UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-36754

EVOFEM BIOSCIENCES, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**20-8527075**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
7770 Regents Rd, Suite 113-618 San Diego, CA	**92122**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: **(858) 550-1900**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	EVFM	OTCQB

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definition of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $88,964,369 as of June 30, 2022, based upon the closing sale price on the Nasdaq Capital Market reported for such date. Shares of common stock held by each executive officer and director and certain holders of more than 10% of the outstanding shares of the registrant's common stock have been excluded in that such persons may be deemed to be affiliates. Shares of common stock held by other persons, including certain other holders of more than 10% of the outstanding shares of common stock, have not been excluded in that such persons are not deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of Registrant's Common Stock outstanding as of April 7, 2023 was 215,961,346.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission relative to the registrant's 2023 Annual Meeting of Shareholders are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K (Annual Report), contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." All statements, other than statements of historical facts, contained in this Annual Report, including statements regarding our strategy, future operations, future financial position, projected costs, prospects, plans and objectives of management, are forward-looking statements. Words such as, but not limited to, "anticipate," "aim," "believe," "contemplate," "continue," "could," "design," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "seek," "should," "suggest," "strategy," "target," "will," "would," and similar expressions or phrases, or the negative of those expressions or phrases, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our ability to continue as a going concern;
- our ability to remediate the material weaknesses in our internal controls and procedures identified by management;
- potential bankruptcy proceedings and the effect of those proceedings on our ongoing and future operations;
- the effect of the Notice of Default received from Baker Bros. Advisors, LP and our ability to resolve the same;
- our ability to obtain necessary approvals of a reverse split proposal or any other corporate action needing stockholder, FINRA, or other approvals;
- our ability to file Annual and Quarterly Reports on a timely basis;
- our ability to raise additional capital to fund our operations;
- our ability to achieve and sustain profitability;
- our estimates regarding our future performance including, without limitation, any estimates of potential future revenues;
- estimates regarding market size;
- our estimates regarding expenses, revenues, financial performance and capital requirements, including the length of time our capital resources will sustain our operations;
- our ability to maintain the listing of our shares on the OTCQB® Venture Market;
- our ability to comply with the provisions and requirements of our debt arrangements, to manage the current defaults pursuant to our debt arrangements and to pay amounts owed, including any amounts that may be accelerated, pursuant to our debt arrangements;
- estimates regarding health care providers' (HCPs) recommendations of Phexxi® (lactic acid, citric acid, and potassium bitartrate) vaginal gel (Phexxi) to patients;
- the rate and degree of market acceptance of Phexxi;
- our ability to successfully commercialize Phexxi and continue to develop our sales and marketing capabilities;
- our estimates regarding the effectiveness of our marketing campaigns;
- our strategic plans for our business, including the commercialization of Phexxi;
- the impacts of the ongoing COVID-19 pandemic including, without limitation, its impact on our business and the commercialization of Phexxi;
- the potential for changes to current regulatory mandates requiring health insurance plans to cover U.S. Food and Drug Administration (FDA)-cleared or -approved contraceptive products without cost sharing;
- our ability to obtain or maintain third-party payer coverage and adequate reimbursement, and our reliance on the willingness of patients to pay out-of-pocket for Phexxi absent full or partial third-party payer reimbursement;
- our ability to obtain the necessary regulatory approvals to market and commercialize any product candidate we may seek to develop;
- the success, cost and timing of our potential future clinical trials, if any;
- our ability to protect and defend our intellectual property position and our reliance on third party licensors;
- our ability to obtain additional patent protection for our product and product candidates;
- our dependence on third parties for the manufacture of Phexxi and in the conduct of potential future clinical trials, if any;
- our ability to expand our organization to accommodate potential growth; and
- our ability to retain and attract key personnel.

Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on our projections of the future that are subject to known and unknown risks and uncertainties and other factors that may cause our actual results, level of activity, performance or achievements expressed or implied by these forward-looking statements, to differ. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement. Forward-looking statements should be regarded solely as our current plans, estimates and beliefs. You should read this Annual Report and the documents that we have filed as exhibits to this Annual Report and incorporated by reference herein completely and with the

understanding that our actual results may be materially different from the plans, intentions and expectations disclosed in the forward-looking statements we make. Moreover, we operate in a very competitive and rapidly changing environment and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. The forward-looking statements contained in this Annual Report are made as of the date of this Annual Report, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

This Annual Report contains estimates and other statistical data made by independent parties and by the Company relating to market size and growth and other data about its industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

To date, only one of our products, Phexxi, has been approved by the FDA for marketing in the United States. Our other product candidates are investigational and have not been submitted to or approved by the FDA. Neither Phexxi nor our other product candidates have been approved by the European Medicines Agency (EMA) or any other regulatory authority anywhere else in the world except in Nigeria, where Phexxi has been approved, on October 6, 2022, as Femidence™ by the National Agency for Food and Drug Administration and Control.

