

# EVOKE PHARMA INC

## **FORM 8-K** (Current report filing)

Filed 08/14/17 for the Period Ending 08/14/17

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

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

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**FORM 8-K**

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**CURRENT REPORT**

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

**Date of Report (Date of earliest event reported): August 14, 2017**

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**EVOKE PHARMA, INC.**

(Exact Name of Registrant as Specified in its Charter)

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**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.)**

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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.

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**Item 2.02 Results of Operations and Financial Condition.**

On August 14, 2017, Evoke Pharma, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 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*

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<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release issued on August 14, 2017

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**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: August 14, 2017

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

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## Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on August 14, 2017



Investor Contact:  
 The Ruth Group  
 Tram Bui  
 Tel: 646-536-7035  
[tbui@theruthgroup.com](mailto:tbui@theruthgroup.com)

## **Evoke Pharma Reports Second Quarter 2017 Results and Highlights**

- Collaborated with Spaulding Clinical Research LLC and today announced the initiation of the comparative exposure pharmacokinetic (PK) study
- Partnered with Rho, Inc. for the preparation of the 505(b)(2) New Drug Application (NDA) for Gimoti™
- NDA submission remains on track for late 2017/early 2018

SOLANA BEACH, CA, August 14, 2017 – Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced its financial results for the second quarter ended June 30, 2017.

Dave Gonyer, R.Ph., President and CEO, stated, “Throughout the first half of the year, we worked diligently toward initiation of our PK study to ensure that the design, which was reviewed by FDA at a Type A meeting in March, was appropriate to demonstrate comparative exposure to the listed drug, Reglan® Tablets. In the second quarter, we announced that we re-engaged Spaulding Clinical Research, LLC, the firm that completed our successful thorough ECG study, for the comparative exposure PK study. Today, we announced the initiation of the PK study marking another milestone in our development path for Gimoti and moving us closer to our planned 505(b)(2) NDA filing. In parallel with the PK study, we have continued preparation of the NDA for submission as quickly as possible following completion of the study. The NDA is being prepared in partnership with Rho, a well-established Contract Research Organization (CRO) that has worked on other successful gastrointestinal NDA submissions in the recent past, and we are leveraging their dedicated team to help prepare a successful NDA for Gimoti. We expect to complete the analysis of the trial data and announce results in the fourth quarter of 2017, followed by a potential NDA submission by the end of this year or in early 2018.”

Mr. Gonyer continued, “As we prepare for the remainder of the year, we believe that we have laid the necessary groundwork to successfully bring Gimoti to potential approval. We have a balance sheet which will allow us to complete the PK study and submit our NDA. Our three meetings with FDA over the past year have reaffirmed our path to submission for Gimoti, and we remain confident that we will be able to introduce a much-needed alternative treatment for patients suffering from diabetic gastroparesis.”

### **Second Quarter 2017 Financial Review**

For the second quarter of 2017, net loss was approximately \$1.6 million, or \$(0.11) per basic share, compared to a net loss of approximately \$3.0 million, or \$(0.41) per share, for the three-month period ended

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June 30, 2016. Research and development expenses totaled approximately \$2.0 million for the three months ended June 30, 2017, compared to approximately \$2.1 million for the three months ended June 30, 2016.

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For the second quarter of 2017, general and administrative expenses were approximately \$872,000 compared to approximately \$803,000 for the second quarter of 2016.

Total operating expenses for the three months ended June 30, 2017 and 2016 were approximately \$2.9 million.

The net loss for the second quarter of 2017 was partially offset by a gain of approximately \$1.3 million due to the change in the fair value of warrant liability. 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 June 30, 2017, our cash and cash equivalents were approximately \$12.6 million.

### **Conference Call and Webcast**

Evoke will hold a conference call on Monday, August 14, 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](http://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 August 21, 2017. The replay can be accessed by dialing 1-844-512-2921 (United States) or 1-412-317-6671 (International) with confirmation code 13666527.

### **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 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](http://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 for a successful 505(b)(2) NDA submission for Gimoti; the timing of announcement of the results of the PK study and the timing of the submission of the NDA to the FDA; Evoke's belief that it has laid the necessary groundwork for potential approval of Gimoti; Evoke's current resources being sufficient to allow Evoke to complete the PK study and submit the NDA; and Evoke's belief that there is a large unmet need for an effective treatment

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for diabetic gastroparesis. 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 initiating, conducting and receiving favorable results from the PK study; 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; risks associated with manufacturing new formulations of Gimoti for use in the PK study; Evoke's dependence on third parties for the manufacture of Gimoti; Evoke's dependence on Spaulding Clinical Research to conduct the PK study; Evoke's depending on Rho, Inc. to assist with the NDA submission for Gimoti; Evoke may require additional funding to complete the PK study 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; 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)

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**Evoke Pharma, Inc.**

**Condensed Balance Sheet**

	<b>June 30, 2017</b>	<b>December 31, 2016</b>
	<b>(Unaudited)</b>	
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 12,556,280	\$ 9,007,071
Prepaid expenses	587,932	267,711
Other current assets	—	7,997
Total current assets	<u>13,144,212</u>	<u>9,282,779</u>
Other assets	11,551	11,551
Total assets	<u>\$ 13,155,763</u>	<u>\$ 9,294,330</u>
<b>Liabilities and stockholders' equity</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 1,121,519	\$ 478,223
Accrued compensation	<u>757,492</u>	<u>933,450</u>
Total current liabilities	1,879,011	1,411,673
Warrant liability	<u>4,506,763</u>	<u>4,095,019</u>
Total liabilities	6,385,774	5,506,692
Stockholders' equity:		
Common stock	1,539	1,235
Additional paid-in capital	72,255,601	62,595,546
Accumulated deficit	<u>(65,487,151)</u>	<u>(58,809,143)</u>
Total stockholders' equity	6,769,989	3,787,638
Total liabilities and stockholders' equity	<u>\$ 13,155,763</u>	<u>\$ 9,294,330</u>

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**Evoke Pharma, Inc.**

**Condensed Statement of Operations  
(Unaudited)**

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Operating expenses:				
Research and development	\$ 2,017,569	\$ 2,095,149	\$ 2,788,255	\$ 4,110,225
General and administrative	871,979	802,655	2,081,549	1,940,408
Total operating expenses	2,889,548	2,897,804	4,869,804	6,050,633
Loss from operations	(2,889,548)	(2,897,804)	(4,869,804)	(6,050,633)
Other income (expense):				
Interest income (expense), net	1,667	(72,694)	2,631	(145,274)
Change in fair value of warrant liability	1,261,912	—	(1,810,835)	—
Total other income (expense), net	1,263,579	(72,694)	(1,808,204)	(145,274)
Net loss	\$ (1,625,969)	\$ (2,970,498)	\$ (6,678,008)	\$ (6,195,907)
Net loss per share of common stock, basic	\$ (0.11)	\$ (0.41)	\$ (0.46)	\$ (0.86)
Net loss per share of common stock, diluted	\$ (0.19)	\$ (0.41)	\$ (0.55)	\$ (0.86)
Weighted-average shares used to compute basic net loss per share	15,343,325	7,217,577	14,435,818	7,192,791
Weighted-average shares used to compute diluted net loss per share	15,421,057	7,217,577	14,474,684	7,192,791