

Edgar Filing: Evoke Pharma Inc - Form 8-K

(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 2.02 Results of Operations and Financial Condition.

On January 9, 2017, Evoke Pharma, Inc. (the “Company” or “Evoke”), announced that its preliminary unaudited cash and cash equivalents as of December 31, 2016 were approximately \$9.0 million.

The preliminary unaudited cash position discussed above is subject to the completion of financial closing procedures and other developments that may arise between now and the time the financial results for the fourth quarter are finalized, as well as the completion of the audit of the 2016 financial statements. Therefore, actual results may differ materially from these estimates. In addition, the above estimates do not present all information necessary for an understanding of Evoke’s financial condition as of December 31, 2016.

In accordance with General Instruction B.2 of Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form

Item 7.01 Regulation FD Disclosure.

Beginning on January 9, 2017, representatives of Evoke will be attending meetings with investors, analysts and other parties in connection with the J.P. Morgan 34th Annual Healthcare Conference in San Francisco, California. During these meetings, Evoke will present the slides attached as Exhibit 99.1 to this Current Report on Form 8-K, which are incorporated by reference.

The information in this Item 7.01, including Exhibit 99.1, is being furnished pursuant to Item 7.01 and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this item of this report.

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 timing of the pharmacokinetic (“PK”) study of Gimoti and submission of a new drug application (“NDA”), the potential approval and commercialization of Gimoti as a new and effective treatment for gastroparesis, the potential market size for Gimoti, the potential for Gimoti to be the only product that has shown symptomatic efficacy in an endpoint, Evoke’s protection of its intellectual property and Evoke’s belief that the PK study may serve as a basis for submission of a 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 press release due to the risks and uncertainties inherent in the Company's business, including, without limitation: the statistically-significant data from the Phase 3 clinical trial of Gimoti only includes a portion of the patients in trial and that the Phase 3 trial failed to reach its primary endpoint; risks associated with successfully commencing and receiving favorable results from the planned PK study; later developments with the Food and Drug Administration ("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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

No.	Description
99.1	Slide Presentation

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: January 9, 2017 By: /s/ Matthew J. D'Onofrio
Name: Matthew J. D'Onofrio
Title: Executive Vice President,
Chief Business Officer and Secretary