

Evoform Biosciences Reports First Quarter 2020 Financial Results and Provides Corporate Update

- On-Track for Phexxi™ PDUFA Date: May 25, 2020 -
- End-of-Phase 2 Meeting with FDA Today to Review Results of the AMPREVENCE Trial -
- Management to Host Conference Call Wednesday, May 6, 2020 at 11:00 a.m. EDT -

SAN DIEGO, May 6, 2020 /[PRNewswire](#)/ -- Evoform Biosciences, Inc. (NASDAQ: EVFM), a clinical-stage biopharmaceutical company, today reported financial results for the three-month period ended March 31, 2020.

"We are now less than three weeks away from the PDUFA date for Phexxi™ and the potential to deliver the first non-hormonal contraceptive innovation in decades. We are encouraged by our ongoing discussions with the FDA regarding the potential label for Phexxi and we look forward to sharing more details about our unique Phexxi TeleContraception™ platform and other launch initiatives on today's call," said Sandra Pelletier, Evoform's Chief Executive Officer.

"Our recent strategic financing agreement for up to \$25 million, coupled with our disciplined approach to resource allocation, gives us the financial flexibility we need to ensure that Phexxi gets the launch it deserves. If approved, we plan to launch Phexxi in early September along with a robust offering of support services designed to facilitate access to Phexxi and establish Evoform as a leader in women's health."

Recent highlights:

- Entered into discussions with the U.S. Food and Drug Administration (FDA) regarding the proposed label for Phexxi™ (L-lactic acid, citric acid, potassium bitartrate), the Company's investigational Multipurpose Vaginal pH Regulator (MVP-R™) for the prevention of pregnancy. The Prescription Drug User Fee Act (PDUFA) target action date for the completion of the FDA's review of the New Drug Application (NDA) for Phexxi is May 25, 2020.
- After careful consideration of the impact of COVID-19 on all aspects of the healthcare landscape, notably restrictions on physician interactions, the Company made a strategic decision to push the planned Phexxi commercial launch to the first week of September.
- End-of-phase 2 meeting with the FDA scheduled for today to discuss the [AMPREVENCE study results](#), and determine the clinical and regulatory path forward for EVO100, the Company's investigational MVP-R candidate for the prevention of urogenital chlamydia and gonorrhea in women.
- Secured up to \$25 million in strategic interim financing, with \$15 million initially funded at close.
- Three new data sets from the Phase 3 AMPPOWER trial of Phexxi for prevention of pregnancy accepted for poster presentations at the 2020 American College of Obstetricians and Gynecologists (ACOG) annual meeting and published in *Obstetrics & Gynecology (The Green Journal)* ([May 2020, Vol 135](#)).

First Quarter Financial Results

For the three months ended March 31, 2020, total operating expenses increased 41% to \$19.2 million. The increase was almost entirely associated with pre-commercialization efforts related to the potential U.S. launch of Phexxi for hormone-free, woman-controlled, on-demand contraception.

Research and development costs decreased \$3.7 million, or 47%, to \$4.2 million versus \$7.9 million in the prior year quarter. The primary driver was a \$5.1 million decrease in clinical trial expenses due to the timing of completing the clinical phases of the AMPPOWER and

AMPREVENCE trials. This reduction was partially offset by a \$0.6 million increase in costs incurred for outside services associated with the Phexxi NDA resubmission and manufacturing in preparation for the anticipated commercial launch of Phexxi, a \$0.5 million increase in payroll related expenses due to increased headcount, and a \$0.2 million increase in noncash stock-based compensation.

Selling and marketing costs were \$7.9 million in the first quarter of 2020, versus \$1.1 million in the prior year quarter; sales and marketing costs for the first quarter of 2019 were reclassified from general and administrative expenses to conform to the current period presentation. The \$6.8 million increase includes a \$3.7 million increase in pre-commercialization marketing related expenses, reflecting preparations for the potential launch of Phexxi for the prevention of pregnancy; a \$1.6 million increase in marketing and medical affairs consulting services; an \$0.8 million increase in payroll-related expenses due to increased headcount; and a \$0.3 million increase in noncash stock-based compensation.

