

Edgar Filing: Evoke Pharma Inc - Form 8-K

Evoke Pharma Inc
Form 8-K
February 02, 2015

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 2, 2015

EVOKE PHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

| | | |
|------------------------------|--------------|---------------------|
| Delaware | 001-36075 | 20-8447886 |
| (State or Other Jurisdiction | (Commission | (IRS Employer |
| of Incorporation) | File Number) | Identification No.) |

505 Lomas Santa Fe Drive, Suite 270

| | |
|--|------------|
| 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.)

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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 February 2, 2015, Evoke Pharma, Inc. (the "Company") provided an update on its clinical program for EVK-001, its novel metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women.

The Company is currently enrolling its Phase 3 clinical trial investigating the use of EVK-001 in a multicenter, placebo-controlled, double-blind, parallel-group study evaluating the efficacy, safety and population pharmacokinetics of EVK-001 in adult female subjects with diabetic gastroparesis. The trial is expected to enroll 200 subjects at sites across the United States. While the study is progressing according to plan at many of the clinical trial sites with previous gastroparesis study experience, overall enrollment has been slower than previously anticipated. To date, the trial has randomized 74 subjects. Although the trial sites have been screening significant numbers of subjects, patients with diabetic gastroparesis typically have symptoms that vary in timing and severity, unpredictable gastric emptying delays, and complex medical histories. This combination of factors creates a challenge for enrollment into diabetic gastroparesis trials. As a result, enrollment is projected to complete in the second half of the year. In response, Evoke has undertaken additional initiatives to increase enrollment to further assist clinical trial sites in the identification of eligible study subjects.

The Company's cash position as of December 31, 2014 was \$14.2 million, and the Company's management believes that this amount will be sufficient to fund the Company's operations through 2015.

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 enrollment completion of the Company's ongoing Phase 3 clinical trial of EVK-001 and the sufficiency of the Company's resources to fund operations through 2015. 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, including continued delays in enrollment and completion of the Phase 3 trial as well as potential delays in any other clinical trials and studies; 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 may spend its available cash faster than it anticipates; the Company 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; the Company's reliance on outsourcing arrangements for many of its activities, including clinical development and supply of EVK-001; and other risks detailed in 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: February 2, 2015 By: /s/ Matthew J. D'Onofrio
Name: Matthew J. D'Onofrio
Title: Executive Vice President,
Chief Business Officer and Secretary