

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 14, 2019, Evoke Pharma, Inc. (“Evoke” or the “Company”) announced that it has submitted its response to the U.S. Food and Drug Administration’s (FDA) multi-disciplinary review (DR) letter that was received on March 1, 2019 in association with the Gimoti 505(b)(2) New Drug Application (NDA).

In addition, the Company requested a meeting with the FDA prior to the Prescription Drug User Fee Act (PDUFA) action date of April 1, 2019. The meeting was granted and will be held on March 21, 2019. The purpose of this meeting is to obtain FDA’s feedback on the Company’s responses.

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 potential timing of FDA action on the NDA and potential approval; and the timing and purpose of the meeting between the Company and the FDA. 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 FDA may choose to postpone or cancel the meeting; the Company may be unable to successfully address the concerns raised by the DR letter; the FDA may not be able to fully consider the Company’s response before it takes final action on the NDA; the increased risk of the FDA issuing a Complete Response Letter (“CRL”) based on the deficiencies raised in the DR letter or other issues identified by the FDA as it completes its review of the NDA; the potential delay in the PDUFA target action date; the inherent risks of clinical development of Gimoti; the Company could face significant additional costs due to additional regulatory requests, litigation or other events; the Company is entirely dependent on the success of Gimoti, and the Company cannot be certain that FDA will approve the NDA for Gimoti; the Company will require substantial additional funding to address any deficiencies raised in a potential CRL, and may be unable to raise capital or obtain funds when needed, including to fund ongoing operations; and other risks detailed in the Company’s 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 14, 2019 By: /s/ Matthew J. D’Onofrio
Name: Matthew J. D’Onofrio
Title: Executive Vice President,
Chief Business Officer and Secretary