Evoke Pharma Inc
Form 8-K
April 04, 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): April 4, 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

(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 8.01Other Events.

SOLANA BEACH, CA, April 4, 2017 – Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that the Company recently completed a positive Type A meeting with the U.S. Food and Drug Administration (FDA) to finalize the design of the pivotal comparative exposure pharmacokinetic (PK) trial and to reach agreement on additional aspects of the Chemistry, Manufacturing & Controls (CMC) section of the New Drug Application (NDA) for Gimoti™, the Company's patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women.

During a pre-NDA meeting announced in December 2016, FDA agreed with Evoke that a comparative exposure PK trial to demonstrate the bioequivalence of Gimoti in healthy volunteers could serve as the basis for a 505(b)(2) NDA submission for Gimoti. FDA recommended that Evoke submit the trial protocol for review prior to initiating the study, which Evoke provided in early March 2017. The Type A meeting was granted to allow comment and discussion with FDA regarding the structure, population and overall design of the PK trial. After discussing the protocol design with FDA, Evoke has agreed with their comments and plans to incorporate the Agency's recommendations in the final protocol.

The pivotal comparative exposure PK trial will be conducted in healthy volunteers to demonstrate the bioequivalence of Gimoti to the reference listed drug, Reglan® Tablets. The Company is preparing to execute the trial and expects to have results in the second half of 2017. Additionally, agreement was received on items related to the CMC section of the NDA during the Type A meeting. The Company believes it will be able to submit the NDA for Gimoti by late 2017 or early 2018.

Forward Looking Statements.

The Company cautions you that statements included in this Current Report on Form 8-K 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 plans to incorporate the Agency's recommendations in the final trial protocol; the trial being the last outstanding item needed prior to submission of the NDA for Gimoti; and Evoke's plans to conduct and complete the PK trial and submit the NDA and the timing thereof. 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 trial; later developments with FDA that may be inconsistent with the already completed pre-new drug application (NDA) and Type A 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 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;; 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: April 4, 2017 EVOKE PHARMA, INC.

By: /s/ Matthew J. D'Onofrio

Name: Matthew J. D'Onofrio

Title: Executive Vice President

Chief Business Officer and Secretary