Evoke Pharma Reports Third Quarter 2018 Results

November 13, 2018

April 1, 2019 PDUFA date for Gimoti™ NDA

Cash runway extended through June 2019

SOLANA BEACH, Calif., Nov. 13, 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 third quarter ended September 30, 2018.

"This quarter we continued to make progress with Gimoti™, our novel nasal delivery of metoclopramide, to offer a new path for the treatment of women suffering from gastroparesis," said, Dave Gonyer, R.Ph., President and CEO. "The NDA review process with FDA is underway as well as preparations for potential commercialization of Gimoti. We project our cash runway to be through June 2019, past the Prescription User Fee Act (PDUFA) target date of April 1, 2019."

Third Quarter 2018 Financial Review

For the third quarter of 2018, net loss was approximately $1.5 million, or $(0.09) per share, compared to a net loss of approximately $5.2 million, or $(0.34) per share, for the three-month period ended September 30, 2017.

Research and development expenses totaled approximately $625,000 for the three months ended September 30, 2018, compared to approximately $2.7 million for the same period in 2017. For the third quarter of 2018, general and administrative expenses were approximately $897,000, compared to approximately $984,000 for the third quarter of 2017.

Total operating expenses for the three months ended September 30, 2018 were approximately $1.5 million, compared to approximately $3.7 million for the same period in 2017.

As of September 30, 2018, our cash and cash equivalents were approximately $6.6 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: the potential timing of FDA action on the NDA for Gimoti; Evoke's plans for commercialization of Gimoti; Evoke's projected cash runway; and the potential of Gimoti to offer a new treatment option for women suffering from gastroparesis. 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 potential for the FDA to delay the PDUFA target action date due to the FDA's internal resource constraints or other reasons; the FDA may disagree that the existing safety database and efficacy data is sufficient to allow approval of the NDA, including as a result of the potential review issues identified by the FDA in the Day-74 Letter such as, among others, C_{max} falling below the bioequivalence range in the comparative exposure PK trial, 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 adequacy of the proposed REMS included in the NDA, and the existing data supporting a female-only indication; 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 possibility of an advisory committee meeting related to the NDA; the inherent risks of clinical development of Gimoti; the possibility of the FDA failing to finally approve Evoke's proposed proprietary name through the NDA review process; Evoke is entirely dependent on the success of Gimoti, and Evoke cannot be certain that FDA will approve the NDA for Gimoti or that Evoke will successfully commercialize Gimoti; Evoke will require substantial additional funding to conduct any new trials required by the FDA, and to conduct pre-commercialization activities and to commercialize

Gimoti, if approved, 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

	September 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current Assets:		
Cash and cash equivalents	$ 6,567,918	$ 7,679,267
Prepaid expenses	438,957	251,046
Total current assets	7,006,875	7,930,313
Other assets	11,551	11,551
Total assets	$ 7,018,426	$ 7,941,864
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 625,994	$ 1,048,927
Accrued compensation	984,683	1,025,911
Total current liabilities	1,610,677	2,074,838
Warrant liability	—	3,701,277
Total liabilities	1,610,677	5,776,115
Stockholders' equity:		
Common stock	1,743	1,541
Additional paid-in capital	82,250,109	73,202,863
Accumulated deficit	(76,844,103)	(71,038,655)
Total stockholders' equity	5,407,749	2,165,749
Total liabilities and stockholders' equity	$ 7,018,426	$ 7,941,864

Evoke Pharma, Inc.
Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 625,497	$ 2,717,698	$ 3,399,654	$ 5,505,953
General and administrative	897,060	984,047	2,846,611	3,065,595
Total operating expenses	1,522,557	3,701,745	6,246,265	8,571,548
Loss from operations	(1,522,557)	(3,701,745)	(6,246,265)	(8,571,548)
Other income (expense):				
Interest income	3,089	2,822	7,425	5,452
Change in fair value of warrant liability	—	(1,544,138)	433,392	(3,354,973)
Total other income (expense)	3,089	(1,541,316)	440,817	(3,349,521)
Net loss	$ (1,519,468)	$ (5,243,061)	$ (5,805,448)	$ (11,921,069)
Net loss per share of common stock, basic	$ (0.09)	$ (0.34)	$ (0.36)	$ (0.81)
Net loss per share of common stock, diluted	$ (0.09)	$ (0.34)	$ (0.36)	$ (0.84)
Weighted-average shares used to compute basic net loss per share	17,129,649	15,351,295	16,327,385	14,740,977
Weighted-average shares used to compute diluted net loss per share	17,129,649	15,351,295	16,327,385	14,766,853

Investor Contact:
The Ruth Group

Tram Bui
Tel: 646-536-7035
tbui@theruthgroup.com

Source: Evoke Pharma, Inc.