Evoke Pharma Inc
Form 8-K
August 14, 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): August 14, 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))
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.

Item 8.01Other Event.

On August 14, 2017, Evoke Pharma, Inc. (“Evoke” or “the Company”) issued a press release announcing the initiation of its comparative exposure pharmacokinetic (PK) trial for Gimoti™, the Company’s patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis.

The study is designed to demonstrate that the proposed dose of Gimoti has similar systemic exposure to that of the listed drug, Reglan® Tablets, and PK data will be part of the basis for the Company’s planned 505(b)(2) new drug application (NDA) to the U.S. Food and Drug Administration (FDA). The study is a single dose, crossover design in which approximately 100 healthy volunteers will receive Reglan Tablets and three different doses of Gimoti. The study will be conducted by Spaulding Clinical Research, a clinical research organization (CRO) that successfully completed the Company’s thorough ECG trial for Gimoti in 2014. The Company expects to complete the analysis of the trial data and announce results in the fourth quarter of 2017, followed by a potential NDA submission in late 2017 or early 2018.

Forward Looking Statement

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 Company’s plans to include the PK data in the 505(b)(2) NDA for Gimoti; the timing of announcement of the results of the PK trial and the timing of the submission of the NDA to the FDA; the Company’s expectation that Spaulding Clinical Research will complete the study; the Company’s expectation that the PK trial will be the final clinical trial for Gimoti; and the Company’s belief that there is a large unmet need for an effective treatment for diabetic gastroparesis. 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 initiating, conducting and receiving favorable results from the 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 submission of the NDA; the Company’s dependence on Spaulding Clinical Research to conduct 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; 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: August 14, 2017

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