Unless the context requires otherwise, references in this Annual Report to “Evofem,” “Company,” “we,” “us” and “our” refer to Evofem Biosciences, Inc. and its subsidiaries.

This Annual Report includes our trademarks, trade names and service marks, including “Phexxi®” and "Femidence™" which are protected under applicable intellectual property laws and are the property of Evofem Biosciences, Inc. or its subsidiaries. Solely for convenience, trademarks, trade names and service marks referred to in this Annual Report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties’ trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

PART I

Item 1. Business.

Overview

We are a San Diego-based commercial-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health. Our first commercial product, Phexxi, was approved by the FDA on May 22, 2020. It is the first and only FDA-approved, hormone-free, woman-controlled, on-demand prescription contraceptive gel for women. We commercially launched Phexxi in September 2020 in the United States. We intend to commercialize Phexxi in all other global markets through partnerships or licensing agreements.

Until October 2022, we were evaluating EVO100 for the prevention of urogenital chlamydia and gonorrhea in women. Chlamydia and gonorrhea are among the many bacterial and viral pathogens that require a higher pH environment to thrive. in 2018, the CDC reported that infections with these two sexually transmitted pathogens cost the U.S. healthcare system $1 billion, in aggregate direct and indirect costs. There are no FDA-approved drugs to prevent these sexually transmitted diseases (STIs), and we believe there is a clear need for new prophylactics given the rising incidence and increasing antibiotic resistance of gonorrhea. We therefore advanced our program to investigate the potential for EVO100 to prevent vaginal infection with these two common pathogens.

Our Phase 2B/3 trial (*AMPREVENCE*) achieved its primary and secondary endpoints, demonstrating statistically significant reductions in chlamydia and gonorrhea infections of 50% and 78%, respectively, in women receiving EVO100 vs. placebo. Based on these highly positive clinical outcomes we initiated a Phase 3 clinical trial (*EVOGUARD*) to evaluate EVO100 for these potential indications in 2020. This randomized, placebo-controlled clinical trial enrolled 1,903 women with a prior chlamydia or gonorrhea infection who were at risk for future infection.

On October 11, 2022, we reported that *EVOGUARD* did not meet its primary efficacy endpoint. We believe COVID-19 related changes in clinical site operations, subject behavior and actions including deviations from following the clinical study protocol requirements related to STI acquisition, detection, and prevention contributed to this outcome. The product safety profile was consistent with what has been observed in prior clinical trials, and only two women (0.1%) in the study discontinued due to adverse events. We believe there is a path forward for EVO100 and may in the future conduct a new Phase 3 clinical trial of EVO100 for these potential indications. However, due to financial constraints, we discontinued investment in this clinical program in October 2022.

Our investigational candidate for the reduction of recurrent bacterial vaginosis (BV), EVO200 vaginal gel, uses the same proprietary vaginal pH modulator platform as Phexxi. In a Phase 1 dose-finding trial for this indication, the highest dose formulation of the study drug demonstrated reduced vaginal pH for up to seven days following a single administration. We may decide to pursue further development of EVO200 in the future. The FDA has designed EVO200 as a Qualified Infectious Disease Product (QIDP) for this indication, which provides several important potential advantages including, but not limited to, longer market exclusivity.

Our Leadership Team

We have assembled a world-class team with industry-recognized expertise in the development and commercialization of products in women's sexual and reproductive health.

The team is led by Saundra Pelletier, an expert is women's health from puberty to menopause. She has served as Chief Executive Officer, President and Executive Director of Evofem 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, led Evofem's transition to the public market in January 2018, and led multiple equity financing rounds which have raised over $500 million.

During her more than 25 years of experience in the pharmaceutical industry, Ms. Pelletier has launched pharmaceutical brands worldwide and expanded indications of female healthcare brands in multiple countries. Her experience includes a comprehensive range of women's healthcare products, cardiovascular drugs, pain management agents, sleep therapeutics and medical devices. She has had oversight and accountability for Sales, Marketing, Operations, Medical Affairs, Regulatory Affairs, Manufacturing, Customer Service, Business Development and Strategic Partnerships.

Our Chief Financial Officer, Ivy Zhang, is a trusted leader and a seasoned finance executive who is dedicated to advancing our mission of addressing the unmet sexual and reproductive health needs of women. She joined Evofem as Chief Financial Officer on April 13, 2023 and leads our finance organization and financial activities including financial planning and analysis, accounting, external audit, tax, controllership, and treasury functions. Ms. Zhang has more than 14 years of financial and accounting experience spanning diverse industries, including pharmaceuticals and medical devices. Most recently she was

Vice President Corporate Controller of HUYABIO International. From March 2018 to November 2022 she held increasingly senior leadership roles in Evofem's finance team, ultimately serving as Controller. Earlier in her career, Ms. Zhang served in finance positions for more than two and a half years at SeaSpine Holdings Corporation (a public medical and therapeutic technology and device company) and approximately seven years at Ernst & Young LLP.

