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): December 17, 2018

EVOFEM BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-36754	20-8527075
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 December 17, 2018, Evofem Biosciences, Inc. (the "Company") issued a press release announcing top-line data from the confirmatory, single-arm, Phase 3 trial entitled "A Single-Arm, Phase III, Open Label, Multicenter, Study in Women Aged 18-35 Years of the Contraceptive Efficacy and Safety of Amphora Contraceptive Vaginal Gel." The press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The Company will host a conference call to discuss the top-line data results on Monday, December 17, 2018 at 8:30 AM Eastern Time.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release dated December 17, 2018

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.

EVOFEM BIOSCIENCES, INC.

Date: December 17, 2018

By: /s/ Justin J. File

Justin J. File
Chief Financial Officer

Exhibit 99.1

Evofem Biosciences Announces Positive Top-Line Results of Phase 3 Study Evaluating Amphora for Hormone-Free Birth Control

- Top-Line Phase 3 Data Demonstrate 86.0% Efficacy, which Met Primary Study Endpoint, and 98.7% Efficacy when Used as Directed -

- Q2 2019 New Drug Application (NDA) Resubmission Planned -

- Management to Host Conference Call at 8:30 a.m. EST -

SAN DIEGO, Dec. 17, 2018 -- Evofem Biosciences, Inc. (NASDAQ: EVFM) ("Evofem" or the "Company") today announced that its Phase 3 clinical trial of Amphora® for the prevention of pregnancy, AMPOWER, successfully met its primary endpoint.

AMPOWER assessed the efficacy, safety and subject satisfaction with Amphora in approximately 1,400 healthy women aged 18-35 years at 112 centers in the U.S. The primary endpoint of the study was the pregnancy rate over seven cycles of use (one cycle = 21-35 days) as assessed by the Kaplan-Meier statistical method. Top-line data analysis demonstrates a cumulative pregnancy rate of 14.0% over seven cycles of use (95% CI 10.0, 18.0). This corresponds to an 86.0% efficacy rate (referred to as typical use), which meets the pre-determined endpoint of this clinical trial.

In women who correctly used Amphora per study protocol, the cumulative pregnancy rate was 1.3% over seven cycles of use (95% CI 0.4, 2.1). This corresponds to a 98.7% efficacy rate. The results demonstrate that when Amphora is used as directed, the efficacy in which women can have confidence is similar to other frequently used contraceptive methods.

Overall in the AMPOWER study there were more than 24,000 acts of intercourse in which Amphora use was reported. Of these, Amphora was used as directed 88.9% of the time.

There were minimal side effects reported by AMPOWER study participants, and there were no serious treatment-related adverse events reported.[1]

This positive outcome supports the potential of Amphora (L-lactic acid, citric acid and potassium bitartrate), Evofem's Multipurpose Vaginal pH Regulator™ (MVP-R), to become the first non-hormonal, on-demand, woman-controlled prescription birth control vaginal gel.

"We are excited by these compelling study results, which solidify Amphora's position as the most substantial birth control innovation in nearly 20 years and a significant advancement for women and their sexual and reproductive health," said Saundra Pelletier, Chief Executive Officer of Evofem Biosciences. "We look forward to further data analysis and to submitting the Amphora NDA to the FDA in the second quarter of 2019. If approved, we plan to commercialize this first-in-class MVP-R for birth control in January 2020 to meet the needs of the 16.5 million women who are not using a contraceptive method but do not want to get pregnant, including women who cannot or will not use hormonal birth control methods."[2]

"In my experience, the most effective birth control method is one that women will consistently use," said Dr. Bassem Maximos, MD, MPH, FACOG, a principal investigator for the AMPOWER study and a practicing

obstetrician-gynecologist. "Given the efficacy rate of 98.7% when used as directed and the low rates of side effects, Amphora will be an important new birth control option for women. Health care providers will finally be able to offer patients an effective birth control method that is non-hormonal, on-demand, and woman-controlled. These benefits will encourage many women who do not use birth control to reconsider their approach to managing their reproductive health."

Amphora is designed to regulate vaginal pH within the normal range of 3.5 to 4.5. This maintains an acidic environment, which is inhospitable to sperm as well as certain viral and bacterial pathogens associated with sexually transmitted infections but is integral to the survival of healthy bacteria in the vagina.

As with all contraceptive trials, the number of pregnancies and evaluable cycles included in Evofem's calculation of the pregnancy rate using the Kaplan-Meier method is subject to review by the FDA as part of its overall review of Amphora's NDA.

Data from AMPOWER, including an exploratory secondary endpoint of sexual satisfaction, will be submitted for presentation at upcoming scientific conferences and for publication in peer-reviewed journals following further analyses.

Conference Call

The Evofem management team will host a conference call to discuss the top-line AMPOWER results as follows:

Date	December 17, 2018
Time	8:30 a.m. EST
Dial-in numbers	(866) 503-5561 (U.S. toll-free) or (253) 336-2965
Passcode	4959407
Webcast (live and archived)	www.evofem.com under "Investors" or click here

The teleconference replay will be available approximately two hours after completion through Friday, December 21, 2018, at (855) 859-2056 (U.S.) or (404) 537-3406 (International). The replay access code is 4959407. The archived webcast will be available via the aforementioned URLs.

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.

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 gonorrhea* 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.

References

[1]Data on file. Evofem Biosciences, Inc., San Diego, CA
[2]Derived from NCHS Data Brief No. 173_December 2014 and the 2016 US Census Bureau data

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