



EVOFORM
BIOSCIENCES®

Evoform Biosciences, Inc.

7770 Regents Road, Suite 113-618

San Diego, CA 92122

Phone: (858) 550-1900

<https://www.evofem.com/>

Ticker (Exchange)	EVFM-OTCQB
Recent Price (05/13/2024)	\$0.0136
52-week Range	\$0.01 to 2.35
Shares Outstanding	45.9 mm
Market Capitalization	\$624K
Average 10-day volume	936.9K
Insider Ownership +>5%	—
Institutional Ownership	—
EPS (Qtr. ended 12/31/2023)	(\$0.05)
Employees	36



COMPANY DESCRIPTION

Evoform Biosciences, Inc. (“Evoform” or “the Company”) is a commercial-stage biopharmaceutical company focused on addressing unmet needs within the women’s sexual and reproductive healthcare markets. The Company’s initial Food and Drug Administration (FDA)-approved product, Phexxi®, is a hormone-free, on-demand prescription contraceptive vaginal gel. Packaged in boxes containing twelve pre-filled applicators (like a tampon), Phexxi is inserted within one hour before intercourse and works to prevent pregnancy by maintaining the vaginal pH, which reduces sperm motility and lowers the chance of sperm reaching the egg. Evoform’s Phexxi has no systemic activity in the body, which is important to the 23 million women who are beyond using contraceptives containing hormones due to the pervasive side effects or risk of drug-drug interactions. These include women who may be breastfeeding or breast cancer patients/survivors, as well as those using **GLP-1s**[†] for weight loss who need supplemental birth control because oral contraceptive pills are less effective at certain times of the GLP-1 dosing regimen. Evoform’s common stock trades on the OTCQB Venture Market under the ticker symbol “EVFM.”

KEY POINTS

- On December 11, 2023, Evoform and Aditxt, Inc. (ADTX-NASDAQ) entered into a Merger Agreement under which Aditxt intends to acquire Evoform. On May 2, 2024, the companies reinstated the Merger Agreement, as amended, and entered into the Fourth Amendment to the Agreement and Plan of Merger. The companies are working toward close in the second half of 2024.
- The women’s healthcare market is highly profitable, where small percentages of market share can deliver big results. Evoform’s **wholesale acquisition cost (WAC)** for a box of twelve prefilled Phexxi applicators is \$348. Evoform is averaging \$209/box, net. On average, a woman fills her prescription six times a year (with Evoform’s cost of goods per box of 12 at ~\$35).
- As of January 1, 2023, most insurers and **pharmacy benefit managers (PBMs)** must cover FDA-approved contraceptives, such as Phexxi, with no out-of-pocket costs (\$0 copay) when prescribed by a healthcare provider. In January 2024, the Biden administration announced new guidance to enable expanded access to all FDA-approved contraceptives without cost. Implementation could eliminate financial barriers for contraceptives like Phexxi for ~49 million women.
- Evoform has intellectual property protection into at least 2033, including four Orange Book listed U.S. patents and one newly allowed patent covering Phexxi and its labeled indication.
- The Company’s management team holds over 85 years of combined experience in the healthcare and pharma industry.
- Evoform is working to expand Phexxi’s global presence through licenses outside the U.S. The product is approved in Nigeria, with regulatory submissions in Ghana, Ethiopia, and Mexico.

Table of Contents

Executive Overview3

Company Leadership7

Corporate Strategy and Potential Milestones11

Intellectual Property12

Core Story14

Investment Highlights32

Historical Financial Results34

Recent Events37

Risks and Disclosures42

Glossary46

Executive Overview

Evoform Biosciences, Inc. (“Evoform” or “the Company”) is a commercial-stage biopharmaceutical company focused on addressing unmet needs within the women’s sexual and reproductive healthcare markets. The Company was established with a goal of enhancing the well-being of women globally, empowering them with greater control over their sexual and reproductive health, and delivering better solutions to current options. The Company’s first Food and Drug Administration (FDA)-approved product, Phexxi® (lactic acid, citric acid and potassium bitartrate), is a hormone-free prescription contraceptive gel (a **vaginal pH modulator [VPM]**), which is designed for on-demand use. Phexxi works to prevent pregnancy by maintaining the vaginal pH, which reduces sperm motility and lowers the chance of sperm reaching the egg. This revolutionary mechanism of action is unique to Phexxi, with no other contraceptive product like it available on the market. The Company’s common stock trades on the OTCQB Venture Market under the ticker symbol “EVFM.”

The U.S. women’s contraceptive market is large, with more than 72 million women in the U.S. of reproductive age. Of these, 23 million women rely on non-hormonal methods or use no contraceptive at all. This is likely due to the pervasive side effects of hormonal contraceptives—specifically from pills, patches, **intrauterine devices (IUDs)**, etc. Side effects from hormones can include weight gain, acne, bleeding, and headaches, as well as emotional highs and lows, which can become overwhelming. An additional 20 million women use prescription birth control methods, which are predominantly hormonal.

Phexxi (where the “xx” represents the female chromosome) is available in a 4-inch prefilled applicator (similar in size to a tampon applicator) containing 5 ml of gel. A box, which is intended to be a one-month supply, contains twelve applicators. One to three boxes are typically dispensed with each prescription (Figure 1). Phexxi is self-administered from zero to 60 minutes before each act of vaginal intercourse; it can be inserted immediately before sex.

Women are very aware of the hormones that they put in their bodies; approximately 75% of women have concerns or completely oppose hormonal birth control. These women are a part of the 23 million women who are currently not using hormonal birth control methods and who are becoming a large subset of early adopters of Phexxi. Evoform intends to expand Phexxi’s global reach and further increase its commercial potential through ex-U.S. licenses. The product is approved in Nigeria, and regulatory dossiers have been submitted in Ghana, Ethiopia, and Mexico.

Figure 1
PHEXXI®



Source: Evoform Biosciences, Inc.

Contraceptive Options

The modern contraceptive market was established in the 1960s with the introduction of “the pill,” the first oral contraceptive widely available to women in the U.S. There was no significant innovation within women’s reproductive health until almost 30 years after the “the pill” was introduced when pharmaceutical companies launched the non-hormonal copper intrauterine device (IUD) and synthetic hormonal products with different hormonal delivery systems, including the hormonal IUD, implants, the patch, and the **vaginal ring**.

Today, among the hormone-free contraceptive options available, there are condoms, spermicide, fertility tracking, copper IUD, vaginally inserted barrier methods (diaphragm, cervical cap, and female condom), and **tubal ligation** (i.e., getting your tubes tied). Hormone-containing options include the birth control pill (of which there are roughly 150 different pill versions currently on the market), as well as the patch, vaginal ring, hormonal IUD, implant, and hormone injections.

Many of these hormone-containing options are associated with undesirable side effects, such as weight gain, acne, headache, loss of libido, mood changes, and a slight risk of blood clots, which may lead women to discontinue their use and seek alternative contraceptive methods. As well, a peer-reviewed analysis published in the journal *PLOS Medicine* in March 2023 found that the use of hormonal birth control was associated with a slight increase in the risk of breast cancer.

Phexxi

Evoform launched Phexxi in the U.S. in September 2020, believing that the product addresses significant gaps regarding underserved and unmet needs within the contraceptive market. Among all contraceptive options currently available to women, Phexxi is unique in that it is:

- *Hormone-free.* Phexxi is an innovative gel that works to prevent pregnancy without the use of hormones. Because Phexxi is completely hormone-free, there is no need for women to worry about the hormone-related side effects associated with hormonal birth control methods.
- *Non-systemic.* Phexxi acts locally in the vagina and does not enter the bloodstream. Therefore, there is no need for women to worry about potential interactions with other medications they may be taking. This is of particular concern to women using GLP-1s for diabetes or weight loss; some of these drugs may reduce the efficacy of oral contraceptive pills (OCs) at certain periods in the dosing regimen. Women concurrently taking GLP-1s and OCs are counseled to change methods or use a supplemental hormone-free contraceptive, like Phexxi, in those periods of the GLP-1 dosing regimen.
- *Only when needed.* With Phexxi, women no longer need to have birth control in their bodies 24/7. Phexxi is used in the moment, prior to every act of intercourse, where there is no daily commitment needed. This also makes Phexxi easily reversible, providing women with a flexible option for family planning.
- *First in class.* Phexxi is the first and only hormone-free prescription contraceptive gel that women control. It works to prevent pregnancy by maintaining the natural vaginal pH, which reduces sperm motility and lowers the chance of sperm reaching the egg. This mechanism of action is unique to Phexxi with no other products like it in the market.
- *Woman-controlled.* Phexxi puts women in control of their bodies and their pregnancy prevention. There is no need to rely on a partner using a condom and no need to visit a doctor for an injection or procedure to prevent pregnancy. Phexxi was designed with spontaneity and convenience in mind.

Vaginal pH Modulator (VPM) Mechanism of Action

As a vaginal pH modulator (VPM), Phexxi's prefilled applicator contains 5 ml of gel at pH 3.55. This gel is a combination of three active ingredients: (1) L-lactic acid; (2) citric acid; and (3) potassium bitartrate. Inactive ingredients include a preservative (benzoic acid); gelling agents (alginic acid and xanthan gum); humectant (glycerin); sodium hydroxide; and water. The gel is very viscous and bioadhesive, to where it does not leak out, and is very lubricating.

A normal vaginal pH range of 3.5 to 4.5 is important for maintaining good vaginal health. At this optimal pH level, the vagina contains a balance of necessary healthy bacteria and is inhospitable to sperm as well as certain viral and bacterial pathogens. Typically, the introduction of semen (which has a pH of between 7.2-8.0) into the vagina causes a rise in pH above 6.0 due to the alkalinity of the ejaculate, which neutralizes the normally acidic vaginal environment and allows for the survival of sperm. The active ingredients in Phexxi maintain a normal vaginal pH (3.5-4.5) even in the presence of semen, creating an inhospitable environment for sperm. The maintenance of the slightly acidic vaginal pH reduces the availability of calcium ions which are needed to drive sperm tail movement. As a result, Phexxi can prevent pregnancy by reducing sperm motility, inhibiting sperm from reaching the ovum to form a zygote.

In 2022, Evofem developed and introduced a new contraceptive educational chart for patients and healthcare providers, which details high-level information about birth control methods currently available to women in the U.S., including its vaginal pH modulator Phexxi. This new educational tool has been extremely well received and has had a positive impact with healthcare providers and patients alike. The poster, which is shown in gynecologists' offices (see Figure 4, page 17), highlights the difference between hormone-free contraceptives versus those with hormones, and is intended to form the basis for counseling conversations between patients and their physicians as it relates to the most appropriate contraceptive option for a patient.

Addressing an Underserved and Unmet Market

The Company believes that Phexxi could increase the prescription birth control user market when considering the 23 million women who are currently at risk for pregnancy and do not use hormone-based contraceptives as their primary form of contraception, including the 13 million women who do not use contraception at all. In addition, as women's expectations change throughout their contraceptive journey, Phexxi could compete for market share in at least three contraceptive categories (1) hormonal short-acting reversible contraceptives, consisting of oral contraceptive pills, patches, and rings; (2) long-acting reversible contraception, comprising IUDs, implants, and injectables; and (3) over-the-counter (OTC) methods, dominated by the male condom. Specifically, the non-hormonal options available today include the condom (male and female), the diaphragm, the cervical cap, Paragard (a copper IUD that prevents pregnancy without artificial hormones), as well as spermicides containing **nonoxynol-9 (N-9)**, as described below.

Phexxi versus Spermicide

Spermicides have been on the market for some time, and are available in many forms: vaginal gels, creams, foams, suppositories, sponges, and films. However, the active ingredient, N-9, has faced restrictions in many regions globally; it is banned in Africa and carries a warning label in the U.S. due to its detergent-like properties, which can potentially damage the vaginal wall's epithelial lining and increase susceptibility to **human immunodeficiency virus (HIV)** transmission or other sexually transmitted infections (STIs) from an infected partner.

Phexxi's three key ingredients are pharmaceutical grade L-lactic acid, citric acid, and potassium bitartrate. These three ingredients are so safe that the U.S. Prescribing Information (USPI) for Phexxi notes that in the registrational Phase 3 clinical trial, less than 2% of patients discontinued use due to adverse events.

Contraceptive Trial Data: Results from Phase 3 AMPOWER Contraception Clinical Trial

The FDA approved Phexxi in May 2020 based on the registrational AMPOWER trial. AMPOWER was a single-arm, Phase 3, open label, multi-center clinical trial in women aged 18-35 years to evaluate the contraceptive efficacy and safety of Phexxi (previously referred to as AMPHORA®) contraceptive vaginal gel. AMPOWER enrolled 1,384 women in the U.S.; combined safety data from AMPOWER and a previous Phase 3 trial, AMP-001, together provided more than 19,000 cycles of exposure in 2,804 women from the U.S.

In the AMPOWER trial, Phexxi demonstrated contraceptive efficacy with a 7-cycle cumulative pregnancy rate of 13.7% (95% CI: 10.0%, 17.5%) with typical use and 6.7% with perfect use (95% CI: 4.61%, 8.73). This corresponds to an efficacy rate of 86.3% and 93.3%, respectively, in preventing pregnancy.

In June 2022, Evofem announced results from a *post hoc* analysis of the registrational Phase 3 AMPOWER trial investigating the ability of Phexxi to prevent pregnancy. In the analysis, Phexxi prevented 99% of pregnancies per act of intercourse. This was based on 101 pregnancies over 24,289 acts of intercourse with typical use in 1,182 women. These data points are included in the Phexxi label. The per-act-of-intercourse pregnancy risk of 0.415% was not statistically tested in AMPOWER and, as such, is not in the USPI (U.S. Prescribing Information) approved by the FDA or used in any marketing materials for Phexxi.

Evofem has not studied Phexxi's efficacy and safety in comparison to other contraceptives.

Commercial Strategies

Evofem is focused on commercializing Phexxi, initially targeting the U.S. market which it believes represents a significant opportunity for the product. As such, the Company has deployed a dedicated sales team and developed a telehealth platform and media strategy for Phexxi in the U.S., where Evofem promotes the product directly to obstetrician/gynecologists and their affiliated health professionals through its own salesforce, with these professionals collectively writing most prescriptions for contraceptive products. As of March 31, 2024, Evofem's sales force consisted of sixteen sales representatives and three business managers, supported by a self-guided virtual health care provider (HCP) learning platform.

Outside the U.S., Evofem seeks to commercialize Phexxi through strategic partnerships or license agreements in several key target regions, including the Greater European Union plus the United Kingdom (EU), Asia Pacific (APAC), Latin America (LATAM), Middle East and North Africa (MENA), and Africa. This strategy is expected to enable the Company to effectively deploy its capital to maximize Phexxi's inherent value.

Liquidity

In 2023, Evofem made \$1.2 million in payments to a U.S.-based, healthcare-focused institutional investor as required by the Fourth Amendment to the Securities Purchase and Security Agreement dated April 2020, as amended, under which this investor purchased \$25 million of convertible senior secured promissory notes from Evofem in 2020. The payments included the \$1 million initial payment and a quarterly payment of \$0.2 million. As of December 31, 2023, the Company had \$0.6 million of restricted cash versus \$2.8 million of unrestricted cash and \$1.2 million of restricted cash at December 31, 2022. The Company received \$1.0 million from Aditxt in May 2024 in consideration for the reinstatement and Fourth Amendment to the Merger Agreement, as amended.

Corporate Information

Evofem is headquartered at 7770 Regents Road, Suite 113-618, San Diego, CA 92122, and as of March 31, 2024, had a total of thirty-six full-time employees and one part-time employee. The Company hires consultants and contract workers on an as-needed basis.

Company Leadership

Evoform's leadership has over 85 years of combined experience within the healthcare and pharmaceutical industry. Together, the Company's team launched Phexxi vaginal gel, the first vaginal pH modulator, a unique mechanism of action, to bring much-needed non-hormonal innovation to the contraceptive space. Biographies of key individuals within Evoform's management team and Board of Directors are provided in the accompanying section.