On March 20, 2023 and in connection with a Reduction in Workforce, our Board of Directors agreed to (i) eliminate the Chief Commercial Officer role effective March 17, 2023; and (ii) to reduce the Chief Executive Officer's salary by 40%.

On April 5, 2023, our Board of Directors appointed Saundra Pelletier as Secretary and on April 13, 2023, Ms. Pelletier resigned as Secretary and the Board of Directors appointed Ivy Zhang.

Our Strategy

Key elements of our strategy include:

- Successfully commercialize Phexxi. Currently, our primary focus is the successful commercialization of Phexxi in the United States. Outside the United States, we intend 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), and Latin America (LATAM). We believe this approach will allow us to effectively deploy our capital to maximize the inherent value of Phexxi for the benefit of all stakeholders.

- ***Leverage our vaginal pH modulator platform to develop and commercialize novel, first-in-class products for women***. Following the successful development and FDA approval of Phexxi for the prevention of pregnancy, we are seeking partnerships to continue the development of our vaginal pH modulator platform.

- ***Expand our intellectual property position by pursuing opportunities to extend the exclusivity of our highly differentiated and proprietary product candidates***. We intend to aggressively pursue additional and new patent applications to broaden our intellectual property portfolio. We continue to seek domestic and international patent protection and endeavor to proactively file patent applications for new commercially valuable inventions.

- ***Build our product portfolio and leverage our U.S. sales force through business development***. We intend to opportunistically acquire or in-license additional products and/or product candidates to enhance our offerings and complement our core competencies in women's health.

Contraceptive Market Overview

United States Contraceptive Market

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*).

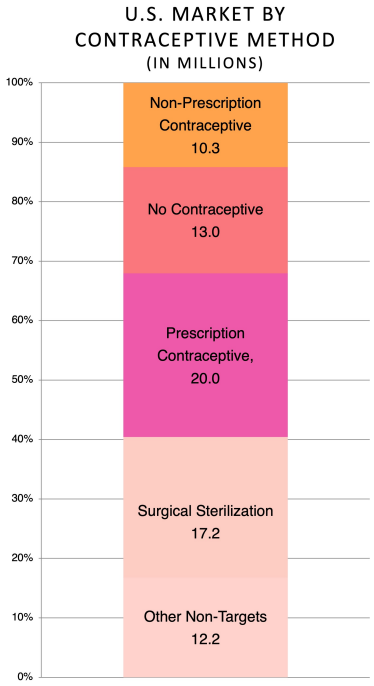
In the United States, current contraceptive options include:

- devices designed to prevent pregnancy through physical means, such as condoms and diaphragms.
- hormone-based pharmaceutical products, including oral contraceptives (OCs), vaginal rings, transdermal patches, intramuscular injections, subcutaneous implants and intrauterine devices (IUDs). These can be associated with undesirable side effects such as weight gain, loss of libido and mood changes that may lead women to discontinue their use and seek alternative contraceptive methods. Further, a peer-reviewed analysis published in the journal *PLOS Medicine* in March 2023 found that the use of all kinds of hormonal birth control is associated with a slight increase in the risk of breast cancer.
- a hormone-free copper IUD; and
- Phexxi, a prescription vaginal pH modulator that was introduced to the market in September 2020.

The only non-hormonal option within the top five sales-generating segments in 2019 was the male condom, which is an over-the-counter (OTC) product. Besides condoms, the only currently available OTC products in the United States are nonoxynol-9 containing (N-9) spermicides. These surfactant-based products can potentially cause genital irritation and inflammation that may increase the risk of contracting human immunodeficiency virus (HIV) or other STIs from an infected partner. 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."

As shown in the chart below, in the United States, 13.0 million women use no method of birth control, putting them at risk of unintended pregnancy. An additional 10.3 million women in the United States rely on condoms or some other form of non-hormonal OTC birth control (e.g. rhythm, withdrawal). Another 20.0 million women in the United States use prescription birth control methods, which are predominantly hormone-based with the sole exception of the copper IUD.



Source: Daniels-K-and-Abma-J.-Current-Contraceptive-Status-Among-Women-Aged-15-49_NCHS-Data-Brief-Number-388-October-2020.pdf (evofem.com)

Market Opportunity: Contraception

Hundreds of millions of women worldwide seek sexual and reproductive health products that provide them with their self-defined control of their individual needs during their (on average) 30+ years of fertility. However, an estimated 257 million women who want to avoid pregnancy are not using safe, modern methods of contraception and nearly half of all pregnancies - 121 million each year - are unintended according to the United Nations 2022 State of World Population 2022 report.

Innovation and new product introductions in the women's reproductive and sexual health care arena have been limited when compared to other therapeutic categories. While several new contraceptive category entrants have been introduced in recent years, we believe Phexxi is the first innovative contraceptive method introduced in the United States since NuvaRing was approved by the FDA in 2001.

