spent over 11 years overseeing finance organizations at Thermo Fisher Scientific, a global leader in serving science.

Third Quarter 2017 Financial Results
As of September 30, 2017, Tetraphase had cash and cash equivalents of $161.4 million and 51.2 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 early 2019.

Revenues during the third quarter of 2017 were $4.1 million compared to $0.9 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 increase was primarily due to the scope and timing of activities related to our government contracts conducted during the third quarter of 2017.

Research and development (R&D) expenses for the third quarter of 2017 were $28.8 million compared to $17.2 million for the same period in 2016. The increase in R&D expenses was primarily due to conduct of our IGNITE3 phase 3 clinical trial.

General and administrative (G&A) expenses for the third quarter of 2017 were $5.6 million compared to $4.9 million for the same period in 2016. This increase was primarily due to an increase in legal and headcount related costs.

For the third quarter of 2017, Tetraphase reported a net loss of $30.0 million, or $0.63 per share, compared to a net loss of $21.1 million, or $0.58 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-Q, filed with the Securities and Exchange Commission on November 1, 2017. In addition, the forward-looking statements included in this press release represent our views as of November 2, 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 Statements of Operations (Unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Revenues	$ 4,067	$ 850	$ 7,138	$ 4,055
Operating expenses				
Research and development	28,777	17,190	83,237	44,459
General and administrative	5,600	4,858	15,797	14,870
Total operating expenses	34,377	22,048	99,034	59,329
Loss from operations	(30,310)	(21,198)	(91,896)	(55,274)
Other income (expense)				
Other income (expense), net	302	88	620	255
Net loss	$ (30,008)	$ (21,110)	$ (91,276)	$ (55,019)
Net loss per share-basic and diluted	$ (0.63)	$ (0.58)	$ (2.23)	$ (1.50)
Weighted-average number of common shares used in net loss per share applicable to common stockholders-basic and diluted	47,347	36,692	40,942	36,640

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

	September 30, 2017	December 31, 2016
Assets		
Cash and cash equivalents	$ 161,365	$ 142,086
Accounts receivable	3,565	1,789
Prepaid expenses and other current assets	5,493	6,582
Property and equipment, net	1,424	1,054
Other assets, noncurrent	199	199
Total assets	$ 172,046	$ 151,710
Liabilities and Stockholders' equity		
Accounts payable and accrued expenses	$ 21,781	$ 10,240
Total deferred revenue	782	1,255
Other liabilities, noncurrent	119	162
Total stockholders' equity	149,364	140,053
Total liabilities and stockholders' equity	$ 172,046	$ 151,710

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