

**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): March 1, 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, 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 2.02. Results of Operations and Financial Condition.**

On March 1, 2019, Evofem Biosciences, Inc. issued a press release announcing its financial results for the fourth quarter and year end 2018. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth under this Item 2.02 and in Exhibit 99.1 is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof, regardless of any general incorporation language in any such filing, except as shall be expressly set forth by specific reference in such a filing.

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

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release dated March 1, 2019</a>

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Exhibit 99.1

**Evofem Biosciences Reports Fourth Quarter and Year-End 2018  
Financial Results and Provides Corporate Update**

*Positive Phase 3 Amphora Results Enabling NDA Submission*

*Management to Host Conference Call at 11:00 a.m. EST*

SAN DIEGO, March 1, 2019 - Evofem Biosciences, Inc., (NASDAQ: EVFM) ("Evofem" or the "Company"), a clinical stage biopharmaceutical company, today reported financial results for the three- and twelve- month periods ended December 31, 2018. Fourth quarter and recent highlights include:

- Successfully completed AMPOWER, the second Phase 3 trial of Amphora for non-hormonal birth control, with positive top-line AMPOWER results positioning Evofem to re-submit the Amphora New Drug Application (NDA) in the second quarter of 2019; and,
- Patient enrollment in AMPREVENANCE, the Phase 2b clinical trial evaluating the ability of Amphora to prevent chlamydia and gonorrhea, is over 90% complete; top-line data is expected in the fourth quarter of 2019.

If approved, Amphora will be the first Multi-purpose Vaginal pH Regulator (MVP-R) birth control method in the U.S. Amphora is hormone-free, female controlled, and used on-demand only when needed.

"We are very pleased with the promising results from the AMPOWER trial, which met the agreed-upon primary endpoint," said Sandra Pelletier, Chief Executive Officer of Evofem. "The time is right for Amphora. We haven't seen significant innovation in on-demand women's birth control in almost 20 years and many women are dissatisfied with the current hormonal birth control options. In fact, more than 16 million women are not using any form of birth control, presenting a strong commercial opportunity for Evofem and the women who need new options."

**Upcoming Clinical Milestones**

Evofem is also exploring Amphora's potential beyond contraception, as it shows promise in preventing certain sexually transmitted diseases.

AMPREVENANCE, the ongoing Phase 2b trial evaluating Amphora for the prevention of chlamydia and gonorrhea, remains on track to complete enrollment in the first half of 2019 with top-line results to be reported by the end of this year.

**Fourth Quarter Financial Results**

For the quarter ended December 31, 2018, total operating expense was \$15.0 million, compared to total operating expense of \$15.3 million for the quarter ended December 31, 2017.

Research and development costs were \$9.8 million in the fourth quarter of 2018 versus \$11.2 million in the prior year quarter. The \$1.4 million decrease was driven by a \$5.4 million decrease in clinical trial costs related to AMPOWER, from which the last patient exited in November 2018, which was partially offset by a \$3.0 million increase in clinical trial costs related to AMPREVENANCE, which commenced enrollment in

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December 2017. This net aggregate decrease in clinical trial costs was offset by a \$0.5 million increase in costs incurred for outside services associated with clinical trial activities and a \$0.2 million increase in noncash stock-based compensation associated with stock-based awards granted during 2018.

General and administrative costs were \$5.2 million in the fourth quarter of 2018 versus \$4.1 million in the prior year quarter. The \$1.1 million increase was mainly due to a \$1.3 million increase in noncash stock-based compensation associated with stock-based awards granted during 2018, a \$0.6 million increase in costs incurred for requirements as a public company and various pre-commercialization activities in advance preparation of the potential launch of Amphora in early 2020, and a \$0.5 million increase in salaries and bonus expense from higher headcount. These increases were partially offset by a \$1.1 million decrease in professional fees related to legal, audit and taxes.

