Evofem Biosciences Reports Fourth Quarter and Year-end 2019 Financial Results and Provides Corporate Update

-- U.S. Food and Drug Administration (FDA) Grants Conditional Approval for New Brand Name - Phexxi™ --

-- PDUFA Date of May 25, 2020 Assigned for Phexxi New Drug Application (NDA) --

-- End-of-Phase 2 Meeting Scheduled with FDA to Review Results of the AMPREVENCE Trial --

-- Management to Host Conference Call Thursday, March 12, 2020 at 11:00 a.m. EDT --

SAN DIEGO, March 12, 2020 /PRNewswire/ -- Evofem Biosciences, Inc. (NASDAQ:EVFM), a clinical-stage biopharmaceutical company, today reported financial results for the three- and twelve- month periods ended December 31, 2019.

The Company also announced that the FDA granted conditional approval for the brand name Phexxi™ (L-lactic acid, citric acid, potassium bitartrate) Vaginal Gel 1.8%/1%/0.4% on February 25, 2020. With this approval, the Company will now refer to its Multipurpose Vaginal pH Regulator (MVP-R ™) candidate as Phexxi for the prevention of pregnancy and EVO100 for the prevention of chlamydia and gonorrhea.

"The Evofem team's exceptional execution in 2019 laid the groundwork for what will be a transformative year for the Company," said Saundra Pelletier, Chief Executive Officer, Evofem Biosciences. "We are rapidly approaching the established FDA PDUFA date for our innovative, hormone-free, investigational contraceptive gel, which we are thrilled to share is now branded as *Phexxi*.

"We remain focused on establishing a best-in-class sales force, initiating pre-commercial activities and continuing to disseminate compelling new data via conferences and publications. We are also preparing for other important catalysts that have the potential to drive future growth, including an end-of-phase 2 meeting with the FDA to discuss the potential path forward for EVO100 for the prevention of chlamydia and gonorrhea."

Fourth quarter and recent highlights include:

- Resubmitted the NDA for Phexxi for the prevention of pregnancy and received a six-month review and Prescription Drug User Fee Act (PDUFA) goal date of May 25, 2020 from the FDA.
- Reported positive, statistically significant top-line results from the Phase 2b AMPREVENCE study evaluating EVO100 for the prevention of chlamydia and gonorrhea in women. The study met its primary and secondary endpoints, demonstrating a 50% relative risk reduction in chlamydia infection and a 78% relative risk reduction in gonorrhea infection compared to placebo.
- Three abstracts from the Phase 3 AMPOWER trial of Phexxi for prevention of pregnancy accepted for poster presentation at the American College of Obstetricians and Gynecologists' annual meeting.
- Appointed Lisa Rarick, M.D., F.A.C.O.G., former FDA Division Director for the Division of Reproductive and Urologic Products, to the Company's Board of Directors.
- Granted end-of-phase 2 meeting with the FDA to discuss AMPREVENCE study results and determine the clinical and regulatory path forward for EVO100.

Fourth Quarter Financial Results

For the quarter ended December 31, 2019, total operating expenses decreased 14% to $12.9

million, compared to $15.0 million for the quarter ended December 31, 2018.

Research and development costs decreased $6.4 million, or 65%, to $3.4 million in the fourth quarter of 2019 versus $9.8 million in the prior year quarter. The decrease was primarily driven by lower clinical trial expenses reflecting completion of the clinical phase of the Phase 3 AMPOWER study in November 2018 and of the Phase 2b AMPREVENCE study in August 2019, offset by higher payroll related and consulting service fees.

General and administrative costs increased $4.2 million, or 81%, to $9.4 million in the fourth quarter of 2019 versus $5.2 million in the prior year quarter. This includes a $1.8 million increase in pre-commercialization sales and marketing related expenses, reflecting preparations for the potential approval and launch of Phexxi for the prevention of pregnancy in the second quarter of 2020; a $1.0 million increase in payroll related expenses due to increased headcount; a $1.0 million increase in consulting services; and a $0.1 million increase in noncash stock-based compensation in the fourth quarter of 2019.

As a result, net loss attributable to common stockholders improved to $12.7 million, or $(0.27) per share, for the fourth quarter of 2019 compared with a net loss of $15.0 million, or $(0.58) per share, for the prior year quarter.

