

**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): October 30, 2018**

**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, with 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 (*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.

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**Item 8.01. Other Events.**

On October 30, 2018, Evofem Biosciences, Inc. (the "Company") sent a letter from its chief executive officer, Sandra Pelletier, to certain stockholders of the Company and other individuals (the "CEO Letter"). A copy of the CEO Letter is attached to this Current Report on Form 8-K as Exhibit 99.1. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#"><u>CEO Letter dated October 30, 2018</u></a>

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Exhibit 99.1

Good morning -

With the third quarter behind us and completion of Evofem's Phase 3 clinical trial of Amphora<sup>®</sup> for the prevention of pregnancy (AMP002) rapidly approaching, I wanted to pause and take a moment to let you know how grateful we are for your ongoing support of Evofem. Our optimism and enthusiasm for our mission to develop and commercialize innovative products to address unmet needs in women's sexual and reproductive health is unwavering.

Our research and development programs center on advancing Multipurpose Vaginal pH Regulator (MVP-R) product candidates for critical areas in women's health where we believe current options are either insufficient or absent entirely.

We remain on track to complete AMP002 by year-end 2018. We over-enrolled this pivotal trial ahead of schedule due to strong demand; an indicator of this is that 500 additional women were in the screening progress when we closed enrollment in February 2018. The last patients in this trial have completed their last cycles and are in the process of completing their last office visits. This will enable us to lock our database and move forward with data analyses. We continue to expect top-line data from AMP002 by the end of this year.

Assuming positive data from AMP002, we plan to re-submit the Amphora New Drug Application (NDA) in the second quarter of 2019. Subject to timely FDA approval of this NDA, we will launch Amphora in January of 2020 as the first and only hormone-free, woman-controlled, on-demand birth control drug product in the U.S.

When and if Amphora is approved, we plan to focus initially on driving uptake of the product among the 16.5 million women in the U.S. who say they do not want to get pregnant, yet they are not doing anything to prevent pregnancy. According to the National Institutes of Health, these women have an 85% risk of becoming pregnant within one year if they continue this behavior. These statistics are staggering! "One size definitely does not fit all" when it comes to women and their bodies.

Equally important is the rise of sexually transmitted diseases (STDs) in our country. Under-reported STDs are in the national spotlight. In August 2018 the CDC released preliminary data showing that in 2017, reported cases of chlamydia, gonorrhea and syphilis increased for the fourth consecutive year. Amphora has vaginal pH regulating properties which may enable it to prevent the transmission of certain STDs including chlamydia and gonorrhea.

The standard of care for chlamydia and gonorrhea involves treatment with antibiotics. The current consensus in the medical community is that preventive measures are greatly needed, but there is no approved drug to prevent transmission of these vexing and rising STDs.

Evofem's pioneering research in STD prevention includes our ongoing Phase 2b clinical trial evaluating Amphora to prevent urogenital transmission of chlamydia and gonorrhea in women.

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We are building awareness of the need for a form of hormone-free, woman-controlled, on-demand birth control through poster and oral presentations at scientific and medical society meetings. Recent presentations include the American Society of Reproductive Medicine (ASRM) Annual Congress, the Initiative for Multipurpose Prevention Technologies (IMPT) and the International Federation of Gynecology and Obstetrics (FIGO) World Congress.

Similarly, through presentations and participation in multiple equity conferences and ongoing outreach, we continue to build relationships with analysts and investors with potential to cover and invest in Evofem. We are very pleased to have added several new institutional investors to our shareholder mix through open market purchasing in Q3 and into Q4. Welcome!

Another important audience is the media. On World Contraception Day we released results of a commissioned Consumer Survey conducted by The Harris Poll, which affirmed that 55% of sexually active American women at risk for pregnancy currently use no birth control method, and among American women who do use birth control, 36% would prefer non-hormonal birth control. We continue to build relationships with reporters writing on women's sexual and reproductive health, with a focus on birth control and STD prevention.

The coming few months will be very exciting for us all.

- We hope you will join us on Wednesday, November 7<sup>th</sup> for our third quarter results call, and again on Thursday, November 15<sup>th</sup> for a luncheon with Key Opinion Leaders (KOLs) in New York City. Details and webcast access for both events will be available through the investor relations section of website; investors and analysts who wish to attend the KOL luncheon in person should email [ir@evofem.com](mailto:ir@evofem.com) to RSVP.
- We look forward to announcing when the last patient's last visit has occurred in AMP002.
- We continue to expect top-line data from AMP002 by the end of this year.

We are poised to execute our strategy to successfully launch Amphora in the U.S. in early 2020 as a new and disruptive birth control method. We firmly believe this product will be a game-changer, and a welcome option for women desiring a hormone-free method that they control.

Thank you again for your support.

Sincerely,  
Saundra

Saundra Pelletier  
CEO, Evofem Biosciences, Inc.  
(Nasdaq: EVFM)

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## **Forward-Looking Statements**

Statements in this letter about Evofem Biosciences, Inc.'s (Evofem) 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 are often characterized by terminology such as "poised," "believes," "hopes," "optimistic," "may," "anticipates," "should," "could," "would," "intends," "plans," "will," "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. These forward looking statements include, but are not limited to, statements about the anticipated results of the AMP002 trial and the Phase 2b clinical trial of Amphora to prevent urogenital acquisition of *Chlamydia trachomatis* and *Neisseria gonorrhoea* in women, and any expected completion dates, data availability dates or general timing for these clinical trials; statements regarding FDA approval and the timing of any FDA approval; statements regarding future commercial launch activities and related plans; and any statements regarding potential market acceptance or product uptake for Amphora or any Evofem product candidate. Forward-looking statements in this communication are made as of October 30, 2018, and Evofem undertakes no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of the Evofem'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 Evofem'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. These forward-looking statements should not be relied upon as representing Evofem's views as of any date subsequent to the date hereof. Evofem has included in this letter certain information from government publications which was obtained from sources believed to be reliable, although Evofem does not guarantee the accuracy or completeness of such information. Evofem has not independently verified market and industry data from any third-party sources.