

Evoke Pharma Inc
Form 8-K
January 07, 2019

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): January 5, 2019

EVOKE PHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

**Delaware
(State or Other Jurisdiction**

of Incorporation)

420 Stevens Avenue, Suite 370

**001-36075
(Commission**

File Number)

**20-8447886
(IRS Employer**

Identification No.)

92075

Solana Beach, California
(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 1.01 Entry into a Definitive Material Agreement.

On January 5, 2019, Evoke Pharma, Inc. (the Company) entered into a commercial services agreement (the Agreement) with Novos Growth, LLC (NGP) for the commercialization of Gimoti, the Company's nasal spray product candidate for the relief of symptoms in adult women with acute and recurrent diabetic gastroparesis. Pursuant to the Agreement, NGP will manage the commercial operations for a dedicated sales team to market Gimoti, if approved by the U.S. Food and Drug Administration (FDA), to gastroenterologists and other targeted health care providers.

Under the terms of the Agreement, the Company maintains ownership of the Gimoti New Drug Application (NDA), as well as legal, regulatory, and manufacturing responsibilities for Gimoti. The Company will also retain a contract sales organization, which would be managed by NGP. The Company will record sales for Gimoti and retain more than 80% of product profits. NGP will receive a percentage of product profits in the mid-to-high teens as a service fee. Product profits are the net sales (as defined in the Agreement) of Gimoti, less the costs of goods sold, specified commercialization costs and the interest to be paid on the Working Capital Loan, as described below (such product profit amount, the Contribution Profits). During the term of the Agreement, NGP agreed to not commercialize a competing product in the United States other than pursuant to the Agreement.

Pursuant to the Agreement, NGP has agreed to finance the Company's working capital requirements for specified commercialization costs (including costs related to marketing, sales and patient assistance programs) in an amount by which Contribution Profits are expected to fall (or do actually fall) below zero (as projected by sales forecasts and a commercialization budget) to be drawn by the Company on a monthly basis, as needed (Working Capital Loan), pursuant to a credit agreement to be negotiated in good faith by the Company and NGP (Credit Agreement). The Working Capital Loan will be repaid by the Company, if at all, only out of positive Contribution Profits, unless the Agreement is terminated (a) by NGP due to a material breach by the Company, or (b) by the Company other than due to the gross negligence or intentional misconduct of NGP. Termination of the Agreement by NGP for any other reason (including, without limitation, minimum net sales thresholds and negative Contribution Profits, as described below) will cause the Working Capital Loan to be forgiven in full. The interest rate and other terms of the Working Capital Loan will be set forth in the Credit Agreement.

In addition, under the Agreement NGP has agreed to provide a line of credit of up to \$5.0 million to the Company following NDA approval of Gimoti, if any, and for a period of up to nine months thereafter. The line of credit will be extended pursuant to a credit agreement to be negotiated in good faith by the parties. NGP will receive a low single digit percentage on net sales of Gimoti in lieu of any interest on the line of credit (the Credit Fee); provided that in no event shall the cumulative Credit Fee exceed twice the amount of the principal borrowed by the Company. The line of credit will mature on the earlier of 30 days following the date the Credit Fee is twice the amount of the borrowed principal and the two year anniversary of the date the principal is borrowed by the Company. In the event the Company secures financing from a third party wholesale distributor for the purchase of Gimoti for launch in excess of \$2.5 million, NGP will no longer be required to offer the line of credit.

