

EVOKE PHARMA INC

FORM 8-K (Current report filing)

Filed 05/15/17 for the Period Ending 05/15/17

Address	420 STEVENS AVENUE SUITE 370 SOLANA BEACH, CA 92075
Telephone	858-345-1494
CIK	0001403708
Symbol	EVOK
SIC Code	2834 - Pharmaceutical Preparations
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	12/31

**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 15, 2017

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.)

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 15, 2017, Evoke Pharma, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2017. 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

Exhibit No.	Description
99.1	Press Release issued on May 15, 2017

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 15, 2017

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

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on May 15, 2017



Investor Contact:
 The Ruth Group
 David Burke
 Tel: 646-536-7009
dburke@theruthgroup.com

Evoke Pharma Reports First Quarter 2017 Results

- Confirmed FDA acceptability of comparative exposure pharmacokinetic (PK) study design and agreement on related CMC data package elements for Gimoti™ new drug application (NDA)
- Partnered with Spaulding Clinical Research to complete PK study in second half of 2017
- Received FDA agreement that a Human Factors Validation Study is not required for the NDA
- Phase 3 clinical data for Gimoti presented as a late-breaker poster session at Digestive Disease Week (DDW) 2017
- Projecting 505(b)(2) NDA submission for Gimoti in late 2017/early 2018

SOLANA BEACH, CA, May 15, 2017 – Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal diseases, today announced its financial results for the first quarter ended March 31, 2017.

Dave Gonyer, R.Ph., President and CEO, stated, “We started 2017 with a number of positive developments that bring us closer to filing the 505(b)(2) NDA for Gimoti™. This includes reaching agreement with FDA that a Human Factors (HF) Validation Study, a requirement for drug/device combinations, is not needed for Gimoti. Additionally, before the close of the quarter, we completed a positive Type A meeting in which FDA confirmed the acceptability of the design of our planned comparative exposure PK study for Gimoti, as well as certain other chemistry, manufacturing & controls (CMC) items associated with the proposed NDA. This PK trial in healthy volunteers, which is designed to establish comparative exposure of Gimoti to the listed drug, Reglan® Tablets, will serve in part as the basis for a 505(b)(2) NDA submission for Gimoti. We recently announced our partnership with Spaulding Clinical Research to conduct the PK trial and expect to initiate and complete the study in the second half of 2017. Finally, we believe that the pre-NDA agreements with FDA further reduce potential risks and save additional resources as we continue to prepare the NDA for submission in late 2017 or early 2018.”

Mr. Gonyer continued, “From a financial perspective, Evoke completed a capital raise in March, which significantly enhanced our balance sheet and will allow us to complete the PK trial and focus on the NDA filing. We believe this capital infusion confirms our investors’ confidence in our strategy and intent to seek approval for Gimoti as rapidly and efficiently as possible. As we look forward to the rest of the year, we believe there is a clear path for an NDA submission and we are working hard to bring Gimoti to those patients suffering from diabetic gastroparesis.”

First Quarter 2017 Financial Review

For the first quarter of 2017, net loss was approximately \$5.1 million, or \$(0.37) per share, compared to a net loss of approximately \$3.2 million, or \$(0.45) per share, for the three-month period ended March 31, 2016. The year-over-year increase in net loss was primarily due to adjusting for the fair value of the warrant liability at March 31, 2017, which resulted in a significant non-cash expense.

Research and development expenses totaled approximately \$771,000 for the three months ended March 31, 2017, compared to approximately \$2.0 million for the three months ended March 31, 2016. The decrease was due primarily to the expenses related to our Phase 3 clinical trial which was still being conducted during the three month ended March 31, 2016. This trial was completed in the second quarter of 2016 and the analysis of the trial data occurred during the second half of 2016.

For the first quarter of 2017, general and administrative expenses were approximately \$1.2 million compared with approximately \$1.1 million for the first quarter of 2016.

Total operating expenses for the three months ended March 31, 2017 were approximately \$2.0 million, compared to total operating expenses of approximately \$3.2 million for the three months ended March 31, 2016.

