

# Evoform Biosciences Reports Second Quarter 2019 Financial Results and Provides Corporate Update

Amphora NDA Resubmission Remains on Track for Q4 2019

Management to Host Conference Call Tuesday August 6, 2019 at 11:00 a.m. EDT

SAN DIEGO, Aug. 5, 2019 /PRNewswire/ -- Evoform Biosciences, Inc., (NASDAQ: EVFM) ("Evoform" or the "Company"), a clinical stage biopharmaceutical company, today reported financial results for the three- and six- month period ended June 30, 2019. Second quarter and recent highlights include:

- Raised \$80 million through a private placement of common stock from new and existing investors, including a strategic investment from PDL BioPharma (NASDAQ: PDLI);
- Additional data from Phase 3 'AMPOWER' study of Amphora®, an investigational Multipurpose Vaginal pH Regulator (MVP-R™), for prevention of pregnancy confirmed that an increased number of women reported an improved sex life compared with the contraceptive methods they used before entering the AMPOWER study and confirmed certain previously reported safety and efficacy data; and,
- The last subject is expected to complete her final visit this month in the Phase 2b 'AMPREVENCE' trial evaluating the ability of Amphora to prevent urogenital acquisition of *Chlamydia trachomatis* (primary endpoint) and *Neisseria gonorrhea* (secondary endpoint) in women, keeping Evoform on track to report top-line data in November 2019.

"We are pleased to have closed the second quarter of 2019 with a strengthened balance sheet supporting the planned resubmission of the Amphora NDA for the prevention of pregnancy and our preparations to commercialize this first-in-class hormone-free birth control method in the U.S. in 2020, assuming FDA approval," said Sandra Pelletier, Chief Executive Officer of Evoform.

## Financial Results

For the quarter ended June 30, 2019, total operating expense decreased 49% to \$11.9 million, compared to \$23.2 million for the quarter ended June 30, 2018.

Research and development costs decreased 56% to \$5.2 million in the second quarter of 2019 versus \$11.8 million in the prior year quarter. The \$6.6 million decrease was primarily related to a \$5.2 million decrease in AMPOWER trial costs compared to the prior year period. A \$2.0 million decrease in noncash stock-based compensation also contributed. These aggregate decreases were offset by a \$0.9 million increase in costs incurred for outside services associated with the planned Amphora NDA resubmission for hormone-free prevention of pregnancy.

General and administrative costs decreased 41% to \$6.7 million in the second quarter of 2019 versus \$11.4 million in the prior year quarter. A \$6.2 million decrease in noncash stock-based compensation was mainly associated with stock-based awards granted in March 2018, for which a significant amount of noncash stock-based compensation expense was recognized during the second quarter of 2018. The decrease associated with noncash stock-based compensation was partially offset by a \$0.5 million increase in payroll related expenses due to increased headcount, a \$0.4 million increase in public relations and pre-commercialization marketing related expenses and a \$0.3 million increase in recruiting and consulting services.

Total other expense was \$23.5 million in the second quarter of 2019, and included noncash charges associated with our \$80 million private placement that closed during the current

period. There was no total other expense in the comparative quarter.

As a result, net loss attributable to common stockholders was \$35.5 million, or \$(0.97) per share, for the quarter ended June 30, 2019, compared with a net loss of \$23.2 million, or \$(1.11) per share, for the prior year quarter.

For the six months ended June 30, 2019, total operating expense decreased 42% to \$25.6 million, compared to total operating expense of \$44.2 million for the six months ended June 30, 2018.

Research and development costs decreased 45% to \$13.1 million versus \$23.8 million in the prior year period, primarily related to clinical trial activity. A \$12.7 million decrease in AMPOWER trial costs was partially offset by a \$2.5 million increase in AMPREVENCE trial costs in the first half of 2019. In addition, there was a \$1.9 million decrease in noncash stock-based compensation during the current period mainly associated with the aforementioned stock-based awards granted in March 2018. These aggregate decreases were partially offset by a \$1.4 million increase in costs incurred for outside services associated with the planned Amphora NDA resubmission as previously mentioned.

General and administrative costs decreased 39% to \$12.4 million versus \$20.4 million in the prior year period. A \$4.9 million decrease in noncash stock-based compensation within the current period was mainly associated with the aforementioned stock-based awards. Professional services and personnel costs were \$3.7 million lower due to the absence of one-time costs associated with the January 2018 merger, while public relations and pre-commercialization marketing related expenses increased by \$0.6 million in the current period.

Total other expense was \$27.9 million in the first half of 2019 and included noncash charges of \$23.6 million associated with the private placement that closed during the second quarter of 2019 and a noncash change in fair value of warrants of \$4.4 million which resulted from modifications to the warrants exercised and related reload warrants issued in February 2019. Total other expense in the prior year quarter was \$48.1 million and included noncash losses on the issuance of warrants and for the change in fair value of the Series D 2X liquidation preference.

As a result, net loss attributable to common stockholders was \$53.5 million, or \$(1.68) per share, for the six months ended June 30, 2019, compared with a net loss of \$92.4 million, or \$(5.15) per share, for the prior year period.

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

Unrestricted cash was \$50.7 million at June 30, 2019, as compared to \$0.2 million at March 31, 2019.

