

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))
-

Item 8.01 Other Events.

On September 28, 2015, Evoke Pharma, Inc. (“Evoke” or “the Company”), announced that the Company has reached a key milestone under its \$4.5 million loan and security agreement (the credit facility) with Square 1 Bank (Square 1). As of today, the Company has enrolled 150 patients in its current Phase 3 clinical trial of EVK-001, its patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women.

According to the terms of the credit facility, Evoke is required to fulfill a 75% patient enrollment covenant in its ongoing Phase 3 clinical trial prior to November 1, 2015, which was achieved as of September 25, 2015.

Safe Harbor Statement

Evoke 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 enrollment completion of Evoke's ongoing Phase 3 clinical trial of EVK-001 and the potential approval and commercialization of EVK-001 as a safe and effective treatment for gastroparesis. The inclusion of forward-looking statements should not be regarded as a representation by Evoke that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risk and uncertainties inherent in Evoke's business, including, without limitation: the inherent risks of clinical development of EVK-001, including continued delays in enrollment and completion of the Phase 3 trial as well as potential delays in any other clinical trials and studies; Evoke is entirely dependent on the success of EVK-001, for which it has commenced a Phase 3 clinical trial and male companion trial, and Evoke cannot be certain that it will be able to obtain regulatory approval for, or successfully commercialize, EVK-001; the results observed in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in Evoke's Phase 2b clinical trial of EVK-001 may not be predictive of the safety and efficacy results in the Phase 3 clinical trial; Evoke will require substantial additional funding to complete the Phase 3 clinical trial and 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 Evoke'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. 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: September 28, 2015 By: /s/ Matthew J. D'Onofrio
Name: Matthew J. D'Onofrio
Title: Executive Vice President,
Chief Business Officer and Secretary