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): March 10, 2016

EVOKE PHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-36075 (Commission File Number)

505 Lomas Santa Fe Drive, Suite 270 Solana Beach, California (Address of Principal Executive Offices) 20-8447886 (IRS Employer Identification No.)

> 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))

Item 2.02 Results of Operations and Financial Condition.

On March 10, 2016, Evoke Pharma, Inc. issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2015. 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> 99.1

Press Release issued on March 10, 2016.

Description

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: March 10, 2016

By:/s/ Matthew J. D'OnofrioName:Matthew J. D'OnofrioTitle:Executive Vice President,
Chief Business Officer and Secretary



Investor Contact: The Ruth Group

David Burke Tel: 646-536-7009 <u>dburke@theruthgroup.com</u>

Media Contact: The Ruth Group Kirsten Thomas Tel: 646-536-7014 kthomas@theruthgroup.com

Evoke Pharma Reports Fourth Quarter and Year End 2015 Results

Provides Outlook for Completing Phase 3 Clinical Trial and Upcoming NDA Submission

SOLANA BEACH, CA, March 10, 2016 – Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced its financial results for the fourth quarter and year ended December 31, 2015.

Dave Gonyer, R.Ph., President and CEO, stated, "2015 was a significant year for Evoke, as we hit numerous milestones needed for the submission of a New Drug Application (NDA) for EVK-001, our lead product candidate to treat diabetic gastroparesis in women. In addition to these development objectives, including commercial scale production and advancing the Phase 3 trial, we maintained an active and productive dialogue with the FDA. This open communication resulted in a favorable response from the FDA, as they accepted our pediatric study plan, which included a full waiver of the requirement to conduct pediatric studies. In addition, the FDA published draft guidance which contained their current recommendations on clinical trial design and study endpoints for drug development in the treatment of gastroparesis. We believe these recommendations are consistent with our Phase 3 trial design, and based on this guidance, we believe there is less regulatory risk with our development program for EVK-001 as we approach the end of our current Phase 3 trial."

Mr. Gonyer continued, "Looking ahead, we believe that 2016 is a pivotal year for the Company. There are several key objectives we have been targeting since our inception, and we are positioned to achieve them this year. First, we are on track to complete enrollment of our Phase 3 trial in the near term with data expected soon after the last subject is out. Once these results are finalized, we will be able to move forward with a pre-NDA meeting with the FDA and NDA submission for potential approval. We will be considering many strategic avenues for commercialization and partnership in concert with the reporting of the data. These efforts may allow us to provide a safe and more effective treatment option for a disease that impacts the daily lives of up to 16 million patients in the United States."

Fourth Quarter and Year End Financial Review

For the fourth quarter of 2015, net loss was approximately \$2.6 million, or \$0.37 per share, compared to a net loss of approximately \$2.9 million, or \$0.48 per share, for the three-month period ended December 31, 2014. For the year ended December 31, 2015, the net loss was approximately \$12.1 million, or \$1.87 per share. This compares to a net loss of approximately \$13.2 million, or \$2.20 per share, for 2014.

Research and development expenses totaled approximately \$1.7 million for the three months ended December 31, 2015, compared to approximately \$2.2 million for the three months ended December 31, 2014. For the full year 2015, research and development expenses were approximately \$8.2 million compared to approximately \$10.0 million in the prior year. The year-over-year decrease in research and development expense was primarily related to a prior year milestone payment and completion of a thorough ECG (QT/QTc) clinical trial.

For the fourth quarter of 2015, general and administrative expenses were approximately \$843,000 compared with approximately \$738,000 for the three months ended December 31, 2014. For the year ended December 31, 2015, general and administrative expenses were approximately \$3.7 million versus approximately \$3.2 million for the full year of 2014. The increase is attributable to an increase in stock-based compensation expense, as well as market research activities.

Total operating expenses for the three months ended December 31, 2015 were approximately \$2.6 million, compared to total operating expenses of approximately \$2.9 million for the three months ended December 31, 2014. For the year ended December 31, 2015, total operating expenses were approximately \$11.8 million compared to \$13.2 million for the full year of 2014.

As of December 31, 2015, the Company's cash and cash equivalents were approximately \$8.7 million.

