Evoke Pharma Inc
Form 8-K
May 10, 2018

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 9, 2018

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		92075
(Address of Principal Executive Offices)		(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 Event.

On May 10, 2018, Evoke Pharma, Inc. (the “Company”) announced that the Mexican Institute of Industrial Property has issued a Notice that it intends to grant Mexican Patent Application MX/a/2014/002125 for Gimoti™, covering uses of metoclopramide for intranasal delivery for the treatment of symptoms associated with diabetic gastroparesis specifically for women. This will be the first North American patent for Gimoti with expiry in 2032.

Gastroparesis, which often compromises the ability for oral medications to pass through the stomach to allow predictable absorption, remains a significant burden on patients, 80% of whom are women. Through Evoke’s extensive research in this disease space, it has developed Gimoti, its intranasal formulation of metoclopramide intended to deliver an effective medication while bypassing the dysfunctional stomach. This non-oral treatment is critical in relieving symptoms of this disease, where approximately 4 million prescriptions of oral metoclopramide are written each year in the United States.

The Company is currently preparing to submit its 505(b)2 New Drug Application (NDA) for Gimoti to the U.S. Food and Drug Administration (FDA) within the second quarter 2018. The Company will also include definitive evidence from safety, efficacy and pharmacokinetic trials, including over 1,400 subjects, with the NDA in seeking FDA approval for Gimoti.

Safe Harbor Statement

The Company cautions you that statements included in this press release 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 anticipated expiration date of the Mexican patent; the Company’s plans to continue development of Gimoti specifically for women; anticipated timing to submit an NDA for Gimoti; and the potential timing of FDA approval, if any, of the NDA for Gimoti. 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 Company may spend its available cash faster than it anticipates; the FDA may disagree that the existing safety database is sufficient to allow an NDA submission and approval; risks associated with FDA review of the final results from the comparative exposure pharmacokinetic (PK) trial, including the FDA may not agree with the Company's interpretation of such results; later developments with the FDA that may be inconsistent with the already completed pre-NDA meetings and most recent correspondence; the inherent risks of clinical development of Gimoti; the Company may not be able to obtain, maintain and enforce its patents and other intellectual property rights, and it may be prohibitively difficult or costly to protect such rights; the scope of the patent to be issued by the Mexican Institute of Industrial Property may not provide the protections we expect; Evoke is entirely dependent on the success of Gimoti, and the Company cannot be certain that it will be able to submit an NDA for Gimoti or obtain regulatory approval for or successfully commercialize Gimoti; the Company will require substantial additional

funding to conduct any new safety trials required by the FDA, and may be unable to raise capital when needed, including to fund ongoing operations; 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 Evoke undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. his 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: May 10, 2018

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