According to the CDC, reducing the percentage of all unintended pregnancies has been one of the National Health Promotion Objectives since its establishment in 1980. Despite efforts to reduce their incidence, over two million unintended pregnancies occur in the United States annually. Following decades of minimal change or increase, the percentage of unintended pregnancies in the United States decreased slightly from 2008 to 2011. Despite this decrease, 45%, or 2.8 million of the 6.1 million total pregnancies in the United States, were unintended in 2011 (Finer *et al., NEJM*, 2016).

Our Commercial Product

Phexxi as a Contraceptive

Phexxi vaginal gel is the only FDA-approved, hormone-free, on-demand, woman-controlled prescription contraceptive drug product available in the United States. We believe Phexxi's attributes address significant gaps and underserved and unmet needs in the contraceptive market and make it an attractive contraceptive choice for women.

Phexxi key benefits:

- **Hormone-free:** Phexxi is an innovative gel that works to prevent pregnancy without the use of hormones. Because Phexxi is completely hormone-free, women are less likely to worry about the hormone related side effects like weight gain, mood swings, or blood clots which are associated with hormonal birth control methods.
- **Only when you need it:** With Phexxi, women no longer need to have birth control in their bodies 24/7. Phexxi is used in the moment, right before each and every act of sex, so no daily commitment is required. 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. 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, meaning we know of no other products like it in the market.
- **Woman-controlled:** Phexxi puts women in control of their bodies and their pregnancy prevention. With Phexxi, there is no need to rely on a partner to bring a condom and no need to head into the doctor's office for an injection or procedure to prevent pregnancy. The quick and easy pre-sex application is designed with spontaneity and convenience in mind.

We believe Phexxi is a disruptive entry to the U.S. contraceptive landscape. Phexxi is designed to address underserved and unmet needs in the birth control market, as seen in the table below. Women are becoming highly aware of the hormones that they put in their bodies, with ~75% of women having some concerns or completely opposing 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 we are seeing as a large subset of early adopters of Phexxi.

Our sales data further support the uptick of early adopters with almost half of prescriptions coming from women who were not using a method of contraception in the previous year. This data indicates that the Phexxi reach goes beyond those women who have fallen out of the birth control funnel, and extends to a robust amount of women who are switching from other prescription birth control methods to Phexxi, further highlighting that the key attributes of Phexxi are appealing to a wide range of women. Additionally, we are seeing that the majority of women (~80%) starting Phexxi are under the age of 40, which is promising for long term adoption of the brand.

Prescription Contraceptive Products and Associated Benefits

Phexxi is designed to address underserved and unmet needs in the birth control market, as seen in the table below.

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			✓	

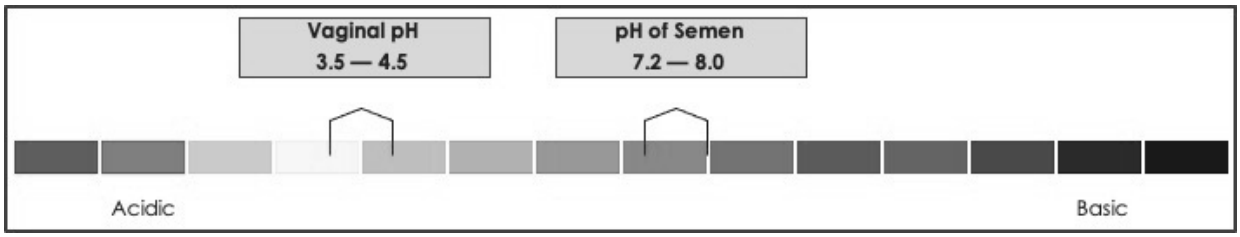
Vaginal pH Modulator Mechanism of Action

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. Additionally, a vaginal pH in this range is inhospitable to sperm as well as certain viral and bacterial pathogens.

Phexxi was developed to have acid-buffering (pH 3.5), lubricating and viscosity-retaining properties to provide effective acidification of the male ejaculate in the vagina. Typically, the introduction of semen (pH = 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 produce 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. *In vitro* studies show immediate sperm motility reduction. Phexxi prevents pregnancy by reducing sperm motility, inhibiting sperm from reaching the ovum to form a zygote. Other properties contributing to Phexxi's mechanism of action are its capacity to maintain sufficient viscosity even upon

dilution with the introduction of semen into the vagina, impede cervical mucus penetration by sperm, and form a protective layer over the vaginal and cervical epithelium.

The diagram below shows the respective pH levels of the vagina and semen.



Commercialization Strategy

Our strategy is to commercialize Phexxi and to leverage our vaginal pH modulator platform to develop and commercialize novel, first-in-class products for women. We have deployed a dedicated sales team and developed a telehealth platform and media strategy focused on maximizing the commercial return from Phexxi in the United States.

Outside of the United States, we plan to focus on three key regions – the European Union, Asia Pacific (APAC), and Latin America (LATAM). Our intent is to establish regional and/or global partnerships in these regions by either sublicensing the commercialization rights or entering into distribution agreements with one or more third parties for the commercialization of Phexxi and our product candidate. We expect these third parties to be involved in the regulatory process in their respective markets as well as any clinical trials to support regulatory submissions, if required.

