Evofem Biosciences Reports Second Quarter 2018 Financial Results and Provides Corporate Update

SAN DIEGO, Aug. 2, 2018 /PRNewswire/ -- Evofem Biosciences, Inc., (NASDAQ: EVFM) ("Evofem" or the "Company"), a clinical-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health, today reported financial results for the three- and six- month periods ended June 30, 2018.

Second Quarter Financial Results and Recent Highlights:

- Significant numbers of women completed the 6-month treatment phase of our fully enrolled, confirmatory, Phase 3 clinical trial of Amphora® (L-lactic acid, citric acid, and potassium bitartrate) vaginal gel for the prevention of pregnancy (AMP002). With the study continuing to move ahead of schedule, the Company now expects to report top-line results in late 2018.
- Received positive early findings from a market research survey querying user satisfaction among women who have completed AMP002 and their male partners, and related observations from participating study investigators. Evofem expects to present results of the commissioned User Experience Satisfaction Survey at medical society meetings once completed.
- Advanced patient enrollment in our Phase 2b clinical trial evaluating the ability of Amphora to prevent urogenital acquisition of Chlamydia trachomatis (primary endpoint). 1.6 million new cases of chlamydia were reported in 2016 in the U.S. alone.[1]
- Raised $37.5 million in net proceeds from a public offering of stock and pre-funded warrants to new and existing institutional investors, net of underwriting discounts and commissions but excluding estimated offering costs.
- Unrestricted cash increased to $22.8 million at June 30, 2018, as compared to $5.0 million at March 31, 2018.

"The second quarter of 2018 was highlighted by the successful completion of a financing that significantly strengthened our balance sheet while bringing several new healthcare-focused institutional investors into our shareholder base," said Saundra Pelletier, CEO of Evofem.

"Since completing enrollment in our confirmatory Phase 3 trial of Amphora for contraception ahead of schedule in February 2018, we have been actively supporting the 112 participating U.S. study centers as women complete the treatment phase, while preparing for data lock and analysis. Over 400 women have now completed their last visit, and based on progress of the remaining women we now anticipate the last participant out will be this fall, enabling us to report top-line results in late 2018. Assuming positive results, we will re-submit the Amphora New Drug Application (NDA) in the first half of 2019, positioning us to commercialize Amphora as the first and only hormone-free, on-demand contraceptive drug in early 2020."

Evofem's Chief Commercial Officer, Russell Barrans, commented, "The early findings of the commissioned User Experience Satisfaction Survey among women who have completed the AMP002 clinical trial and their male partners increase our optimism about the potential demand for Amphora, if approved.

"In the U.S., approximately 16.5 million women do not wish to become pregnant but do not or cannot use hormones and currently use no form of contraception[2]. A majority of them have tried and stopped using hormonal contraceptives due to undesirable side effects, including weight gain, headaches, acne, bloating, breast tenderness and the loss of sexual desire. However, doing nothing places them at 85% relative risk to become pregnant within one year[2]. These women will make up the primary target audience for Amphora, if approved, and we are confident that we have the right marketing plan in place to reach these women and their physicians," Barrans added.

Financial Results

For the three months ended June 30, 2018, total operating expense was $23.2 million, compared to total operating expense of $6.4 million for the three months ended June 30, 2017. Higher research and development costs were driven primarily by a $5.3 million increase in clinical trial costs related to the ongoing confirmatory Phase 3 clinical trial of Amphora for prevention of pregnancy and the ongoing Phase 2b clinical trial of Amphora for prevention of chlamydia and gonorrhea, both of which trials initiated in the second half of 2017, and a $2.3 million increase in non-cash stock-based compensation associated with options granted in the second quarter of 2018. Higher general and administrative costs in the second quarter of 2018 were due to a $8.7 million increase in personnel costs, which included a $8.1 million increase in non-cash stock-based compensation associated with options granted in the second quarter of 2018.

There was no total other expense for the second quarter of 2018, compared to $0.2 million in the prior year quarter. As a result, net loss attributable to common stockholders was $23.2 million, or $(1.11) per share, for the three months ended June 30, 2018, compared with a net loss of $7.4 million, or $(3.78) per share, for the prior year quarter.

For the six months ended June 30, 2018, total operating expense was $44.2 million, compared to total operating

expense of $11.3 million for the six months ended June 30, 2017. Higher research and development costs were driven primarily by a $14.4 million increase in clinical trial costs related to the ongoing confirmatory Phase 3 clinical trial of Amphora for prevention of pregnancy and the ongoing Phase 2b clinical trial of Amphora for prevention of chlamydia and gonorrhea, both of which were initiated in the second half of 2017, and a $2.3 million increase in non-cash stock-based compensation associated with the aforementioned option grant during the current period. Higher general and administrative costs were predominantly due to one-time, merger-related costs incurred in the first quarter of 2018 and the aforementioned option grant.

