Evoke Pharma Inc
Form 8-K
December 15, 2016

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): December 15, 2016

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.)

505 Lomas Santa Fe Drive, Suite 270

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.

Evoke Pharma, Inc. (the “Company”), a specialty pharmaceutical company focused on treatments for gastrointestinal diseases, today announced positive guidance from a recent second pre-NDA (New Drug Application) meeting to discuss clinical data for inclusion in a 505(b)(2) NDA for Gimoti™ with the US Food and Drug Administration (“FDA”). This pre-NDA meeting was the second 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.

Following discussion of the clinical data the Company provided for this meeting, the FDA agreed that demonstration of equivalent exposure to the listed drug (Reglan® 10 mg Tablets) in a healthy volunteer pharmacokinetic (“PK”) trial could serve as a portion of an NDA for Gimoti. Upon demonstration of appropriate exposure in a PK trial, the Company will submit the PK data and prior clinical studies to the Agency for review in the Gimoti NDA. The FDA agreed that no new efficacy or safety study would be required, if bioequivalence criteria were met. During NDA review and labeling negotiations, safety and efficacy data from completed Gimoti studies, including the thorough ECG study, may be used to support information included in the Gimoti label.

For this pre-NDA meeting, the Company provided Phase 3 data that showed statistically significant efficacy compared to placebo for patients with moderate to severe symptoms at baseline in a post-hoc analysis. The moderate to severe population consisted of more than half of the 205 women participating in the trial. The benefit for Gimoti compared to placebo in this population was demonstrated at various time points in the intent-to-treat, per protocol, and completer populations. In addition, favorable safety data from the placebo-controlled studies in diabetic gastroparesis patients and the studies in healthy volunteer will support the planned Gimoti NDA.

In the first pre-NDA meeting with the FDA held in August 2016, the Company confirmed various regulatory, chemistry, manufacturing, and control, and non-clinical requirements for the Company’s potential NDA submission.

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: the submission of an NDA for Gimoti based on a new PK trial without the need for additional efficacy studies and the FDA’s agreement on such approach, and the Company’s plans to conduct the PK trial and submit the NDA and potentially receive regulatory approval of Gimoti. The inclusion of

forward-looking statements should not be regarded as a representation by the Company 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 the Company's business, including, without limitation: risks associated with successfully commencing and receiving favorable results from the planned PK trial; later developments with the FDA that may be inconsistent with the already completed pre-NDA meetings, including inconsistent conclusions reflected in the official meeting minutes from the FDA; the inherent risks of clinical development of Gimoti; the Company is entirely dependent on the success of Gimoti, and the Company 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; the Company's dependence on third parties for the manufacture of Gimoti as well as the conduct of the PK trial; the Company 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; the Company 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 the Company's 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 the Company undertakes no obligation to revise or update this report 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.

EVOKE PHARMA, INC.

Date: December 15, 2016

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