Total other expense was not significant in the fourth quarter of 2018, compared to \$4.1 million in the prior year quarter that included noncash losses on the issuance of Series D redeemable convertible preferred stock (Series D) and for the change in fair value of the Series D liquidation preference in 2017. As a result, net loss attributable to common stockholders was \$15.0 million, or \$(0.58) per share, for the quarter ended December 31, 2018, compared with a net loss of \$20.7 million, or \$(10.55) per share, for the prior year quarter.

### **Full Year Financial Results**

For the year ended December 31, 2018, total operating expense was \$77.6 million, compared to total operating expense of \$35.7 million for the year ended December 31, 2017.

Research and development costs were \$43.4 million versus \$23.5 million in the prior year. The \$19.9 million increase was driven primarily by a \$14.9 million increase in clinical trial costs related to AMPOWER and AMPREVENGE, a \$2.8 million increase in noncash stock-based compensation associated with stock-based awards granted during 2018, and a \$1.5 million increase in costs incurred for outside services associated with clinical trial activities.

General and administrative costs were \$34.2 million versus \$12.1 million in the prior year. The \$22.1 million increase was predominantly due to one-time, merger-related costs of \$4.3 million incurred in the first quarter of 2018, \$13.7 million of noncash stock-based compensation associated with stock-based awards granted during 2018, and a \$2.1 million increase in salaries and bonus expense from increased headcount.

Total other expense for the year ended December 31, 2018 was \$48.1 million, compared to \$69.6 million in the prior year. The decrease was driven primarily by noncash activity in both periods, including a loss on the issuance of warrants associated with the reverse merger in 2018, compared to a loss on the issuance of Series D stock and a loss recognized in association with a change in fair value of the Series D stock liquidation preference in 2017. Net loss attributable to common stockholders was \$125.8 million, or \$(5.74) per share, for the year ended December 31, 2018, compared with a net loss of \$109.3 million, or \$(55.78) per share, for the prior year.

### **Liquidity and Subsequent Material Events**

Unrestricted cash was \$1.3 million at December 31, 2018, as compared to \$12.1 million at September 30, 2018. With the completion and re-submission of the NDA and pre-commercialization activities for Amphora, the Company expects quarterly use of cash will increase and average between \$15 million and \$17 million per quarter during 2019. As a result, we need to raise additional capital to execute on our current business plan. As a part of that effort, in February 2019 the Company received approximately \$6.3 million in gross proceeds from the exercise of 2,376,062 warrants by certain institutional investors. As part of the transaction,

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Evofem granted to participating shareholders reload warrants to purchase 1,188,029 shares of common stock with an exercise price of \$5.20 per share.

### Conference Call

As previously announced, the Evofem management team will host a conference call to discuss its financial results and business highlights as follows:

Date	March 1, 2019
Time	11:00 a.m. EST
Dial-in numbers	(866) 503-5561 (U.S. toll-free) or (253) 336-2965
Passcode	5892398
Webcast (live and archived)	<a href="http://www.evofem.com">www.evofem.com</a> under " <a href="#">Investors</a> " or <a href="#">click here</a>

The teleconference replay will be available approximately two hours after completion through Wednesday, March 6, 2019, at (855) 859-2056 (U.S.) or (404) 537-3406 (International). The replay access code is 5892398. The archived webcast will be available via the aforementioned URLs for one year.

### About Amphora

Amphora® (L-lactic acid, citric acid and potassium bitartrate) is an investigational Multi-Purpose Vaginal pH Regulator (MVP-R) 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.

AMPOWER, the Phase 3 clinical trial evaluating Amphora for the prevention of pregnancy in approximately 1,400 women at 112 centers in the United States successfully met the study's agreed-upon primary efficacy endpoint. There were minimal side effects reported by AMPOWER study participants, and no serious treatment-related adverse events were reported.

The Company is actively enrolling AMPREVENCE, a double-blinded placebo-controlled Phase 2b clinical trial of Amphora to prevent urogenital acquisition of *Chlamydia trachomatis* (primary endpoint) and *Neisseria gonorrhoea* (secondary endpoint) in women. This study is designed to enroll 844 women at approximately 50 centers in the United States for a four-month interventional period and subsequent one-month follow-up period.

