

Evoke Pharma Inc
Form 8-K
September 07, 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): September 7, 2016

EVOKE PHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

505 Lomas Santa Fe Drive, Suite 270

001-36075
(Commission

File Number)

20-8447886
(IRS Employer

Identification No.)

92075

Solana Beach, California

(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.)

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 7, 2016, Evoke Pharma, Inc. (the Company) announced that it has completed a pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA) regarding its lead product candidate, Gimoti, its patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women. The focus of this pre-NDA meeting with FDA was the content of the regulatory, chemistry, manufacturing, and control (CMC), and non-clinical sections of the Company's planned NDA filing for Gimoti.

Prior to the pre-NDA meeting, the Company submitted an information package describing the proposed content and format of the regulatory, CMC, and non-clinical sections of the Gimoti NDA. The subsequent face-to-face pre-NDA meeting afforded the Company the opportunity to gain further understanding of the FDA's expectations regarding these key sections of the NDA.

Based on the FDA's response to the information package and the pre-NDA meeting discussion, the Company believes it now has the information needed to complete these sections of the NDA in a manner that will be acceptable for the FDA's review of the complete package.

The Company expects to request an additional pre-NDA meeting with the FDA in the near future regarding the clinical data to be included in the NDA.

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, 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: Gimoti's potential to benefit patients suffering from gastroparesis; potential NDA submission and regulatory pathway submission strategies for Gimoti, including the Company's belief that the sections of the NDA regarding the regulatory, CMC and non-clinical information will be acceptable to the FDA; the timing, if any, of an additional pre-NDA meeting with the FDA to discuss the clinical sections of the NDA; and the potential for regulatory approval and commercialization of Gimoti. 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 risk and uncertainties inherent in the Company's business, including, without limitation: additional analyses of data from the Phase 3 trial may produce negative or inconclusive results and may not serve as the basis for an NDA submission or regulatory approval; the final FDA minutes may be inconsistent with the Company's understanding of the FDA's position on the matters addressed at the meeting; or may be inconsistent with previously announced topline results; the inherent risks of clinical development of Gimoti; the Company is entirely dependent on the success of Gimoti, and it cannot be certain that it will be able to conduct additional trials of Gimoti or obtain regulatory approval for or successfully commercialize Gimoti; the Company will require substantial additional funding to continue to develop and commercialize Gimoti, and may be unable to raise capital when needed, including to fund ongoing operations; the Company may not be able to successfully commercialize Gimoti, if approved, as a result of risks associated with market acceptance, coverage and reimbursement and competing products; 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: September 7, 2016

By: /s/ Matthew J. D Onofrio

Name: Matthew J. D Onofrio

Title: Executive Vice President, Chief Business Officer
and Secretary