Commercialization of Phexxi in the United States

We believe the United States market is the largest commercial opportunity for Phexxi. Our sales force promotes Phexxi directly to obstetrician/gynecologists and their affiliated health professionals, who collectively write the majority of prescriptions for contraceptive products. As of April 7, 2023, our sales force consisted of 16 sales representatives and three business managers, supported by a self-guided virtual health care provider (HCP) learning platform. Additionally, we offer women direct access to Phexxi via our telehealth platform. Using the platform, women can directly meet with an HCP to determine their eligibility for a Phexxi prescription and, if eligible, have the prescription written by the HCP, filled, and mailed directly to them by a third-party pharmacy.

Our commercial strategy for Phexxi includes targeting women of reproductive potential in the United States, including the approximately 23 million women who are not using hormonal contraception and the approximately 18.8 million women who are using a prescription contraceptive, some of whom, particularly pill users, may be ready to move to an FDA-approved, non-invasive, hormone-free contraceptive, as well as certain identified target HCP segments.

According to our market research since Phexxi's commercial launch, HCPs indicate they would recommend Phexxi to approximately:

- 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.

Additional research into the demographics of more than 5,000 women who are using Phexxi revealed that 79% of Phexxi users are between 18 to 34 years of age. Among the subset of Phexxi users for whom prior contraceptive data is available (n=2,512), 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.

In February 2021, we launched a direct-to-consumer advertising campaign, known as "Get Phexxi," designed to increase awareness and educate women on the benefits of Phexxi. The campaign highlighted some of the struggles women face when choosing among the many available methods of contraception, including the lack of control with condoms, daily use of the pill, and abstinence required for cycle tracking.

In September 2021, we launched a national brand ambassador campaign featuring Emmy Award-winning celebrity Annie Murphy designed to broaden awareness and drive uptake of Phexxi. This award-winning campaign, known as "House Rules," significantly raised our brand awareness among our target audience and helped drive significant increases in new HCPs recommending and prescribing Phexxi.

In January 2022 we adjusted our patient support programs to increase the profit margin on Phexxi units dispensed. These adjustments, coupled with growth in prescriptions and dispensed units, enabled us to achieve record Phexxi net product sales in 2022.

Our experienced team of key account directors and medical affairs team also focus 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.

Payer and Reimbursement Strategy: United States

Pricing Strategy

Our pricing strategy for Phexxi was informed by extensive payer research including discussions with decision makers at major health plans and PBMs across the United States who control nearly 83 million commercial lives. Based on this gathered intelligence, we initially priced Phexxi at $267.50 per box of 12 applicators. As of October 1, 2022, Phexxi is priced at $338.10 per box of 12 applicators, which when annualized is comparable to all other commercially available branded contraceptives.

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."

Third-party Payers

Market acceptance and sales of Phexxi will depend in part on the extent to which reimbursement is available from third-party payers, which include government health administration authorities, managed care organizations, private health insurers and PBMs. Third-party payers decide which therapies they will pay for and establish reimbursement levels. Decisions regarding the extent of coverage and amount of reimbursement to be provided for any product are made on a payer-by-payer basis. One payer's determination to provide coverage for a drug does not assure that other payers will also provide coverage and adequate reimbursement for that drug.

Managed care organizations and other private insurers frequently adopt their own payment or reimbursement reductions. The continued integration between commercial health plans and PBMs has increased the negotiating power of these entities. Third-party payers increasingly employ 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. We continue to work with health plans and PBMs to secure additional formulary positioning for Phexxi.

In the second quarter of 2022, we successfully negotiated a contract with one of the largest PBMs in the nation, which added Phexxi to its formulary with no restrictions for most women covered by the plan. The agreement took effect July 1, 2022 and is representative of approximately 48 million lives.

As of December 2022, IQVIA reported that approximately 79% of commercial and Medicaid Phexxi prescriptions are being approved by payers. Managed Markets Insight & Technology, LLC (MMIT) reports that we have coverage for approximately 60% of U.S. commercial lives, including approximately 16.4 million lives covered at no out-of-pocket cost as of February 10, 2023. An additional 13.7 million lives are covered under our December 2020 contract award from the U.S. Department of Veterans Affairs.

We also participate in government programs including the 340B and the Medicaid Drug Rebate Program, which took effect January 1, 2021, and affords access to Phexxi for the U.S. Medicaid population, comprising approximately 68 million members, including approximately 16.8 million women 19-49 years of age.

Affordable Care Act

The Affordable Care Act (ACA) guarantees coverage of women's preventive services, including free birth control and contraceptive counseling, for all individuals and covered dependents with reproductive capacity. This includes all contraceptives approved, granted, or cleared by the FDA.