Full Year Financial Results

For the year ended December 31, 2019, total operating expenses decreased 32% to $52.7 million, compared to total operating expenses of $77.6 million for the year ended December 31, 2018.

Research and development costs decreased 49% to $22.2 million, compared to $43.4 million in the prior year period. The $21.2 million decrease in clinical trial costs during the year ended December 31, 2019 was primarily related to completion of the clinical phase of the AMPOWER and AMPREVENCE studies as previously noted.

General and administrative costs decreased 11% to $30.5 million, compared to $34.2 million in the prior year period. Noncash stock-based compensation decreased $7.2 million in the current period, since the majority of stock-based awards granted in 2018 vested that year. Professional services and personnel costs were $3.8 million lower due to the absence of one-time costs associated with the Company's January 2018 merger. These were offset by a $3.4 million increase in pre-commercialization advertising agency fees, public relations and sales support-related costs during the current period. Additionally, payroll related expenses and consulting services increased $2.3 million and $1.4 million, respectively, in the current period.

Total other expense was $27.3 million for the year ended December 31, 2019 and was primarily attributable to noncash charges related to the closing of our private placement during the second quarter of 2019, and to recognize various changes in the fair value of warrants of $4.4 million in the first quarter of 2019. Total other expense in the year ended December 31, 2018 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 improved to $80.0 million, or $(1.99) per share, for the year ended December 31, 2019, compared with a net loss of $125.8 million, or $(5.74) per share, for the year ended December 31, 2018.

Liquidity and Subsequent Material Events

Unrestricted cash and short-term investments were $23.8 million at December 31, 2019, as

compared to $35.8 million at September 30, 2019.

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 12, 2020
Time	11:00 a.m. EDT (8:00 a.m. PDT)
Dial-in numbers	(866) 503-5561 (U.S. toll-free) or (253) 336-2965
Passcode	5595046
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 Tuesday, March 17, 2020 at (855) 859-2056 (U.S.) or (404) 537-3406 (International), access code 5595046. The webcast will be archived at https://evofem.investorroom.com/events.

About Phexxi™
Phexxi (L-lactic acid, citric acid, potassium bitartrate) Vaginal Gel 1.8%/1%/0.4% 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 to 7.0 to 8.0. 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™ and Multipurpose Vaginal pH Regulator (MVP-R™) 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 gonorrhea* 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 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.

Investor Contact
Amy Raskopf
Evofem Biosciences
araskopf@evofem.com
M: (917) 673-5775

Media Contact
Cara Miller
Evofem Biosciences, Inc.
cmiller@evofem.com
O: (858) 550-1900 x272

(Tables follow)

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

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 15,571	$ 1,330
Restricted cash	304	431
Short-term investments	8,233	—
Note payable	—	4,010
Total current liabilities	12,659	27,329
Total stockholders' equity (deficit)	15,636	(23,356)

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,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 3,432	$ 9,772	$ 22,230	$ 43,415
General and administrative	9,440	5,209	30,512	34,227
Total operating expenses	12,872	14,981	52,742	77,642
Loss from operations	(12,872)	(14,981)	(52,742)	(77,642)
Other income (expense):				
Interest income	120	30	458	127
Other income (expense), net	35	(30)	301	(145)
Loss on issuance of warrants	—	—	—	(47,920)
Loss on issuance of Purchase Rights	—	—	(674)	—
Change in fair value of warrants	—	—	(7,755)	—
Change in fair value of Purchase Rights	—	—	(19,617)	—
Change in fair value of Series D 2X liquidation preference	—	—	—	(130)
Total other income (expense), net	155	—	(27,287)	(48,068)
Loss before income tax	(12,717)	(14,981)	(80,029)	(125,710)
Income tax expense	—	—	(4)	(2)
Net loss	(12,717)	(14,981)	(80,033)	(125,712)
Accretion of Series D redeemable convertible preferred stock dividends	—	—	—	(66)
Net loss attributable to common stockholders	$ (12,717)	$ (14,981)	$ (80,033)	$ (125,778)
Net loss per share attributable to				

common stockholders, basic and diluted	$ (0.27)	$ (0.58)	$ (1.99)	$ (5.74)
Weighted-average shares used to compute net loss attributable to common stockholders, basic and diluted	47,443,632	25,819,183	40,228,517	21,900,574

SOURCE Evofem Biosciences, Inc.