Evoke Pharma Inc
Form 8-K
August 18, 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): August 18, 2015

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		
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.)

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 8.01Other Events.

On August 18, 2015, Evoke Pharma, Inc. (the "Company") announced the receipt of a letter from the U.S. Food and Drug Administration ("FDA") indicating the agency’s concurrence with the Company’s proposed pediatric study plan for EVK-001. Pursuant to the terms of the letter, the FDA has accepted the Company’s EVK-001 pediatric study plan, which included a request for a full waiver of the requirement to conduct pediatric studies on the basis that diabetic gastroparesis is an adult disease. The Company expects that the pediatric study plan will be included in the Company’s anticipated New Drug Application ("NDA") filing with the FDA.

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 submission of an NDA with the FDA. 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; the FDA’s letter regarding the Company’s pediatric study plan is not binding on the FDA, and the FDA may revise its indications regarding such plan; 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 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 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: August 18, 2015

By: /s/ Matthew J. D'Onofrio
Name: Matthew J. D'Onofrio
Title: Executive Vice President,
Chief Business Officer and Secretary