Management

Sandra Pelletier, Chief Executive Officer and interim Chair of the Board

Sandra Pelletier has served as Chief Executive Officer, President, and Executive Director of Evoform Biosciences since February 2015, and as interim Chair of the Board since November 2021. She has been responsible for the Company's growth and evolution, leading Evoform's transition to the public market in January 2018, and heading up multiple equity financing rounds, which have raised over \$500 million. In her more than 25 years of experience in the pharmaceutical industry, Ms. Pelletier has launched pharmaceutical brands worldwide and expanded indications on female healthcare brands in multiple countries. Her experience includes a comprehensive range of women's healthcare products, cardiovascular, pain management, and sleep therapies, as well as medical devices. She has had oversight and accountability for sales, marketing, operations, medical affairs, regulatory affairs, manufacturing, customer service, business development, and strategic partnerships. Prior to Evoform, Ms. Pelletier served as Executive Director at Woman Care Global, launching a sustainable supply chain providing access to reproductive healthcare in low- and middle-income countries. She is a published author, keynote speaker, executive coach, and staunch advocate for innovation in women's healthcare. Earlier in her career, Ms. Pelletier was Global Franchise Leader for G.D. Searle, where she managed a \$250 million business unit overseeing worldwide partnerships. She successfully moved up the corporate ladder, starting as a top performing sales representative, sales trainer, managed care leader, national sales director, domestic and international marketing, vice president of global markets, chief strategy officer, chief executive officer, and board chair. She is a Director of TRACON Pharmaceuticals, Inc., a clinical stage biopharmaceutical company focused on novel targeted therapeutics for cancer, where she serves as the chair of the Governance/Nomination Committee and is a member of the Audit Committee. Ms. Pelletier has appeared at TEDx San Diego, Harvard School of Public Health, Davos World Economic Forum, the Clinton Global Initiative, MAKERS Conference, Women Deliver, University of Virginia's Darden School of Business, University of Oregon's Lundquist School of Business, and University of California, San Diego. She was named as a New Champion for Reproductive Health by the United Nations Foundation, awarded the Athena San Diego's Pinnacle Award for Life Sciences, named the 2019 Businesswoman of the Year by the San Diego Business Journal, and named to Inc. Magazine's 2020 Female Founders 100 List.

Ivy Zhang, Chief Financial Officer

Ivy Zhang is dedicated to advancing Evoform's mission of addressing the unmet sexual and reproductive health needs of women. She joined Evoform as Chief Financial Officer and Secretary in April 2023 and leads the Company's finance organization and financial activities, including financial planning and analysis, accounting, external audit, tax, controllership, and treasury functions. A seasoned finance executive, Ms. Zhang has more than 15 years of financial and accounting experience spanning diverse industries, including pharmaceuticals and medical devices. Earlier in her career, she served in finance positions for approximately seven years at Ernst & Young LLP, and for more than two and a half years at SeaSpine Holdings Corporation (a public medical and therapeutic technology and device company). Ms. Zhang joined Evoform in March 2018, serving as Director of SEC Reporting and SOX Compliance until her promotion to Controller in April 2020. She rejoined Evoform in April 2023 from HUYABIO International, where she served as Vice President Controller from November 2022 until April 2023. Ms. Zhang holds a master's in assurance from Virginia Tech and a master's in economics from the University of Victoria, Canada. She is a certified public accountant (CPA) in the state of California.

Ellen Thomas, Chief of Staff

Ellen Thomas, Evofem's Chief of Staff, has over 30 years of professional experience in board management and corporate governance, healthcare communications, global operations, marketing, thought leader engagement, global meeting/conference event management, pharmaceutical sales, continuing medical education, and management consulting. She joined Evofem in January 2013 and has worked for Sandra Pelletier since July 2009. Prior to Evofem, Ms. Thomas spent six years in pharmaceutical sales with Eli Lilly & Company and ten years in private sector pharmaceutical consulting, where she provided strategic oversight in the design and implementation of communications, marketing, scientific, and educational programs for multiple therapeutic teams at Pfizer, Eisai, Amgen, Roche, Organon, Pharmacia, Talecris, Quintiles, and Covance. Her therapeutic experience spans women's reproductive health, central nervous system (CNS), anti-infectives, gastroenterology, anti-fungals, cardiology, smoking cessation, endocrinology, ophthalmology, oncology, and nephrology. She previously worked as a Peace Corps Volunteer for two and a half years in a rural health clinic in Niger, West Africa, and has consulted with International Planned Parenthood Federation. Ms. Thomas holds a Bachelor of Science degree from Michigan Technological University and a master's in public health from Columbia University in New York.

Amy Raskopf, SVP, Investor Relations

Amy Raskopf has more than 24 years of experience planning and executing investor relations (IR) programs for public and private companies, collaborating with companies in the healthcare sector whose products have the potential to significantly improve patients' lives. Ms. Raskopf joined Evofem in February 2018, shortly after the Company's transition to the public market and ahead of its first public equity raise. She has worked with the Evofem team to successfully navigate disclosure of statistically significant clinical trial data, the FDA-approval and launch of Phexxi for hormone-free, on-demand contraception, multiple fundraising rounds, and a myriad of other corporate advancements. Since December 2022, she has also served as interim head of business development, focused on partnership and licensing opportunities for Phexxi in foreign markets and opportunities to leverage Evofem's U.S. commercial infrastructure. Prior to joining Evofem, Ms. Raskopf was Director of Corporate Communications and IR for women's health therapeutics company Juniper Pharmaceuticals (f/k/a Columbia Laboratories), where, during her 14-year tenure, she led communications surrounding and was the Company's key spokesperson regarding clinical trial results, product licensing, an FDA AdComm meeting, corporate re-branding, M&A, and more. She previously held a senior consulting role at In-Site Communications, a healthcare-focused investor relations firm. She began her career at Ogilvy Public Relations Worldwide, working with cross-functional teams in the investor relations and healthcare communications divisions. Ms. Raskopf holds a Bachelor of Arts degree from Smith College and a Master of Fine Arts from Southern Methodist University.

Kathy Gallo-Doyle, Vice President of Sales

Kathy Gallo-Doyle joined Evofem in January 2021 as Vice President of Sales. She has been responsible for effectively designing and executing sales force strategies to drive significant revenue growth and an optimal sales team. She specializes in aligning sales initiatives with corporate goals and building and leading high-performing sales teams that succeed through a culture of inclusion, collaboration, and engagement. Ms. Gallo-Doyle is an experienced leader in sales operational transformations, fostering key relationships and partnerships, and implementing continuous improvements. Ms. Gallo-Doyle began her career in women's healthcare 27 years ago as a sales consultant. During her career, she moved her way through management of both people and accounts, while winning multiple awards. Her passion for women and the opportunity to change the landscape of contraceptive choices drove her enthusiasm to join the team at Evofem.

Board of Directors

Sandra Pelletier, Chief Executive Officer and interim Chair of the Board

Biography on page 7.

Kim Kamdar, Ph.D.

Dr. Kamdar has served as a member of the Evofem Biosciences Board of Directors since January 2018. She is a Managing Partner of Domain Associates, LLC, a life sciences venture capital firm, which she joined in 2005. Dr. Kamdar is current Chair of the Board of Directors and CEO of Aspen Neuroscience and chair of the Board of Directors of Truvian Sciences. She also serves on the Board of Directors of Epic Sciences, Obalon Therapeutics, Omniome, ROX Medical, Sera Prognostics, and Singular Genomics. Past investments include Ariosa (acquired by Roche), Corthera (acquired by Novartis), BiPar Sciences (acquired by Sanofi-Aventis), and Achaogen. Formerly, Dr. Kamdar was a Kauffman Fellow with MPM Capital. Prior to joining MPM, Dr. Kamdar was a research director at Novartis, where she built and led a research team that focused on the biology, genetics, and genomics of model organisms. Dr. Kamdar is the author of ten papers as well as the inventor of seven patents. She received her B.A. from Northwestern University and Ph.D. in biochemistry and genetics from Emory University. Dr. Kamdar serves as an advisory board member of Dr. Eric Topol's NIH-supported Clinical and Translational Science Award for Scripps Medicine and is also on the non-profit board for Access Youth Academy, an organization that is transforming the lives of underserved youth through academic enrichment, health and wellness, social responsibility, and leadership through squash.

Tony O'Brien

Tony O'Brien has served as a member of the Evofem Biosciences Board of Directors since January 2018. He served as the Director General of Ireland's Health Service Executive, or HSE, an organization responsible for the provision of health and personal social services for the residents of Ireland from July 2012 to May 2018. Prior to his role as Director General, Mr. O'Brien was the Chief Operating Officer of the Department of Health's Special Delivery Unit and a member of the Department's Management Board. Mr. O'Brien previously served as Director of Clinical Strategy and Programs in the HSE and Chief Executive Officer of the National Treatment Purchase Fund. He served as Chief Advisor to the HSE on the implementation of the National Cancer Control Strategy, Project Director for the National Plan for Radiation Oncology, and is a former Chairman of the National Cancer Registry Board. Mr. O'Brien was the founding Chief Executive Officer of the National Cancer Screening Service from 2007 to May 2011, Director of BreastCheck, CervicalCheck, and an Associate and Interim Director of the National Cancer Control Programme. Prior to joining the HSE, Mr. O'Brien served as Chief Executive of the Irish Family Planning Association and as the Chief Executive of the UK Family Planning Association. Mr. O'Brien is a Council Member and Associate Faculty Member of the Irish Management Institute, a former Member of the Healthy Ireland Council and a Chartered Director of the Institute of Directors in Ireland. He also currently serves as a director and owner of Global Leadership and Governance Solutions Limited, a private limited company organized in the Republic of Ireland. Mr. O'Brien also holds a Master of Sciences in Management Practice from Trinity College, University of Dublin. He is also Adjunct Assistant Professor in Health Strategy and Management at Trinity College Dublin.

Lisa Rarick, MD, FACOG

Dr. Rarick has served as a member of the Evofem Biosciences Board of Directors since February 2020. She is a board-certified obstetrician/gynecologist and regulatory affairs expert with 35 years' experience in women's health and 15 years' experience leading several offices within the U.S. Food and Drug Administration (FDA). Dr. Rarick began her career at the FDA in 1988 as a Medical Officer, responsible for the management of products indicated for a variety of reproductive health conditions, including oral, transdermal, and vaginal contraceptives. She became the Director for the Division of Reproductive and Urologic Products, when it was formed in 1996, and later held several management roles in the Center for Drug Evaluation and Research (CDER), including Deputy Director of the Office of Drug Evaluation II and Associate Director in the Office of the Center Director. Her final year at the FDA was spent in the Office of Women's Health, where she focused on HIV prevention, pregnancy prevention, pre- and post-pregnancy care and menopausal therapy. She is currently a reproductive health and regulatory affairs consultant who has helped numerous companies navigate the development of their products from early-stage development through FDA approval. Dr. Rarick received a B.S. and M.D. from the Loma Linda University School of Medicine and completed her residency training in Obstetrics and Gynecology at Georgetown University. She has been a member of the Scientific Advisory Committee for the National Institute of Child Health and Human Development since 2004 and served on the Board of Directors for Alliance Partners 360 from June 2017 to June 2019.

Colin Rutherford

Colin Rutherford has served as a member of the Evofem Biosciences Board of Directors since November 2015. He recently joined the Board of Spanish Biopharma business, Hifas da Terra SA, which is a leading product innovator in the field of mycotherapy, providing applications for use in both immunotherapy and oncology. Mr. Rutherford also serves on the Board and is Audit Committee Chairman of Mitchells & Butlers Plc, the UK's largest quoted F&B leisure group. He further serves on the Board and Audit Committee of the quoted Oil & Gas shipping logistics business, Renaissance Services SAOG, based in Muscat and Dubai. Mr. Rutherford is Chairman of Brookgate Limited, a UK property development business backed by Goldman Sachs and TPG. He serves independently on three private Scottish based family company boards in healthcare, retail, and timber. From 2012 to 2014, Mr. Rutherford served as Chairman of European Healthcare Group Limited, before its acquisition by two U.S.-based hedge funds. From 2008 to 2011, he served as Chairman and CEO of the quoted UK fund management group, MAM Funds Plc. From 2004 to 2009, Mr. Rutherford served as Chairman of SGI Funds, a Guernsey, Cayman and Hong Kong-based diversified fund management group. From 2003 to 2006, he was Chairman and oversaw the restructuring of Noble House Group Limited, a large UK leisure business, which was sold in 2006. In 2002, as Chairman and CEO, he led the restructuring and sale of quoted UK finance specialist Euro-Sales Plc with eighteen offices across Europe. Mr. Rutherford graduated in Accountancy and Finance from Heriot Watt University and qualified as a chartered accountant with Touche Ross in 1984 and is a Harvard Business School Alumni.

Corporate Strategy and Potential Milestones

Corporate Strategy

Key elements of Evofem's corporate strategy include:

- **Successfully commercialize Phexxi.** The Company's primary focus is the successful commercialization of Phexxi in the U.S. Outside the U.S., Evofem seeks to commercialize Phexxi through strategic partnerships or license agreements in several key target regions, including the Greater European Union plus the United Kingdom (EU), Asia Pacific (APAC), Latin America (LATAM), Middle East and North Africa (MENA), and Africa. This strategy is expected to enable the Company to effectively deploy its capital to maximize Phexxi's inherent value.
- **Expand Evofem's intellectual property position by pursuing opportunities to extend the exclusivity of its proprietary product candidates.** The Company has stated its intent to aggressively pursue additional and new patent applications to broaden its intellectual property portfolio. A new U.S. patent allowance covering Phexxi was announced in April 2024. Evofem expects to continue to seek domestic and international patent protection and endeavor to proactively file patent applications for new commercially valuable inventions.
- **Build the Company's product portfolio and leverage its U.S. salesforce through business development.** Evofem expects to opportunistically acquire, in-license, or otherwise access additional products to enhance its offerings and complement its core competencies within women's healthcare.

Potential Milestones

- **Increase the use of Phexxi in women of reproductive age who take oral contraceptives in conjunction with GLP-1 agonists, such as Mounjaro and Zepbound.** These drugs may make oral birth control pills less effective at certain points in the dosing schedule. As such, patients are advised to use a non-systemic, non-hormonal method, like Phexxi, to prevent unintended pregnancy during these times.
- **Realize the benefit from a 3% increase in the Phexxi wholesale acquisition cost (WAC), which took effect January 1, 2024.**
- **Achieve ongoing success in executing the Phexxi market access strategy,** including recent wins removing the Prior Authorization for Phexxi for 1.8 million lives in Washington state and the successful negotiation with Medi-Cal of the Phexxi rebate; effective July 2024, Evofem will pay a 7.4% lower rebate on Phexxi prescriptions from Medi-Cal.

Intellectual Property

Evofem is focused on protecting its proprietary vaginal pH modulator gel technology both internationally and domestically. The Company seeks to maintain patents intended to cover its product and its methods of use, along with any other inventions that it believes could be significant to its business. Evofem endeavors to properly file patent applications for new inventions that may hold commercial value. The Company furthermore relies on trade secrets to protect aspects of its business that are not amenable to, or may not be appropriate for, patent protection.

The Company's success is expected to largely depend on its ability to obtain and maintain patents and other proprietary protection for commercially important technology, inventions, and know-how related to its business; to defend and enforce its patents and other intellectual property rights; and to preserve the confidentiality of its trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. Evofem also expects to rely on continuing technological innovation and in-licensing opportunities to develop and maintain its proprietary position.

As of March 21, 2024, the Company owned or had exclusive license to approximately 47 issued patents and allowed applications in the U.S. and other countries and jurisdictions and had approximately 16 patent applications pending in the U.S. and other countries and jurisdictions. This includes four U.S. patents, which cover Phexxi and its labeled indication that are listed in the U.S. FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) through 2033, as listed in Figure 2 and profiled below.

Figure 2
EVOFEM BIOSCIENCES, INC.
PATENT AND EXCLUSIVITY FOR: N208352

Product 001

CITRIC ACID; LACTIC ACID; POTASSIUM BITARTRATE (PHEXXI) GEL 1%; 1.8%; 0.4%

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	6706276	03/06/2025		DP			06/03/2020
001	10568855	03/15/2033			U-1		06/03/2020
001	11337989	03/15/2033			U-1		09/06/2022
001	11439610	03/15/2033	DS	DP			09/15/2022

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
001	NP	05/22/2023

Source: Evofem Biosciences, Inc.

- (1) U.S. Patent No. 6,706,276: Composition of matter patent covering Phexxi;
- (2) U.S. Patent No. 10,568,855: Method of use patent covering contraception using the L-Lactic Acid Phexxi formulation;
- (3) U.S. Patent No. 11,337,989: Method of use patent covering contraception using the L-Lactic Acid Phexxi formulation; and
- (4) U.S. Patent No. 11,439,610: Composition of matter patent covering compositions containing L-Lactic Acid, including the Phexxi formulation.

A fifth U.S. patent was recently allowed - patent application 17/823,020 entitled, "Compositions and Methods for Enhancing the Efficacy of Contraceptive Microbicides." The allowed claims cover methods of contraception with a composition that encompasses Phexxi vaginal gel. The patent, when issued, will be Evofem's fifth patent for Phexxi in the United States and is expected to be Orange Book listable.

Evofem solely owns several patent application families relating to the composition and therapeutic use of its vaginal pH modulator gel, which, upon issue, would expire at the earliest in 2033. The Company also has the Rush License IP, which provides general protection for its vaginal pH modulator platform (further described on page 31). Its vaginal pH modulator platform could be eligible for regulatory extensions to at least 2026 in the U.S. and in certain European jurisdictions if granted by those regulatory bodies. For the U.S. patent that Evofem has licensed from Rush University, multiple Orders Granting Interim Extension (OGIEs) were received from the USPTO, extending the expiration of this patent to March 2025.

Of note is that the Company has a white paper that was written by the former head of the generic division of the FDA, Dena Hixon, MD, regarding how difficult it would be to establish a bioequivalent of a generic of Phexxi and to get it through the FDA's rigorous review process. Dr. Hixon concluded that a generic version of Phexxi could not be evaluated for bioequivalence with the comparative pharmacokinetic blood testing that is most used to establish bioequivalence of systemic generic drugs.