Chlamydia is the most frequently reported bacterial sexually transmitted infection in the U.S. The CDC recently reported that domestic rates of gonorrhea and chlamydia have climbed for the fourth consecutive year. Nearly 2.3 million U.S. cases of these STDs were diagnosed in 2017, according to preliminary data, an increase of over 200,000 cases as compared with 2016.<sup>3</sup> There are currently no FDA-approved products for the prevention of chlamydia or gonorrhea.

### 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 Biosciences aims to advance the lives of women by developing innovative solutions, such as woman-controlled contraception and potential protection from certain sexually transmitted infections (STIs). The Company is leveraging its proprietary Multi-purpose Vaginal pH Regulator™ (MVP-R) platform to develop Amphora which, if approved, will be the first on-demand and female controlled MVP-R birth control method in the U.S. For more information regarding Evofem, please visit [www.evofem.com](http://www.evofem.com).

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

<sup>1</sup> NHS Data Brief #173, December 2014, "Current Contraceptive Status Among Women Aged 15-44 (Based on National Survey of Family Growth data)

<sup>2</sup> Trussell J. Contraceptive Efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M. Contraceptive Technology: Twentieth Revised Edition. New York NY: Ardent Media, 2011.

<sup>3</sup> Centers for Disease Control and Prevention (2018): STD Preliminary Data Accessed August 2018.

## 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 that address activities, events or developments that the Company intends, expects, projects, believes or anticipates will or may occur in the future; statements about the anticipated timing and outcome of the re-submission of the NDA for Amphora for prevention of pregnancy; statements about the anticipated results of the Phase 2b clinical trial of Amphora to prevent urogenital acquisition of *Chlamydia trachomatis* and *Neisseria gonorrhoea* in women, and any expected completion dates or general timing for this clinical trials. 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: the Company's ability to raise the additional funds necessary to commercialize Amphora as a contraceptive 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; 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.

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(Tables follow)

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**EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEET DATA**  
(Unaudited)  
(In thousands)

	December 31, 2018	December 31, 2017
Cash and cash equivalents	\$ 1,330	\$ 1,211
Restricted cash	431	490
Note payable	4,010	—
Series D 2X liquidation preference	—	79,870
Total current liabilities	27,329	103,347
Total stockholders' deficit	(23,356)	(289,546)

**EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(Unaudited)  
(In thousands, except share and per share data)

	Quarter Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
<b>Operating expenses:</b>				
Research and development	\$ 9,772	\$ 11,216	\$ 43,415	\$ 23,539
General and administrative	5,209	4,130	34,227	12,148
Total operating expenses	14,981	15,346	77,642	35,687
Loss from operations	(14,981)	(15,346)	(77,642)	(35,687)
Other income (expense):				
Interest income	30	33	127	128
Other expense, net	(30)	(34)	(145)	(46)
Loss on issuance of Series D redeemable convertible preferred stock	—	(2,782)	—	(8,522)
Loss on issuance of warrants	—	—	(47,920)	—
Change in fair value of Series D 2X liquidation preference	—	(1,364)	(130)	(61,175)
Total other expense, net	—	(4,147)	(48,068)	(69,615)
Loss before income tax	(14,981)	(19,493)	(125,710)	(105,302)
Income tax expense	—	—	(2)	(3)
Net loss	(14,981)	(19,493)	(125,712)	(105,305)
Accretion of Series D redeemable convertible preferred stock dividends	—	(1,178)	(66)	(4,017)
Net loss attributable to common stockholders	\$ (14,981)	\$ (20,671)	\$ (125,778)	\$ (109,322)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.58)	\$ (10.55)	\$ (5.74)	\$ (55.78)
Weighted-average shares used to compute net loss attributable to common stockholders, basic and diluted	25,819,183	1,959,904	21,900,574	1,959,904

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