
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): May 8, 2019

EVOKE PHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36075
(Commission
File Number)

20-8447886
(IRS Employer
Identification No.)

420 Stevens Avenue, Suite 370
Solana Beach, California
(Address of Principal Executive Offices)

92075
(Zip Code)

Registrant's telephone number, including area code: (858) 345-1494

(Former Name or Former Address, if Changed Since Last Report.)

Title of each class
Common Stock,
par value \$0.0001 per share

Trading symbol
EVOK

Name of each exchange on which registered
The Nasdaq Capital Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On May 8, 2019, Evoke Pharma, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2019. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on May 8, 2019.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

EVOKE PHARMA, INC.

Date: May 8, 2019

By: /s/ Matthew J. D'Onofrio
Name: Matthew J. D'Onofrio
Title: Executive Vice President,
Chief Business Officer and Secretary



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Evoke Pharma Reports First Quarter 2019 Financial Results

Projected cash runway extended to first quarter 2020

SOLANA BEACH, CA, May 8, 2019 – 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, 2019.

“We remain diligent in the preparation of our resubmission of the Gimoti™ (metoclopramide nasal spray) new drug application (NDA) to address the approvability issues raised in the complete response letter from FDA. As requested by FDA, and as previously planned, we expect to start manufacturing registration batches of Gimoti prior to the end of this quarter through our partner, Thermo Fisher Scientific, a global contract development and manufacturing organization. With this manufacturing, we will also be in a position to provide FDA with additional acceptance criteria support for the proposed droplet size distribution and other pump performance characteristics of the nasal sprayer. We have also initiated a root cause analysis to identify the source of the pharmacokinetic (PK) variability observed in less than 5% of the administered doses of Gimoti in our completed PK study. Based on the analysis findings, the NDA resubmission may include potential mitigation strategies. We look forward to meeting with FDA to finalize our plans and to implement the Agency’s recommendations for addressing these remaining approvability issues,” said Dave Gonyer, R.Ph., President and CEO.

“Furthermore, as we continue to effectively manage our cash position, we have extended our cash runway into the first quarter of 2020, which we believe will be sufficient to see us through the NDA resubmission,” concluded Mr. Gonyer.

First Quarter 2019 Financial Review

For the first quarter of 2019, net loss was approximately \$2.0 million, or \$0.11 per basic share, compared to a net loss of approximately \$2.0 million, or \$0.13 per basic share for the first quarter of 2018.

Research and development expenses totaled approximately \$0.7 million for the first quarter of 2019, compared to approximately \$1.4 million for the first quarter of 2018.

For the first quarter of 2019, general and administrative expenses were approximately \$1.2 million compared to approximately \$1.0 million for the first quarter of 2018.

Total operating expenses for the first quarter of 2019 were approximately \$2.0 million, compared to total operating expenses of approximately \$2.4 million for the prior period of 2018.

As of March 31, 2019, the Company’s cash and cash equivalents were approximately \$4.0 million. Based on Evoke’s current operating plan, the Company’s existing cash and cash equivalents, we believe, will be sufficient to fund operations into the first quarter of 2020.

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 Evoke’s resubmission of the Gimoti NDA; the timing and volume of Evoke’s manufacturing run with Thermo Fisher Scientific; the potential timing of FDA action on the NDA and potential approval and product launch for Gimoti; Evoke’s belief that it can address the approvability issues raised by the FDA in the complete response letter to the Gimoti NDA, including pump performance issues raised by FDA; Evoke’s expectations that it can include a risk mitigation strategy acceptable to FDA; and Evoke’s projected cash runway into the first quarter of 2020 and the expected expenses required to resubmit the Gimoti NDA; . 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 could incur significant additional expenses prior to the Gimoti NDA resubmission which could significantly shorten our projected cash runway; FDA may not agree with our plan to resubmit the NDA, including our plan to address the approvability issues raised by FDA in its complete response letter; FDA may disagree that the root cause analysis or the registration batches will address the PK variability or droplet size distribution issues raised by FDA; FDA may not agree with Evoke’s interpretation of the results of clinical trials of Gimoti; later developments with FDA that may be inconsistent with the already completed meetings; the possibility of an advisory committee meeting related to the NDA; the inherent risks of clinical development of Gimoti; Evoke’s reliance on a third party, Novos Growth Partners (NGP), for critical aspects of the commercialization of Gimoti; the performance of NGP and its adherence to the terms of the agreement with Evoke; Evoke’s ability to timely secure a contract sale organization; Evoke could face unexpected costs due to additional regulatory requests, litigation or other events; 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 and NGP will successfully commercialize Gimoti; Evoke may require substantial additional funding, and may be unable to raise capital or obtain funds under the working capital loan or line of credit when needed, including to fund ongoing operations; Evoke may not be able to obtain, maintain and enforce its patents and other intellectual property rights, and the scope of patent protection may not provide the protections Evoke expects; 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

	<u>March 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
	<u>(Unaudited)</u>	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 4,028,550	\$ 5,319,004
Prepaid expenses	219,479	329,218
Other current assets	11,551	—
Total current assets	<u>4,259,580</u>	<u>5,648,222</u>
Operating lease right-of-use asset	103,252	—
Other assets	—	11,551
Total assets	<u><u>\$ 4,362,832</u></u>	<u><u>\$ 5,648,222</u></u>
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 491,831	\$ 476,202
Accrued compensation	692,304	1,158,251
Operating lease liability	103,252	—
Total current liabilities	<u>1,287,387</u>	<u>1,634,453</u>
Stockholders' equity:		
Common stock	1,788	1,743
Additional paid-in capital	83,643,658	82,628,312
Accumulated deficit	<u>(80,570,001)</u>	<u>(78,604,735)</u>
Total stockholders' equity	<u>3,075,445</u>	<u>4,025,320</u>
Total liabilities and stockholders' equity	<u><u>\$ 4,362,832</u></u>	<u><u>\$ 5,659,773</u></u>

Evoke Pharma, Inc.

Statements of Operations

	Three Months Ended March 31,	
	2019	2018
Operating expenses:		
Research and development	\$ 746,882	\$ 1,385,366
General and administrative	1,223,013	1,032,245
Total operating expenses	<u>1,969,895</u>	<u>2,417,611</u>
Loss from operations	(1,969,895)	(2,417,611)
Other income:		
Interest income	4,629	1,433
Gain from change in fair value of warrant liability	—	433,392
Total other income	<u>4,629</u>	<u>434,825</u>
Net loss	<u>\$ (1,965,266)</u>	<u>\$ (1,982,786)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.13)</u>
Weighted-average shares used to compute basic and diluted net loss per share	<u>17,484,318</u>	<u>15,427,037</u>