Evofem believes that its licensed and solely owned patents and pending patent applications, combined with its substantial knowledge within this field, will continue to provide opportunities to establish significant market barriers for entry.

Trade Secrets

In addition to patents, Evofem relies on trade secrets and expertise to develop and maintain its competitive positions. For example, certain aspects of the composition, manufacturing, and use of Phexxi are protected by unpatented trade secrets and knowledge. Although trade secrets and knowledge can be difficult to protect, the Company seeks to protect its proprietary technology and processes, in part, through confidentiality agreements with its employees, consultants, scientific advisors, collaborators, and contractors. Evofem also works diligently to preserve the integrity and confidentiality of its data and trade secrets by maintaining physical security of its premises, and through the physical and electronic security of its information technology systems.

Trademark Basics and Strategy

Evofem owns or has rights to various trademarks, copyrights, and trade names used in its business, including Evofem, Phexxi, and Femidence. All of its logos and trademarks are also the property of Evofem Biosciences, Inc.

Core Story

Background

Individuals employ diverse protective measures in their daily routines to ensure their safety and overall well-being. When driving or riding in cars, people conscientiously fasten seat belts; for health protection, they prioritize vaccinations; and individuals implement home security systems to safeguard their belongings and loved ones. For women seeking to prevent pregnancy, birth control is a key form of protection. Since the inception of the initial birth control pill in the U.S. in 1960, women have consistently received the message that they should prioritize daily protection, irrespective of their current level of sexual activity. This prolonged routine, extending across weeks, months, and even years, prompts them to question the logic behind subjecting themselves to daily medication when such practices are not universally adopted in other aspects of their lives. The importance of daily usage stems, in part, from the characteristics of available methods to prevent pregnancy, which necessitate regular adherence. Over the counter (OTC) alternatives have traditionally lacked FDA approval, leading women to opt for daily medications. However, the normalization of daily hormone usage raises concerns, especially since these medications can carry side effects, which may include headaches, weight gain, bleeding, emotional fluctuations, the potential for blood clots, among others.

Throughout history, women’s health has encountered challenges in medical research as studies have focused on men. Despite notable strides in innovating women’s healthcare, only a handful of companies are at the forefront, grappling with challenges and receiving limited support. Dispelling myths surrounding women’s bodies and advocating for improved choices, both in terms of narrative and healthcare options, becomes paramount for ensuring women’s well-being. The priority for innovation, investment, and a shift in perspective emphasizes the need to empower women with better choices for their health.

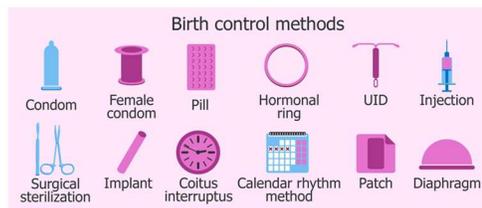
Formed due to the lack of innovation from the contraception category, Evofem Biosciences is focused on commercializing innovative products that address unmet needs within the women’s sexual and reproductive health markets. The Company’s first commercial product, Phexxi, is the first and only U.S. FDA-approved, hormone-free, woman-controlled, on-demand prescription contraceptive gel for women. Phexxi received FDA approval in May 2020 and the Company commercially launched the product into U.S. markets in September 2020.

Contraceptive Options

The modern contraceptive market was established in the 1960s with the introduction of “the pill,” the first oral contraceptive widely available to women in the U.S. As shown in Figure 3, there was no noteworthy innovation to provide additional options within women’s reproductive health until almost 30 years after the introduction of “the pill,” when pharmaceutical companies introduced the non-hormonal copper intrauterine device (IUD) and synthetic hormonal products with different hormonal delivery systems, including the hormonal IUD, implants, the patch, and the vaginal ring.

Figure 3
CONTRACEPTIVE TIMELINE

1960: Enovid



2020: Phexxi



Source: Evofem Biosciences, Inc.

Today, as further described in the accompanying sections (and sorted by prescription contraceptive products and non-prescription OTC contraceptive products), *hormone-free* contraceptive options include condoms (male and female), spermicide, fertility tracking, diaphragm, cervical cap, copper IUD, and tubal ligation (i.e., getting your tubes tied). *Hormone-containing* contraceptive options include the birth control pill (of which there are roughly 150 currently on the market), as well as the patch, vaginal ring, hormone IUD, implant, and hormone injections. These can be associated with undesirable side effects, such as weight gain, loss of libido, and mood changes, which may lead women to discontinue their use and seek alternative contraceptive methods.

Prescription Contraceptive Products

Of the estimated 20 million U.S. women using prescription contraception, oral contraceptives (OCs), also known as “the pill”, are the most common. The two main types of hormonal OCs include combination birth control pills, which contain both estrogen and progestin, and the progestin-only pill. Either pill is associated with a slight increase in the risk of breast cancer. To be effective, OCs must be taken at the same time every day.

In a crucial step in terms of accessibility of contraception, in July 2023, the FDA approved the first OTC contraceptive pill, enabling women to purchase the hormone-based (progestin-only) daily contraceptive Opill without a prescription. The approval came as more states moved to ban abortion following a ruling by the Supreme Court in 2022 that overturned the *Roe v. Wade* decision to legalize the procedure nationwide. Opill, which will be sold by Perrigo (PRGO), was first approved for prescription use in 1973; this approval enables women to obtain the Opill without seeing a healthcare provider for a prescription.

Beyond the pill, other prescription contraceptives currently available on the market include:

- *Long-acting reversible contraception (LARC)*. Long-acting reversible contraception (LARC) is not dependent on user adherence. This appeals to those who benefit from a passive form of birth control with no daily requirement to take a pill. LARC methods include the Intrauterine Device (IUD) and the contraceptive implant, described below.
 - *IUDs*. Introduced to the market in 1988, the *copper IUD* provides protection by disrupting sperm motility and damaging sperm so that they are prevented from joining with an ovum. The copper IUD is principally marketed by Cooper Surgical, Inc. as Paragard®. The *hormonal IUD* is principally offered under the brand names, Kyleena®, Skyla® and Mirena®—a family of products from Bayer Pharmaceuticals. All IUDs must be inserted and removed by a physician.

Many women have opted against the IUD for (1) fear of a bad insertion experience; a peer-reviewed study published in 2015 found that “all women had a high expectation of pain prior to IUD insertion.” (*Source: Brima et al. A comparison of the expected and actual pain experienced by women during insertion of an intrauterine contraceptive device. Open Access J Contracept. 2015 Feb 16;6:21-26. doi: 10.2147/OAJC.S74624*), and (2) concern over having something in them (i.e., a “foreign body effect”), which has been frequently demonstrated in medical literature. (*Source: Ferguson et al. Patient Opinions About Foreign Body Contraceptives. Women’s Health Rep (New Rochelle). 2020 Oct 8;1(1):451-458. doi: 10.1089/whr.2020.0048*). Among women who opt for the insertion procedure, many remove their IUD due to the hormonal and other side effects.

- *Implants*. The contraceptive implant must be embedded under the skin and removed by a qualified healthcare provider, requiring a medical procedure. Implants provide contraception by releasing hormones over a three-year period. The implant is marketed in the U.S. as Nexplanon® by Organon.
- *Contraceptive Patch*. The weekly contraceptive patch was introduced in 2000 by Johnson & Johnson’s Janssen division; however, deaths resulting from **venous thromboembolism** due to hormonal exposure had a significant negative impact on the patch and led to label changes restricting utilization. Following the loss of exclusivity, Johnson & Johnson’s Janssen division exited women’s healthcare and contraception as a promotional category. A new branded weekly birth control patch was launched in late 2020 under the brand name Twirla® (Agile

Therapeutics) and is competing against a generic entrant, once weekly Xulane® (Mylan Pharmaceuticals Inc., a Viatris Company).

- *Vaginal Ring.* In 2001, the *monthly* hormonal vaginal ring was introduced to the market by Merck & Company, with generic versions now available. The ring is used for three weeks and then removed for a week during menses and a new hormonal vaginal ring is inserted. The efficacy of the vaginal ring is like hormonal oral contraception. A meta-analysis of eighteen studies found that users of the vaginal ring reported more vaginal irritation and discharge than combination pill users, but less nausea, acne, irritability, depression, and emotional changes (Source: Lopez et al. *Skin patch and vaginal ring versus combined oral contraceptives for contraception. Cochrane Database Syst Rev. 2013 Apr 30;2013(4):CD003552. doi: 10.1002/14651858.CD003552.pub4*).

In 2020, an *annual* hormonal vaginal ring was launched in the U.S. under the brand name Annovera® (Mayne Pharma).

- *Injectables.* The primary injectable hormonal contraceptive on the market is Depo-Provera® by Pfizer Inc. Each injection provides protection for up to 12 to 14 weeks; patients, however, must receive injections once every 12 weeks to get optimal contraceptive protection. Depo-Provera was introduced to the market in 1992.
- *Barrier methods.* Rx barrier methods of contraception are worn inside the vagina and used on-demand. They are available by prescription and must be inserted into the vagina prior to each act of intercourse.
 - *Diaphragm.* A diaphragm prevents pregnancy by covering the cervix, thus preventing sperm from entering the uterus. Diaphragms must be used with Phexxi or spermicide to work. Diaphragms come in different sizes, so a doctor will fit the user for one, show her how to insert and remove it, and give her a prescription. FDA approved diaphragms available in the U.S. include Caya®.
 - *Cervical Cap.* A cervical cap is made from soft silicone and shaped like a sailor's hat. It prevents pregnancy by covering the cervix, thus preventing sperm from entering the uterus. Concurrent use of Phexxi or spermicide makes the cervical cap much more effective. The only brand of internal condom that is FDA approved and available in the U.S. is called FemCap®.
 - *Female Condoms.* Female condoms prevent pregnancy by stopping sperm from meeting an egg. The only brand of internal condom that is FDA approved and available in the U.S. is the FC2 Female Condom®.

Non-Prescription OTC Contraceptive Products

In the U.S., an estimated 10.3 million women rely on non-prescription OTC products for their contraceptive needs.

- *Condoms.* Condoms are the leading product offering in OTC sales. Approximately 6 million women depend on condom use with their partners as their only method of birth control. The predominant brands are Trojan® (Church & Dwight) and Durex® (Reckitt Benckiser).
- *Other OTC products.* Other OTC products include spermicides, which are available in sponges, jelly/creams, and foams. Spermicides rely on nonoxynol-9 (N-9), a detergent, and has limited utilization. Greater details on spermicides are provided on page 22 as a comparison to Evofem's Phexxi vaginal pH modulator. With regard to spermicides, the FDA requires specific warnings to appear on all N-9 products that state: "this product does not protect against HIV/AIDS or other STDs and may increase the risk of getting HIV from an infected partner" as well as "do not use if you or your sex partner has HIV/AIDS. If you do not know if you or your sex partner is infected, choose another form of birth control method."

Vaginal pH Modulator

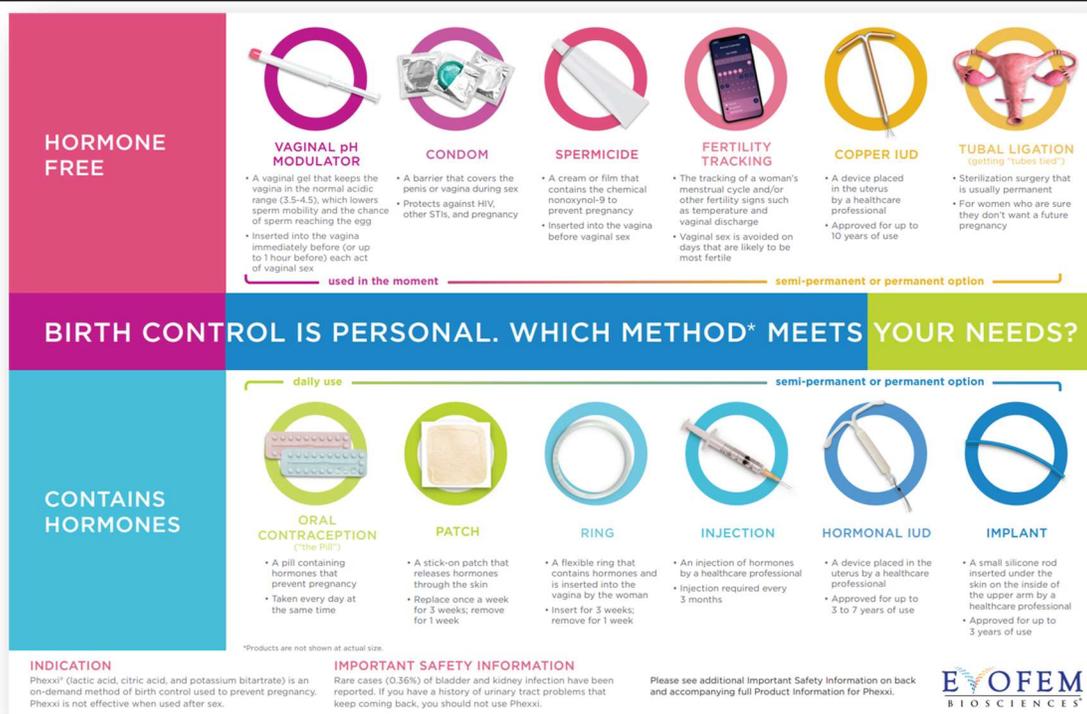
The newest of the hormone-free prescription contraceptive options available to women is Phexxi (where the “xx” represents the female chromosome). Evofem launched this vaginal pH modulator in September 2020 to provide women with a new option prevent pregnancy while managing the side effects potentially associated with then-available birth control options. Phexxi offers a hormone-free option to women who:

- May want to space their pregnancies and not experience any potential side effects that may arise from the use of hormonal birth control products.
- Are concerned about drug-drug interactions and want a non-systemic contraceptive method. This includes women who may need supplemental contraception while taking GLP-1s for diabetes or weight loss. These drugs make oral birth control pills less effective for four-week periods during the dosing regimen.
- Do not want to take an exogenous hormone every day when they are not having sex every day.

Evofem believes that choice matters. No one method is right for every woman. Her contraceptive needs are likely to change throughout her lifetime. Women typically migrate between three to four different birth control products and methods in their reproductive years from puberty through menopause.

In 2022, Evofem developed and introduced a new contraceptive educational chart for patients and healthcare providers that details high-level information about birth control methods currently available to women in the U.S., including the Company’s vaginal pH modulator. This new Contraceptive Counseling Tool has been extremely well received and has had a positive impact with healthcare providers and patients alike. The poster, which is shown in gynecologists’ offices (Figure 4), highlights the difference between hormone-free contraceptives versus those with hormones, and is intended to form the basis for counseling conversations between patients and their physicians as it relates to the most appropriate contraceptive option for a patient.

Figure 4
CREATING THE VAGINAL pH MODULATOR CATEGORY



Source: Evofem Biosciences, Inc.

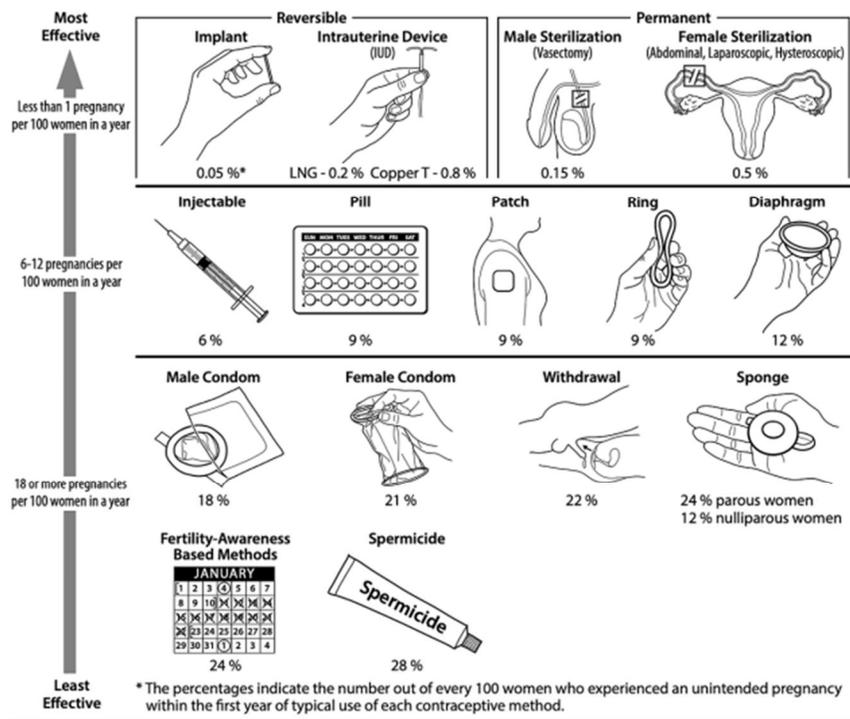
This updated chart makes the conversation about whether the hormones are tolerable to a patient, and if they are not, provides alternatives. This is a critical point in the contraceptive counseling process. This chart provides the checklist and the information to determine whether the patient is comfortable taking the hormones and/or if she is experiencing side effects. If she cannot or will not use hormones, this information helps to provide alternative options, which is significant as it is not only focused on the method of contraception and what is going to work based on efficacy, but also the totality of the process—something which has been game changing in discussions between the physician and patient.

