

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

- Advancing Precommercial Activities in Preparation for Phexxi™ Commercial Launch in September 2020 -

- Pivotal Phase 3 Trial of EVO100 for Prevention of Chlamydia and Gonorrhea on Track for Q4 2020 Initiation -

- Management to Host Conference Call Tuesday, August 4, 2020 at 11:00 a.m. EDT -

SAN DIEGO, Aug. 4, 2020 /[PRNewswire](#)/ -- Evoform Biosciences, Inc., (NASDAQ: EVFM) ("Evoform" or the "Company"), a commercial stage biopharmaceutical company, today reported financial results for the three- and six- month periods ended June 30, 2020.

"The second quarter of 2020 was marked by success across all areas of our business. With the FDA approval of Phexxi in hand, more than \$130 million in gross proceeds from our two financing transactions on the books, and clear guidance from the FDA regarding the clinical path forward for EVO100, we are operating from a position of strength with a clear vision for the future," said Sandra Pelletier, Evoform's Chief Executive Officer. "We are now intensely focused on the successful commercial launch of Phexxi in September and ensuring the team's ongoing excellence in execution with manufacturing timelines, payer coverage, sales force recruitment and the build-out of our unique telemedicine platform — the Phexxi Concierge Experience. It's going to be an exciting third quarter."

Second quarter and recent highlights include:

- Received U.S. Food and Drug Administration (FDA) approval of Phexxi™ (lactic acid, citric acid and potassium bitartrate) for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception;
- Strengthened the balance sheet with approximately \$136 million in gross proceeds from two financing transactions during an incredibly challenging time in the financial markets;
- Both Medi-Span and First Databank, the two major drug information compendiums where the majority of payers obtain pricing and product information, have granted Phexxi new classification in their databases and pricing compendia as the first and only "Vaginal pH Modulator";
- Met with all major commercial payers and garnered early formulary inclusion of Phexxi at \$0 copay from several regional insurers;
- Ongoing publication and presentation of data from the Phase 3 AMPPOWER study of Phexxi for prevention of pregnancy, including [peer-reviewed publication of the pivotal AMPPOWER study results in Contraception](#); and,
- Participated in a productive End-of-Phase 2 meeting with the FDA, which supported and informed the Company's pivotal Phase 3 clinical trial design for EVO100 for the prevention of urogenital chlamydia and gonorrhea in women; study to be initiated in the fourth quarter of 2020.

Financial Results

Total operating expenses were \$22.4 million for the quarter ended June 30, 2020, compared to \$11.9 million for the quarter ended June 30, 2019.

Research and development costs for the second quarter of 2020 were \$2.6 million, compared to \$5.2 million in the prior year quarter, reflecting a \$2.3 million decrease in clinical trial costs due to completion of the AMPREVENCE trial in the fourth quarter of 2019. Additionally, an aggregate \$1 million reduction in outside services cost and payroll related expense was partially offset by a \$500,000 increase in noncash stock-based compensation in the current period.

Selling and marketing costs for the second quarter of 2020 were \$10.0 million. For the second quarter of 2019, selling and marketing costs of \$1.3 million were reclassified from general and administrative expenses to conform to the current period presentation. The increased expense in the current period reflects preparations for the commercial launch of Phexxi for the prevention of pregnancy in September 2020, including increased pre-commercialization marketing expenses, higher payroll-related expenses due to increased headcount, and increased market access and medical affairs expenses.

General and administrative costs for the second quarter of 2020 were \$9.7 million, compared to \$5.4 million in the prior year quarter. The increase is primarily related to an aggregate \$2.1 million increase in costs associated with various operational items associated with the issuance of convertible debt, legal costs, payroll related costs due to increased headcount, and other general business expenses. Additionally, there was a \$2.2 million increase in noncash stock-based compensation mainly associated with stock-based awards granted in February 2020.

Total other expense was \$30.3 million in the second quarter of 2020, and mainly included the noncash loss on the issuance and subsequent change in fair value during the period of convertible notes, warrants, and purchase rights that were issued in connection with the debt transaction that closed during the second quarter of 2020. Total other expense of \$23.5 million in the prior year quarter included noncash charges associated with the \$80 million private placement that closed during that period.

As a result, net loss attributable to common stockholders was \$52.7 million, or \$(0.91) per share, for the quarter ended June 30, 2020, compared with a net loss of \$35.5 million, or \$(0.97) per share, for the prior year quarter.

Unrestricted cash and short-term investments were \$123.6 million at June 30, 2020, compared to \$23.8 million at December 31, 2019.

The Company reiterated its prior guidance for fiscal 2020, including its expectations of:

- General and administrative expense in the upper \$20 million to low \$30 million range, including approximately \$8 to \$10 million of noncash stock-based compensation expense;
- Research and development expense in the high-teens to low \$20 million range, including anticipated noncash stock-based compensation expense of \$2 to \$3 million.
- Sales and marketing expenses of approximately \$63 to \$68 million, including anticipated noncash stock-based compensation expense of \$2.5 million.

The Company continues to expect cash burn of approximately \$36 to \$38 million in the third quarter and approximately \$42 to \$44 million in the fourth quarter of 2020. Based on current forecasts, the Company believes its current cash and short-term investments provide runway into the second quarter of 2021.

