

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))
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Item 8.01 Other Events

On June 1, 2016, Evoke Pharma, Inc. (the "Company") announced that the last subject completed treatment in its pivotal Phase 3 study for EVK-001, the Company's patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women. The primary endpoint in the four-week, U.S. multicenter, randomized, double-blind, placebo-controlled clinical trial is the change in gastroparesis symptoms at week four utilizing a proprietary Patient Report Outcome symptom assessment instrument. A total of 205 subjects, ages 18 to 75, were enrolled in the trial. The Company expects to report top-line Phase 3 study results early in the third quarter of 2016.

Forward-Looking Statements.

The Company cautions you that statements included in this Current Report on Form 8-K 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 timing of data from the Phase 3 clinical trial of EVK-001. 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 risk and uncertainties inherent in the Company's business, including, without limitation: the inherent risks of clinical development of EVK-001 as well as potential delays in any other clinical trials and studies; the Company is entirely dependent on the success of EVK-001, for which it has completed a Phase 3 clinical trial and continues enrollment in a male companion trial, and the Company cannot be certain that it will be able to obtain regulatory approval for EVK-001; the results observed in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in the Company's Phase 2b clinical trial of EVK-001 may not be predictive of the safety and efficacy results in the Phase 3 clinical trial; the Company will require substantial additional funding to potentially commercialize EVK-001 as well as to finance additional development requirements, and may be unable to raise capital when needed, including to fund ongoing operations; the potential for adverse safety findings relating to EVK-001 to delay or prevent regulatory approval or commercialization; and other risks detailed in the periodic reports the Company 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: June 2, 2016 By: /s/ Matthew J. D'Onofrio
Name: Matthew J. D'Onofrio
Title: Executive Vice President,
Chief Business Officer and Secretary