Interest in Phexxi falls into three distinct segments where new adopters are expected to come equally from the following categories: (1) those women who are not currently using hormone-based contraceptives; (2) those women seeking an alternative to hormonal contraception; and (3) those women who are expected to utilize Phexxi as added protection to their current form of birth control. Evofem’s market research has indicated that the hormone-free, on-demand, woman-controlled aspect of Phexxi makes it an attractive option.

Contraceptive Effectiveness

As shown in Figure 5, the effectiveness of different contraceptive options varies tremendously among approved products and methods, with the least effective methods depicted towards the bottom of Figure 5 and the most effective methods depicted towards the top. Importantly, there is a large misconception about the efficacy of condoms and other birth control. If a man uses condoms perfectly every time he has intercourse, they are 98% effective at preventing pregnancy (Source: Planned Parenthood). However, since people are not perfect, condoms are only approximately 85% effective in real life (Source: NHS Inform, <https://bit.ly/3I2yhu5>), where roughly 15 out of 100 people who use condoms as their only birth control method will get pregnant annually. Furthermore, data indicates that women forget to take their birth control pill between one and four times per month, which is the reason women get pregnant while taking the pill.

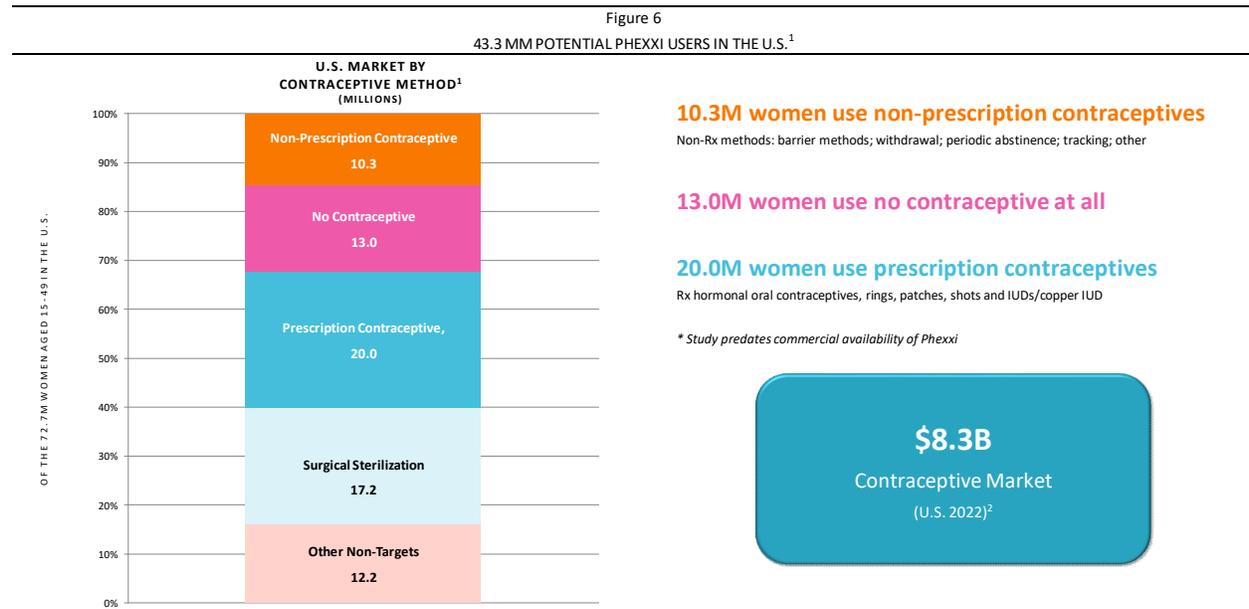
Figure 5
EFFECTIVENESS OF FAMILY PLANNING METHODS



Source: CDC.gov.

Contraceptive Market

As depicted in Figure 6, the current women’s contraception category is large. As such, this market has the potential to deliver meaningful results with more than 72 million women in the U.S. of reproductive age and 23 million women who are beyond hormones, which is likely due to the pervasive side effects from these contraceptives—specifically from pills, patches, IUDs, etc. Side effects from hormones can include weight gain, bleeding, acne, headaches, and a slight risk of blood clots, as well as emotional highs and lows, which can become overwhelming.



1. Daniels-K-and-Abma-J.-Current-Contraceptive-Status-Among-Women-Aged-15-49_NCHS-Data-Brief-Number-388-October-2020.pdf (evofem.com)
2. Grandview Research. U.S. Contraceptive Market Size, Share & Trends Analysis Report By Product (Pills, Intrauterine Devices (IUD), Condoms, Vaginal Ring, Subdermal Implants, Injectable), And Segment Forecasts, 2022 – 2030.

Source: Evofem Biosciences, Inc.

Of the population of 23 million women who are beyond hormones, this group is divided into two categories: 10.3 million who use non-prescription contraception (i.e., barrier methods; withdrawal; periodic abstinence; tracking; other), where for this group of women, the risk of getting pregnant is less important to them than the side effects that they have experienced; and 13 million women who use no contraceptive at all. An additional 20 million women use prescription contraceptives (i.e., prescription hormonal oral contraceptives, rings, patches, shots, and IUDs/copper IUDs).

The total U.S. contraceptive market was valued at \$8.3 billion in 2022 and is expected to reach approximately \$12 billion by 2030 with a compound annual growth rate of 4.7% (Source: *April 2022 Research and Markets U.S. Contraceptive Market Report*).

Contraceptive Market Opportunity

Globally, hundreds of millions of women seek sexual and reproductive health products that provide them with control of their individual needs during 30+ years (on average) of fertility. However, an estimated 257 million women trying to avoid pregnancy are not using safe, modern methods of contraception as nearly half of all pregnancies (121 million each year) are unintended (Source: The United Nations 2022 State of World Population 2022 report). According to the Centers for Disease Control and Prevention (CDC), reducing the percentage of all unintended pregnancies has been one of the National Health Promotion objectives since its establishment in 1980.

While efforts are made to reduce their incidence, there remain over two million unintended pregnancies in the U.S. every year. New product innovations and introductions within the women’s reproductive and sexual health care arena have been limited compared to other therapeutic categories. Although several new contraceptive products have been introduced in recent years, Evofem believes that Phexxi represents the first innovative contraceptive method introduced in the U.S. since NuvaRing was approved by the FDA in 2001 (23 years ago).

Evofem’s Phexxi®

Phexxi is the first and only FDA-approved contraceptive vaginal gel. The product was developed by Rush University in the early 1990’s (detailed on page 31) for HIV prevention. Rush University recognized that the mechanism of action also had potential to prevent women from getting pregnant and to prevent infection with pH-sensitive pathogens like chlamydia and gonorrhea.

A Phexxi selling unit is a box containing twelve prefilled applicators. A woman can discreetly put an applicator in her purse or pocket (Figure 7). Women, on average, have intercourse seven times a month; a box of twelve applicators is designed to get most women through a little over a month; Evofem conservatively estimates that most women will use approximately five boxes per year. More active women may have two boxes of Phexxi in one prescription. Phexxi is self-administered up to one hour before each act of vaginal intercourse, noting that an additional dose must be used prior to each subsequent act of vaginal intercourse. The gel is very viscous and bioadhesive, where it does not leak out.

Figure 7
SUMMARY OF PHEXXI®

THE FIRST AND ONLY ON-DEMAND, NONHORMONAL PRESCRIPTION CONTRACEPTIVE VAGINAL GEL

- Vaginal pH Modulator
- Hormone-free
- FDA-approved for prevention of pregnancy
- Woman-controlled
- Used only when you need it
- Box of 12 Phexxi applicators



Source: Evofem Biosciences, Inc.

Vaginal pH Modulator (VPM) Mechanism of Action

As a vaginal pH modulator (VPM), the prefilled applicator contains 5 ml of gel at pH 3.55. This gel is a combination of three active ingredients: (1) L-lactic acid; (2) citric acid; and (3) potassium bitartrate. Inactive ingredients include a preservative (benzoic acid); gelling agents (alginic acid and xanthan gum); humectant (glycerin); sodium hydroxide; and water.

Figure 8 (page 21) illustrates the respective pH levels of the vagina and semen. A normal vaginal pH of 3.5 to 4.5 is important for maintaining good vaginal health. At this optimal pH level, the vagina contains a balance of necessary healthy bacteria and is inhospitable to sperm as well as certain viral and bacterial pathogens. Typically, the introduction of semen (which has a pH of between 7.2-8.0) into the vagina causes a rise in pH above 6.0 due to the alkalinity of the ejaculate, which neutralizes the normally acidic vaginal environment and allows for the survival of sperm. The active ingredients in Phexxi maintain a normal vaginal pH (3.5-4.5) even in the presence of semen, creating an inhospitable environment for sperm. The maintenance of the acidic vaginal pH reduces the availability of calcium ions which are needed to drive sperm tail movement.

Figure 8
pH LEVELS OF VAGINA AND SEMEN



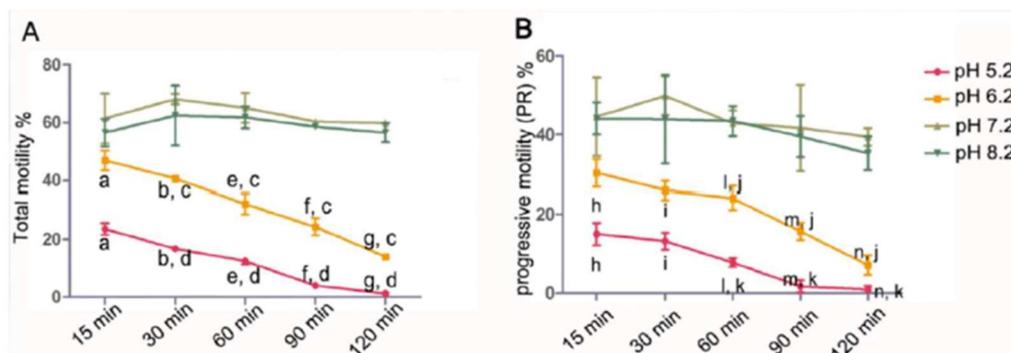
Source: Evofem Biosciences, Inc.

In addition to the acid-buffering (pH 3.5) effect, Phexxi was also developed to be lubricating and to have viscosity-retaining properties, which allow sufficient time for it to work. Young women informed Evofem that they do use lubricant as part of intimacy, and women slightly older and who may have vaginal dryness or pain with intercourse further benefited from the product’s lubricating properties as well. Noteworthy is that in a sexual satisfaction study conducted by Evofem, results show that women and their partners had more sexual satisfaction because of the lubricating properties of Phexxi.

As shown in Figure 9, *in vitro* studies of Phexxi show that the product provides immediate sperm motility reduction. As a result, Phexxi can prevent pregnancy, inhibiting sperm from reaching the ovum to form a zygote.

Figure 9
ACIDIC ENVIRONMENT CAN “NEUTRALIZE” SPERM

Total (A) and progressive (B) motility significantly decreased at acidic pH = 5.2



Source: Zhou J, et al. PLoS One. 2015;10(7):e0132974

Contraceptive Trial Data: Results from Phase 3 AMPOWER Contraception Clinical Trial

In May 2020, the FDA approved Phexxi based on the registrational AMPOWER trial, which enrolled 1,349 women in the U.S., as well as combined safety data from AMPOWER and a previous Phase 3 trial, AMP-001, which together provided more than 19,000 cycles of exposure in 2,804 women from the U.S.

In AMPOWER, Phexxi demonstrated contraceptive efficacy, with a 7-cycle cumulative pregnancy rate of 13.7% (95% CI: 10.0%, 17.5%) with typical use and 6.67% when used as directed (“perfect” use) (95% CI: 4.61%, 8.73%), corresponding to an efficacy rate of 86.3% and 93.3%, respectively, in preventing pregnancy. Evofem has not studied Phexxi’s efficacy and safety in comparison to other contraceptives.

In June 2022, results were announced from a *post hoc* analysis of AMPOWER trial data. In the analysis, Phexxi prevented 99% of pregnancies per act of intercourse. This was based on 101 pregnancies over 24,289 acts of intercourse with typical use in 1,182 women. The per-act-of-intercourse pregnancy risk of 0.415% was not statistically evaluated in AMPOWER and, as such, is not in the U.S. Prescribing Information (USPI) approved by the FDA.

In early 2022, the *Journal of Sexual Medicine* published a *post hoc* analysis of an exploratory endpoint showing that 88.7% of women using Phexxi in AMPOWER improved or maintained their sex life. Furthermore, Evofem presented a *post hoc* analysis at the 2022 American College of Obstetricians and Gynecologists annual clinical and scientific meeting showing that incidences of urinary tract infections in women who used Phexxi in AMPOWER were less compared to the general population (5.8% vs 11.0%, respectively).

Phexxi’s Benefits Versus Alternative Contraceptives

Phexxi has been developed to address needs that are unmet and/or underserved by the pre-existing contraceptive options and can offer patients significant benefits over other contraceptive options, as summarized in Figure 10.

Figure 10
PRESCRIPTION CONTRACEPTIVE PRODUCTS AND ASSOCIATED BENEFITS

Product Class	Non-Hormonal	No Systemic Side Effects	Non-invasive	Convenient
Vaginal pH Modulator (i.e. Phexxi)	✓	✓	✓	✓
28 Day OCs			✓	
Extended Regimen OCs			✓	
Hormone Releasing IUDs				✓
Copper IUD	✓	✓		✓
Implant				✓
Vaginal Ring			✓	✓
Transdermal Patch			✓	

Source: Evofem Biosciences, Inc.

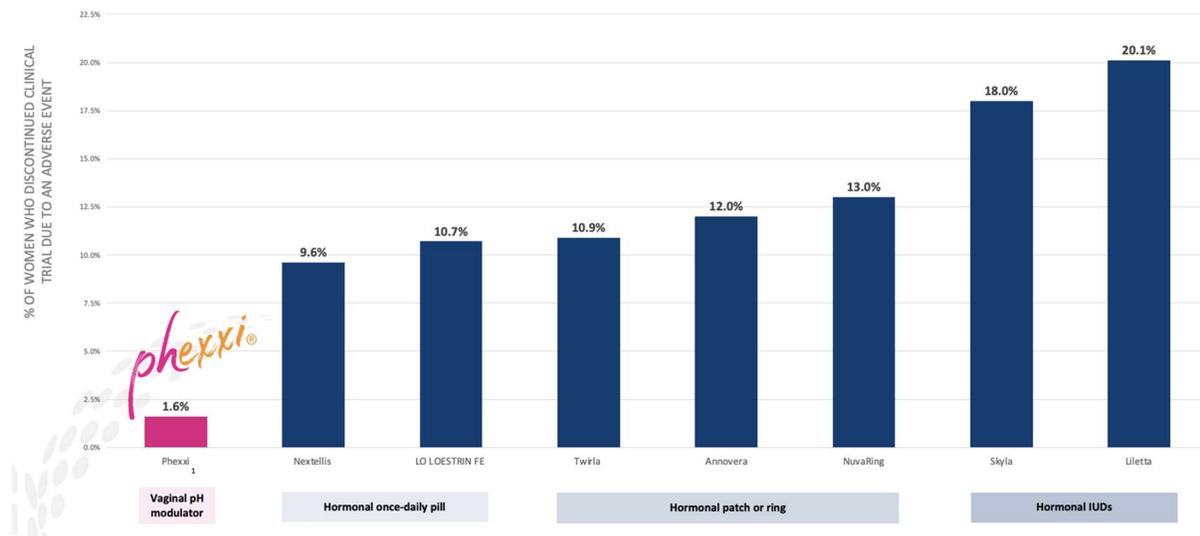
As well, Phexxi can be used with other contraceptive methods, including male/female condoms, diaphragms/cervical caps, hormonal contraceptives (except vaginal contraceptive rings), and IUDs.

Phexxi versus Spermicide: The Only Other Non-Hormonal Birth Control Option

As of 2019, the only non-hormonal option within the top five sales-generating segments was the male condom, which is an OTC product. Apart from condoms, other non-hormonal contraceptive products in the U.S. include vaginally inserted barrier methods (diaphragm, cervical cap and the female condom) and spermicides containing nonoxynol-9 (N-9). Spermicides have been on the market for some time, but their key ingredient N-9 has faced restrictions in many regions globally; it is banned in Africa and carries a warning label in the U.S. due to its detergent-like properties, which can potentially damage the vaginal wall’s epithelial lining and increase susceptibility to human immunodeficiency virus (HIV) transmission or other sexually transmitted infections (STIs) from an infected partner.

Phexxi is a vaginal pH modulator, not a spermicide. Phexxi’s three key ingredients are food grade: L-lactic acid, citric acid, and potassium bitartrate. These three ingredients are so safe that the U.S. Prescribing Information (USPI) for Phexxi notes that in the Phase 3 AMPOWER clinical trial, less than 2% of patients discontinued use due to adverse events. By contrast and as noted in Figure 11 (page 23), in clinical trials of hormonal contraceptives, approximately 10% to 20% of patients discontinued use due to adverse events.

