Tetraphase Pharmaceuticals Reports Second Quarter 2018 Financial Results and Recent Highlights

August 2, 2018

WATERTOWN, Mass., Aug. 02, 2018 (GLOBE NEWSWIRE) -- Tetraphase Pharmaceuticals, Inc. (NASDAQ:TTPH), a biopharmaceutical company focused on developing and commercializing novel antibiotics to treat life-threatening multidrug-resistant (MDR) infections, today reported financial results for the second quarter ended June 30, 2018.

"In the second quarter of 2018, we moved closer to achieving our goal to bring Xerava™ (eravacycline) to market on a global level as an important new antibiotic for patients with serious, often life-threating, complicated intra-abdominal infections (cIAI)," said Guy Macdonald, President and Chief Executive Officer of Tetraphase. "We recently announced a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for Xerava in cIAI, and we expect a final decision on marketing authorization from the European Commission (EC) later this year. In the U.S., we are eagerly looking forward to a decision on our PDUFA (Prescription Drug User Fee Act) date of August 28, 2018 and we are actively preparing for the potential commercial launch of Xerava in the fourth quarter."

Mr. Macdonald added, "We also have continued to make progress on our eravacycline development plans in China, through Everest Medicines, our licensee in Asia. Everest recently submitted an Investigational New Drug (IND) application for eravacycline in cIAI to the China Food and Drug Administration (CFDA) for which we received a $2.5 million milestone payment. We are excited to be moving forward in this collaboration to bring eravacycline to patients in this part of the world. Along with the U.S. and Europe, we believe there is a significant market opportunity for eravacycline in China and other Asian territories for patients with serious infections caused by Gram-negative bacteria, particularly as resistance rates continue to rise."

Key Upcoming Milestones

Potential approval of Xerava in cIAI in U.S. – Q3 2018

Potential approval of Xerava in cIAI in Europe – 2H 2018

Potential commercial launch of Xerava in cIAI in the U.S. – Q4 2018

Complete phase 1 multiple ascending dose studies for TP-271 and TP-6076 – 2H 2018

Second Quarter and Recent Highlights

- Announced that the CHMP of the EMA has recommended Xerava for approval as a treatment for adult patients with cIAI. The CHMP's opinion will be reviewed by the EC which is expected to make a final decision within three months. If approved by the EC, marketing authorization for Xerava will be granted in all 28 countries of the European Union, Norway, Iceland and Liechtenstein.
- Presented data at ASM Microbe 2018, including a poster presentation that shared a pooled analysis of IGNITE1 and IGNITE4, the Company's phase 3 studies to evaluate the efficacy and safety of Xerava versus ertapenem and meropenem, respectively, in patients with cIAI. This is the first post-hoc analysis of IGNITE1 and IGNITE4 to compare the clinical and microbiological responses at the test-of-cure visit for patients in the two treatment groups, with an emphasis on the response of MDR pathogens to Xerava. The Company also presented data highlighting the *in vitro* activity of Xerava and comparators against Gram-negative isolates from a large-scale global surveillance study, as well as the activity of TP-6076 against carbapenem-resistant *Acinetobacter baumannii* isolates.
- Announced Everest Medicines' submission of an IND application for eravacycline in cIAI to the CFDA. Everest has the exclusive license to develop and commercialize eravacycline for the treatment of cIAI and other indications in China, Taiwan, Hong Kong, Macau, South Korea and Singapore. Tetraphase received a milestone payment of $2.5 million following Everest's IND application submission with the CFDA in June 2018.

Second Quarter 2018 Financial Results

As of June 30, 2018, Tetraphase had cash and cash equivalents of $111.2 million and 52.9 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 through the third quarter of 2019.

Revenues during the second quarter of 2018 were $11.6 million compared to $1.6 million for the same period in 2017. The $11.3 million in total revenue consisted of a $7.0 million upfront license fee and the $2.5 million Chinese IND filing milestone, both earned under the Company's license agreement with Everest Medicines Limited, as well as $2.1 million in contract and grant revenue under the Company's U.S. government awards.