General and administrative costs were \$7.1 million in the first quarter of 2020, versus \$4.6 million in the prior year quarter. The \$2.5 million increase includes a \$0.9 million increase in noncash stock-based compensation in the first quarter of 2020; a \$0.6 million increase in payroll related expenses due to increased headcount; and a \$0.6 million increase in consulting service fees predominantly related to sales force recruiting.

As a result, net loss was \$19.1 million, or \$(0.40) per share, for the first quarter of 2020 compared with a net loss of \$18.1 million, or \$(0.67) per share, for the prior year quarter.

Liquidity and Subsequent Material Events

Unrestricted cash and short-term investments were \$10.3 million at March 31, 2020, as compared to \$23.8 million at December 31, 2019.

In April 2020, the Company raised \$15 million from the sale of convertible notes and warrants with a U.S.-based, healthcare-focused institutional investor under a private Securities Purchase Agreement. An additional \$10 million may be funded at the Investor's discretion at any time prior to the Company meeting specific funding requirements defined in the Agreement.

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	May 6, 2020
Time	11:00 a.m. ET (8:00 a.m. PT)
Dial-in numbers	(866) 503-5561 (U.S. toll-free) or (253) 336-2965
Passcode	6295478
Webcast (live and archived)	www.evofem.com under "Investors"

The live webcast and related slide presentation can be accessed on the Company's Investor page at <https://evofem.investorroom.com/events>. Please connect to the Company's website at least 15 minutes prior to the start of the call to download any software that may be required.

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

A telephone replay will be available approximately two hours after the call through Monday, May 11, 2020 at (855) 859-2056 (U.S.) or (404) 537-3406 (International), access code 6295478. The webcast will be archived at <https://evofem.investorroom.com/events>.

About Phexxi™

Phexxi (L-lactic acid, citric acid, potassium bitartrate 1.8%/1%/0.4%) Vaginal Gel is an investigational Multipurpose Vaginal pH Regulator (MVP-R™) designed to regulate vaginal pH within the normal range of 3.5 to 4.5, even in the presence of semen, which normally raises the vaginal pH. This maintains an acidic environment that 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.

About Evofem Biosciences, Inc.

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's lead product candidate, Phexxi™, is currently being reviewed by the U.S. Food and Drug Administration for prevention of pregnancy. The investigational candidate EVO100 is being evaluated for prevention of urogenital transmission of both *Chlamydia trachomatis* infection (chlamydia) and *Neisseria gonorrhoeae* infection (gonorrhea) in women. For more information regarding Evofem, please visit www.evofem.com.

Phexxi™, Multipurpose Vaginal pH Regulator (MVP-R™) and TeleContraception™ are trademarks of Evofem Biosciences, Inc.

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 potential FDA approval of Phexxi™, the anticipated commercial launch of Phexxi, the timing and potential outcome of the scheduled meeting with the FDA to discuss the AMPREVENCE trial results and the clinical path for EVO100 for the prevention of urogenital acquisition of *Chlamydia trachomatis* and *Neisseria gonorrhoea* in women. 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, and Quarterly Report on 10-Q for the first quarter of 2020 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)

EVOFORM BIOSCIENCES, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEET DATA

(Unaudited)
(In thousands)

	March 31, 2020	December 31, 2019
Cash and cash equivalents	\$ 8,785	\$ 15,571
Restricted cash	480	304
Short-term investments	1,486	8,233
Total current liabilities	14,461	12,659
Total stockholders' equity	1,021	15,636

EVOFORM BIOSCIENCES, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2020	2019
Operating expenses:		
Research and development	\$ 4,247	\$ 7,889
Selling and marketing	7,855	1,118
General and administrative	7,142	4,625
Total operating expenses	19,244	13,632
Loss from operations	(19,244)	(13,632)

Other income (expense):

Interest income	102	18
Other expense	(4)	(14)
Change in fair value of warrants	—	(4,440)
Total other income (expense), net	98	(4,436)
Loss before income tax	(19,146)	(18,068)
Income tax expense	—	—
Net loss	(19,146)	(18,068)
Net loss per share, basic and diluted	\$ (0.40)	\$ (0.67)
Weighted-average shares used to compute net loss, basic and diluted	\$ 48,195,951	\$ 26,883,734

SOURCE Evofem Biosciences, Inc.