Figure 11
DISCONTINUATION DUE TO ADVERSE EVENTS AMONG CONTRACEPTIVE BRANDS¹



1. Source: prescribing information in package insert posted on each brand's website. Evofem has not studied Phexxi's efficacy and safety in comparison to other contraceptives
2. For details of AEs reported by women who participated in Phexxi clinical trials, please see <https://22077562.fs1.hubspotusercontent-na1.net/hubfs/22077562/PhexxiIUSPI.pdf>

Source: Evofem Biosciences, Inc.

Effectiveness

Every hormonal birth control in the market is measured by the **Pearl Index**, which shows the longer a woman is on a synthetic hormone, the more effective it is because of the synthetic hormones circulating throughout the body. If a woman takes a combination birth control pill at the same time every night for a year and misses one pill, she is likely not going to get pregnant because she still has the hormones in her body. If she is on the progestin-only pill and she misses the three-hour window, she needs to use a back-up method for two days. Evofem's Phexxi is truly on demand, where if a woman is not using the Phexxi, it does not work (much like a condom).

Because of this, Phexxi is measured by the **Kaplan Meier** method, which is the same metric by which cancer drugs are measured. However, Kaplan Meier relates to how many times a woman gets pregnant when used. In the AMPOWER trial, in just under 25,000 acts of intercourse, there were less than 1% of pregnancies (Note: This data is based on 101 pregnancies in over 24,289 acts of intercourse).

Importantly, the window between application and intercourse is within one hour (as stated in the product label). Consequently, the product can be used anytime within one hour before intercourse, noting that every act of intercourse requires a separate applicator to be effective.

Addressing an Underserved and Unmet Market

Phexxi has been designed to address underserved and unmet needs within the birth control market. Women are highly aware of the hormones that they put in their bodies, with approximately 75% of women having concerns or completely opposing the use of hormonal birth control. These women are a part of the approximately 23 million women who are currently not using hormonal birth control methods and who have become early adopters of Phexxi.

The Company believes that Phexxi could increase the prescription birth control user market when considering the 28.3 million women who are currently at risk for pregnancy and do not use hormone-based contraceptives as their primary form of contraception. As well, as women's expectations change throughout their contraceptive journey, Phexxi could compete for market share in at least three categories:

- (1) Hormonal short acting reversible contraceptives consisting of oral contraceptive pills, patches, and rings;
- (2) Long-Acting Reversible Contraception, comprising IUDs, implants, and injectables; and
- (3) OTC methods, dominated by the male condom.

Target Population and Potential Users

Since the COVID pandemic, women have taken greater account of their quality of life, including the type of birth control they are using. Importantly, Phexxi is among a small group of FDA-approved birth control products that have no systemic activity in the body (the others being copper IUDs, diaphragms, cervical caps, and the female condom). Because there is no systemic effect on the body, it does not matter, for example, what a patient's body mass index (BMI) is or what medications she is taking. As a result, Phexxi can be prescribed to the majority of women (noting the product is contraindicated in women with a history of frequent UTIs). Additionally, it can be prescribed to women who are breastfeeding and do not want to have hormones in their breast milk. Moreover, with over 900,000 women diagnosed with cancer every year—the majority of whom should not use hormones—Phexxi becomes the ideal solution for these women. If a patient is told that she is unable to use hormonal birth control and seeks an alternative prescription product, there are three choices: (1) a copper IUD, which must be inserted and/or removed by a doctor (Paragard® is the product), (2) barrier methods which are cumbersome and not widely used, or (3) Phexxi, which has become a safe and appropriate product for women who are unable to use a hormone, with no need for a doctor to insert or remove it.

Evoform is seeing to grow its patient base, with a key target being young women in college. Research into the demographics of more than 5,000 Phexxi users revealed that 79% of women who use the product are between the age of 18 to 34, with the average age of a Phexxi user being 33 years old. The new movement among doctors, midwives, nurse practitioners, and OBGYNs who are more progressively minded and understand that there is a new way of prescribing birth control involves patient counseling to give a woman what she wants—see Figure 4 (page 17) for Evoform's new Contraceptive Counseling Tool for OBGYNs and their patients. This empowers women to use the product of their choice, as the most effective product is the one that a woman will use consistently and correctly.

Demographics of Potential Users

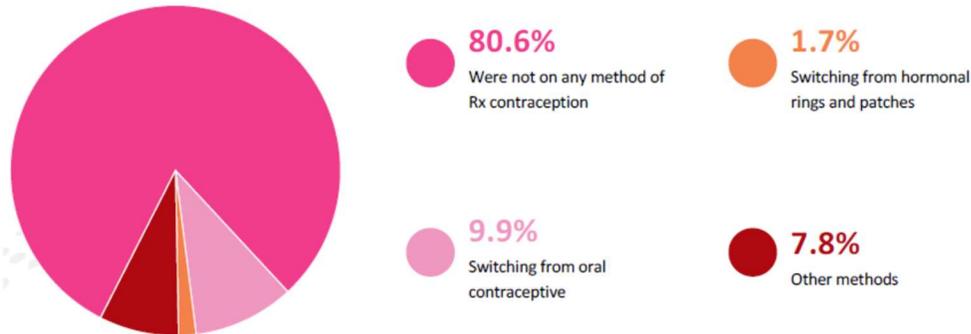
Since the Company's commercial launch, market research indicates that healthcare providers would recommend Phexxi to roughly:

- 47% of patients experiencing side effects from current contraception;
- 37% of patients using non-hormonal prescription contraception;
- 36% of patients seeking pregnancy prevention; and
- 19% of patients using hormonal prescription contraception.

Utilization With Select Patient Types

Evofem analyzed IQVIA Phexxi claims data from July 2022, focusing on the subset of Phexxi users for whom prior contraceptive data was available (n=2,512). Of this cohort, 80% of women who had recently started Phexxi were not on any method of prescription contraception. Another 20% switched to Phexxi from either oral contraceptives, hormonal rings, or patches (Figure 12).

Figure 12
PRIOR CONTRACEPTION AMONG WOMEN SWITCHING TO PHEXXI

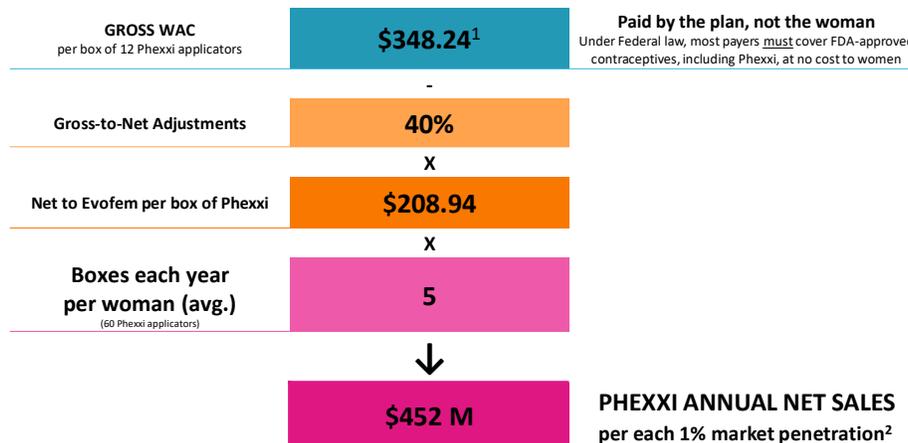


Source: Evofem Biosciences, Inc.

Pricing Strategy

There is significant profitability within the women’s healthcare market, where small percentages of market share can deliver big results. The Company’s strategy for pricing Phexxi was driven by extensive payer research, including discussions with decision makers at major health plans and pharmacy benefit managers (PBMs) across the U.S., who control nearly 83 million commercial lives. Based on this intelligence, Evofem initially priced Phexxi at \$267.50 per box of twelve applicators. As of January 1, 2024, Evofem’s wholesale acquisition cost (WAC) for a box of twelve prefilled Phexxi applicators was \$348.24 per box of twelve applicators, which when annualized is comparable to all other commercially available branded contraceptives. Evofem is averaging net \$208.94/box if a woman fills her prescription six times (with Evofem’s cost of goods per box of twelve at ~\$35). Based on the 43.3 million women in Evofem’s addressable market, filling the prescription five times per year (on average) could equate to \$452 million in annual net sales per each 1% of the market (Figure 13).

Figure 13
EVERY 1% MARKET SHARE OF THE 43.3M WOMEN IN EVOFEM'S ADDRESSABLE MARKET REPRESENTS SIGNIFICANT NET PRODUCT SALES



1. Effective January 1, 2024. WAC: Wholesale Acquisition Cost.

2. Annual net sales calculation: Net \$ to EVFM per box * boxes/year/women * 433,000 women (1% of 43.3M women in Phexxi addressable market)

Source: Evofem Biosciences, Inc.

The Company is seeing women fill their prescriptions between four to six times annually as, on average, women are having intercourse twice a week. If a woman tells her doctor she is having more than twelve sessions per month, her monthly prescription could be two boxes (each containing twelve applicators). This is why IQVIA data on Dispensed Units routinely exceeds Total Prescriptions (TRx) for Phexxi.

Importance of Having Phexxi as a Prescription

Based on the safety profile and the ingredients, Phexxi could have become an OTC product. However, the FDA wanted it to be a prescription product so that patients knew that an applicator must be used for every act of intercourse. Additionally, Evofem wanted Phexxi to be a prescription product due to the **Affordable Care Act (ACA)**, as there is a legislative mandate that says one product in each individual category must be covered. Because there is no generic vaginal pH modulator (VPH), Phexxi is the covered product in its category.

Under the ACA, most private health plans are required to provide birth control at no additional cost. Per the Health Resources and Services Administration (HRSA) and the U.S. Department of Labor, most plans are required to cover FDA-approved contraceptives, like Phexxi, at \$0 cost share, if a healthcare provider deems it medically necessary, whether the method is specifically identified in the current FDA Birth Control Guide or not. Plans may not require patients to try and fail multiple options within a method or force them to try and fail other methods first (a practice commonly referred to as 'step-edits'). In January 2024, the Biden-Harris administration announced new guidance to enable expanded access to all FDA-approved contraceptives without cost. Implementation could eliminate financial barriers for contraceptives like Phexxi for approximately 49 million women.

Third-Party Payers

Market acceptance and sales of Phexxi are dependent on reimbursement, which is available from third-party payers, including government health administration authorities, managed care organizations, private health insurers, and PBMs. Third-party payers determine which therapies they will pay for and establish reimbursement levels. Choices as to the extent of coverage and amount of reimbursement to be provided for any product are made on a payer-by-payer basis. Coverage determination by one payer for a drug does not guarantee that other payers will also provide coverage and adequate drug reimbursement. Managed care organizations and other private insurers often adopt their own payment or reimbursement reductions. The integration of commercial health plans and PBMs has increased the negotiating power of these entities. Third-party payers are increasingly employing formularies, which may not include all the products approved for a particular indication, to control costs by negotiating discounted prices in exchange for formulary inclusion.

Payer Landscape for Phexxi

Evofem's market access team has been successful at gaining preferred formulary position for Phexxi and removing the requirement for Prior Authorizations. As of October 5, 2023, Evofem had 73% coverage within its Commercial and Medicaid books of business. This included 19.2 million lives covered at no out-of-pocket cost.

During the product launch in 2020, the Company made the decision to use a co-pay card to help women gain access to the product and to create a base of product users. Since January 1, 2023, co-pay card utilization has decreased 24%, while claims remained stable. This directly reflects improvements in coverage for Phexxi. Lower out-of-pocket costs results in fewer women needing to rely on the co-pay card.

Currently, 82% of Phexxi prescriptions are getting covered. When they are not covered, a simple Prior Authorization letter is needed; Evofem's sales force collaborates with all stakeholders to ensure Prior Authorizations are understood and executed.

In the second quarter of 2022, Evofem successfully negotiated an agreement with one of the nation's largest PBMs to ensure that most women covered by this plan can fill their Phexxi prescription. The agreement took effect on July 1, 2022, and is representative of approximately 48 million lives.

Phexxi is classified in the databases and pricing compendia of Medi-Span and First Databank (two major drug information databases that payers can consult for pricing and product information) as the first and only “vaginal pH modulator.”

The Company continues working to increase the number of lives covered and gain a preferred formulary position for Phexxi. Current coverage includes:

- *U.S. Department of Veterans Affairs:* Evofem’s December 2020 contract award from the U.S. Department of Veterans Affairs covers approximately 13.7 million commercial lives.
- *The U.S. Medicaid population:* Medicaid provides health coverage to approximately 86 million members as of November 2023, including an estimated 14.9 million women aged 19 to 44. Its members have had access to Phexxi since January 1, 2021, through the Company’s participation in the Medicaid National Drug Rebate Program. Evofem also participates in the 340B program.
- Approximately 19.8 million commercial and Medicaid lives have access to Phexxi at no out-of-pocket cost due, in part, to one of the largest plans in California covering Phexxi with \$0 copay effective August 1, 2022 and subsequent improvements.

As of January 1, 2023, most insurers and PBMs must provide coverage, with no out-of-pocket costs (e.g., \$0 copay) to the subscriber or dependent for FDA-approved contraceptive products, like Phexxi, which are prescribed by healthcare providers. To comply with these guidelines, payers are increasingly covering Phexxi by:

- Adding Phexxi to the formulary (commercial insurers) or preferred drug list (Medicaid);
- Removing the requirement for a Prior Authorization letter from the HCP (commercial insurers); and
- Moving Phexxi to \$0 copay (commercial insurers).

Coverage for and access to Phexxi is expected to further increase as additional insurers and PBMs comply with the January 2022 guidance regarding access to contraception in the U.S. from the Health Resources and Services Administration (HRSA) and the U.S. Department of Labor. The new guidance specifies that most insurers and PBMs must provide coverage, with no out-of-pocket costs to women, to FDA-approved contraceptive products, such as Phexxi, as prescribed by healthcare providers.

In April 2023, Evofem announced a major new development in New York state that improves coverage for Phexxi for more than 5.8 million lives statewide. New York Medicaid transitioned to a single Preferred Drug List effective April 1, 2023, that includes no Prior Authorization requirement on Phexxi. This facilitates access to Phexxi for women covered by New York Medicaid, the largest of all Commercial and Medicaid payers in New York. In October 2023, Evofem gained Phexxi coverage for 21.3 million new lives from payers, including Colorado, New York, Mississippi Medicaid, Indiana State Medicaid, multiple Blue Cross Blue Shield plans, and the largest commercial payer in Michigan. Recently, the Washington State Health Care Authority (HCA) paved the way for nearly 1.8 million covered lives in Washington state, removing the Prior Authorization needed for Phexxi.

In March 2024, Evofem announced that it had successfully renegotiated the rebate for Phexxi with Medi-Cal, the California state Medicaid program. Medi-Cal is funded by the California Department of Health Care Services, the largest health care purchaser in the state, and serves more than 15.4 million beneficiaries. The renegotiated rebate improves (reduces) Evofem’s rebate on Medi-Cal prescriptions by 7.4%, while affording price protection to Medi-Cal against future Phexxi WAC increases. The new rebate will take effect July 1, 2024. The vaginal pH modulator continues to be included on the Medi-Cal Rx Family Planning, Access, Care, and Treatment Pharmacy Formulary. Medi-Cal beneficiaries may receive one box of 12 single-use Phexxi applicators per dispensing, and up to three boxes in any 75-day period.

Figure 14
INCREASING PHEXXI ACCESS THROUGH PAYER WINS

As of October 2023, Evofem has gained Phexxi coverage for more than 21.3M new lives.

Payer	Effective	Preferred Position	PA ² Removed	\$0 Copay?
Colorado Medicaid More than 1.39M lives	Oct. 2, 2023	✓	✓	N/A
Indiana State Medicaid Preferred Agent on Indiana Statewide Uniform Medicaid PDL ² Preferred with no PA ³ for 1.4M Managed Medicaid lives	Jan. 1, 2023 August 15, 2023	✓	✓	N/A
New York Medicaid More than 5.8M lives Largest of all Commercial and Medicaid payers in New York state	April 1, 2023		✓	N/A
Largest Commercial Insurer in Michigan	Jan. 1, 2023	✓	✓	✓
Mississippi Medicaid Preferred Agent on Mississippi Universal PDL ² Affects fee-for-service & Managed Medicaid beneficiaries More than 690,000 lives	Jan. 1, 2023	✓	✓	N/A
Multiple Blue Cross Blue Shield plans	Q1 2023	Varied	Varied	Varied

19.2 million lives covered at no out-of-pocket cost
More than 82% of Phexxi claims are being approved

Source: Evofem Biosciences, Inc.

Commercial Strategies

Evofem’s strategy is to commercialize Phexxi and leverage its sales force to promote additional women’s sexual and reproductive health products, thereby diversifying and growing its revenue stream. The Company believes that the U.S. market is the largest commercial opportunity for Phexxi. As such, Evofem has deployed a dedicated sales team in the U.S., through which the Company promotes Phexxi directly to obstetrician/gynecologists and their affiliated health professionals, who collectively write most prescriptions for contraceptive products. As of December 31, 2023, Evofem’s sales force consisted of 16 sales representatives and three business managers, supported by a self-guided virtual health care provider (HCP) learning platform.

