



Evoke Pharma Reports Fourth Quarter and Full Year 2017 Financial Results and Recent Highlights

March 7, 2018

- Successfully completed pivotal pharmacokinetic trial and finalized the proposed to-be-marketed Gimoti™ dose
- Announced discovery of sex-based pharmacokinetic differences for Gimoti™
- Met with FDA regarding NDA women-only filing strategy and post-marketing plans
- 505(b)(2) NDA submission planned for second quarter of 2018

SOLANA BEACH, Calif., March 07, 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 fourth quarter and full year ended December 31, 2017.

Dave Gonyer, R.Ph., President and CEO, stated, "2017 was a critical year for Evoke as we successfully completed our pivotal comparative exposure pharmacokinetic (PK) study for Gimoti™, an important component of our 505(b)(2) New Drug Application (NDA) for submission to the U.S. Food and Drug Administration (FDA). From the results of the PK trial and recent FDA communications, we were able to confirm the proposed dose for women to be submitted in the NDA. The sex-based NDA submission strategy will allow us to seek approval for a product that is specific to the needs of 80% of the patients who suffer from symptoms of diabetic gastroparesis. We continue to work diligently to ensure that we submit a comprehensive NDA next quarter."

Mr. Gonyer continued, "Financially, we remain conservative with our expenditures and reiterate that we have cash runway into October 2018. We are actively evaluating multiple strategic pathways forward for Gimoti, including debt financing and other potential partnerships."

Fourth Quarter and Year End Financial Review

For the fourth quarter of 2017, net loss was approximately \$308,000, or \$0.02 per basic share, compared to a net loss of approximately \$1.5 million, or \$0.12 per basic share for the fourth quarter of 2016. For the year ended December 31, 2017, the net loss was approximately \$12.2 million, or \$0.82 per basic share. This compares to a net loss of approximately \$10.7 million, or \$1.15 per basic share for 2016.

Research and development expenses totaled approximately \$1.6 million for the fourth quarter of 2017, compared to approximately \$1.5 million for 2016. For the full year 2017, research and development expenses were approximately \$7.1 million compared to approximately \$7.0 million in the prior year.

For the fourth quarter of 2017, general and administrative expenses were approximately \$1.0 million compared with approximately \$822,000 for the fourth quarter of 2016. For the year ended December 31, 2017, general and administrative expenses were approximately \$4.1 million versus approximately \$3.6 million for the full year of 2016.

Total operating expenses for the fourth quarter of 2017 were approximately \$2.7 million, compared to total operating expenses of approximately \$2.3 million for 2016. For the year ended December 31, 2017, total operating expenses were approximately \$11.2 million compared to \$10.5 million for the full year of 2016.

Included in net loss for the fourth quarter of 2017 was a gain of approximately \$2.3 million due to the change in the fair value of the warrant liability. For the year ended December 31, 2017, there was a net loss due to the change in the fair value of the warrant liability of approximately \$1.0 million. The warrant liability is subject to remeasurement at each reporting period and we recognize any change in the fair value of the warrant liability in the statement of operations. We anticipate that the value of the warrants could fluctuate from quarter to quarter and that such fluctuation could have a material impact on our financial statements from quarter to quarter and year to year.

As of December 31, 2017, the Company's cash and cash equivalents were approximately \$7.7 million.

Conference Call and Webcast

Evoke will hold a conference call on Wednesday, March 7, 2018 at 4:30 pm ET to discuss the results. Participants should dial 1-877-407-0789 (United States) or 1-201-689-8562 (International) and mention Evoke Pharma. A live webcast of the conference call will also be available on the investor relations page of the Company's corporate website at www.evokepharma.com.

After the live webcast, the event will be archived on Evoke's website for one year. In addition, a telephonic replay of the call will be available until March 14, 2018. The replay can be accessed by dialing 1-844-512-2921 (United States) or 1-412-317-6671 (International) with confirmation code 13676791.

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 metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent gastroparesis in women with diabetes mellitus. Diabetic gastroparesis is a GI disorder afflicting millions of sufferers worldwide, in which the stomach takes too long to empty its contents resulting in serious digestive system symptoms. Metoclopramide is the only product currently approved in the United States to treat gastroparesis, and is currently available only in oral and intravenous forms. Gimoti is a novel formulation of this drug, designed to provide systemic delivery of metoclopramide through nasal administration. 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: Evoke's plans to pursue approval of Gimoti in adult women with diabetic gastroparesis; Evoke's belief that the sex-based PK differences are important to gastroparesis treatment; Evoke's plans with respect to the content of the NDA submission, including a proposed post-marketing risk management strategy and safety trial; and the timing of the NDA submission. 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 C_{max} 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; the FDA may require additional evidence of sex-based PK differences of Gimoti before making a final decision on Gimoti; risks associated with the size, cost and duration of a post-marketing safety trials; 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 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 trials required by the FDA, and may be unable to raise capital when needed, including to fund ongoing operations; Evoke may not be able to obtain, maintain and enforce intellectual property rights; 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.

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Evoke Pharma, Inc. Balance Sheets

	December 31, 2017	2016
Assets		
Current Assets:		
Cash and cash equivalents	\$ 7,679,267	\$ 9,007,071
Prepaid expenses	251,046	267,711
Other current assets	—	7,997
Total current assets	7,930,313	9,282,779
Other assets	11,551	11,551
Total assets	\$ 7,941,864	\$ 9,294,330
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 1,048,927	\$ 478,223
Accrued compensation	1,025,911	933,450
Total current liabilities	2,074,838	1,411,673
Warrant liability	3,701,277	4,095,019
Total liabilities	5,776,115	5,506,692
Commitments and contingencies		
Stockholders' equity:		
Common stock	1,541	1,235
Additional paid-in capital	73,202,863	62,595,546
Accumulated deficit	(71,038,655)	(58,809,143)
Total stockholders' equity	2,165,749	3,787,638

Total liabilities and stockholders' equity

\$ 7,941,864

\$ 9,294,330

Evoke Pharma, Inc.
Statement of Operations

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	\$ 1,631,540	\$ 1,502,032	\$ 7,137,493	\$ 6,951,600
General and administrative	1,027,594	822,325	4,093,189	3,592,825
Total operating expenses	2,659,134	2,324,357	11,230,682	10,544,425
Loss from operations	(2,659,134)	(2,324,357)	(11,230,682)	(10,544,425)
Other income (expense):				
Interest income (expense), net	1,067	454	6,519	(268,029)
Financing costs related to warrant liability	—	—	—	(533,692)
Change in fair value of warrant liability	2,349,624	796,560	(1,005,349)	597,615
Total other expense, net	2,350,691	797,014	(998,830)	(204,106)
Net loss	\$ (308,443)	\$ (1,527,343)	\$ (12,229,512)	\$ (10,748,531)
Net loss per share of common stock, basic	\$ (0.02)	\$ (0.12)	\$ (0.82)	\$ (1.15)
Net loss per share of common stock, diluted	\$ (0.07)	\$ (0.12)	\$ (0.90)	\$ (1.15)
Weighted-average shares used to compute basic net loss per share	15,368,610	12,305,360	14,897,885	9,338,068
Weighted-average shares used to compute diluted net loss per share	15,503,583	12,305,360	14,951,036	9,338,068

 [Primary Logo](#)

Source: Evoke Pharma, Inc.