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): April 2, 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 April 2, 2019, Evoke Pharma, Inc. (“Evoke” or the “Company”) announced that it had received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for its 505(b)(2) New Drug Application (NDA) for Gimoti™ for the relief of symptoms associated with acute and recurrent diabetic gastroparesis.

The CRL, which cites fewer issues than the recent multidisciplinary review letter, states that FDA has determined it cannot approve the NDA in its present form and provides recommendations to address the two remaining approvability issues in an NDA resubmission. The issues are related to clinical pharmacology and product quality/device quality. The Agency did not request any new clinical data and did not raise any safety concerns.

The clinical pharmacology issue was specific to a low C_{max} in subjects representing less than 5% of the total administered Gimoti doses in the pivotal pharmacokinetic (PK) study. The Agency stated the overall lower mean C_{max} was driven by the data from these few subjects. Without the aberrant doses, the Company’s analysis shows the data met the bioequivalence criteria for both men and women. The Agency recommended a root cause analysis to determine the origin of the PK variability and mitigation strategies to address the issue. Additionally, FDA requested data from previously planned registration batches of commercial product to be manufactured by the Company. These data were requested to provide additional support for the proposed acceptance criteria for droplet size distribution after actuation of the sprayer device.

The Company believes that the issues raised by the CRL, which were related to the concerns over reproducible dose delivery, can be addressed, and expects to meet and work with FDA to gain a full understanding of the Agency’s requirements for approval.

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,” “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 addressability of the approvability issues raised by FDA in the CRL; the Company’s plans to meet and work with FDA on the CRL deficiencies; and the potential for an NDA resubmission. 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 report due to the risks and uncertainties inherent in the Company’s business, including, without limitation: the Company may be unable to timely and successfully address the deficiencies raised in the CRL, including as a result of adverse findings from a root cause analysis or data from newly manufactured product batches; FDA may not agree with the Company's conclusion of the root cause analysis or may require the Company to conduct additional studies; the inherent risks of clinical development of Gimoti; The Company’s dependence on third parties for the manufacture of Gimoti and analysis of the PK data; the Company is entirely dependent on the success of Gimoti, and

the Company cannot be certain that FDA will accept or approve an NDA resubmission for Gimoti; the Company will require substantial additional funding to address the deficiencies raised in the CRL, and may be unable to raise capital or obtain funds when needed, including to fund ongoing operations; the Company could face significant additional costs due to additional litigation or other events; the Company's ability to maintain the continued listing of its common stock on the Nasdaq Capital Market; and other risks detailed in the Company'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: April 2, 2019

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