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): November 13, 2018

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 (<i>see</i> 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. \boxtimes | | | | | | |
| | | | | | | |

Item 2.02 Results of Operations and Financial Condition.

On November 13, 2018, Evoke Pharma, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2018. 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 <u>Press Release issued on November 13, 2018 .</u>

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: November 13, 2018 By: /s/ Matthew J. D'Onofrio

Name: Matthew J. D'Onofrio
Title: Executive Vice President,

Chief Business Officer and Secretary



Investor Contact: The Ruth Group Tram Bui Tel: 646-536-7035 tbui@theruthgroup.com

Evoke Pharma Reports Third Quarter 2018 Results

April 1, 2019 PDUFA date for GimotiTM NDA

Cash runway extended through June 2019

SOLANA BEACH, CA, November 13, 2018 – 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, 2018.

"This quarter we continued to make progress with Gimoti™, our novel nasal delivery of metoclopramide, to offer a new path for the treatment of women suffering from gastroparesis," said, Dave Gonyer, R.Ph., President and CEO. "The NDA review process with FDA is underway as well as preparations for potential commercialization of Gimoti. We project our cash runway to be through June 2019, past the Prescription User Fee Act (PDUFA) target date of April 1, 2019."

Third Quarter 2018 Financial Review

For the third quarter of 2018, net loss was approximately \$1.5 million, or \$(0.09) per share, compared to a net loss of approximately \$5.2 million, or \$(0.34) per share, for the three-month period ended September 30, 2017.

Research and development expenses totaled approximately \$625,000 for the three months ended September 30, 2018, compared to approximately \$2.7 million for the same period in 2017. For the third quarter of 2018, general and administrative expenses were approximately \$897,000, compared to approximately \$984,000 for the third quarter of 2017.

Total operating expenses for the three months ended September 30, 2018 were approximately \$1.5 million, compared to approximately \$3.7 million for the same period in 2017.

As of September 30, 2018, our cash and cash equivalents were approximately \$6.6 million.

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 FDA action on the NDA for Gimoti; Evoke's plans for commercialization of Gimoti; Evoke's projected cash runway; and the potential of Gimoti to offer a new treatment option for women suffering from gastroparesis. 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 potential for the FDA to delay the PDUFA target action date due to the FDA's internal resource constraints or other reasons; the FDA may disagree that the existing safety database and efficacy data is sufficient to allow approval of the NDA, including as a result of the potential review issues identified by the FDA in the Day-74 Letter such as, among others, Cmax falling below the bioequivalence range in the comparative exposure PK trial, 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 adequacy of the proposed REMS included in the NDA, and the existing data supporting a female-only indication; the FDA may not agree with Evoke's interpretation of the results of clinical trials of Gimoti; later developments with the FDA that may be inconsistent with the already completed pre-NDA meetings; the possibility of an advisory committee meeting related to the NDA; the inherent risks of clinical development of Gimoti; the possibility of the FDA failing to finally approve Evoke's proposed proprietary name through the NDA review process; 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 will successfully commercialize Gimoti: Evoke will require substantial additional funding to conduct any new trials required by the FDA, and to conduct pre-commercialization activities and to commercialize Gimoti, if approved, 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. Balance Sheet

| | | eptember 30, 2018 Unaudited) | D | ecember 31, 2017 | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|---------------------------------------------------|----|---------------------------------------------------------------|--|
| Assets | , | · | | | |
| Current Assets: | | | | | |
| Cash and cash equivalents | \$ | 6,567,918 | \$ | 7,679,267 | |
| Prepaid expenses | | 438,957 | | 251,046 | |
| Total current assets | | 7,006,875 | | 7,930,313 | |
| Other assets | | 11,551 | | 11,551 | |
| Total assets | \$ | 7,018,426 | \$ | 7,941,864 | |
| Liabilities and stockholders' equity Current Liabilities: Accounts payable and accrued expenses Accrued compensation Total current liabilities Warrant liability Total liabilities | \$ | 625,994 984,683 1,610,677 — 1,610,677 | \$ | 1,048,927 1,025,911 2,074,838 3,701,277 5,776,115 | |
| Stockholders' equity: | | | | | |
| Common stock | | 1,743 | | 1,541 | |
| Additional paid-in capital | | 82,250,109 | | 73,202,863 | |
| Accumulated deficit | | (76,844,103) | | (71,038,655) | |
| Total stockholders' equity | | 5,407,749 | | 2,165,749 | |
| Total liabilities and stockholders' equity | \$ | 7,018,426 | \$ | 7,941,864 | |

Evoke Pharma, Inc. Statements of Operations (Unaudited)

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|----------------------------------------------------------------------------------------------------------------------|-------------------------------------|-------------|----|-------------|------------------------------------|-------------|----|--------------|
| | | 2018 | | 2017 | | 2018 | | 2017 |
| Operating expenses: | | | | | | | | _ |
| Research and development | \$ | 625,497 | \$ | 2,717,698 | \$ | 3,399,654 | \$ | 5,505,953 |
| General and administrative | | 897,060 | | 984,047 | | 2,846,611 | | 3,065,595 |
| Total operating expenses | | 1,522,557 | | 3,701,745 | | 6,246,265 | | 8,571,548 |
| Loss from operations | | (1,522,557) | | (3,701,745) | | (6,246,265) | | (8,571,548) |
| Other income (expense): | | | | | | | | |
| Interest income | | 3,089 | | 2,822 | | 7,425 | | 5,452 |
| Change in fair value of warrant liability | | <u> </u> | | (1,544,138) | | 433,392 | | (3,354,973) |
| Total other income (expense) | | 3,089 | | (1,541,316) | | 440,817 | | (3,349,521) |
| Net loss | \$ | (1,519,468) | \$ | (5,243,061) | \$ | (5,805,448) | \$ | (11,921,069) |
| Net loss per share of common stock, basic | \$ | (0.09) | \$ | (0.34) | \$ | (0.36) | \$ | (0.81) |
| Net loss per share of common stock, diluted | \$ | (0.09) | \$ | (0.34) | \$ | (0.36) | \$ | (0.84) |
| Weighted-average shares used to compute basic net loss per share Weighted-average shares used to compute diluted net | | 17,129,649 | | 15,351,295 | | 16,327,385 | _ | 14,740,977 |
| loss per share | | 17,129,649 | | 15,351,295 | | 16,327,385 | _ | 14,766,853 |