The Company further offers direct access to Phexxi via Evofem’s telehealth platform, where women can meet directly with a healthcare professional to determine their eligibility for a Phexxi prescription, and, if eligible, have the prescription written by the healthcare professional, filled, and mailed directly by a third-party pharmacy.

Evofem’s commercial strategy for Phexxi further includes marketing and product awareness campaigns targeting women of reproductive age within the U.S., along with other specific segments. The Company has conducted little to no marketing activity since 2022 due to financial constraints.

The Company’s addressable market includes approximately 23 million women who are not using hormonal contraception and roughly 18.8 million women who are currently using a prescription contraceptive—some of whom (predominantly pill users) may be ready to transition to a non-invasive hormone-free contraceptive.

An emerging opportunity is the potential use of Phexxi for supplemental contraceptive protection by women using GLP-1 receptor agonists like Mounjaro and Zepbound who take oral birth control pills. These drugs may make oral birth control pills less effective at certain points in the dosing schedule, making an unintended pregnancy more likely. These women are at increased risk for 4 weeks after they start on the GLP-1 and again for 4 weeks after each time they increase their dose. An on-demand, hormone-free method like Phexxi is a logical choice to provide these patients additional protection.

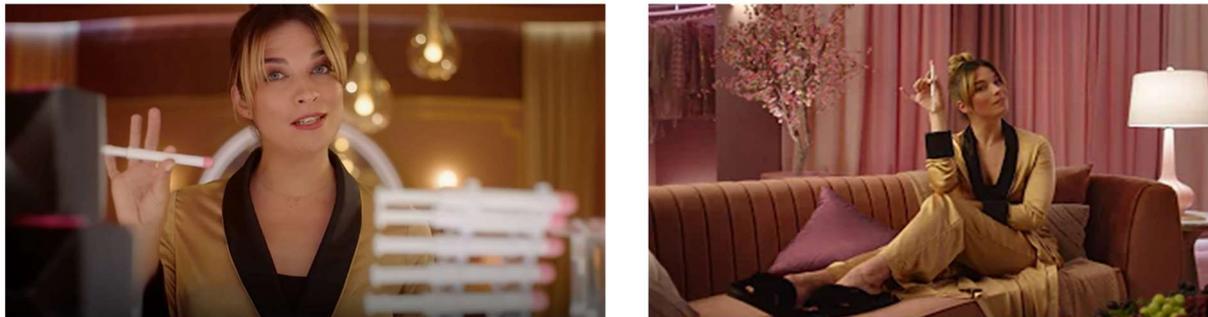
Advertising Campaign

In February 2021, Evofem launched a direct-to-consumer (DTC) advertising campaign, called “Get Phexxi,” to increase awareness and educate women regarding the benefits of using Phexxi. The campaign emphasized the issues faced by women as they determine the best contraceptive option available to them, including the lack of control with condoms, the daily need to take a pill, or abstinence required for cycle tracking.

In September 2021, the Company launched a national brand ambassador campaign featuring Emmy Award-winning celebrity Annie Murphy (a Canadian actress best known for her starring role as Alexis Rose in the sitcom *Schitt’s Creek*, for which she garnered universal acclaim and won a Primetime Emmy Award and a nomination for a Golden Globe Award). The campaign was designed to broaden awareness and drive uptake of Phexxi. This campaign (Figure 15), known as “House Rules,” has significantly raised Evofem’s target audience and overall awareness of Phexxi. Click here to view the video <https://bit.ly/3tTR9rP>. It also helped drive new healthcare professionals in recommending and prescribing Phexxi.

Figure 15

HOUSE RULES™ PHEXXI® COMMERCIAL WITH ANNIE MURPHY



Source: Evofem Biosciences, Inc.

The Company’s team of directors, sales specialists, and medical affairs is further focused on educating key payer accounts, pharmacy benefit managers (PBMs), key opinion leaders, and medical associations about the importance of offering a wider set of options to women seeking non-hormonal, woman-controlled contraceptive methods. These educational activities have been supported by presentation of clinical data at key national congresses (such as the annual meetings of the American College of Obstetricians and Gynecologists, the Society of Family Planning, the American Society for Reproductive Medicine, and Nurse Practitioners in Women’s Health), clinical publications, and additional market development activities.

Phexxi Product Sales

The Company has grown Phexxi net sales in each consecutive year since launch. In March 2024, Evofem reported net sales of \$18.2 million for fiscal 2023. This is despite a 73% reduction in sales force from 2H 2022 levels and the absence of capital to invest in growing the brand. (Figure 16, page 30).

Figure 16

PHEXXI NET PRODUCT SALES GROWTH SINCE LAUNCH



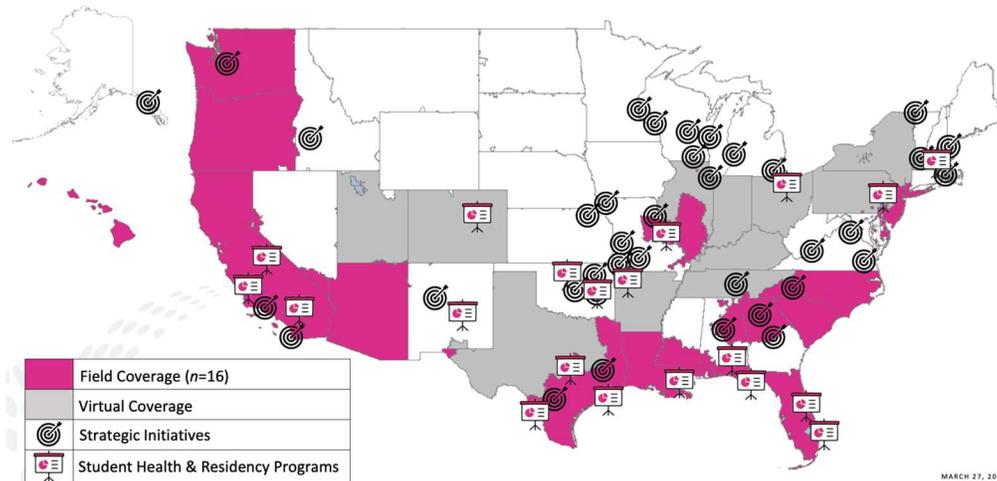
Source: Evofem Biosciences, Inc.

Salesforce

Evofem continues to promote Phexxi through a multifaceted approach involving field sales, virtual engagements, educational initiatives, and strategic endeavors. The sales force comprises 16 field specialists who remain resilient despite the Company’s three downsizings and a constrained marketing budget, exhibiting minimal attrition. These professionals boast extensive experience in women’s health and are driven by the belief that they are contributing to a transformative shift in their field. Notably, alongside ongoing detailing efforts, Evofem directs its attention to untapped market segments, such as student health centers, residency programs, various conventions, and key opinion leaders (KOLs). The sales team diligently follows up on all inquiries and actively cultivates advocates within these target areas. Figure 17 provides a snapshot of the Company’s current sales coverage for Phexxi.

Figure 17

PHEXXI SALES COVERAGE



Source: Evofem Biosciences, Inc.

Non-United States Markets

In markets outside of the U.S., Evofem intends to commercialize Phexxi through regional and/or global partnerships, license agreements, and/or distribution agreements. These third parties are expected to be involved in the regulatory process for their respective markets as well as clinical trials in support of any needed regulatory submissions, if any.

In October 2021, the Company submitted the registration for its hormone-free contraceptive vaginal gel to the Mexican Regulatory Agency COFEPRIS (Comisión Federal para la Protección contra Riesgos Sanitarios). Evofem has also submitted marketing applications for Phexxi under the trademark Femidence™ in Nigeria, Ethiopia, and Ghana. These were the first of several strategic regulatory submissions planned under Evofem's 2020 Global Health Agreement with Adjuvant Capital.

In October 2022, Phexxi was approved in Nigeria, where the product will be potentially marketed under the brand name Femidence™. This is the first regulatory approval for the contraceptive vaginal gel outside the U.S.

Manufacturing

Evofem outsources the manufacturing of Phexxi to a third party. The Company is currently contracted with a gel manufacturer to produce Phexxi in accordance with all applicable **current good manufacturing practices (cGMP) regulations**, as well as in compliance with all applicable laws and other relevant regulatory agency requirements for the manufacture of pharmaceutical drug products and combination drug-device products.

Rush License Agreement

In 2014, Evofem entered into an amended and restated license agreement with Rush University (the Rush License Agreement) pursuant to which Rush University granted Evofem an exclusive, worldwide license of certain patents and know-how related to the Company's multipurpose vaginal pH modulator technology (the Rush License IP), authorizing Evofem to make, distribute, and commercialize products and processes for any and all therapeutic, prophylactic, and/or diagnostic uses, including, without limit, use for female vaginal health and/or birth control.

Pursuant to the Rush License Agreement, Evofem is obligated to pay quarterly royalty payments in amounts equal to a single-digit percentage of the gross amounts received on a quarterly basis, less certain deductions incurred in the quarter based on a sliding scale. Evofem is also obligated to pay a minimum annual royalty amount of \$100,000 to the extent these earned royalties do not equal or exceed \$100,000 each year. A minimum annual royalty amount of \$100,000 was first required for the annual period commencing on January 1, 2021. Royalty costs owed to Rush University pursuant to the Rush License Agreement were \$0.7 million and \$1.1 million for the years ended December 31, 2023 and 2022, respectively.

Evofem also has the right to sub-license its rights to affiliates (without the prior approval of Rush University) and to third parties (with the prior written approval of Rush University). If Rush University approves of a third-party sub-license, in lieu of any royalty payment obligation under the Rush License Agreement, Evofem would then be under an obligation to pay Rush University a sub-license fee equal to a percentage of any sublicensing revenue received from any third-party sub-licensee. Rush University retained a royalty free, non-exclusive license from Evofem for the Rush License IP for non-commercial research purposes (described in the Intellectual Property section, pages 12-13). The Rush License Agreement may be terminated upon mutual written consent of both parties or by a non-breaching party if the other party commits a breach or default of any covenant in the agreement and fails to cure this breach within 30 days after receiving written notice of the breach or default.

The Rush License Agreement continues until the expiration, revocation, or invalidation of the last of the patents or the abandonment of the last patent application included within the licensed patents and technology, including any patent claiming an improvement made during the term of the Rush License Agreement in the course of research supported or developed by Rush University utilizing the technology, unless terminated in accordance with its terms.

Investment Highlights

- ***Evoform Biosciences, Inc. (“Evoform” or “the Company”) is a commercial-stage biopharmaceutical company focused on addressing unmet needs within the women’s sexual and reproductive healthcare markets.*** The Company’s initial Food and Drug Administration (FDA)-approved product, Phexxi®, is a hormone-free, on-demand prescription contraceptive vaginal gel. Packaged in boxes containing twelve pre-filled applicators, Phexxi is inserted up to one hour prior to intercourse and works to prevent pregnancy by maintaining the vaginal pH (a vaginal pH modulator [VPM]), which reduces sperm motility and lowers the chance of sperm reaching the egg.
- ***As the only FDA approved and marketed hormone-free contraceptive vaginal gel that has no systemic activity in the body, Phexxi addresses significant gaps and underserved and unmet needs in the contraceptive market.*** This is important to the 23 million women who are beyond hormones and will not or cannot use hormonal contraceptives, including women who may be breast feeding or breast cancer patients/survivors.
- ***On December 11, 2023, Evoform entered into a Merger Agreement with Aditxt, Inc. (ADTX-NASDAQ), under which Aditxt intends to acquire Evoform.***
- ***On April 26, 2024, Evoform delivered a termination letter to Aditxt*** because the required and agreed \$2.0 million investment in Evoform was not made on or prior to April 1, 2024. The Merger Agreement was immediately terminated upon delivery of this letter.
- ***On May 2, 2024, Evoform and Aditxt reinstated the Merger Agreement, as amended, and entered into the Fourth Amendment to the Agreement and Plan of Merger.*** Aditxt paid \$1 million to Evoform in consideration of the reinstatement and Fourth Amendment. The companies are working toward closing in the second half of 2024.
- ***While new contraceptive products have been introduced in recent years, Evoform believes that Phexxi represents the first innovative contraceptive method introduced in the U.S. since NuvaRing was approved by the FDA in 2001 (23 years ago).***
- ***Key attributes of Phexxi include:***
 - ***Hormone-free.*** Phexxi is an innovative gel that works to prevent pregnancy without the use of hormones. Since the product is entirely hormone-free, there is no concern of any hormone-related side effects, which may include weight gain, acne, headaches, mood swings, or the slight risk of blood clots, which are associated with hormonal birth control methods.
 - ***Use when needed.*** Since Phexxi is used in the moment, prior to intercourse, there is no daily pill commitment or the need to take hormones. This also makes Phexxi easily reversible, providing women with a flexible option for family planning.
 - ***First in class.*** Phexxi is the first and only hormone-free prescription birth control gel that women control. The product works to prevent pregnancy by maintaining the vaginal pH, which reduces sperm motility and lowers the chance of sperm reaching the egg. This mechanism of action is unique to Phexxi, with no comparable products available on the market.
 - ***Woman-controlled.*** Phexxi places women in control of their bodies in terms of pregnancy prevention. With Phexxi, there is no need to rely on a partner to bring a condom and no need to visit a doctor’s office for an injection or procedure to prevent pregnancy. The product is delivered using an applicator (similar to a tampon) and was developed to be used spontaneously and to be convenient.

-
- ***As of January 1, 2023, most insurers and pharmacy benefit managers (PBMs) must provide coverage with no out-of-pocket costs (e.g., \$0 copay) to the subscriber or dependent for FDA-approved contraceptive products, such as Phexxi, which are prescribed by healthcare providers.***
 - ***As of March 21, 2024, the Company owned or had exclusive license to approximately 47 issued patents and allowed applications in the U.S. and other countries and jurisdictions and had approximately 16 patent applications pending in the U.S. and other countries and jurisdictions.*** This includes four U.S. patents, which cover Phexxi and its labeled indication through 2033, that are listed in the U.S. FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book).
 - ***There is a significant opportunity for profit within the women’s healthcare market, where small percentages of market share can deliver big results.*** Evofem’s wholesale acquisition cost (WAC) for a box of 12 prefilled Phexxi applicators is \$348.24. Factoring a 40% gross-to-net adjustment, Evofem is averaging \$208.94/box (with Evofem’s cost of goods per box of twelve at ~\$35).
 - ***Partnership discussions are ongoing for the commercialization of Phexxi in international markets*** as Evofem intends to expand the product’s global reach and further increase its commercial potential through ex-U.S. licenses. The product is approved in Nigeria, and regulatory dossiers have been submitted in Ghana, Ethiopia, and Mexico.
 - ***For the year ended December 31, 2023, net product sales were \$18.2 million compared to \$16.8 million in net product sales in the prior year.*** The increase was primarily driven by more favorable reimbursements, leading to a better gross to net ratio, and the Phexxi WAC increase that took effect October 1, 2022.
 - ***Evofem’s leadership team has over 85 years of combined experience within the healthcare and pharmaceutical industry.*** Together, these individuals have launched the first vaginal pH modulator, a unique mechanism of action, to bring much-needed non-hormonal innovation to the contraceptive space with Phexxi vaginal gel.
 - ***As of December 31, 2023, the Company had \$0.6 million of restricted cash versus \$2.8 million of unrestricted cash and \$1.2 million of restricted cash at December 31, 2022.***

Historical Financial Results

Figures 18, 19, and 20 provide the Company's condensed consolidated statements of operations, its condensed consolidated balance sheets, and its consolidated statements of cash flows for the year ended December 31, 2023.

Figure 18
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)

	Years Ended December 31,	
	2023	2022
Product sales, net	\$ 18,218	\$ 16,837
Operating expenses:		
Cost of goods sold	6,512	4,415
Research and development	2,939	25,032
Selling and marketing	11,664	43,951
General and administrative	14,950	27,563
Total operating expenses	36,065	100,961
Loss from operations	(17,847)	(84,124)
Other income (expense):		
Interest income	31	85
Other expense, net	(2,628)	(2,087)
Loss on issuance of financial instruments	(6,776)	(72,993)
Gain (loss) on debt extinguishment	75,337	(24,487)
Change in fair value of financial instruments	4,879	106,952
Total other income, net	70,843	7,470
Income (loss) before income tax	52,996	(76,654)
Income tax expense	(17)	(44)
Net income (loss)	52,979	(76,698)
Deemed dividends	(2,984)	(1,316)
Net income (loss) attributable to common stockholders	\$ 49,995	\$ (78,014)
Net income (loss) per share attributable to common stockholders:		
Basic (Note 2)	\$ 10.36	\$ (167.42)
Diluted (Note 2)	\$ 0.05	\$ (167.42)
Weighted-average shares used to compute net income (loss) per share:		
Basic	4,826,763	465,967
Diluted	984,038,574	465,967

Source: Evofem Biosciences, Inc.

