
**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): May 20, 2020

EVOKE PHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36075
(Commission
File Number)

20-8447886
(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.)

Title of each class
Common Stock,
par value \$0.0001 per share

Trading symbol
EVOK

Name of each exchange on which registered
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.

On May 20, 2020, Evoke Pharma, Inc. (“Evoke” or the “Company”) announced that the U.S. Food and Drug Administration (“FDA”) has conditionally accepted the proprietary brand name, “Gimoti,” for the Company’s nasal spray product candidate for the relief of symptoms in adult women with acute and recurrent diabetic gastroparesis as resubmitted in the 505(b)(2) New Drug Application (“NDA”).

The name Gimoti (pronounced “jye-MOH-tee”) was developed in compliance with FDA’s *Guidance for Industry, Contents of a Complete Submission for the Evaluation of Proprietary Names*. Based on the development program, which included research with physicians and pharmacists, as well as an international name assessment, the Company believes Gimoti is a proprietary name with strong marketing potential that is also consistent with FDA’s goal of preventing medication errors and potential harm to the public by ensuring that only appropriate proprietary names are approved for use.

About Evoke Pharma, Inc.

Evoke is a specialty pharmaceutical company focused primarily on the development of drugs to treat GI disorders and diseases. The Company is developing Gimoti, a nasal spray formulation of metoclopramide, for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women.

Diabetic gastroparesis is a GI disorder affecting millions of patients worldwide, in which the stomach takes too long to empty its contents resulting in serious GI symptoms as well as other systemic complications. The gastric delay caused by gastroparesis can compromise absorption of orally administered medications. Metoclopramide is currently available only in oral and injectable formulations and is the only drug currently approved in the United States to treat gastroparesis. Visit www.EvokePharma.com for more information.

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: whether conditional proprietary brand name approval will support the Company’s commercialization strategy, if Gimoti is approved; and potential FDA approval of the Gimoti NDA. 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: FDA may not approve the Gimoti NDA or give final approval of the Gimoti brand name; the potential for FDA to delay the PDUFA target goal date due to FDA’s internal resource constraints or other reasons; FDA may not agree with the Company’s conclusion of the results from the manufacturing testing or the root cause analysis the Company provided to address the deficiencies raised in the Complete Response Letter (CRL) regarding Gimoti; FDA may require the Company to conduct additional studies; 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; and other risks detailed in the Company’s prior 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.

Date: May 20, 2020

EVOKE PHARMA, INC.

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