Evoke Pharma Inc
Form 8-K
July 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): July 6, 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		
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 July 6, 2016, Evoke Pharma, Inc. (the “Company”) entered into a Master Services Agreement (the “Agreement”) with inVentiv Commercial Services, LLC (“inVentiv”), in connection with the Company’s preparation for commercial activities for EVK-001, its lead product candidate for the treatment of diabetic gastroparesis in women. The Company recently completed its Phase 3 clinical trial for EVK-001, with data expected early in the third quarter.

The Company’s partnership with inVentiv will enable the Company to build its commercial infrastructure as it prepares for the potential commercialization of EVK-001, pending the filing of a New Drug Application (“NDA”) and U.S. Food and Drug Administration (“FDA”) approval. Under the terms of the Agreement, inVentiv may provide services including, but not limited to, sales representatives, sales management, marketing, account management, advertising, medical communications, distribution support, and overall commercial management. The Company and inVentiv will negotiate project agreements to add commercial team members and capabilities on an as-needed basis over the coming months as certain development and regulatory milestones are met.

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," "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 sufficiency of such data and the other activities completed to data providing a basis for the submission of an NDA for EVK-001 to the FDA and the timing thereof; and the potential commercialization 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 as well as potential delays in any other clinical trials and studies; the Company is entirely dependent on the success of EVK-001, for which it has completed a Phase 3 clinical trial and continues enrollment in a 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 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 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; the Company may not be able to successfully commercialize EVK-001, 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: July 7, 2016 By: /s/ Matthew J. D'Onofrio
Name: Matthew J. D'Onofrio
Title: Executive Vice President,
Chief Business Officer and Secretary