Evoke Pharma Reports First Quarter 2018 Results and Highlights

May 14, 2018

The Company will hold a conference call following submission of Gimoti NDA

- NDA submission for Gimoti™ on track for second quarter of 2018
- Announced discovery of sex-based pharmacokinetic differences for Gimoti
- Waiver of the PDUFA fee for Gimoti NDA granted by FDA
- Cash runway extended into April 2019

SOLANA BEACH, Calif., May 14, 2018 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced its financial results for the first quarter ended March 31, 2018.

Dave Gonyer, R.Ph., President and CEO, stated, “After successfully completing our comparative exposure pharmacokinetic (PK) trial late last year, we entered 2018 with a discovery of sex-based PK differences for Gimoti. With this significant finding and additional direction from the U.S. Food and Drug Administration (FDA), we are in the process of finalizing our 505(b)(2) New Drug Application (NDA) for Gimoti. The proposed indication for Gimoti is the relief of symptoms of acute and recurrent diabetic gastroparesis in adult women, which comprise an estimated 80% of the patients suffering from the disease. In line with prior guidance, we plan to submit the NDA in the second quarter.”

Mr. Gonyer continued, “We have continued to efficiently manage our cash resources and have benefited from the waiver of the Prescription Drug User Fee Act (PDUFA) NDA submission fee and Mallinckrodt’s agreement to defer near term milestone payments until one year after approval of Gimoti. We believe our current cash will now extend until April 2019. We look forward to holding a conference call later this quarter once the NDA is submitted to FDA.”

First Quarter 2018 Financial Review

For the first quarter of 2018, net loss was approximately $2.0 million, or $(0.13) per share, compared to a net loss of approximately $5.1 million, or $(0.37) per share, for the three-month period ended March 31, 2017.

Research and development expenses totaled approximately $1.4 million for the three months ended March 31, 2018, compared to approximately $0.8 million for the three months ended March 31, 2017. For the first quarter of 2018, general and administrative expenses were approximately $1.0 million, compared to approximately $1.2 million for the first quarter of 2017.

Total operating expenses for the three months ended March 31, 2018 were approximately $2.4 million, compared to approximately $2.0 million for the same period in 2017.

Included in net loss for the first quarter of 2018 was a gain of approximately $433,000 due to the change in the fair value of the warrant liability. The warrant liability was subject to remeasurement at each reporting period until the time the warrants were amended in March 2018. We recognized any change in the fair value of the warrant liability in the statement of operations. Following the amendment of the warrants, the warrants were reclassified to equity and no longer require remeasurement on a quarterly basis.

As of March 31, 2018, our cash and cash equivalents were approximately $5.4 million.

About Evoke Pharma, Inc.

Evoke is a specialty pharmaceutical company focused primarily on the development of drugs to treat GI disorders and diseases. The Company is developing Gimoti, a nasal spray formulation of metoclopramide, for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women.

Diabetic gastroparesis is a GI disorder affecting millions of patients worldwide, in which the stomach takes too long to empty its contents resulting in serious digestive system symptoms. The gastric delay caused by gastroparesis can compromise absorption of orally administered medications. Metoclopramide is currently available only in oral and injectable formulations and is the only drug currently approved in the United States to treat gastroparesis. Visit www.EvokePharma.com for more information.

Safe Harbor Statement

Evoke cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negatives of these terms or other similar expressions. These statements are based on the company's current beliefs and expectations. These forward-looking statements include statements regarding:

anticipated timing to submit an NDA for Gimoti; Evoke's plans to hold an investor conference call following submission of the NDA for Gimoti; the potential timing of FDA acceptance and approval, if any, of the NDA for Gimoti; and Evoke's projected cash runway. The inclusion of forward-looking statements should not be regarded as a representation by Evoke that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Evoke's business, including, without limitation: the FDA may disagree that the existing safety database and efficacy data is sufficient to allow an NDA submission and approval, including risks associated with Cmax falling below the bioequivalence range in the comparative exposure PK trial and the proposed duration of use for Gimoti being shorter as compared to the maximum approved dosing duration for the referenced listed drug, Reglan Tablets, and the available safety database supporting such duration; ; the FDA may not agree with Evoke's interpretation of the results of clinical trials of Gimoti; later developments with the FDA that may be inconsistent with the already completed pre-NDA meetings; the inherent risks of clinical development of Gimoti; Evoke may spend its available cash faster than it anticipates; Evoke is entirely dependent on the success of Gimoti, and Evoke cannot be certain that it will be able to submit an NDA for Gimoti or obtain regulatory approval for or successfully commercialize Gimoti; Evoke will require substantial additional funding to conduct any new safety trials required by the FDA, and may be unable to raise capital when needed, including to fund ongoing operations; and other risks detailed in Evoke's prior press releases and in the periodic reports it files with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Evoke undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

(Financial Statements to Follow)

Evoke Pharma, Inc.
Balance Sheet

	March 31, 2018 (Unaudited)	December 31, 2017
Assets		
Current Assets:		
Cash and cash equivalents	$ 5,405,944	$ 7,679,267
Prepaid expenses	167,364	251,046
Other current assets	11,551	—
Total current assets	5,584,859	7,930,313
Other assets	—	11,551
Total assets	$ 5,584,859	$ 7,941,864
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 545,975	$ 1,048,927
Accrued compensation	649,618	1,025,911
Total current liabilities	1,195,593	2,074,838
Warrant liability	—	3,701,277
Total liabilities	1,195,593	5,776,115
Stockholders' equity:		
Common stock	1,568	1,541
Additional paid-in capital	77,409,139	73,202,863
Accumulated deficit	(73,021,441)	(71,038,655)
Total stockholders' equity	4,389,266	2,165,749
Total liabilities and stockholders' equity	$ 5,584,859	$ 7,941,864

Evoke Pharma, Inc.
Statements of Operations

	Three Months Ended March 31, 2018	2017
Operating expenses:		
Research and development	$ 1,385,366	$ 770,686
General and administrative	1,032,245	1,209,570
Total operating expenses	2,417,611	1,980,256

Loss from operations	(2,417,611)	(1,980,256)
Other income (expense):		
Interest income	1,433	964
Change in fair value of warrant liability	433,392	(3,072,747)
Total other income (expense), net	434,825	(3,071,783)
Net loss	$ (1,982,786)	$ (5,052,039)
Net loss per share of common stock, basic and diluted	$ (0.13)	$ (0.37)
Weighted-average shares used to compute basic and diluted net loss per share	15,427,037	13,528,311

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Primary Logo

Source: Evoke Pharma, Inc.