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): February 21, 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, 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. ☒

Item 8.01. Press Release.

On February 21, 2018, Evofem Biosciences, Inc. issued a press release announcing its Fast Track designation for Amphora® for prevention of chlamydia. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated February 21, 2018

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: February 21, 2018

By: /s/ Saundra Pelletier
Saundra Pelletier
Chief Executive Officer

Exhibit 99.1

Evofem Biosciences Receives Fast Track Designation for Amphora for Prevention of Chlamydia

San Diego, CA, February 21, 2018 — Evofem Biosciences, Inc., (NASDAQ: EVFM) ("Evofem" or the "Company"), a biotechnology company developing innovative products to fill women's unmet healthcare needs, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for Amphora® (L-lactic acid, citric acid, and potassium bitartrate) vaginal gel for the prevention of urogenital chlamydia in women.

Amphora is an investigational drug being studied for the prevention of certain sexually transmitted infections (STIs) and as an on-demand, non-hormonal vaginal contraceptive. Fast Track designation is designed to facilitate the development and expedite the review of new therapies to treat serious conditions and fill unmet medical needs.

"We are pleased that the FDA has recognized the need for a product such as Amphora to prevent this common STI," said Dr. Kelly Culwell, Evofem's Chief Medical Officer. "We look forward to working closely with the FDA to facilitate the development of this preventive therapeutic."

Chlamydia is the most commonly reported sexually transmitted infection in the United States. Approximately 1.6 million new cases were reported in 2016 alone, an increase of 4.7% from the prior year. While treatment with antibiotics is effective, repeat infection is common. Multiple chlamydial infections increase a woman's risk of serious reproductive health complications including pelvic inflammatory disease and ectopic pregnancy.

The clinical development program for Amphora in prevention of STIs includes an ongoing double-blinded placebo-controlled Phase 2b/3 study to evaluate the efficacy of Amphora in preventing urogenital acquisition of *Chlamydia trachomatis* (primary endpoint) and *Neisseria gonorrhea* (secondary endpoint) in women when applied up to one hour prior to vaginal intercourse. This study is designed to enroll approximately 850 women at up to 20 centers in the United States. Subjects will be evaluated during a four-month interventional period and subsequent one-month follow-up period.

Evofem is also developing Amphora as an on-demand, non-hormonal vaginal contraceptive. The Company announced on February 15, 2018 the early completion of enrollment in its single-arm, open-label, Phase 3 clinical trial. This study is designed to evaluate the contraceptive efficacy and safety of Amphora in approximately 1,350 women aged 18-35 years who are at risk of pregnancy. Over 100 centers in the United States are participating. The primary endpoint is the contraceptive efficacy of Amphora over seven cycles of use. Data is expected in the first quarter of 2019.

“Our hormone-free, on-demand vaginal gel holds great promise for the prevention of chlamydia and gonorrhea, as well as to prevent pregnancy,” said Saundra Pelletier, Evofem Biosciences’ CEO. “While each of these women’s health issues is important in its own right, Amphora holds even greater promise as a potential combined preventive therapy for all three, which we believe could revolutionize women’s health.”

For more information on ongoing clinical trials of Amphora, visit www.clinicaltrials.gov.

About Amphora

Amphora is a non-hormonal, surfactant-free bioadhesive vaginal gel designed for on-demand use as needed or desired by a woman. This investigational new drug is being developed as an on-demand, non-hormonal vaginal contraceptive and for the prevention of certain sexually transmitted infections (STIs). A Phase 3 clinical trial of Amphora for the prevention of pregnancy and a Phase 2b/3 clinical trial of Amphora for the prevention of urogenital chlamydia and gonorrhea in women are underway. Amphora received Fast Track designation from the U.S. Food and Drug Administration (FDA) for the prevention of urogenital chlamydia in women, and is designated as a Qualified Infectious Disease Product (QIDP) by the U.S. Food & Drug Administration for the prevention of urogenital gonorrhea infection in women. The Company’s second multipurpose prevention technology (MPT) vaginal gel candidate has QIDP designation for the reduction of reoccurrence of bacterial vaginosis. These designations may enable Evofem Biosciences to more rapidly evaluate and make these drugs available to women at risk of these infections.

About Evofem Biosciences

Evofem Biosciences, Inc., (NASDAQ: EVFM) is a biotechnology company that develops and anticipates commercializing innovative products to address unmet needs in women’s sexual and reproductive health. For more information regarding Evofem, 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 about the anticipated results of the Phase 2b/3 STI clinical trial and any expected completion date for the this clinical trial as well as statements about the anticipated results of the Phase 3 contraceptive clinical trial of Amphora and any expected completion date for the this clinical trial.

Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including whether Evofem will be able to raise the additional funding necessary to complete its clinical trials, including the Phase 3 contraceptive clinical trial and Phase 2b/3 STI clinical trial; whether Evofem’s product candidates will advance through the clinical trial process on a timely basis, according to the presently contemplated schedules or at all; whether Evofem’s product candidates will receive approval from regulatory agencies on a timely basis or at all; whether, if product candidates obtain approval, they will be successfully distributed and marketed and other factors discussed in the “Risk Factors-Risks Related to Evofem” section of a registration statement on Form S-4 initially filed with the Securities and Exchange Commission (the SEC) by Evofem Biosciences, Inc.

(formerly known as Neothetics, Inc.) on November 15, 2017, a copy of which is available on the Evofem website. In addition, the forward-looking statements included in this press release represent Evofem's views as of the date hereof. Evofem anticipates that subsequent events and developments will cause its views to change. However, while Evofem may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Evofem's views as of any date subsequent to the date hereof.

Evofem Biosciences' Contact
Amy Raskopf
Investor Relations
araskopf@evofem.com
858-550-1900 x167

###