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): February 15, 2017

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.)

420 Stevens Avenue, Suite 370 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 8.01 Other Events.

On February 15, 2017, Evoke Pharma, Inc. (the “Company” or “Evoke”), announced that it has received a letter from FDA exempting its late stage product, Gimoti™ from a Human Factors (HF) Validation study requirement prior to submission of a New Drug Application (NDA).

In February 2016, FDA published new guidance entitled “Applying Human Factors and Usability Engineering to Medical Devices”, which requires drug products classified as a drug/device combination, such as Gimoti, undergo evaluation that may require an HF Validation study as described in FDA’s Guidance.

To comply with this new Guidance, Evoke evaluated the need for an HF Validation study and submitted a HF assessment report to FDA for Gimoti using a Failure Mode and Effects Analysis risk analysis taking into account the intended uses, users, use environments, product-user interface, and associated medical factors. In their written response, FDA stated Evoke had adequately considered the risks associated with the proposed Gimoti nasal spray and determined that an HF Validation study is not needed at this time. The favorable FDA response helps reduce potential risks and saves additional resources in the development process including NDA preparation.

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 FDA’s decision to exempt the Company from conducting an HF Validation study prior to submitting the NDA for Gimoti; and the timing of Evoke’s submission of the NDA for Gimoti to 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 press release due to the risks and uncertainties inherent in the Company’s business, including, without limitation: the FDA may determine based on further review to require the Company to complete an HF Validation study prior to submitting the NDA for Gimoti; risks associated with successfully commencing and receiving favorable results from the planned pharmacokinetic (“PK”) study; later developments with the FDA that may be inconsistent with the already completed pre-NDA meetings, including that the FDA will not accept selected data from our Phase 3 clinical trial; the FDA may change its recommendations regarding evaluation of drugs for the treatment of gastroparesis; the inherent risks of clinical development of Gimoti; Evoke is entirely dependent on the success of Gimoti, and Evoke cannot be certain that it will be able to submit an NDA for Gimoti or obtain regulatory approval for or successfully commercialize Gimoti; risks associated with manufacturing new formulations of Gimoti for use in the PK trial; Evoke’s dependence on third parties for the manufacture of Gimoti as well as the conduct of the PK trial; Evoke may require additional funding to complete the PK study and submit the NDA, and will require substantial additional funding to commercialize Gimoti, and may be unable to raise capital when needed, including to fund ongoing operations; Evoke 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 Evoke 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.

Date: February 15, 2017

EVOKE PHARMA, INC.

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