Conference Call and Webcast

Evoke will hold a conference call on Thursday, March 10, 2016, at 4:30 p.m. ET to discuss the results. The dial-in numbers are 1-877-407-0789 for domestic callers and 1-201-689-8562 for international callers. The conference ID number for both is 13631636. 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 remain archived on Evoke's website for one year. In addition, a telephonic replay of the call will be available until March 17, 2016. The replay dial-in numbers are 1-877-870-5176 for domestic callers and 1-858-384-5517 for international callers. Please use event passcode 13631636.

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 EVK-001, 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. EVK-001 is a novel formulation of this drug, designed to provide systemic delivery of metoclopramide through nasal administration. Visit <u>www.EvokePharma.com</u> 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 enrollment completion of Evoke's ongoing Phase 3 clinical trial of EVK-001; and the submission of an NDA to the FDA and the regulatory approval process for EVK-001; the commercialization of or strategic partnering opportunities for EVK-001; and the potential approval and commercialization of EVK-001 as a safe and effective treatment for 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 risk and uncertainties inherent in Evoke's business, including, without limitation: the inherent risks of clinical development of EVK-001, including delays in enrollment and completion of the Phase 3 trial as well as potential delays in any other clinical trials and studies; Evoke is entirely dependent on the success of EVK-001, for which it has commenced a Phase 3 clinical trial and male companion trial, and Evoke cannot be certain that it will be able to obtain regulatory approval for, or successfully commercialize, EVK-001; the results observed in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in Evoke's Phase 2b clinical trial of EVK-001 may not be predictive of the safety and efficacy results in the Phase 3 clinical trial; Evoke will require substantial additional funding to potentially commercialize EVK-001 as well as to finance additional development requirements, if any, and may be unable to raise capital when needed, including to fund ongoing operations; the potential for adverse safety findings relating to EVK-001 to delay or prevent regulatory approval or commercialization; risks associated with changes in the FDA's draft guidance or in the FDA's view on the sufficiency of Evoke's trial design; 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 forwardlooking 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 Sheets

	D	December 31,					
	2015		2014				
Assets							
Current Assets:							
Cash and cash equivalents	\$ 8,691,1		14,155,809				
Prepaid expenses	833,2	276	931,461				
Other current assets			137,812				
Total current assets	9,524,4		15,225,082				
Other assets		997	7,997				
Total assets	<u>\$ </u>	428 \$	15,233,079				
Liabilities and stockholders' equity							
Current Liabilities:							
Accounts payable and accrued expenses	\$ 927,0	506 \$	1,011,629				
Accrued compensation	760,7	782	697,245				
Other current liabilities			12,313				
Current portion of long-term debt	146,0		126,806				
Total current liabilities	1,834,4	140	1,847,993				
Long-term debt, net of current portion	4,233,0		4,196,422				
Total liabilities	6,067,4	199	6,044,415				
Commitments and contingencies							
Stockholders' equity:							
Common Stock	·	720	611				
Additional paid-in capital	51,524,8	321	45,127,202				
Accumulated deficit	(48,060,0	512)	(35,939,149)				
Total stockholders' equity	3,464,9)29	9,188,664				
Total liabilities and stockholders' equity	\$ 9,532,4	428 \$	15,233,079				

Evoke Pharma, Inc. Statements of Operations

	Three Months Ended December 31,			Year Ended December 31,				
	2015		2014		2015		2014	
Operating expenses:								
Research and development	\$	1,708,302	\$	2,176,388	\$	8,154,144	\$	9,991,855
General and administrative		842,777		738,012		3,664,159		3,158,179
Total operating expenses		2,551,079		2,914,400		11,818,303		13,150,034
Loss from operations		(2,551,079)		(2,914,400)		(11,818,303)		(13,150,034)
Other expense		(73,073)		(5,403)		(303,160)		(97,647)
Net loss	\$	(2,624,152)	\$	(2,919,803)	\$	(12,121,463)	\$	(13,247,681)
Net loss per common share, basic and diluted	\$	(0.37)	\$	(0.48)	\$	(1.87)	\$	(2.20)
Weighted-average shares used to compute basic and diluted net loss per share		7,123,163		6,065,841		6,485,794		6,032,560