

Evoform Biosciences Issues Mid-Year 2020 Letter to Stockholders

- On-Track for September Launch of Phexxi™, the First FDA-Approved, Non-Hormonal, On-Demand Prescription Contraceptive Gel -
- Advancing EVO100 for the Prevention of Urogenital Chlamydia and Gonorrhea -
- ~ \$136 Million Gross Proceeds Raised; Funding Expected to Carry the Company into Q2 2021 -

SAN DIEGO, July 1, 2020 /[PRNewswire](#)/ -- Evoform Biosciences, Inc. (NASDAQ: EVFM), a commercial-stage biopharmaceutical company, today announced that it has issued a letter to its stockholders providing an update on recent events and outlook for the remainder of 2020 and early 2021.

The full text of the **letter** follows below.

A MESSAGE FROM OUR CHIEF EXECUTIVE OFFICER

To My Fellow Stockholders:

As we begin the second half of what has been an unprecedented and unpredictable year, I want to begin with a message of gratitude, admiration and support:

- For the healthcare workers who are putting themselves at risk to treat and care for patients with COVID-19;
- For the essential business owners and employees who have been instrumental in ensuring people have access to food, water and other basic needs; and
- For the individuals who remain steadfast in their fight against racism and inequality in all its forms.

We appreciate and celebrate your commitment to challenging the status quo, putting others first and addressing disparities in our healthcare system and beyond.

I am proud to say that Evoform Biosciences has long been a champion for equal rights – working to break down barriers to equality and advance new products that put women in control of their own sexual and reproductive health. We are a female-forward company supported by a predominantly female Executive Team and Board of Directors (50% and 60%, respectively) and our values reflect a focus on diversity, inclusion and opportunity.

Together, this team has advanced from clinical trials through U.S. Food and Drug Administration (FDA) approval, the first contraceptive innovation in decades – Phexxi™ (lactic acid, citric acid and potassium bitartrate). Phexxi speaks to a significant unmet need in Women's Health – offering women a safe and effective female-controlled, non-hormonal, on-demand contraceptive gel for use *only* when she needs it and *never* when she doesn't.

We are also focused on the lack of innovation in the prevention of women's acquisition of urogenital chlamydia and gonorrhea. These two dangerous sexually transmitted diseases impact more than 2.1 million people in the U.S., yet there are still no FDA-approved preventative prescription products.

As we are now at the halfway mark of one of the most transformational years in the history of

Evoform Biosciences, it seemed timely and appropriate for me to provide an update on the significant regulatory and financial milestones we have already achieved, as well as our expectations for the remainder of 2020.

Key Accomplishments in the First Half of 2020

- Received U.S. FDA approval of Phexxi for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception;
- Participated in a productive end-of-Phase 2 meeting with the FDA to discuss the clinical and regulatory path forward for EVO100 for the prevention of urogenital chlamydia and gonorrhea, laying the foundation for us to advance this important program into a Phase 3 clinical trial later this year;
- Strengthened our Board of Directors with the addition of former FDA Division Deputy Director Lisa Rarick, M.D., F.A.C.O.G.;
- Published three new data abstracts from the Phase 3 AMPOWER trial of Phexxi for prevention of pregnancy in *Obstetrics & Gynecology (The Green Journal)*. These data were also accepted for presentation at the 2020 American College of Obstetricians and Gynecologists (ACOG) annual meeting; and,
- Raised approximately \$136 million in gross proceeds from the close of two transactions during an incredibly challenging time in the financial markets:
 - An underwritten public offering of common stock that both launched and closed in early June; and
 - A private placement of convertible notes and warrants with a U.S.-based, healthcare-focused institutional investor.

We believe the tremendous show of support we received in the first half of 2020 from such a diverse group of institutional investors with impressive biotech and pharmaceutical portfolios speaks to their confidence in Evoform's management team and in our commercialization strategy for Phexxi.

