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): March 4, 2019

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** **(Address of Principal Executive Offices)**	**92075** **(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 8.01 Other Events.

On March 4, 2019, Evoke Pharma, Inc. (“Evoke” or the “Company”) announced the receipt of a multi-disciplinary review (“DR”) letter from the U.S. Food and Drug Administration (“FDA”) in association with the Gimoti 505(b)(2) New Drug Application (“NDA”). A DR letter is used by the FDA to convey preliminary thoughts on deficiencies identified during the initial stage of NDA review.

The letter described concerns in three sections of the NDA: Chemistry (combination product quality control and reproducibility specific to the commercially available sprayer device used with Gimoti); Clinical (lack of adequate information to support sex-based efficacy differences); and Clinical Pharmacology (maximum concentration (Cmax) not within the parameters for bioequivalence for abbreviated NDAs). Although a DR letter reflects preliminary comments that are subject to change and does not reflect a final FDA decision on the NDA, approval of Gimoti by the PDUFA date of April 1, 2019 is uncertain given the letter.

The Company plans to respond to the deficiencies raised in the DR letter to allow time for potential FDA review prior to the PDUFA date.

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: the potential timing of FDA action on the NDA and potential approval; and Evoke’s plans to respond to and address the deficiencies raised in the DR letter, and the potential for the FDA to review such responses prior to the PDUFA date. 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: Evoke may be unable to timely respond and successfully address the concerns raised by the DR letter; the FDA may not be able to consider Evoke’s response before it takes final action on the NDA; the increased risk of the FDA issuing a Complete Response Letter (“CRL”) based on the deficiencies raised in the DR letter or other issues identified by the FDA as it completes its review of the NDA; the potential delay in the PDUFA target action date; the inherent risks of clinical development of Gimoti; Evoke could face significant additional costs due to additional regulatory requests, litigation or other events; Evoke is entirely dependent on the success of Gimoti, and Evoke cannot be certain that FDA will approve the NDA for Gimoti; Evoke will require substantial additional funding to address any deficiencies raised in a potential CRL, and may be unable to raise capital or obtain funds 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 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: March 4, 2019

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