



Evoke Pharma Reports Third Quarter 2019 Financial Results

November 7, 2019

Gimoti NDA resubmission on track for fourth quarter 2019

SOLANA BEACH, Calif., Nov. 07, 2019 (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, 2019.

"We made significant progress toward addressing the regulatory requests from the U.S. Food and Drug Administration (FDA) during the third quarter, and we continue to prepare for the resubmission of our New Drug Application (NDA) for Gimoti during the fourth quarter," said David A. Gonyer, R.Ph., President and CEO of Evoke Pharma, Inc. "We successfully completed manufacturing of commercial scale batches of Gimoti, which allows us to collect Chemistry, Manufacturing and Controls data as well as undertaking the analysis of pump performance characteristics on the nasal spray devices that will be used to support the NDA and bring us one step closer to commercial readiness. In addition, we believe that we have sufficient capital to support our operations into the second quarter of 2020."

Third Quarter 2019 Financial Review

For the third quarter of 2019, net loss was approximately \$1.6 million, or \$0.07 per share, compared to a net loss of approximately \$1.5 million, or \$0.09 per share for the third quarter of 2018.

Research and development expenses totaled approximately \$0.8 million for the third quarter of 2019, compared to approximately \$0.6 million for the third quarter of 2018. Research and development expenses were primarily related to responding to requests for additional information from FDA for the Gimoti NDA and manufacturing registration batches of Gimoti.

For the third quarter of 2019, general and administrative expenses were approximately \$0.8 million compared to approximately \$0.9 million for the third quarter of 2018.

Total operating expenses for the third quarter of 2019 were approximately \$1.6 million, compared to total operating expenses of approximately \$1.5 million for the third quarter of 2018.

As of September 30, 2019, the Company's cash and cash equivalents were approximately \$6.5 million.

About Evoke Pharma, Inc.

Evoke is a specialty pharmaceutical company focused primarily on the development of drugs to treat Gastrointestinal (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 for an NDA resubmission and the timing thereof and Evoke's expected 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: Evoke's resubmission of the NDA may be delayed and Evoke cannot be certain that FDA will accept or approve an NDA resubmission for Gimoti; Evoke may be unable to timely and successfully address the deficiencies raised in the CRL, including as a result of adverse findings from a root cause analysis or data from newly manufactured product batches; FDA may not agree with Evoke's conclusion of the root cause analysis or may require Evoke to conduct additional studies; the inherent risks of clinical development of Gimoti; Evoke's dependence on third parties for the manufacture of Gimoti and analysis of the PK data; Evoke is entirely dependent on the success of Gimoti; Evoke will require substantial additional funding to continue its operations beyond the second quarter of 2020, and may be unable to raise capital or obtain funds when needed, including to fund ongoing operations; Evoke could face significant additional costs due to litigation or other events; Evoke's ability to maintain the continued listing of its common stock on the Nasdaq Capital Market; 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.

Condensed Balance Sheets

	September 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current Assets:		
Cash and cash equivalents	\$ 6,504,802	\$ 5,319,004
Prepaid expenses	775,607	329,218
Other current assets	11,551	—
Total current assets	7,291,960	5,648,222
Operating lease right-of-use asset	35,398	—
Other assets	—	11,551
Total assets	\$ 7,327,358	\$ 5,659,773
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 1,154,520	\$ 476,202
Accrued compensation	964,243	1,158,251
Operating lease liability	35,398	—
Total current liabilities	2,154,161	1,634,453
Stockholders' equity:		
Common stock, \$0.0001 par value; authorized shares - 50,000,000; issued and outstanding shares - 24,231,914 and 17,427,533 at September 30, 2019 and December 31, 2018, respectively	2,423	1,743
Additional paid-in capital	89,482,936	82,628,312
Accumulated deficit	(84,312,162)	(78,604,735)
Total stockholders' equity	5,173,197	4,025,320
Total liabilities and stockholders' equity	\$ 7,327,358	\$ 5,659,773

Evoke Pharma, Inc.

Condensed Statements of Operations

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 822,444	\$ 625,497	\$ 2,774,924	\$ 3,399,654
General and administrative	814,218	897,060	2,955,371	2,846,611
Total operating expenses	1,636,662	1,522,557	5,730,295	6,246,265
Loss from operations	(1,636,662)	(1,522,557)	(5,730,295)	(6,246,265)
Other income:				
Interest income	8,597	3,089	22,868	7,425
Gain from change in fair value of warrant liability	—	—	—	433,392
Total other income	8,597	3,089	22,868	440,817
Net loss	\$ (1,628,065)	\$ (1,519,468)	\$ (5,707,427)	(5,805,448)
Net loss per share of common stock, basic and diluted	\$ (0.07)	\$ (0.09)	\$ (0.26)	\$ (0.36)
Weighted-average shares used to compute basic and diluted net loss per share	24,113,956	17,129,649	21,618,947	16,327,385

Investor Contact:
The Ruth Group
Tram Bui

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



Source: Evoke Pharma, Inc.