Included in net loss for the first quarter of 2017 was an increase of net loss due to the change in the fair value of the warrant liability of approximately \$3.1 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.

In March 2017, we completed a public offering of approximately 2.8 million shares of common stock at \$2.90 per share, with gross proceeds of approximately \$8.0 million, before underwriting discounts and commissions and estimated offering costs.

As of March 31, 2017, our cash and cash equivalents were approximately \$14.7 million.

Conference Call and Webcast

Evoke will hold a conference call on Monday, May 15, 2017, 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 May 22, 2017. The replay can be accessed by dialing 1-844-512-2921 (United States) or 1-412-317-6671 (International) with confirmation code 13660963.

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: the clear path forward with respect to submission of an 505(b)(2) NDA submission for Gimoti based on a comparative exposure PK trial; Evoke's plans to initiate and complete the PK trial and submit the NDA and potentially receive regulatory approval of Gimoti; and the timing thereof, and Evoke's expectation that it will not need to raise additional capital to complete the comparative exposure PK trial and submit the NDA for Gimoti. 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: risks associated with successfully commencing and receiving favorable results from the planned comparative exposure PK trial; later developments with the FDA that may be inconsistent with the already completed pre- NDA meetings, including inconsistent conclusions reflected in the official meeting minutes from the FDA; 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; risks associated with manufacturing new formulations of Gimoti for use in the comparative exposure PK trial; Evoke's dependence on third parties for the manufacture of Gimoti as well as the conduct of the PK trial; Evoke may require additional funding to complete the PK trial and submit the NDA, and will require substantial additional funding to commercialize Gimoti, and may be unable to raise capital when needed, including to fund ongoing operations; Evoke may not be able to successfully commercialize Gimoti, if approved, as a result of risks associated with market acceptance, coverage and reimbursement and competing products; 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

	March 31, 2017	December 31, 2016
	<u>(Unaudited)</u>	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 14,654,998	\$ 9,007,071
Prepaid expenses	171,524	267,711
Other current assets	—	7,997
Total current assets	<u>14,826,522</u>	<u>9,282,779</u>
Other assets	11,551	11,551
Total assets	<u>\$ 14,838,073</u>	<u>\$ 9,294,330</u>
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 549,039	\$ 478,223
Accrued compensation	586,772	933,450
Total current liabilities	<u>1,135,811</u>	<u>1,411,673</u>
Warrant liability	<u>5,768,675</u>	<u>4,095,019</u>
Total liabilities	6,904,486	5,506,692
Stockholders' equity:		
Common stock	1,539	1,235
Additional paid-in capital	71,793,230	62,595,546
Accumulated deficit	<u>(63,861,182)</u>	<u>(58,809,143)</u>
Total stockholders' equity	<u>7,933,587</u>	<u>3,787,638</u>
Total liabilities and stockholders' equity	<u>\$ 14,838,073</u>	<u>\$ 9,294,330</u>

Evoke Pharma, Inc.

**Condensed Statements of Operations
(Unaudited)**

	Three Months Ended	
	March 31,	
	<u>2017</u>	<u>2016</u>
Operating expenses:		
Research and development	\$ 770,686	\$ 2,015,076
General and administrative	<u>1,209,570</u>	<u>1,137,753</u>
Total operating expenses	<u>1,980,256</u>	<u>3,152,829</u>
Loss from operations	(1,980,256)	(3,152,829)
Other expenses:		
Interest income (expense), net	964	(72,580)
Change in fair value of warrant liability	<u>(3,072,747)</u>	<u>—</u>
Total other expenses	<u>(3,071,783)</u>	<u>(72,580)</u>
Net loss	<u>\$ (5,052,039)</u>	<u>\$ (3,225,409)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.37)</u>	<u>\$ (0.45)</u>
Weighted-average shares used to compute basic and diluted net loss per share	<u>13,528,311</u>	<u>7,168,005</u>