Figure 19
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value and share data)

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	\$ -	\$ 2,769
Restricted cash	580	1,207
Trade accounts receivable, net	5,738	1,126
Inventories	1,697	5,379
Prepaid and other current assets	1,195	2,218
Total current assets	<u>9,210</u>	<u>12,699</u>
Property and equipment, net	1,203	3,940
Operating lease right-of-use assets	106	4,406
Other noncurrent assets	35	4,118
Total assets	<u>\$ 10,554</u>	<u>\$ 25,163</u>
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 17,020	\$ 14,984
Convertible notes payable carried at fair value (Note 4)	14,731	39,416
Convertible notes payable - Adjuvant (Note 4)	28,537	26,268
Accrued expenses	4,227	4,124
Accrued compensation	2,609	2,175
Operating lease liabilities - current	97	2,311
Derivative liabilities	1,926	1,676
Other current liabilities	3,316	2,876
Total current liabilities	<u>72,463</u>	<u>93,830</u>
Operating lease liabilities - non-current	8	3,133
Total liabilities	<u>72,471</u>	<u>96,963</u>
Commitments and contingencies (Note 7)		
Convertible and redeemable preferred stock, \$0.0001 par value, Senior to common stock Series B-1, B-2, C, E-1, and F-1 convertible preferred stock, 5,000, 5,000, 1,700, 2,300, and 95,000 shares authorized; 1,874 shares of E-1 and 22,280 shares of F-1 issued and outstanding at December 31, 2023; no other shares issued and outstanding at December 31, 2023 or 2022	4,593	-
Stockholders' deficit:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized; no shares issued and outstanding at December 31, 2023 or 2022		-
Common Stock, \$0.0001 par value; 3,000,000,000 shares authorized; 20,007,799 and 984,786 shares issued and outstanding as of December 31, 2023 and 2022, respectively	2	-
Additional paid-in capital	823,036	817,367
Accumulated other comprehensive income (loss)	(849)	49,527
Accumulated deficit	(888,699)	(938,694)
Total stockholders' deficit	<u>(66,510)</u>	<u>(71,800)</u>
Total liabilities, convertible and redeemable preferred stock and stockholders' deficit	<u>\$ 10,554</u>	<u>\$ 25,163</u>

Source: Evofem Biosciences, Inc.

Figure 20
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net income (loss)	\$ 52,979	\$ (76,698)
Adjustments to reconcile net income (loss) to net cash and restricted cash used in operating activities:		
Loss on issuance of financial instruments	6,776	72,993
Gain on debt extinguishment	(75,337)	24,487
Change in fair value of financial instruments	(4,879)	(106,952)
Financial instrument modification expense	-	1,067
Stock-based compensation	1,189	3,313
Depreciation	477	1,015
Noncash interest expenses	2,270	2,176
Noncash right-of-use amortization	1,304	1,031
Noncash inventory reserve for excess & obsolescence	1,576	(300)
Net gain on lease termination	(466)	-
Noncash instrument exchange expense	-	514
Loss on disposal and write-down of property and equipment	2,511	926
Gain on accounts payable settlements	(2,096)	-
Changes in operating assets and liabilities:		
Trade accounts receivable	(4,612)	5,323
Inventories	2,106	1,566
Prepaid and other assets	3,661	2,593
Accounts payable	4,090	4,474
Accrued expenses and other liabilities	527	(4,106)
Accrued compensation	434	(2,478)
Lease liabilities	(1,478)	(1,354)
Net cash and restricted cash used in operating activities	<u>(8,968)</u>	<u>(70,410)</u>
Purchases of property and equipment		
	(4)	(341)
Net cash and restricted cash used in investing activities	<u>(4)</u>	<u>(341)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock - exercise of warrants	290	25,211
Proceeds from issuance of common stock and warrants, net of offering costs	-	24,882
Proceeds from issuance of common stock - Public Offering, net of commissions - ATM transactions	-	7,438
Proceeds from issuance of common stock- ESPP and exercise of stock options	-	20
Borrowings under term notes	5,640	11,500
Payments under term notes	(1,154)	(5,892)
Cash repurchase of fractional common stock after reverse stock split	-	(18)
Cash paid for offering costs	-	(1,202)
Net cash and restricted cash provided by financing activities	<u>4,776</u>	<u>61,939</u>
Net change in cash, cash equivalents and restricted cash	(4,196)	(8,812)
Cash, cash equivalents and restricted cash, beginning of period	4,776	13,588
Cash, cash equivalents and restricted cash, end of period	<u>\$ 580</u>	<u>\$ 4,776</u>
Supplemental cash flow information:		
Cash paid for interest	338	698
Cash paid for taxes	4	26
Supplemental disclosure of noncash investing and financing activities:		
Exchange of convertible notes to Series E-1 Shares	1,800	-
Exchange of warrants and partial purchase rights value to Series F-1 Shares	2,761	-
Issuance of common stock upon exercise of purchase rights	426	1,007
Series E-1 shares dividends	74	-
Right-of-use assets obtained in exchange for operating lease liabilities	-	219
Purchases of property and equipment included in accounts payable and accrued expenses	-	105
Conversion of series B-2 and B-1 convertible preferred stock to common stock	-	1,187
Exchange of series B-2 convertible preferred stock to series C convertible preferred stock	-	1,616
Issuance of common stock for prepaid advertising	-	3,412
Exchange of Adjuvant Notes for Purchase Rights	-	634
Exchange of term notes for Purchase Rights	-	4,806

Source: Evofem Biosciences, Inc.

Recent Events

May 2, 2024—Evoform and Aditxt, Inc. (ADTX-NASDAQ) reinstated the Merger Agreement, as amended, and entered into the Fourth Amendment to the Agreement and Plan of Merger, in consideration for which Aditxt paid \$1.0 million to Evoform. Notable adjustments under the Fourth Amendment include that:

- Aditxt will invest an additional \$2.5 million in Evoform through the purchase of Series F-1 Convertible Preferred Stock prior to July 1, 2024. To fund these mandated investments, Aditxt will allocate to Evoform, from any capital raise, 40% of the gross proceeds up to \$1.5 million prior to June 17, 2024, and \$1 million prior to July 1, 2024.
- Aditxt consented to allow Evoform to pursue potential investments in the Company.
- If Evoform receives a superior proposal to the Merger Agreement, the Company will notify and allow Aditxt ten days to negotiate a competing offer.
- The \$4 million termination fee has been deleted from the Merger Agreement in its entirety, enabling Evoform to accept and consummate a superior proposal with no penalty.

The companies are working toward closing in the second half of 2024. Requirements for closing of the proposed Transaction include timely investment by Aditxt of \$2.5 million in Evoform as stipulated by the Fourth Amendment; the purchase by Aditxt of Evoform’s senior secured debt from the debtholders on or before July 15, 2024, as stipulated by the Third Amendment; and the affirmative vote of both Aditxt’s and Evoform’s stockholders on the proposals seeking approval of the proposed Transaction at the companies’ respective Stockholder Meetings.

April 26, 2024—Evoform terminated the December 2023 Merger Agreement, as amended, with Aditxt, Inc. because Aditxt did not make the required and agreed \$2.0 million investment in Evoform on or prior to April 1, 2024.

April 18, 2024—Announced that the United States Patent and Trademark Office (USPTO) issued to the Company a Notice of Allowance for patent application 17/823,020 entitled, “Compositions and Methods for Enhancing the Efficacy of Contraceptive Microbicides.” This Notice of Allowance is expected to result in the issuance of a U.S. patent once administrative processes are completed. The allowed claims cover methods of contraception with a composition that encompasses Phexxi® (lactic acid, citric acid, and potassium bitartrate) vaginal gel. Evoform expects the resulting patent will be Orange Book-listable. The patent, when issued, will be Evoform’s fifth patent for Phexxi in the United States.

March 27, 2024—Announced financial results for the fourth quarter and year ended December 31, 2023. Highlights include: \$18.2 million of Phexxi net product sales in 2023, an impressive increase compared to 2022 given the 73% reduction in field force and absence of growth capital in 2023; sales and marketing expense was 64% of net sales for 2023, a key milestone for the Company and a significant improvement from prior years; 73% reduction in selling and marketing expenses in 2023 versus the prior year; and improved loss from operations by 79% versus 2022 levels.

March 20, 2024—Announced successful renegotiation of the rebate for Phexxi with Medi-Cal, the California state Medicaid program. Medi-Cal is funded by the California Department of Health Care Services, the largest health care purchaser in the state, and serves more than 15.4 million beneficiaries. The renegotiated rebate improves Evoform’s rebate on Medi-Cal prescriptions by 7.4%, while affording price protection to Medi-Cal against future Phexxi WAC increases. The new rebate will take effect July 1, 2024.

March 7, 2024—Use of GLP-1 receptor agonists, or GLP-1s, is skyrocketing in the U.S., with more than nine million prescriptions for Ozempic, Wegovy, Mounjaro, and similar diabetes and obesity drugs written during the last three months of 2022 alone. Zepbound weekly prescriptions hit 25,000 in December 2023, just one month after it was approved to treat obesity. These drugs may make oral birth control pills less effective at certain points in the dosing schedule, making an unintended pregnancy more likely. Users of oral birth control considering GLP-1 treatment are encouraged to plan ahead to prevent unintended pregnancy. Having a contraceptive strategy in place and the right

product at your fingertips enables spontaneous intimacy no matter where you are in your GLP-1 dosing schedule. An on-demand, hormone-free method is a logical choice to provide these patients with additional protection they need. One such option, Phexxi vaginal gel, puts the power in her hands and with an FDA-approved contraceptive that she uses only when she needs it.

February 29, 2024—Evoform and Aditxt entered into the third amendment to the Merger Agreement. Noteworthy changes include extending the filing date of the joint proxy statement to April 30, 2024 and a stipulation that Aditxt must purchase Evoform’s senior secured debt from the debtholders on or before the close of the proposed Transaction. Additionally, the amendment removed the requirement that Aditxt loan Evoform \$3 million by February 29, 2024, and replaced it with the requirement that Aditxt will make a \$3.5 million aggregate equity investment into Evoform consisting of (1) the purchase of 2,000 shares of Evoform Series F-1 Preferred Stock for \$2.0 million, in aggregate, on or prior to April 1, 2024, and, (2) the purchase of 1,500 shares of Evoform Series F-1 Preferred Stock for \$1.5 million, in aggregate, on or prior to April 30, 2024.

February 1, 2024—Announced preliminary, unaudited results for fiscal 2023, including record net sales of Phexxi and the Company’s lowest total operating expenses since becoming a commercial stage company in 2020. Achieved preliminary net product sales in the range of \$18.1 to \$18.3 million in 2023, an impressive increase compared to 2022 given the 73% reduction in field force and absence of growth capital in 2023. The Company reached a key milestone with net product sales higher than sales and marketing expense for 2023. Evoform reduced total operating expense by more than 60% from 2022 levels and improved loss from operations by more than 75% versus 2022 levels.

January 30, 2024—Evoform and Aditxt entered into the second amendment to the Merger Agreement, which changed the deadline for Aditxt to loan Evoform \$3 million to February 29, 2024; changed the date by which Evoform may terminate the Merger Agreement for failure to receive the loan from Aditxt to February 29, 2024; and changed the filing date for the companies to file the Joint Proxy Statement to April 1, 2024.

January 10, 2024—Evoform and Aditxt entered into the first amendment to the Merger Agreement, which changed the filing date for the Joint Proxy Statement regarding the proposed Transaction to February 14, 2024.

January 8, 2024—The Washington State Health Care Authority (HCA) removed the Prior Authorization from Phexxi, which upgrades Phexxi coverage for nearly 1.8 million Washingtonians across all Medicaid plans (HCA’s Managed Medicaid and Fee for Service Medicaid).

December 12, 2023—Aditxt, Inc., a company dedicated to discovering, developing, and deploying promising health innovations, and Evoform announced the signing of a definitive agreement under which Aditxt intends to acquire Evoform (the “Merger Agreement”).

November 14, 2023—Evoform announced financial results for the third quarter and nine months ended September 30, 2023. Highlights include: \$5.1 million in net product sales of Phexxi for the third quarter of 2023 and \$13.4 million year-to-date 2023; more than 82% of Phexxi claims are now being approved; improvements in coverage have driven a 24% decrease in co-pay card utilization since January 1, 2023; 75% reduction in selling and marketing expenses versus the third quarter of 2022; sales and marketing expense as a percentage of net sales was 58% for the third quarter of 2023, the most favorable ratio since the Phexxi launch in 2020; third quarter total operating expenses of \$8.7 million for 2023, a decrease of 65% as compared to the same period last year; and a narrowed loss from operations by 81% in the third quarter of 2023 as compared to the prior year quarter. During the quarter, Evoform made the required \$1 million initial payment to a U.S.-based, healthcare-focused institutional investor as required by the to the Securities Purchase and Security Agreement dated April 2020, as amended, under which this investor purchased \$25 million of convertible senior secured promissory notes (the “Notes”) from Evoform in 2020.

October 24, 2023—Announced preliminary results for the third quarter of 2023, including sequential growth in net product sales of Phexxi and the positive impact of ongoing cost containment initiatives. Phexxi net product sales are expected to be \$5.0 to \$5.2 million for the third quarter of 2023 with Evofem remaining on track to deliver its third consecutive year of net product sales growth. Selling and marketing expenses were more than 75% lower and total operating expenses were more than 65% lower in the third quarter of 2023 than the third quarter of 2022. Loss from operations was reduced by more than 80% in the third quarter of 2023 as compared to the third quarter of 2022.

October 24, 2023—Saundra Pelletier, Chief Executive Officer and Amy Raskopf, Senior Vice President, Investor Relations of Evofem participated in the Virtual Investor Ask the CEO Conference

September 27, 2023—Announced that Padagis Israel Pharmaceuticals Ltd. (Padagis) has withdrawn the Paragraph IV certification in its previously-submitted Abbreviated New Drug Application (ANDA) for a generic version of Phexxi and has instead converted to a Paragraph III certification. With this pivot to Paragraph III certification, rather than challenging the Phexxi patents and seeking approval of the ANDA prior to expiration of any of those patents, Padagis is instead now asking the U.S. Food and Drug Administration (FDA) to wait until after all the Phexxi patents expire before issuing final approval of the ANDA. The latest-expiring Phexxi patents do not expire until 2033.

September 14, 2023—Stockholders approved amending the Company’s Restated Certificate to increase the total number of common shares authorized to 3,000,000,000.

September 11, 2023—Announced it has successfully negotiated and entered into a Fourth Amendment to its Securities Purchase and Security Agreement dated April 2020, as amended (the “2020 S.P.A.”), with a U.S.-based, healthcare-focused institutional investor, under which the Investor purchased \$25 million of convertible senior secured promissory notes from Evofem. Most notably, in the Fourth Amendment, the Investor withdraws and waives the March 2023 Event of Default and allows for the Company to repurchase the Notes for no more than \$25 million and as little as \$14 million, less any interim payments, if repurchased by September 8, 2024.

August 22, 2023—Announced it has signed a confidential non-binding letter of intent (LOI) relating to a merger with a publicly-traded entity which, if consummated, could result in Evofem being listed on a national stock exchange.

August 14, 2023—Announced financial results for the second quarter and first half of 2023. For the three months ended June 30, 2023, net product sales were \$2.5 million compared to \$6.0 million in the prior year period. The 59% decrease was primarily due to lower Phexxi ex-factory unit sales due to the absence of marketing and DTC promotion and the 73% reduction in sales force in the current period, coupled with \$1.6 million in product returns in the current period; this was product manufactured to meet anticipated demand based on pre-launch, pre-COVID sales forecasting. At the time of manufacture, the product shelf life was 30 months. The Company succeeded in extending the product shelf life to 48 months in June 2022, but product sold prior to that date could not be relabeled. Because COVID hindered Evofem’s ability to access HCPs, fully execute its commercial strategy, and meet forecasted sales levels, some of the 30-month labelled product was returned. These factors were offset, in part, by more favorable payer coverage in the current period.

July 12, 2023—Saundra Pelletier, Chief Executive Officer, and Amy Raskopf, Senior Vice President, Investor Relations of Evofem, participated in the Virtual Investor Summer Spotlight. The virtual event included a brief overview of the Company’s business, a moderated roundtable discussion, and an interactive Q&A session.

June 16, 2023—Announced financial results for the first quarter of 2023, including growth in net product sales of Phexxi. Highlights for and since the quarter include increased Phexxi net product sales 37% to \$5.8 million; reduced total operating expenses 72% to \$9.4 million; implemented measures in March 2023 to further decrease operating expenses; loss from operations decreased 88% to \$3.6 million; and the Company is on track to be EBITDA break-even on a quarterly basis by year-end 2023.

June 1, 2023—Announced strong preliminary results for the first quarter of 2023, including robust growth in net product sales of Phexxi. During the quarter, the Company increased Phexxi net product sales more than 35% to approximately \$5.8 million in Q1 2023 versus \$4.3 million in Q1 2022; reduced total operating expenses more than 70% to approximately \$9.4 million versus \$33.2 million in Q1 2022; decreased loss from operations by more than 85% to approximately \$3.6 million versus a loss of \$28.9 million in Q1 2022; is on track to be EBITDA break-even on a quarterly basis by year-end 2023; and regained compliance with certain debt covenants through a shareholder-approved reverse split on May 18, 2023.

