

Edgar Filing: Evoke Pharma Inc - Form 8-K

Evoke Pharma Inc
Form 8-K
May 03, 2016

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): May 3, 2016

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 May 3, 2016, Evoke Pharma, Inc. (the "Company") announced that it expects to provide top line data results from its pivotal Phase 3 clinical trial of EVK-001 in women with symptoms associated with diabetic gastroparesis early in the third quarter of 2016. The study was designed to enroll approximately 200 subjects and the Company has confirmed that 205 subjects have now been randomized in the trial. EVK-001 is the Company's patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women.

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 and completion of the Phase 3 trial as well as potential delays in any other clinical trials and studies; the Company is entirely dependent on the success of EVK-001 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; 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: May 3, 2016 By: /s/ Matthew J. D'Onofrio
Name: Matthew J. D'Onofrio
Title: Executive Vice President,
Chief Business Officer and Secretary