Evoke Pharma Inc
Form 8-K
August 16, 2018

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 16, 2018

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 Events.

On August 16. 2018, Evoke Pharma, Inc. (“Evoke” or the “Company”) announced that the Company’s 505(b)(2) New Drug Application (“NDA”) for Gimoti™ has been accepted for review by the U.S. Food and Drug Administration (“FDA”). In its Filing Communication/Day-74 letter, FDA stated that the NDA is sufficiently complete to permit a substantive review and set a target goal date under the Prescription Drug User Fee Act (“PDUFA”) of April 1, 2019.

The Day-74 letter did not indicate that FDA is planning to hold an advisory committee meeting to discuss the NDA. Additionally, in a separate communication, FDA has conditionally accepted the proprietary brand name, Gimoti.

Safe Harbor Statement

The Company 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,” “predic “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 potential timing of FDA action on the NDA for Gimoti; and Evoke’s plans to work with FDA during the NDA review process. 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 report due to the risks and uncertainties inherent in Evoke's business, including, without limitation: the potential for FDA to delay the PDUFA target action date due to FDA's internal resource constraints or other reasons; FDA may disagree that the existing safety database and efficacy data is sufficient to allow approval of the NDA, including as a result of the potential review issues identified by FDA in the Day-74 letter such as, among others, C_{max} falling below the bioequivalence range in the comparative exposure PK trial, the proposed duration of use for Gimoti being shorter as compared to the maximum approved dosing duration for the referenced listed drug, Reglan Tablets, and the available safety database supporting such duration, the adequacy of the proposed REMS included in the NDA, and the existing data supporting a female-only indication; FDA may not agree with Evoke's interpretation of the results of clinical trials of Gimoti; later developments with FDA that may be inconsistent with the already completed pre-NDA meetings; the possibility of an advisory committee meeting related to the NDA; the inherent risks of clinical development of Gimoti; the possibility of FDA failing to finally approve Evoke’s proposed proprietary name through the NDA review process; Evoke is entirely dependent on the success of Gimoti, and Evoke cannot be certain that FDA will approve the NDA for Gimoti or that Evoke will successfully commercialize Gimoti; Evoke will require substantial additional funding to conduct any new trials required by FDA, 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 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 16, 2018

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