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): May 10, 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01 Regulation FD Disclosure.

On May 10, 2017, Evoke Pharma, Inc. (the "Company") announced that data from its Phase 3 trial of Gimoti™, its patented nasal delivery of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women, were presented at the Digestive Disease Week® (DDW) 2017 Meeting held in Chicago, Illinois.

The poster presentation entitled *"Symptom Severity Influences Drug Efficacy in Women with Diabetic Gastroparesis: Results of a Phase 3 Study with Metoclopramide Nasal Spray"* illustrated that patients with moderate to severe symptoms at study entry, which included 105 of the 205 patients (51%) enrolled in the study, responded clinically and statistically significantly better to Gimoti than placebo at multiple time points in the Intent-to-Treat (ITT) and Per Protocol populations. Focusing on the benefits in patients with moderate to severe symptoms is consistent with the U.S. Food and Drug Administration (FDA) guidance on the clinical evaluation of drugs for the treatment of gastroparesis issued in July 2015 (Gastroparesis: Clinical Evaluation of Drugs for Treatment, Draft Guidance).

In the Phase 3 trial, Gimoti was particularly effective in reducing nausea and upper abdominal pain, the most common and debilitating symptoms in patients with moderate to severe symptoms. This was similar to the benefits experienced by female patients in the Company's Phase 2b trial. Safety data from the Phase 3 trial were consistent with favorable results from previous Gimoti studies. In particular, there were no adverse events of special interest, such as the central nervous system (CNS) effects observed with oral and parenteral formulations of metoclopramide. Based on recent FDA discussions, these data are anticipated to be submitted as part of a new drug application (NDA) for Gimoti.

The Phase 3 trial was a U.S. multicenter, randomized, double-blind, placebo-controlled, parallel-group study of the efficacy and safety of Gimoti compared to placebo in adult female subjects with symptomatic diabetic gastroparesis and delayed gastric emptying. Eligible patients were randomized 1:1 between Gimoti or placebo administered as a single nasal spray four times daily; 30 minutes before meals and at bedtime for a total of four weeks. The primary endpoint was the change in the total symptom score from baseline to week four. The trial data was not statistically significant in the ITT group (N=205, p=0.881).

Forward Looking Statements.

The Company cautions you that statements made in this Current Report on Form 8-K 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 plans to present at DDW and discuss the data from its Phase 3 trial for Gimoti; the benefits Gimoti may have for patients with moderate to severe gastroparesis symptoms; the timing of any 505(b)(2) NDA submission for Gimoti with the FDA; the Company's plans to conduct the comparative exposure PK study and include the results in the Gimoti NDA; and the utility of the Gimoti data to scientists and clinicians at DDW. 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: risks associated with successfully commencing and receiving favorable results from the planned PK trial; later developments with the FDA that may be inconsistent with the already completed pre- NDA meetings, including inconsistent conclusions reflected in the official meeting minutes from the FDA; the inherent risks of clinical development of Gimoti, in particular since the Phase 3 trial failed to reach its primary endpoint in the ITT population; the Company is entirely dependent on the success of Gimoti, and the Company 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; the Company's dependence on third parties for the manufacture of Gimoti as well as the conduct of the PK trial; the Company may require additional funding to complete the PK trial 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; the Company 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 Company's prior press releases and in the periodic reports it 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 press release 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: May 10, 2017

EVOKE PHARMA, INC.

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