During the second quarter of 2019, the Company raised \$80 million from the sale of an aggregate of 17,777,779 shares of common stock to PDL BioPharma, Woodford Investment Management and Invesco Asset Management, LTD at \$4.50 per share and warrants to purchase up to 4,444,446 shares of Evofem common stock at an exercise price of \$6.38 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	August 6, 2019
Time	11:00 a.m. EDT
Dial-in numbers	(866) 503-5561 (U.S. toll-free) or (253) 336-2965
Passcode	1953988
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>

If participating by phone, please dial in approximately 10 minutes prior to the start of the call.

A slide presentation related to the call will be available via the aforementioned webcast link on the Evofem website <https://evofem.investorroom.com/investors-home>. Please connect to the website at least 15 minutes prior to the call to allow for any software download that may be necessary.

A replay of the teleconference will be available approximately two hours after completion through Sunday, August 11, 2019, at (855) 859-2056 (U.S.) or (404) 537-3406 (International). The replay access code is 1953988. The archived webcast will be available via the aforementioned URLs for one year.

### **About AMPOWER**

The Phase 3 'AMPOWER' clinical trial assessed the effectiveness and safety of the investigational product Amphora in preventing pregnancy over seven menstrual cycles of use in approximately 1,330 women at 112 centers in the United States. Evofem's lead candidate Amphora met the pre-specified primary endpoint of this trial, had a favorable safety profile, and was well tolerated.

### **About Evofem Biosciences**

Evofem Biosciences, Inc., is a clinical-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health. The Company is leveraging its proprietary Multipurpose Vaginal pH Regulator (MVP-R™) platform to develop its first product candidate, Amphora® (L-lactic acid, citric acid and potassium bitartrate). Amphora is an investigational 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.

Evofem plans to resubmit the Amphora New Drug Application (NDA) for prevention of pregnancy and vaginal lubrication in the fourth quarter of 2019. If approved, the Company plans to launch Amphora in 2020 as the first-in-class MVP-R for hormone-free, woman-controlled birth control.

This investigational MVP-R is also in development for prevention of certain sexually transmitted infections. Evofem expects to report top-line data from AMPREVENCE, the ongoing Phase 2b trial of Amphora to prevent urogenital acquisition of *Chlamydia trachomatis* (primary endpoint) and *Neisseria gonorrhea* (secondary endpoint) in women, in the fourth quarter of 2019.

For more information, please visit [www.evofem.com](http://www.evofem.com).

## Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements related to the closing of the second tranche, quarterly use of cash, the anticipated results of the Phase 2b clinical trial of Amphora to prevent urogenital acquisition of *Chlamydia trachomatis* and *Neisseria gonorrhea* in women, and any expected completion date or general timing for this clinical trial, the potential FDA approval of Amphora, and the potential commercial launch of Amphora. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from those, express or implied, in these forward-looking statements. Important factors that could impair the value of Evofem Biosciences' assets and business are disclosed in the risk factors contained in its Annual Report on Form 10-K filed with the Securities and Exchange Commission and subsequent filings. All forward-looking statements are expressly qualified in their entirety by such factors. Evofem Biosciences does not undertake any duty to update any forward-looking statement except as required by law.

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(Tables follow)

## **EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES** **CONDENSED CONSOLIDATED BALANCE SHEET DATA**

(Unaudited)  
(In thousands)

	<b>June 30, 2019</b>	<b>December 31, 2018</b>
Cash and cash equivalents	\$ 50,679	\$ 1,330
Restricted cash	401	431
Note payable	—	4,010
Total current liabilities	18,623	27,329
Total stockholders' equity (deficit)	35,792	(23,356)

**EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(Unaudited)

(In thousands, except share and per share data)

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
Operating expenses:				
Research and development	\$ 5,246	\$ 11,833	\$ 13,135	\$ 23,792
General and administrative	6,695	11,409	12,438	20,436
Total operating expenses	11,941	23,242	25,573	44,228
Loss from operations	(11,941)	(23,242)	(25,573)	(44,228)
Other income (expense):				
Interest income	108	32	126	62
Other expense, net	(7)	(32)	(21)	(82)
Loss on issuance of warrants	—	—	—	(47,920)
Loss on issuance of Purchase Rights	(674)	—	(674)	—
Change in fair value of warrants	(3,315)	—	(7,755)	—
Change in fair value of Purchase Rights	(19,617)	—	(19,617)	—
Change in fair value of Series D 2X liquidation preference	—	—	—	(130)
Total other expense, net	(23,505)	—	(27,941)	(48,070)
Loss before income tax	(35,446)	(23,242)	(53,514)	(92,298)
Income tax expense	(4)	(2)	(4)	(2)
Net loss	(35,450)	(23,244)	(53,518)	(92,300)
Accretion of Series D redeemable convertible preferred stock dividends	—	—	—	(66)
Net loss attributable to common stockholders	\$ (35,450)	\$ (23,244)	\$ (53,518)	\$ (92,366)

Net loss per share attributable to common stockholders, basic and

diluted	\$ (0.97)	\$ (1.11)	\$ (1.68)	\$ (5.15)
Weighted-average shares used to compute net loss attributable to common stockholders, basic and diluted	36,732,568	20,868,554	31,941,850	17,937,788

SOURCE Evofem Biosciences, Inc.

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