Evoke Pharma Inc
Form 8-K
February 15, 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): February 15, 2018

EVOKE PHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

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|---|---|---|
| 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 February 15, 2018, Evoke Pharma, Inc. (the "Company") announced additional findings from its comparative exposure pharmacokinetic (PK) trial for Gimoti™, the Company's novel nasal spray delivery of metoclopramide for the treatment of symptoms associated with gastroparesis. Further analysis of the PK data by sex revealed statistically significant differences in exposure between women and men given the same metoclopramide dose (nasal and oral). The Company has filed new patent applications related to the discovery.

In December 2016, the Company announced the U.S. Food and Drug Administration (FDA) had agreed that a PK trial could serve as a basis for submission of a 505(b)(2) new drug application (NDA), along with efficacy and safety data from previous clinical trials. Recently, the Company announced that the comparative exposure PK trial met bioequivalence criteria for total exposure, or area under the curve (AUC). After additional analysis of the PK data, statistically significantly lower AUC's were found in men compared to women and was not explicitly attributable to the subject's body mass index (BMI) or weight. Similar differences in the metoclopramide PK parameters between women and men, regardless of the route of administration (nasal, oral and IV), were also found in a retrospective analysis of data from an earlier PK study conducted by the Company.

In the most recent comparative exposure PK trial, measurements for women independently met bioequivalence criteria for $AUC_{0\text{-}inf}$ and $AUC_{0\text{-}t}$ at the tested Gimoti dose to be proposed in the NDA. The Company plans to submit its NDA for a female-only indication based on a dose in women with equivalent exposure to Reglan Tablets (the reference listed drug) and will submit supporting efficacy and safety data from its Phase 2b and Phase 3 trials, specifically for women, at doses similar or lower than the dose to be proposed in the NDA.

In parallel, the Company recently held an additional pre-NDA meeting with FDA to discuss and clarify the Agency's expectations of items being prepared for inclusion in the NDA for Gimoti. The planned NDA will include the Company's proposal for a risk management strategy and a post-approval safety study that will be designed to confirm prior safety findings and rule-out possible differences with side effects compared to the Reglan oral tablet over 8 weeks. The Company expects to discuss the details of the post-marketing safety trial with FDA during the NDA review process. With the new sex-based findings, and to fully incorporate the feedback received by FDA at the pre-NDA meeting, the Company now expects to file the Gimoti NDA in the second quarter of 2018.

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," "predic "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 plans to pursue approval of Gimoti in adult women with diabetic gastroparesis; the Company's belief that the sex-based PK differences are important to gastroparesis treatment; the Company's plans with respect to the content of the NDA submission, including a proposed post-marketing risk management strategy and safety trial; and the timing of the NDA submission. 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 FDA may disagree that the existing safety database and efficacy data is sufficient to allow an NDA submission and approval, including risks

associated with $C_{max}$ falling below the bioequivalence range in the comparative exposure PK trial and the proposed duration of use for Gimoti being shorter as compared to the maximum approved dosing duration for the referenced listed drug, Reglan Tablets, and the available safety database supporting such duration; the FDA may not agree with the Company's interpretation of the results of clinical trials of Gimoti; the FDA may require additional evidence of sex-based PK differences of Gimoti before making a final decision on Gimoti; risks associated with the size, cost and duration of a post-marketing safety trials; later developments with the FDA that may be inconsistent with the already completed pre-NDA meetings; the inherent risks of clinical development of Gimoti; 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 trials required by the FDA, and may be unable to raise capital when needed, including to fund ongoing operations; the Company may not be able to obtain, maintain and

enforce intellectual property rights; 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.

EVOKE PHARMA, INC.

Date: February 15, 2018

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