Evoke Pharma Inc
Form 8-K
October 23, 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): October 23, 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 October 23, 2017, Evoke Pharma, Inc. (the “Company”) announced positive topline results from the Company’s comparative exposure pharmacokinetic (“PK”) study. The trial was designed to demonstrate that a proposed dose of Gimoti, the Company’s patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis, has similar systemic exposure to that of the referenced listed drug (“RLD”), Reglan Tablets. Based on these results, the Company will submit a 505(b)(2) New Drug Application (“NDA”) with a selected Gimoti dose to the U.S. Food and Drug Administration (“FDA”) in the first quarter of 2018.

The PK study was an open label, 4-way crossover and enrolled 108 male and female healthy volunteers who were each to receive one Reglan Tablet dose and three different doses of Gimoti in a random sequence. Following discussions at pre-NDA meetings with FDA, Evoke planned to select a Gimoti dose based on criteria that includes a 90% confidence interval for the ratio of area under the plasma concentration curve (“AUC”) falling within the bioequivalence range of 80-125% of the RLD. Two of the three doses tested met the selection criteria. The maximum observed plasma concentration (C_{max}) for Gimoti was slightly lower than the bioequivalence range, which had been previously discussed with FDA as a likely outcome given the different route of administration and prior Gimoti PK study results. Additionally, data showed the AUC and C_{max} increased in a dose related manner across all three strengths tested. Relative to safety, all Gimoti doses were well tolerated with no clinically significant adverse events reported following any of the doses.

Safe Harbor Statement

Evoke cautions you that statements included in this report 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’s beliefs about the study data, including that the objective of the PK study has been met on the measure of AUC and that the topline results demonstrate comparable bioequivalence between the oral Reglan Tablets and Gimoti’s nasal delivery; beliefs that the AUC measurement is the most clinically relevant PK parameter for this study; the timing of the submission of the NDA to the FDA; Evoke’s expectation that the PK trial will be the final clinical trial for Gimoti prior to NDA submission; Evoke’s believe that Gimoti may become the new standard of care for patients suffering from gastroparesis; and Evoke’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 Evoke's business, including, without limitation: the topline data Evoke has reported from the PK study is based on preliminary analysis of key data, and such data may change following a more comprehensive review of the data related to the PK study and such topline data may not accurately reflect the complete results of the study, and the FDA may not agree with Evoke’s interpretation of such results, including risks associated with C_{max} falling below the bioequivalence range; 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; risks that the FDA may require additional efficacy or safety studies prior to submission or approval of the NDA;

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; Evoke's dependence on third parties for the manufacture of Gimoti as well as the submission of the NDA; Evoke may require additional funding to submit the NDA and conduct any additionally required studies, 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 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 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: October 23, 2017

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