History

Under section 2713 of the Public Health Service (PHS) Act, group health plans and health insurers are required to cover preventive care and screenings under guidelines issued by the Health Resources and Services Administration (HRSA). PHS Act section 2713 took effect when added by the Affordable Care Act (ACA) in 2010.

HRSA guidelines issued in 2019 required broad coverage of contraceptive care and services for women. HRSA issued updated guidelines in late 2021, under which:

a. The full range of FDA- approved, -granted, or -cleared contraceptives, effective family planning practices, and sterilization procedures should be available as part of contraceptive care.
b. The full range of contraceptives includes those currently listed in the FDA's Birth Control Guide and any additional contraceptives approved, granted, or cleared by the FDA.

The current HRSA Women's Preventive Services Guidelines took effect on January 1, 2023, for calendar year plans.

Separately, on January 10, 2022, the U.S. Department of Health and Human Services (HHS), alongside the Departments of Labor and of the Treasury (the "Departments") issued updated guidance related to contraceptive access.

Under the Departments' FAQ Update:

a. Plans are required to cover an FDA- approved, cleared, or granted contraceptive, if a provider deems it medically necessary, at $0 cost share, whether or not it is specifically identified in the current FDA Birth Control Guide.
b. Plans may not require patients to try and fail multiple options within a method, or force trying and failing other methods, if a provider deems a product medically necessary.

The Departments also established clear communications channels for consumers with concerns about their plan's compliance with HSRA requirements.

Collectively, this new guidance specifies that most insurers and pharmacy benefit managers (PBMs) must provide coverage, with no out-of-pocket costs to women, for FDA-approved contraceptive products, like Phexxi® (lactic acid, citric acid and potassium bitartrate), prescribed by healthcare providers.

In July 2022 after the fall of Roe v. Wade and in the wake of action in many states to restrict access to emergency contraception, the Departments released further guidance regarding birth control coverage. Key points of this guidance include:

– Most private health plans and health insurance issuers must cover contraceptives at no additional cost to individuals under the Affordable Care Act no matter where they live or work.
– Violators of the preventive care coverage requirements may be subject to the $100 per person per day excise tax under section 4980D of the Internal Revenue Code or a civil monetary penalty under PHS Act section 2723.
– The Departments "will take enforcement action as warranted."

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, like Phexxi, prescribed by healthcare providers.

As a result, to comply with these Guidelines, payers are increasingly covering Phexxi by:

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

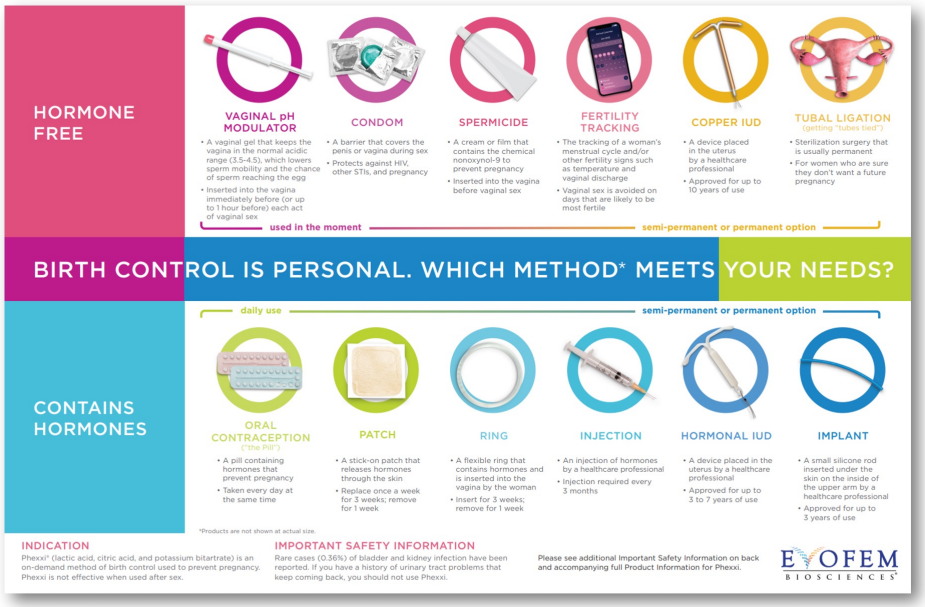
Birth Control Guide

While highly favorable to Phexxi, the updated HSRA Guidelines remove the impetus for the FDA to update its Birth Control Guide (the Guide) to include methods that were approved by the FDA after the development of the Guide more than a decade ago, including the vaginal pH modulator (Phexxi). We believe there is still merit to the Guide being current and accurate, and continue to work with the FDA's Office of Women's Health to update the Guide.

The Guide was developed and is used as an educational tool by many obstetrician/gynecologists to assist in counseling patients on their contraceptive options and to help them find the method that best suits their needs. Methods not on the current, outdated Guide may be underrepresented in these contraceptive counseling dialogues. We therefore believe the Guide should include all FDA-approved methods of birth control.