The term of the Agreement is five years from the date of commercial launch of Gimoti, if any, after which the Company will recapture 100% of product sales and assume all corresponding responsibilities. Within 30 days after each one year anniversary of the Agreement, either party may terminate the Agreement if net sales of Gimoti do not meet certain annual thresholds. Either party may terminate the Agreement for the material breach of the other party, subject to a 60-day cure period, or in the event an insolvency petition of the other party is pending for more than 60 days. Either party may also terminate the Agreement upon 30 days written notice to the other party if Gimoti is subject to a safety recall, the parties are unable to agree to a commercialization plan and budget by a specified date, or if the Contribution Profit is negative for any

calendar quarter beginning with the first full calendar quarter nine months following commercial launch. In addition, NGP may terminate the Agreement if Gimoti is not approved by the FDA by April 30, 2019, the Company withdraws Gimoti from the market for more than 180 days, or if the Company is unable to provide product samples for use by the salesforce in a timely manner. The Company may also terminate the Agreement upon a change of control of the Company, subject to a one-time payment equal to between four times and one times annualized service fees paid by the Company under the Agreement, with such amount based on which year (between one and five years) after commercial launch the change of control occurs, provided if the change of control occurs within one year of commercial launch such amount will be the greater of the specified annualized service fee amount and \$5 million.

Item 2.02 Results of Operations and Financial Condition.

The Company estimates that its cash and cash equivalents were \$5.3 million as of December 31, 2018. This amount is unaudited and preliminary and is subject to 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 2018 financial statements. As a result, this amount may differ from the amount that will be reflected in the Company's financial statements as of and for the year ended December 31, 2018.

In accordance with General Instruction B.2 of Form 8-K, the information in this 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 liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing.

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The information with respect to the Working Capital Loan and line of credit set forth under Item 1.01 above is incorporated herein by reference.

Item 8.01 Other Information.

The Company believes its estimated cash and cash equivalents as of December 31, 2018, and the Working Capital Loan, may extend the Company's cash runway into 2020 without accounting for any future Gimoti product revenue. However, the Company's forecast of the period of time through which its financial resources will be adequate to support its operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. The Company has based this estimate on assumptions that may prove to be wrong, and the Company could use its capital resources sooner than it expects.

Safe Harbor Statement

The Company cautions you that statements included in this report 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, 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 potential approval and product launch for Gimoti; NGP's management of commercialization activities for Gimoti; the Company's retention of a contract sales organization; NGP providing a Working Capital Loan and line of credit and

the parties entering into agreements with respect thereto; and the Company's expectations on its cash balance as of December 31, 2018 and future cash runway. 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 potential for FDA to delay the PDUFA target action date of the NDA due to FDA's internal resource constraints or other reasons; FDA may disagree that the existing safety database and efficacy data is sufficient to allow approval of the NDA, including as a result of the potential review issues identified by FDA in the Day-74 Letter such as, among others, C_{max} falling below the bioequivalence range in the comparative exposure pharmacokinetic trial, the proposed duration of use for Gimoti being shorter as compared to the maximum approved dosing duration for the referenced listed drug, Reglan Tablets, and the available safety database supporting such duration, the adequacy of the proposed REMS included in the NDA, and the existing data supporting a female-only indication; FDA may not agree with the Company's interpretation of the results of clinical trials of Gimoti; later developments with FDA that may be inconsistent with the already completed pre-NDA meetings; the possibility of an advisory committee meeting related to the NDA; the inherent risks of clinical development of Gimoti; the Company's reliance on a third party, NGP, for critical aspects of the commercialization of Gimoti; the performance of NGP and its adherence to the terms of the agreement with the Company; the Company's ability to timely secure a contract sales organization; the Company could face unexpected costs due to additional regulatory requests, litigation or other events; potential changes in estimated cash based on the completion of financial closing procedures and audit of the 2018 financial statements; the Company is entirely dependent on the success of Gimoti, and the Company cannot be certain that FDA will approve the NDA for Gimoti or that the Company and NGP will successfully commercialize Gimoti; the inability of the Company and NGP to reach agreement on the Credit Agreement and line of credit; the Company may require substantial additional funding, and may be unable to raise capital or obtain funds under the Working Capital Loan or line of credit when needed, including to fund ongoing operations; and other risks detailed in the Company's 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 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: January 7, 2019

By: /s/ Matthew J. D Onofrio

Name: Matthew J. D Onofrio

Title: Executive Vice President, Chief Business Officer
and Secretary