

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 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 3, 2019

EVOFEM BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36754
(Commission
File Number)

20-8527075
(I.R.S. Employer
Identification Number)

12400 High Bluff Drive, Suite 600, San Diego, CA 92130
(Address of principal executive offices) (zip code)

(858) 550-1900
(Registrant's telephone number, including area code)

Not applicable.
(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:

- 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 8.01. Other Events.

On January 3, 2019, Evofem Biosciences, Inc. issued a press release providing its recent 2018 highlights and announcing its upcoming milestones for 2019. The press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated January 3, 2019



Exhibit 99.1

Evofem Biosciences Provides Corporate Update and Announces Upcoming Milestones

- Company to Resubmit New Drug Application (NDA) for Amphora as Hormone-free Birth Control in Q2 2019 Based on Positive Top-line Phase 3 Study Results -

San Diego, Jan. 3, 2019 - Evofem Biosciences, Inc., (NASDAQ: EVFM) today provided insight into anticipated 2019 milestones and events across its clinical pipeline. The Company recently reported that its Phase 3 trial evaluating Amphora® for the prevention of pregnancy met its primary endpoint, and plans to resubmit the Amphora NDA in the second quarter of 2019. Additional highlights are below.

“We made substantial clinical progress in 2018, highlighted by our successful Phase 3 clinical trial of Amphora for the prevention of pregnancy, and remain committed to translating this into increased shareholder value,” said Sandra Pelletier, Chief Executive Officer of Evofem Biosciences. “We expect 2019 to be a pivotal year for Evofem as we focus on refiling the Amphora NDA and establishing the commercial infrastructure to successfully launch this first-in-class Multipurpose Vaginal pH Regulator™ for hormone-free birth control in January 2020.”

2019 Planned Objectives:

- Resubmit Amphora NDA the second quarter of 2019.
- Present data from AMPOWER, the recently-completed Phase 3 clinical trial of Amphora for the prevention of pregnancy, including data on exploratory secondary endpoint of sexual satisfaction, at an appropriate medical meeting.
- Complete enrollment in AMPREVENANCE, the Phase 2b clinical trial of Amphora for the prevention of urogenital acquisition of *Chlamydia trachomatis* (primary endpoint) and *Neisseria gonorrhoea* (secondary endpoint) in women, in the first half of 2019.
- Report top-line AMPREVENANCE data in the fourth quarter of 2019.
- Secure partnership for commercialization of Amphora in at least one ex-U.S. market.

2018 Recent Highlights:

- Reported positive top-line AMPOWER results which met the Phase 3 study’s primary efficacy endpoint. Data demonstrated 86.0% efficacy (referred to as typical use) and 98.7% efficacy when Amphora was used as directed per study protocol.
 - Announced detailed results of the Consumer Survey, which revealed that 88% of subjects were not using any birth control method prior to entering the AMPOWER study. These findings underscore that currently available contraceptive methods are insufficient to meet the needs of women.
 - Advanced enrollment in the Phase 2b AMPREVENANCE trial with over 70% of the planned 844 women enrolled at year-end 2018.
 - Hosted Key Opinion Leader event on new perspectives in birth control, featuring presentations on Amphora’s potential, if approved, to drive change in women’s birth control choices.
 - Presented data at the 2018 American Society for Reproductive Medicine (ASRM) Annual Congress from two clinical trials of Amphora, AMP001 and EVO-002.
 - Completed public offering raising net proceeds of \$36.4 million.
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About Evofem Biosciences

Evofem Biosciences, Inc., (NASDAQ: EVFM) is a clinical-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health. Evofem is leveraging its proprietary Multipurpose Vaginal pH Regulator™ (MVP-R) gel to develop product candidates for multiple indications, including prevention of pregnancy, prevention of urogenital transmission of chlamydia and gonorrhea in women and the prevention of recurrent bacterial vaginosis. For more information regarding Evofem, please visit www.evofem.com.

Amphora® is a registered trademark and Multipurpose Vaginal pH Regulator™ is a trademark of Evofem Biosciences, Inc.

Forward-Looking Statements

Statements in this press release about Evofem's future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to statements regarding objectives, plans and strategies as well as statements, other than historical facts, that address activities, events or developments that the Company intends, expects, projects, believes or anticipates will or may occur in the future. These statements are often characterized by terminology such as "believes," "hopes," "may," "anticipates," "should," "intends," "plans," "will," "could," "would," "expects," "estimates," "projects," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of the Company's control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in the Company's filings with the Securities and Exchange Commission (SEC), including its Quarterly Report for the period ended March 31, 2018, as filed with the SEC on Form 10-Q on May 14, 2018, and include but are not limited to the following: whether the FDA will approve Amphora as a contraceptive based on the resubmitted NDA; whether and the degree to which women choose to use Amphora as a birth control method and whether and the degree to which physicians prescribe Amphora; the Company's ability to raise the additional funds necessary to commercialize Amphora as a contraceptive, if approved, and/or to complete the development of Amphora to prevent urogenital acquisition of *Chlamydia trachomatis* and *Neisseria gonorrhoea* in women; the Company's reliance on third parties to conduct its clinical trials, research and development and manufacturing and the extent to which these third parties perform their respective activities subject to and in compliance with FDA requirements; the availability of reimbursement from government authorities and health insurance companies for the Company's products; the impact of potential product liability lawsuits; the influence of extensive and costly government regulation; the volatility of the trading price of the Company's common stock, and the concentration of power in its stock ownership. Forward-looking statements in this press release are made as of the date of this press release, and the Company undertakes no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. These forward-looking statements should not be relied upon as representing Evofem's views as of any date subsequent to the date hereof. We have included certain information from government publications and general publications and research, surveys and studies conducted by third parties. This information has been obtained from sources believed to be reliable, although they do not guaranty the accuracy or completeness of such information. We have not independently verified market and industry data from any third-party sources.

Contact

Amy Raskopf

Evofem Biosciences, Inc.

araskopf@evofem.com

C: (917) 673-5775

O: (858) 550-1900 x167

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