

Edgar Filing: Evoke Pharma Inc - Form 8-K

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 March 5, 2018, Evoke Pharma, Inc. (the “Company”) announced that the U.S. Food and Drug Administration (FDA) granted the Company’s request for a small business waiver of the Prescription Drug User Fee Act (PDUFA) fee of approximately \$2.4 million for its 505(b)(2) New Drug Application (NDA) for Gimoti™, the Company’s nasal delivery of metoclopramide for the treatment of symptoms associated with gastroparesis in women. The Company remains on track to file the Gimoti NDA in the second quarter of 2018.

Item 7.01 Regulation FD Disclosure.

Additionally, the Company announced it is now able to extend its cash runway into October 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,” “predicts,” “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: March 5, 2018 By: /s/ Matthew J. D'Onofrio
Name: Matthew J. D'Onofrio
Title: Executive Vice President,
Chief Business Officer and Secretary