

Edgar Filing: Evoke Pharma Inc - Form 8-K

Evoke Pharma Inc
Form 8-K
March 21, 2017

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 21, 2017

EVOKE PHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	001-36075	20-8447886
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

420 Stevens Avenue, Suite 370

Solana Beach, California	92075
(Address of Principal Executive Offices)	(Zip Code)

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

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(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 7.01 Regulation FD Disclosure.

On March 21, 2017, Evoke Pharma, Inc. (the "Company") announced that the Company's abstract detailing Phase 3 trial data for Gimoti™ (metoclopramide nasal spray) for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women, was accepted for a poster presentation at Digestive Disease Week® (DDW) 2017. The poster presentation is entitled: Symptom Severity Influences Drug Efficacy in Women with Diabetic Gastroparesis: Results of a Phase 3 Study with Metoclopramide Nasal Spray.

The information in this Item 7.01 is being furnished pursuant to Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this item of this report.

Forward Looking Statements.

The Company cautions you that statements made in this Current Report on Form 8-K 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 to present at DDW and discuss the data from its Phase 3 trial for Gimoti; the benefits Gimoti may have for patients with moderate to severe gastroparesis symptoms; the utility of the Gimoti data to scientists and clinicians at DDW. 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 pharmacokinetic (PK) trial; later developments with the Food and Drug Administration (FDA) that may be inconsistent with the already completed pre-new drug application (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 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.

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.

Date: March 21, 2017 EVOKE PHARMA, INC.

By: /s/ Matthew J. D'Onofrio

Name: Matthew J. D'Onofrio

Title: Executive Vice President

Chief Business Officer and Secretary