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): June 26, 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))

Title of each class	**Trading symbol**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	EVOK	The Nasdaq Capital Market

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 June 27, 2019, Evoke Pharma, Inc. (“Evoke” or the “Company”) issued a press release announcing that it has submitted a type A meeting request and meeting package to the U.S. Food and Drug Administration (FDA) to discuss the Complete Response Letter (CRL) dated April 1, 2019 regarding Evoke’s New Drug Application (NDA) for Gimoti™ for the relief of symptoms associated with acute and recurrent diabetic gastroparesis.

The purpose of the meeting is to discuss and gain clarity on the approvability issues relating to clinical pharmacology and product quality/device quality described in the CRL. During the meeting, Evoke plans to discuss the Company’s strategy to address these issues as well as any other matters pertaining to the steps required for the resubmission of the Gimoti NDA. No safety concerns were raised and no additional clinical data were requested in the CRL.

The type A meeting, if granted, is expected to occur within thirty days of FDA’s receipt of the meeting request and meeting package. Evoke will provide an update on the timing of resubmission of the NDA for Gimoti after receipt of the FDA’s final meeting minutes, which typically become available within 30 days after the type A meeting.

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 cited by FDA in the CRL; the potential for a Type A meeting to occur and the Company’s plans at such meeting and generally with respect to addressing 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 to schedule a Type A meeting; 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 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 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: June 27, 2019

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