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): January 21, 2020

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 January 21, 2020, Evoke Pharma, Inc. (the "Company") announced that the U.S. Food and Drug Administration ("FDA") has accepted the Company's resubmission of its 505(b)(2) New Drug Application ("NDA") for Gimoti™, the Company's nasal spray product candidate for the relief of symptoms in adult women with acute and recurrent diabetic gastroparesis.

A six-month period of review from the FDA's date of receipt has been assigned for the resubmitted NDA and the application has been assigned a new Prescription Drug User Fee Act ("PDUFA") target goal date of June 19, 2020.

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 timing and results of any decision regarding the NDA from the FDA, including whether FDA will act by the PDUFA target goal date; the Company's belief that Gimoti, if approved, can fill an unmet medical need for the management of diabetic gastroparesis and improve the quality of life for patients suffering from the disease; and the Company's plans to focus on commercial readiness. 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 press release due to the risks and uncertainties inherent in the Company's business, including, without limitation: the potential for the FDA to delay the PDUFA target goal date due to the FDA's internal resource constraints or other reasons; the Company may be unable to timely and successfully address the deficiencies raised in the Complete Response Letter ("CRL") regarding Gimoti, 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; the FDA may later determine to hold an advisory committee meeting and risks associated therewith; the inherent risks of clinical development and regulatory approval 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 into 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 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: January 21, 2020

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