

Edgar Filing: Evoke Pharma Inc - Form 8-K

Evoke Pharma Inc
Form 8-K
April 14, 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): April 14, 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 April 14, 2015, Evoke Pharma, Inc. (the "Company") announced that it has completed the production of a commercial scale lot of EVK-001 as required by the U. S. Food and Drug Administration ("FDA").

With the completion of this large scale production of EVK-001, the Company has demonstrated its ability to manufacture EVK-001, its patented intranasal formulation of metoclopramide, at commercial scale quantities in accordance with the FDA standards for chemistry, manufacturing, and controls ("CMC"). In addition to data from this recent program, the Company has a three-year registration stability data package from previous studies which have all met proposed specifications. These CMC datasets will be used as part of a New Drug Application ("NDA") following data readout from the Company's ongoing pivotal Phase 3 clinical trial for EVK-001.

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 Company's datasets and completed and ongoing trials and studies serving as a basis for submission of an NDA. 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 Company is entirely dependent on the success of EVK-001, for which it has commenced a Phase 3 clinical trial and male companion trial, and the Company cannot be certain that it will be able to obtain regulatory approval for, or successfully commercialize, EVK-001; risks that issues with future manufacturing production will arise, whether as a result of noncompliance with CMC requirements or otherwise; the Company's reliance on outsourcing arrangements for many of its activities, including clinical development, manufacturing and supply of EVK-001, and the Company's current lack of long-term commercial manufacturing agreements; 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 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 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: April 14, 2015 By: /s/ Matthew J. D'Onofrio
Name: Matthew J. D'Onofrio
Title: Executive Vice President,
Chief Business Officer and Secretary