Research and development (R&D) expenses for the second quarter of 2018 were $14.4 million compared to $28.5 million for the same period in 2017. The decrease in R&D expenses was primarily due to the completion of our IGNITE phase 3 clinical studies for Xerava.

General and administrative expenses for the second quarter of 2018 were $7.2 million compared to $5.1 million for the same period in 2017. This increase was primarily due to pre-commercialization expenses.

For the second quarter of 2018, Tetraphase reported a net loss of $9.5 million, or ($0.18) per share, compared to a net loss of $31.8 million, or ($0.83) per share, for the same period in 2017.

About Xerava
Xerava is a novel, fully-synthetic fluorocycline antibiotic being developed for the treatment of cIAI and other serious infections, including those caused by MDR pathogens that have been highlighted as urgent public health threats by both the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC). Xerava has demonstrated potent *in vitro* activity against MDR pathogens, including carbapenem-resistant Enterobacteriaceae, *Acinetobacter baumannii*, and colistin-resistant bacteria carrying the *mcr-1* gene.

Xerava was investigated for the treatment of cIAI as part of the Company's **I**nvestigating **G**ram-**n**egative **I**nfections **T**reated with **E**ravacycline (IGNITE) phase 3 program. In IGNITE1, a pivotal phase 3 trial in patients with cIAI, twice-daily intravenous (IV) Xerava met the primary endpoint by demonstrating statistical non-inferiority of clinical response compared to ertapenem, was well-tolerated and achieved high cure rates in patients with Gram-negative pathogens, including resistant isolates. In IGNITE4, a second phase 3 clinical trial in patients with cIAI, twice-daily IV Xerava met the primary endpoint by demonstrating statistical non-inferiority of clinical response compared to meropenem, was well-tolerated and achieved high cure rates. Xerava has not been approved for commercial use.

About Tetraphase Pharmaceuticals, Inc.
Tetraphase is a 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 MDR bacteria highlighted as urgent public health threats by the WHO and CDC. The Company has created more than 3,000 novel tetracycline compounds using its proprietary technology platform. Tetraphase's pipeline includes three antibiotic clinical candidates: Xerava, TP-271 and TP-6076. Xerava has completed phase 3 clinical testing and is under review for potential approval in cIAI by the FDA and has received a positive opinion from the CHMP of the EMA. TP-271 and TP-6076 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" 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 the Company's regulatory submission for Xerava (eravacycline) will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether, if any clinical candidate, including Xerava 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 for the period ended June 30, 2018, filed with the Securities and Exchange Commission on August 2, 2018. In addition, the forward-looking statements included in this press release represent our views as of August 2, 2018. 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue				
License revenue	$ 9,500	$ -	$ 9,500	$ -
Government revenue	2,079	1,586	3,969	3,071
Total revenue	11,579	1,586	13,469	3,071
Operating expenses				
Research and development	14,370	28,513	32,497	54,460
General and administrative	7,165	5,065	12,869	10,198
Total operating expenses	21,535	33,578	45,366	64,658
Loss from operations	(9,956)	(31,992)	(31,897)	(61,587)
Other income (expense)				
Other income (expense), net	413	181	778	318
Net loss	$ (9,543)	$ (31,811)	$ (31,119)	$ (61,269)
Net loss per share-basic and diluted	$ (0.18)	$ (0.83)	$ (0.42)	$ (1.63)
Weighted-average number of common shares used in net loss per share applicable to common stock per share applicable to common stockholders-basic and diluted	51,839	38,273	51,721	37,686

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

	June 30, 2018	December 31, 2017
Assets		
Cash and cash equivalents	$ 111,202	$ 136,411
Accounts receivable	3,112	4,653
Prepaid expenses and other current assets	6,031	6,382
Property and equipment, net	1,246	1,395
Other assets, noncurrent	199	199
Total assets	$ 121,790	$ 149,040
Liabilities and Stockholders' equity		
Accounts payable and accrued expenses	$ 10,854	$ 17,865
Total deferred revenue	109	660
Other liabilities, noncurrent	96	105
Total stockholders' equity	110,731	130,410
Total liabilities and stockholders' equity	$ 121,790	$ 149,040

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Source: Tetraphase Pharmaceuticals, Inc.