May 17, 2023—Announced a 1-for-125 reverse stock split of the Company’s common stock, which was approved by the stockholders of the Company at the special meeting of stockholders held on March 15, 2023. On May 18, 2023, the Company’s common stock will open for trading under a new CUSIP (30048L302) on the OTC Venture Market, on a split-adjusted basis, under the ticker symbol “EVFMD.” After 20 business days, the ticker symbol will change back to “EVFM.” The reverse stock split is intended to ensure the Company has a sufficient number of authorized shares of common stock to cover the number of common shares underlying the Company’s financial instruments on a fully diluted basis.

April 28, 2023—Reported financial results for the year ended December 31, 2022. Highlights include: increased Phexxi net product sales by 104% to \$16.8 million in 2022; gained Phexxi coverage for more than 22.1 million new lives since January 1, 2023; more than 80% of Phexxi claims are now being approved (as of February 2023, the most current data); reduced total operating expenses by \$74.1 million in 2022 versus 2021, exceeding the Company’s stated goal to reduce costs by \$50 million in 2022; implemented measures in March 2023 to further decrease operating expenses, with the goal of reaching EBITDA break-even by year-end 2023; and appointed Ivy Zhang as Chief Financial Officer and Secretary effective April 13, 2023.

April 14, 2023—Announced the appointment of Ivy Zhang as Chief Financial Officer (CFO) and Secretary, effective April 13, 2023. Reporting to Chief Executive Officer Sandra Pelletier, Ms. Zhang will lead Evofem’s finance organization and financial activities, including financial planning and analysis, accounting, external audit, tax, controllership, and treasury functions.

April 12, 2023—Announced a major new win in New York state that improves coverage for Phexxi for more than 5.8 million lives statewide. New York Medicaid transitioned to a single Preferred Drug List effective April 1, 2023, that includes no Prior Authorization requirement on Phexxi. This facilitates access to Phexxi for women covered by New York Medicaid, the largest of all Commercial and Medicaid payers in New York. In the first quarter of 2023, Evofem gained Phexxi coverage for 16.3 million new lives from payers including Mississippi Medicaid, Indiana State Medicaid, multiple Blue Cross Blue Shield plans, and the largest commercial payer in Michigan.

March 21, 2023—Announced it has implemented measures to lower its operating expenses, with the goal of reaching cash flow break even by year-end 2023. These measures include a 39% reduction of payroll expenses through a combination of: salary cuts for certain employees, including a 40% reduction in Chief Executive Officer compensation and a 20% reduction in pay for other continuing members of the executive team versus prior year levels; consolidation of three sales territories; and elimination of eight office and management positions, including the Chief Commercial Officer role, effective March 17, 2023.

March 9, 2023—Announced the appointment of Albert Altro as Interim Chief Financial Officer of the Company. He replaces Jay File, who is leaving the Company to explore other opportunities.

February 28, 2023—Announced that reproductive telehealth leader SimpleHealth now offers Phexxi. Launched in 2016, SimpleHealth is a leading digital healthcare platform that makes access to reproductive wellness convenient and easy for its patients. The Company is focused on providing access and expert care to allow women to realize their potential through a healthy reproductive system.

February 27, 2023—Announced that two additional U.S. patents which cover Phexxi and its labeled indication are now listed in the U.S. Food and Drug Administration (FDA) publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

February 23, 2023—Announced that its Board of Directors has unanimously approved a comprehensive strategic process to explore and evaluate strategic alternatives to maximize shareholder value. Potential strategic alternatives to be explored or evaluated as part of this process may include, but are not limited to, a merger, reverse merger, other business combination, sales of assets, licensing, or other strategic transactions involving the Company.

January 10, 2023—Announced that Phexxi was added to the Costco Member Prescription Program, giving millions of additional women access to this innovative hormone-free contraceptive. The Costco Member Prescription Program is a prescription drug discount card program that provides eligible Costco members and their eligible dependents the ability to obtain lower prices on Phexxi and other participating drugs at participating pharmacies. Costco members who are uninsured and want to pay cash for their Phexxi prescription, or who have been denied coverage by their insurer, may use this program to fill their Phexxi prescriptions for less than the typical cash pay cost.

January 9, 2023—Announced multiple new insurance wins that give millions of additional women access to Phexxi for the hormone-free prevention of pregnancy. Three recent Medicaid wins move Phexxi to a Preferred formulary position with no restrictions, improving Phexxi coverage for more than 3.7 million lives in eleven states. Evofem also expanded its commercial coverage for Phexxi with wins including a marquis university health plan in Pennsylvania (effective November 30, 2022) and the largest commercial payer in Michigan (effective January 1, 2023). These payers serve over 2.25 million lives in aggregate. Both payors have removed the Prior Authorization and moved Phexxi to Preferred formulary status; Phexxi's new position is \$0 Preferred with no restrictions.

January 6, 2023—Filed its Quarterly Report on Form 10-Q for the quarter ended September 30, 2022.

December 29, 2022—Announced that it was granted additional time by the OTC Markets Group to file its Quarterly Report on Form 10-Q for the quarter ended September 30, 2022. Previously, the OTC Markets Group provided until December 29, 2022, to file the 10-Q.

Risks and Disclosures

This Executive Informational Overview® (EIO) has been prepared by Crystal Research Associates, LLC (“CRA”) with the assistance of Evofem Biosciences, Inc. (“Evofem” or “the Company”) based upon information provided by the Company. CRA has not independently verified such information. Some of the information in this Executive Informational Overview (EIO) relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in Evofem’s statements on forms filed from time to time.

The content of this report with respect to Evofem has been compiled primarily from information available to the public released by the Company through news releases and other filings. Evofem is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by Evofem or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, for year one of its agreement, CRA has been compensated by the Company in cash of fifty thousand dollars for its services in creating this report and for quarterly updates.

Investors should carefully consider the risks and information about Evofem’s business, as described below. Investors should not interpret the order in which considerations are presented in this document or other filings as an indication of their relative importance. In addition, the risks and uncertainties covered in the accompanying sections are not the only risks that the Company faces. Additional risks and uncertainties not presently known to Evofem or that it currently believes to be immaterial may also adversely affect the Company’s business. If any of such risks and uncertainties develops into an actual event, Evofem’s business, financial condition, and results of operations could be materially and adversely affected.

This report is published solely for information purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. For more complete information about the risks involved in investing in the Company, as well as for copies of this report, please contact Evofem by emailing ir@evofem.com.

Risks Related to the Company’s Financial Condition and Capital Requirements

The Company is currently over 90 days past due on a considerable number of vendor obligations, including pursuant to previous lease agreements. It may not be able to refinance, extend, or repay the substantial indebtedness owed to Evofem’s secured and unsecured lenders, which would have a material adverse effect on its financial condition and ability to continue as a going concern.

Evofem has incurred significant losses and negative cash flows since its inception and the Company anticipates that it will continue to incur significant losses and negative cash flow for the foreseeable future.

The Company must raise significant additional funds to finance its operations and to remain a going concern. If it is unable to raise additional capital when needed or on acceptable terms, Evofem may be forced to delay, reduce, and/or eliminate one or more of its business initiatives.

Evofem has a limited number of shares of common stock available for future issuance, which could adversely affect its ability to raise capital or consummate strategic transactions.

Risks Related to Potential Bankruptcy

Evofem is subject to risks and uncertainties associated with potential bankruptcy proceedings, including a long and protracted restructuring.

The Company's financial results may be volatile and may not reflect historical trends.

Risks Related to Commercialization of Phexxi

Failure to successfully commercialize Phexxi for prevention of pregnancy would likely cause the Company's business to fail.

The Company faces competition from other medical device, biotechnology, and biopharmaceutical companies and its operating results will suffer if the Company is unable to compete effectively.

Phexxi may not gain sufficient market acceptance among physicians, patients, or the medical community, thereby limiting the Company's potential to generate revenue, which would undermine its future growth prospects.

Risks Related to Regulatory Approvals

Even though the Company has received approval from the FDA in the U.S. to market Phexxi for the prevention of pregnancy, it may fail to receive similar approvals outside the U.S.

Evofem has not paid its fiscal year 2023 PDUFA Invoice for Phexxi to the FDA and the balance due continues to incur interest, penalties, and may apply retroactively. The Company cannot submit any new applications or supplements until paid.

Risks Related to the Company's Post-Marketing Legal and Regulatory Compliance

Developments after a product reaches the market may adversely affect sales of the product.

Product liability lawsuits against Evofem could cause the Company to incur substantial liabilities and to limit commercialization of Phexxi. If Evofem is unable to obtain adequate insurance or is required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, its insurance coverage, a material liability claim could adversely affect the Company's financial condition.

If Evofem fails to comply with environmental, health, and safety laws and regulations, it could become subject to fines or penalties or incur costs that could have a material adverse effect on its business, financial condition, or results of operations.

Risks Related to the Company's Intellectual Property

Evofem's rights to develop and commercialize Phexxi are subject to, in part, the terms and conditions of licenses granted to it by third parties. The patent protection and patent prosecution of Phexxi is dependent on third parties.

If the Company is unable to obtain and maintain patent protection for Phexxi or other proprietary technologies, it may develop or acquire, or if the scope of the patent protection it has or will obtain is not sufficiently broad, competitors could develop and commercialize products and technology similar or identical to its products and technology, and the Company's ability to successfully commercialize Phexxi, its product candidates, and other proprietary technologies the Company may develop may be adversely affected.

Evoform may not be able to protect its intellectual property and proprietary rights throughout the world.

Issued patents covering Phexxi and other proprietary technologies the Company may develop could be found invalid or unenforceable if challenged in court or before administrative bodies in the U.S. or abroad.

If the Company does not obtain patent term extensions (PTE) for its products or product candidates, the Company's business may be materially harmed.

The patent protection and patent prosecution for Evoform's product candidates are dependent on third parties, including Rush University.

If an event of default occurs under the Company's senior secured promissory notes issued pursuant to the Securities Purchase and Security Agreement dated April 2020, as amended, the note holders could take possession of all assets owned by Evoform, including any directly owned intellectual property.

If the Company is unable to protect the confidentiality of its trade secrets, Evoform's business and competitive position would be harmed.

The Company may be subject to claims that its employees have wrongfully used or disclosed or wrongfully used alleged trade secrets of their former employers.

Some intellectual property that Evoform has in-licensed may have been discovered through government funded programs and thus may be subject to federal regulations, such as "march-in" rights, certain reporting requirements, and a preference for U.S.-based companies. Compliance with such regulations may limit the Company's exclusive rights and limit its ability to contract with non-U.S. manufacturers.

Risks Related to Reliance on Third Parties

The Company's success relies on third-party suppliers and one contract manufacturer. Any failure by these third parties, including their inability to successfully perform and comply with regulatory requirements, could negatively impact Evoform's business and its ability to market Phexxi and develop and market its product candidates, and the Company's business could be harmed.

Evoform has no significant internal distribution capabilities. The Company intends to engage third-party distributors for distribution of products outside the U.S., if approved, and has engaged additional third-party wholesale distributors for the distribution of Phexxi in the U.S. Evoform's inability to identify, or enter into an agreement with, any such third-party distributor would likely have a material adverse effect on its business and operations.

Risks Related to the Company's Commercialization of Healthcare Products

Changes in healthcare laws and regulations may eliminate current requirements for health insurance plans to cover and reimburse FDA-cleared or FDA-approved contraceptive products without cost sharing, which could reduce demand for products such as Phexxi.

Despite FDA approval for Phexxi, and even if the Company is successful in obtaining rights to market other FDA-approved products in the U.S., revenues may be adversely affected if Phexxi or any other approved product does not obtain coverage and adequate reimbursement from third-party payers in the United States.

Healthcare legislative reform measures may have a negative impact on the Company's business and results of operations.

Evoform's business may be adversely affected by unfavorable macroeconomic conditions.

Risks Related to the Company's Business Operations

Evofem will need to expand the size of its organization and may experience difficulties in managing this growth or be unable to successfully commercialize Phexxi or otherwise implement its business plan.

Risks Related to Common and Preferred Stock

The Company's management has identified material weaknesses in its internal controls and procedures.

Evofem's shares of Common Stock were delisted from the Nasdaq Capital Market in 2022, which resulted in, among other things, a decline in the price of its common stock and less liquidity for holders of shares of its common stock.

Evofem's stock price is and may continue to be volatile.

There may not be an active, liquid trading market for the Company's equity securities.

Because the Company's Common Stock is subject to the "penny stock" rules, brokers cannot solicit the purchase of Evofem's Common Stock, which adversely affects its liquidity and market price.

Evofem's Common Stock could be further diluted as the result of the issuance of additional shares of Common Stock, convertible securities, warrants, or options.

The Company is and may continue to be subject to short-selling strategies.

Evofem's business could be negatively affected because of the actions of activist stockholders.

The Company may become a defendant in one or more stockholder derivative or class-action litigation(s), and any such future lawsuit(s) may adversely affect its business, financial condition, results of operations, and cash flows.

Glossary

Affordable Care Act (ACA)—Formally known as the Patient Protection and Affordable Care Act and colloquially known as Obamacare, is a landmark U.S. federal statute enacted by the 111th United States Congress and signed into law by President Barack Obama on March 23, 2010.

Current Good Manufacturing Practices (cGMP) regulations—For drugs, contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have.

Glucagon-like peptide-1 (GLP-1)—GLP1 is a hormone produced by the lining of the small intestine. It plays a vital role in the digestion and absorption of fats and carbohydrates in the body. GLP1 regulates the levels of insulin and glucose in the blood, which helps to regulate blood sugar. It also helps with heart rate regulation, appetite control, and gut motility. GLP1 analogs, such as liraglutide, are often used in the treatment of type 2 diabetes.

Human Immunodeficiency Virus (HIV)—The two species of Lentivirus that infect humans. Over time, they cause acquired immunodeficiency syndrome, a condition in which progressive failure of the immune system allows life-threatening opportunistic infections and cancers to thrive.

Intrauterine devices (IUDs)—A little, T-shaped piece of plastic inserted into the uterus by a healthcare provider to provide birth control. A copper IUD lasts up to 12 years and can serve as emergency contraception if inserted within 5 days after unprotected sex.

Kaplan Meier—The Kaplan–Meier estimator, also known as the product limit estimator, is a non-parametric statistic used to estimate the survival function from lifetime data. In medical research, it is often used to measure the fraction of patients living for a certain amount of time after treatment.

Nonoxynol-9 (N-9)—A detergent used in a form of birth control that kills sperm and works to prevent pregnancy.

Pearl Index—Also called the Pearl rate, is the most common technique used in clinical trials for reporting the effectiveness of a birth control method.

Pharmacy Benefit Managers (PBMs)—Manage prescription drug benefits for clients ranging from health insurers and Medicare Part D drug plans to large employers. PBMs are one of the few parts of the prescription drug supply chain specifically dedicated to lowering costs.

Tubal ligation—Surgical procedure to prevent pregnancy. It has commonly been called “getting your tubes tied.” It is also called a female sterilization. Tubal refers to the fallopian tubes. Each month, an egg is released from an ovary and travels through the fallopian tube to the uterus. Ligation means to tie off.

Vaginal pH modulator [VPM]—A non-hormonal vaginal gel that maintains the pH of the vagina in the presence of semen to immobilize sperm and prevent pregnancy.

Vaginal ring—A small, flexible piece of silicone that is inserted into the vagina where it releases hormones to provide birth control. It works like the pill, but only needs to be inserted once a month.

Venous thromboembolism (VTE)—A condition that occurs when a blood clot forms in a vein. VTE includes deep vein thrombosis (DVT) and pulmonary embolism (PE). DVT occurs when a blood clot forms in a deep vein, usually in the lower leg, thigh, or pelvis.

Wholesale Acquisition Cost (WAC)—The manufacturer’s list price for drug or biological to wholesalers or direct purchasers in the U.S., not including prompt pay or other discounts, rebates, or reductions in price.

Intentionally Blank



About Our Firm: For the past decade, Crystal Research Associates, LLC (www.crystalra.com) has successfully articulated the exceptional stories of small- and mid-cap companies to the Wall Street investor community. Our methods are well-established and diverse, from compiling and disseminating objective, factual information for both institutional and retail investor audiences to capitalizing on our expansive line of targeted distribution channels, which include industry-leading financial data and information providers. Our distribution efforts are accompanied by the use of prominent social media channels and by strategic and targeted appearances on national news programs and print media.

Crystal Research Associates is led by Wall Street veterans, Jeffrey Kraws and Karen Goldfarb. Together, Kraws and Goldfarb have built a unique business model, capitalizing on decades of experience as an award-winning sell-side analyst team to produce institutional-quality industry and market research in a manner that is easily understood by investors and consumers. Our firm's approach has been proven successful over the years as our products are published and available on Bloomberg, Thomson Reuters/First Call, Capital IQ, FactSet, Yahoo! Finance, and scores of other popular forums.