Total other expense for the first half of 2018 was $48.1 million, compared to $0.5 million in the prior year period due to a non-cash loss on issuance of warrants to Invesco in the first quarter of 2018 associated with our reverse merger; there was no comparable expense in the 2017 period. Net loss attributable to common stockholders was $92.4 million, or $(5.15) per share, for the six months ended June 30, 2018, compared with a net loss of $13.6 million, or $(6.92) per share, for the prior year period.

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	Thursday August 2, 2018
Time	11:00 a.m. EDT
Dial-in numbers	(866) 503-5561 (U.S. toll-free) or (253) 336-2965
Passcode	2086111
Webcast (live and archived)	www.evofem.com under "**Investors**" or **click here**

The teleconference replay will be available approximately two hours after completion through Tuesday, August 7, 2018, at (855) 859-2056 (U.S.) or (404) 537-3406 (International). The replay access code is 2086111. The archived webcast will be available via the aforementioned URLs.

About Amphora

Amphora is an investigational non-hormonal vaginal gel designed to maintain an optimal vaginal pH of 3.5 to 4.5, an environment inhospitable to sperm as well as certain viral and bacterial pathogens associated with sexually

transmitted infections, but integral to the survival of healthy bacteria in the vagina.

Evofem's single-arm, open-label, multi-center, Phase 3 clinical trial (AMP002) is evaluating Amphora vaginal gel for the prevention of pregnancy. AMP002 enrolled 1,400 women aged 18-35 who are at risk of pregnancy at 112 centers in the United States. The primary endpoint of the study is the contraceptive efficacy of Amphora over seven cycles of use. Top-line data are expected in late 2018.

The Company is also conducting a Phase 2b double-blinded placebo-controlled efficacy trial of Amphora to prevent urogenital acquisition of Chlamydia trachomatis (primary endpoint) and Neisseria gonorrhea in women. This study is designed to enroll 844 women at up to 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 United States. 1.6 million new cases were reported in 2016, and the CDC estimates 2.9 million infections occur annually in the U.S.[1] In a 2007 study of 411 young women[3], roughly half of all chlamydia infections diagnosed were recurrent and the median time to recurrent infection was 5.2 months. There are currently no FDA-approved products for the prevention of chlamydia in women.

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 Multi-purpose Prevention Technology vaginal gel to develop product candidates for multiple indications, including contraception, the prevention of urogenital transmission of chlamydia and gonorrhea in women, and recurrent bacterial vaginosis. For additional information, please visit **www.evofem.com**.

[1]Chlamydia - CDC Fact Sheet (Detailed), accessed 2018.07.17. **https://www.cdc.gov/std/chlamydia/stdfact-chlamydia-detailed.htm**

[2]NHS Data Brief #173, December 2014, "Current Contraceptive Status Among Women Aged 15-44 (Based on National Survey of Family Growth data)

[3]Niccolai, M et al. Arch Pediatr Adolesc Med. 2007;161(3):246-251. doi:10.1001/archpedi.161.3.246

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 are often characterized by

terminology such as "believes," "hopes," "may," "anticipates," "should," "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. 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: 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; risks and uncertainties associated with market conditions; statements about the anticipated results of the Phase 3 clinical trial evaluating Amphora as a contraceptive and the Phase 2b clinical trial of Amphora to prevent urogenital acquisition of Chlamydia trachomatis and Neisseria gonorrhea in women, and any expected completion dates, designed enrollment, or general timing for these clinical trials; 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 guarantee 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)

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEET DATA

(Unaudited)
(In thousands)

	June 30, 2018	December 31, 2017
Cash and cash equivalents	$ 22,788	$ 1,211
Restricted cash	554	490
Series D 2X liquidation preference	—	79,870
Total current liabilities	20,840	103,347
Total stockholders' equity (deficit)	5,258	(289,546)

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended	Six Months Ended

	June 30,		June 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 11,833	$ 4,078	$ 23,792	$ 6,060
General and administrative	11,409	2,280	20,436	5,211
Total operating expenses	23,242	6,358	44,228	11,271
Loss from operations	(23,242)	(6,358)	(44,228)	(11,271)
Other income (expense):				
Interest income	32	32	62	63
Other (expense) income, net	(32)	64	(82)	30
Loss on issuance of warrants	—	—	(47,920)	—
Change in fair value of Series D 2X liquidation preference	—	(250)	(130)	(600)
Total other expense, net	—	(154)	(48,070)	(507)
Loss before income tax	(23,242)	(6,512)	(92,298)	(11,778)
Income tax expense	(2)	—	(2)	(3)
Net loss	(23,244)	(6,512)	(92,300)	(11,781)
Accretion of Series D redeemable convertible preferred stock dividends	—	(897)	(66)	(1,785)
Net loss attributable to common stockholders	$ (23,244)	$ (7,409)	$ (92,366)	$ (13,566)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.11)	$ (3.78)	$ (5.15)	$ (6.92)
Weighted-average shares used to compute net loss attributable to common stockholders, basic and diluted	20,868,554	1,959,904	17,937,788	1,959,904

SOURCE Evofem Biosciences, Inc.