Further, even though the FDA Guide was intended as an educational tool, certain insurers have used it to block coverage of methods not included on the Guide. While this is explicitly prohibited by the current HSRA Guidelines, and there has been considerable progress since January 1, 2023, two notable plans continue to flout the law.

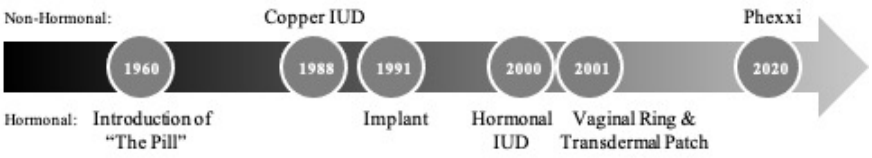
With the FDA not yet moving to update its Guide, in 2022 Evofem developed and introduced a new educational chart that provides high-level information about birth control methods that are currently available to women in the United States, adding new categories including vaginal pH modulator.



This new educational tool has been extremely well received and has had a positive impact with HCPs and patients alike.

Contraceptive Market Landscape

The modern contraception market was established in 1960 with the introduction of "the pill," the first oral contraceptive widely available to women in the United States. As shown in the timeline below, there was no notable innovation providing additional options in women's reproductive health until almost 30 years after the introduction of "the pill," when pharmaceutical companies introduced the non-hormonal copper IUD and synthetic hormonal products with different hormonal delivery systems, including the hormonal IUD, implants, the patch, and vaginal ring.



We expect that Phexxi vaginal gel will grow 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. Additionally, as women's expectations change throughout their contraceptive journey, we expect Phexxi to 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 primarily by the male condom.

U.S. Market

Unless otherwise noted, the source for all data in this section is Daniels K and Abma J, *Current Contraceptive Status Among Women Aged 15–49: United States, 2017–2019*, which was published in NCHS Data Brief No. 388 in October 2020.

Prescription Contraception

In the United States, an estimated 18.8 million women use prescription contraception.

Oral contraceptives (OCs), also known as the pill, are the most commonly used form of birth control in the United States today. There are two main kinds of hormonal OCs: combination birth control pills, which contain both estrogen and progestin, and the progestin only pill. Use of either kind is associated with a slight increase in the risk of breast cancer. OCs typically must be taken at the same time every day to be the most effective.

LARC

Long-acting reversible contraception (LARC) is not dependent on user adherence, which 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.

IUDs

The copper IUD was introduced to the market in 1988 and provides protection by disrupting sperm motility and damaging sperm so that they are prevented from joining with an ovum. Today, 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. Womens Health Rep (New Rochelle). 2020 Oct 8;1(1):451-458. doi: 10.1089/whr.2020.0048.*). Among women who opt in to the insertion procedure, many decide to remove their IUD due to the hormonal and other side effects that they experience.

Implants

The contraception implant must be implanted under the skin and removed by a qualified HCP, requiring a medical procedure. It provides contraception by releasing hormones over a three-year period. The implant is marketed in the United States 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 health care and contraception as a promotional category. A new branded patch was launched in late 2020 under the brand name Twirla (Agile Therapeutics) and is competing against a generic entrant Xulane (Mylan).

Vaginal Ring

The hormonal vaginal ring was introduced to the market in 2001 by Merck & Co.; generic versions are 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 similar to hormonal oral contraception. A meta-analysis of 18 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)*.

An annual hormonal vaginal ring was launched in the United States in 2020 under the brand name Annovera (Mayne Pharma).

Injectables

The primary injectable hormonal contraceptive on the market is Depo-Provera offered by Pfizer Inc. Each injection provides protection for up to 12 to 14 weeks, but patients must receive injections once every 12 weeks to get optimal contraceptive protection. Depo-Provera was introduced to the market in 1992.

Non-prescription OTC Products

In the United States, an estimated 10.3 million women rely on OTC products for their contraceptive needs.

Condoms are the dominant product offering in OTC sales. Approximately six million women depend on condom use as their only method of birth control. The predominant brands are Trojan (Church & Dwight) and Durex (Reckitt Benckiser).

Additional OTC products include spermicides, which are available in sponges, jelly/creams and foams. Spermicides rely on Nonoxynol-9 (N-9), a detergent, and have very limited utilization. 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

New adopters of Phexxi are expected to come equally from each category discussed, as interest in Phexxi falls into three distinct segments: (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. Our market research has indicated that the hormone-free, on-demand, woman-controlled aspect of Phexxi makes it an attractive option across the entire competitive set.

Ex-United States Markets

In markets outside of the United States, we intend to establish regional and/or global partnerships by either sublicensing the commercialization rights or entering into distribution agreements with one or more third parties for the commercialization of Phexxi and/or the applicable product candidate in that market.