Planned Milestones in the Second Half of 2020

Heading into the second half of 2020, we have a strengthened balance sheet with cash runway expected to fund planned operations into Q2 2021, clear direction from the FDA on our plans for EVO100 and a concentrated focus on several key deliverables, including:

- Launch preparations for Phexxi, which have been underway for months, and the "Coming Soon" campaign, which will launch this summer. This campaign is designed to raise awareness among women and health care providers of the pending commercial availability of an innovative hormone-free, on-demand contraceptive.
- The full commercial launch and product availability of Phexxi, which is on track for early September and includes the Phexxi Concierge Experience, a comprehensive telemedicine support system designed to make access to Phexxi for women who are "beyond hormones," seamless and rapid. The Phexxi Concierge Experience will also provide physicians with on-demand educational support, and speed and simplify women's access to Phexxi.
- A robust publication and presentation plan that includes:
 - Publication of the full Phase 3 AMPOWER study results in a well-respected, peer-reviewed journal;
 - Presentation/publication of additional data from AMPREVENCE, the Phase 2b trial of EVO100 for prevention of chlamydia and gonorrhea in women.
- Initiation of the pivotal Phase 3 clinical trial for EVO100 for the prevention of urogenital chlamydia and gonorrhea, slated to begin in the fourth quarter of 2020 - positioning us to report top-line results in 2022.

Despite the challenges of the current external environment, Evoform is operating from a position of financial and executional strength. Our experienced management team is focused on driving the successful launch of Evoform's innovative, FDA-approved prescription contraceptive asset; continuing to address unmet needs in women's sexual and reproductive health; and executing on our long-term strategy to create value for women and stockholders alike.

In Closing

We are highly confident in our ability to deliver the first new contraceptive innovation in decades to the millions of women who have been waiting for an option that speaks to *them* because we understand their needs and are leveraging the three critical pillars for success:

- Unmet need. In the United States today, there are more than 17 million women who don't want to get pregnant, don't want hormones in their birth control, and who are fed up with their current options. What they do want is protection, control, an option that doesn't require hormones and one that speaks to their needs.
- Innovation. Phexxi is the first and only non-hormonal, prescription contraceptive product that women can use at their discretion to protect themselves when they need it.
- An experienced team that knows how to execute. Our organization is made up of people who have ensured the success of some of the largest and most successful assets in this category, and we are confident that we have developed an innovative and comprehensive launch strategy for Phexxi.

As you might imagine, we are very excited about the future potential of Evofem Biosciences and we are thrilled to have you with us on this journey. We appreciate your ongoing support.

Warmest regards,

Saundra Pelletier
President, Chief Executive Officer and Shareholder
Evofem Biosciences

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

Phexxi is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

Limitations of Use

Phexxi is not effective for the prevention of pregnancy when administered after intercourse.

Warnings and Precautions

Few cases (0.36%) reported adverse reactions of cystitis, pyelonephritis and other upper urinary tract infection (UTI) have been reported in Phexxi clinical studies. Of these, one case of pyelonephritis was considered serious and required hospitalization. Avoid use of Phexxi in females of reproductive potential with history of recurrent urinary tract infection or urinary tract abnormalities.

Adverse Reactions

Most common adverse reactions ($\geq 2\%$) were vulvovaginal burning sensation, vulvovaginal pruritus, vulvovaginal mycotic infection, urinary tract infection, vulvovaginal discomfort, bacterial vaginosis, vaginal discharge, genital discomfort, dysuria, and vulvovaginal pain.

Patients should be counseled on the following:

- **To contact and consult with their healthcare provider for severe or prolonged genital irritation or experiencing urinary tract symptoms.**
- **To discontinue Phexxi if they develop a local hypersensitivity reaction.**
- **That Phexxi does not protect against HIV infection (AIDS) or other sexually transmitted infections.**

Please see full Prescribing Information for Phexxi. To report suspected adverse reactions, contact Evofem at toll-free phone 1-833-EVFMBIO or you may 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. Evofem Biosciences aims to advance the quality of life for women by developing innovative solutions, such as 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 approved in the United States for the prevention of pregnancy. The Company is advancing EVO100 for the prevention of urogenital transmission of both *Chlamydia trachomatis* infection (chlamydia) and *Neisseria gonorrhoeae* infection (gonorrhea) in women.

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 quarter ended March 31, 2020 filed with the SEC on May 6, 2020 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.

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