Evoke Pharma Inc
Form 8-K
July 18, 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): July 18, 2016

EVOKE PHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-36075**	**20-8447886**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
505 Lomas Santa Fe Drive, Suite 270		**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 July 18, 2016, Evoke Pharma, Inc. (the Company) a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, announced topline results from its Phase 3 clinical trial of EVK-001 in female patients with symptomatic diabetic gastroparesis. In this study, EVK-001, the Company s patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women, did not achieve its primary endpoint of symptom improvement at Week 4.

Preliminary review of topline data across all study sites revealed similar improvement in the EVK-001 and placebo groups at Week 4 as measured by the total symptom score as well as the individual scores for each of the signs and symptoms, but these results were not consistent across the study sites. Further evaluation of topline data revealed diary data from 28 of 41 of the enrolling sites showed a statistically-significant benefit at Week 4 for EVK-001 (p=0.006) in contrast to results from the other 13 sites that showed statistically significant benefit for placebo (p=0.002). Once the complete datasets and PK data are available, additional analyses will be conducted to further understand the discrepant results.

Safety results were consistent with findings from previous EVK-001 studies that showed the nasal formulation of metoclopramide has a favorable safety profile and is well-tolerated by healthy volunteers and patients with diabetic gastroparesis. In this Phase 3 study, there were slightly more reports of nasal irritation in subjects receiving placebo than in subjects receiving EVK-001.

The study was a U.S.-based, multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial to evaluate the efficacy, safety and population pharmacokinetics (PK) of EVK-001 in 205 adult female subjects with diabetic gastroparesis who received EVK-001 or placebo four times daily for four weeks. The primary endpoint was the change in symptoms from the baseline period to Week 4 as measured using a proprietary Patient Reported Outcome (PRO) instrument. The PRO was used to calculate a weekly score based on daily telephone diary entries by study subjects who reported the frequency and severity of their gastroparesis signs and symptoms.

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, , or 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 the Company s plans to conduct additional analysis of the trial data. 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: additional analyses of data from the Phase 3 trial may produce negative or inconclusive results, or may be inconsistent with previously announced topline results; the inherent risks of clinical development of EVK-001; Evoke is entirely dependent on the success of EVK-001, and Evoke cannot be certain that it will be able to conduct additional trials of EVK-001 or obtain regulatory approval for EVK-001; Evoke will require substantial additional funding to continue to develop EVK-001, and may be unable to raise capital when needed, including to fund ongoing operations; Evoke s ability to comply with the financial and other covenants under its loan and security agreement with Pacific Western Bank, which could result in an event of default and an acceleration of outstanding amounts owed under the loan; 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: July 18, 2016

By: /s/ Matthew J. D Onofrio
Name: Matthew J. D Onofrio
Title: Executive Vice President,

Chief Business Officer and Secretary