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 4, 2020
Time	11:00 a.m. EDT (8:00am PDT)
Dial-in numbers	(866) 503-5561 (U.S. toll-free) or (253) 336-2965
Passcode	5884198

Webcast (live and archived)

www.evofem.com under "Investors" or [click here](#)

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 Friday, August 7, 2020 at (855) 859-2056 (U.S.) or (404) 537-3406 (International), conference ID 5884198.

The webcast will be archived at <https://evofem.investorroom.com/events>.

About PHEXXI™ (lactic acid, citric acid, and potassium bitartrate) Vaginal Gel

Phexxi is a prescription vaginal gel used to prevent pregnancy in females who choose to use an on-demand method of birth control. Phexxi is only effective when used immediately **before** (or up to one hour before) each act of vaginal sex. It is not effective when used after vaginal sex.

Important Safety Information

What are the possible side effects of Phexxi?

There have been a few cases of urinary bladder infection and kidney infection reported in clinical studies. One of the cases was serious. Avoid Phexxi if you have had repeated urinary tract infections or other urinary tract problems.

The **most common side effects** were vaginal burning, vaginal itching, vaginal yeast infection, urinary tract infection, vaginal area discomfort, bacterial vaginosis, and vaginal discharge. Women also reported genital discomfort, pain while urinating, and vaginal pain. Some male partners reported genital discomfort.

What else should I know about using Phexxi?

Phexxi does not protect against any sexually transmitted diseases, including HIV. Avoid using Phexxi with a vaginal ring.

Contact your healthcare provider if you are experiencing severe genital irritation or discomfort or urinary tract symptoms. Avoid Phexxi if you or your sexual partner is allergic to lactic acid, citric acid, potassium bitartrate, or any of the ingredients in Phexxi. Stop using Phexxi if you develop an allergic reaction.

Please see [full Prescribing Information](#) for Phexxi, including Patient Information.

Please report side effects by contacting Evofem Biosciences toll-free at 1-833-EVFM BIO or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

About Evofem Biosciences, Inc.

Evofem Biosciences, Inc., (NASDAQ: EVFM) is a commercial-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health, including hormone-free, woman-controlled contraception and protection from certain sexually transmitted infections (STIs). The Company's first commercial product, Phexxi™ (lactic acid, citric acid and potassium bitartrate), is the first and only hormone-free, prescription gel approved in the United States for the prevention of pregnancy. The Company is also advancing EVO100 into Phase 3 clinical trials for the prevention of urogenital transmission of both *Chlamydia trachomatis* infection (chlamydia) and *Neisseria gonorrhoeae* infection (gonorrhea) in women. For more information, please visit www.evofem.com.

Forward-Looking Statements

This press release includes "forward-looking statements," within the meaning of the safe harbor for forward-looking statements provided by Section 21E of the Securities Exchange Act of 1934, as

amended; and the Private Securities Litigation Reform Act of 1995, including, without limitation, statements related to Evofem's expectations regarding its burn rate and cash runway, the success and timing of the commercial launch of Phexxi, the success of the Phexxi Concierge Experience, the execution and success of our publication and presentation plan, and the timing of our Phase 3 clinical trial for EVO100. Various factors could cause actual results to differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Important factors that could cause actual results to differ materially from those discussed or implied in the forward-looking statements, or that could impair the value of Evofem Biosciences' assets and business, are disclosed in Evofem's SEC filings, including its Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 12, 2020, its Quarterly Report on Form 10-Q for the quarters ended March 31, and June 30, 2020 filed with the SEC on May 6, 2020 and August 4, 2020, respectively, and its Current Report on Form 8-K filed with the SEC on June 2, 2020. All forward-looking statements are expressly qualified in their entirety by such factors. Evofem does not undertake any duty to update any forward-looking statement except as required by law.

Phexxi[™] is a trademark of Evofem Biosciences.

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(Tables follow)

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

(Unaudited)

(In thousands)

	June 30, 2020	December 31, 2019
Cash and cash equivalents	\$ 123,556	\$ 15,571
Restricted cash	200	304
Short-term investments	—	8,233
Total current liabilities	61,806	12,659

Total liabilities	66,517	12,659
Total stockholders' equity	68,539	15,636

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

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 2,640	\$ 5,246	\$ 6,887	\$ 13,135
Selling and marketing	9,997	1,313	17,852	2,431
General and administrative	9,735	5,382	16,877	10,007
Total operating expenses	22,372	11,941	41,616	25,573
Loss from operations	(22,372)	(11,941)	(41,616)	(25,573)
Other income (expense):				
Interest income	29	108	131	126
Other expense	(349)	(7)	(353)	(21)
Loss on issuance of financial instruments	(64,049)	(674)	(64,049)	(674)
Change in fair value of financial instruments	34,075	(22,932)	34,075	(27,372)
Total other expense, net	(30,294)	(23,505)	(30,196)	(27,941)
Loss before income tax	(52,666)	(35,446)	(71,812)	(53,514)
Income tax expense	—	(4)	—	(4)
Net loss	(52,666)	(35,450)	(71,812)	(53,518)
Net loss per share, basic and diluted	(0.91)	(0.97)	(1.36)	(1.68)
Weighted-average shares used to compute net loss per share, basic and diluted	57,696,519	36,732,568	52,946,235	31,941,850

SOURCE Evofem Biosciences, Inc.

