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): December 20, 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.)

Securities registered pursuant to Section 12(b) of the Exchange Act

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

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 December 20, 2019, Evoke Pharma, Inc. (the "Company") announced that it has resubmitted its 505(b)(2) New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for Gimoti, the Company's nasal spray product candidate for the relief of symptoms in adult women with acute and recurrent diabetic gastroparesis.

The NDA for Gimoti was resubmitted based on feedback received during the Type A meeting with FDA in July 2019. The meeting was held to obtain feedback and agreement on the items cited as deficiencies in the Complete Response Letter ("CRL") issued by FDA in April 2019. In the CRL, FDA stated the NDA was not approvable as originally submitted and provided recommendations to address approvability issues related to clinical pharmacology and product quality/device quality

Based on specific FDA feedback, in the resubmission the Company has provided the requested additional information intended to address the deficiencies cited in the CRL. To address the clinical pharmacology issues, the resubmission includes an in-depth root cause analysis, and patient use and experience data from our clinical trials. To address product quality/device quality issues cited in the CRL, the resubmission includes 3-month stability data from commercial scale registration batches that met all product specifications and support the proposed acceptance criteria for performance characteristics and device quality control. Additionally, as requested by FDA, the resubmission includes data from an analysis of pump performance characteristics for the product used in the comparative bioavailability study and the product from commercial scale registration batches. The results of this testing showed all products performed within specifications.

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 Company's ability to address the issues raised by the FDA in its CRL regarding Gimoti, including by providing the information requested by FDA. 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 cannot be certain that FDA will accept or approve an NDA resubmission for Gimoti; 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 the newly manufactured product batches not fully addressing issues raised by the FDA in the CRL and Type A meeting; FDA may not agree with the Company's conclusion of the results from the manufacturing testing or the root cause analysis, or may require the Company to conduct additional studies; further analysis of the manufacturing data as part of the planned NDA resubmission altering the initial conclusions; the inherent risks of clinical development of Gimoti; the Company's dependence on third parties for the manufacture of Gimoti and analysis of the manufacturing data; the Company is entirely dependent on the success of Gimoti; the Company will require substantial additional funding to continue its operations beyond the second quarter of 2020, 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 prior reports filed 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: December 20, 2019

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