In October 2021, we submitted the registration for our hormone-free contraceptive vaginal gel to the Mexican Regulatory Agency COFEPRIS (Comisión Federal para la Protección contra Riesgos Sanitarios) (COFEPRIS). We have 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

We outsource the manufacturing of Phexxi (and our investigational product candidates) to a third party. We are currently contracted with a gel manufacturer to manufacture 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 manufacture of pharmaceutical drug products and combination drug-device products. As of December 31, 2022, we estimated that we had manufactured inventory on hand to support approximately nine months of anticipated demand for Phexxi. An additional six Phexxi batches, included in other non-current assets in the consolidated balance sheets, had been manufactured and awaited release as of that date and are therefore not include in this estimated timing.

Our Pipeline

Phase 3: EVO100 for STI Prevention

Until October 2022, we were evaluating EVO100 for the prevention of urogenital chlamydia and gonorrhea in women. Chlamydia and gonorrhea are among the many bacterial and viral pathogens that require a higher pH environment to thrive. in 2018, the CDC reported that infections with these two sexually transmitted pathogens cost the U.S. healthcare system $1 billion, in aggregate direct and indirect costs. There are no FDA-approved drugs to prevent these sexually transmitted diseases (STIs), and we believe there is a clear need for new prophylactics given the rising incidence and increasing antibiotic resistance of gonorrhea. We therefore advanced our program to investigate the potential for EVO100 to prevent vaginal infection with these two common pathogens.

Our Phase 2B/3 trial (*AMPREVENCE*) achieved its primary and secondary endpoints, demonstrating statistically significant reductions in chlamydia and gonorrhea infections of 50% and 78%, respectively, in women receiving EVO100 vs. placebo. Based on these highly positive clinical outcomes we initiated a Phase 3 clinical trial (*EVOGUARD*) to evaluate EVO100 for these potential indications in 2020. This randomized, placebo-controlled clinical trial enrolled 1,903 women with a prior chlamydia or gonorrhea infection who were at risk for future infection.

On October 11, 2022, we reported that *EVOGUARD* did not meet its primary efficacy endpoint. We believe COVID-19 related changes in clinical site operations, subject behavior and actions including deviations from following the clinical study protocol requirements related to STI acquisition, detection, and prevention contributed to this outcome. The product safety profile was consistent with what has been observed in prior clinical trials, and only two women (0.1%) in the study discontinued due to adverse events. We believe there is a path forward for EVO100 and may in the future conduct a new Phase 3 clinical trial of EVO100 for these potential indications. However, due to financial constraints, we discontinued investment in this clinical program in October 2022.

The FDA granted Fast Track Designation to EVO100 for the prevention of both chlamydia and gonorrhea. The FDA also designated EVO100 a Qualified Infectious Disease Product (QIDP) or the prevention of urogenital chlamydia infection in women and the prevention of urogenital gonorrhea infection in women.

Phase 2- Ready: EVO200 Vaginal Gel for Recurrent Bacterial Vaginosis

Our investigational candidate for the reduction of recurrent bacterial vaginosis (BV), EVO200 vaginal gel, uses the same proprietary vaginal pH modulator platform as Phexxi. In a Phase 1 dose-finding trial for this indication, the highest dose formulation of the study drug demonstrated reduced vaginal pH for up to seven days following a single administration. We may decide to pursue further development of EVO200 in the future. The FDA has designed EVO200 as a Qualified Infectious Disease Product (QIDP) for this indication, which provides several important potential advantages including, but not limited to, longer market exclusivity.

Pre-clinical: MPT Vaginal Gel for HIV Prevention

In December 2021, we launched a collaboration with Orion Biotechnology Canada Ltd. (Orion) to evaluate the compatibility and stability of Orion's novel CCR5 antagonist, OB-002, in Phexxi with the goal of developing a Multipurpose Prevention Technology (MPT) product candidate for indications including the prevention of HIV in women. Assuming positive preclinical results, Evofem and Orion will seek government and philanthropic funding for subsequent clinical trials of any resulting MPT vaginal gel product candidate.

Thin Film Project

In February 2020, we contracted with the University of South Australia to develop a vaginally applied thin film as a second-generation vaginal pH modulator product. The target indications of the thin film are the prevention of pregnancy, chlamydia, and gonorrhea in women. The lead thin film candidates have been selected, and stability data has been generated with positive results. Next steps are to optimize the lead candidates and select the appropriate packaging for long term storage.

Rush License Agreement

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

quarterly royalty payments in amounts equal to a single-digit percentage of the gross amounts we receive on a quarterly basis less certain deductions incurred in the quarter based on a sliding scale. We are 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 in a given year. A minimum annual royalty amount of $100,000 was first required for the annual period commencing on January 1, 2021. The royalty costs for the year ended December 31, 2022 were $1.1 million.

We also have the right to sub-license our rights to affiliates (without the prior approval of Rush University) and to third parties (with the prior written approval of Rush University). To the extent Rush University approves of a third-party sub-license, in lieu of any royalty payment obligation under the Rush License Agreement, we 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 us for the Rush License IP for non-commercial research purposes.

The Rush License Agreement contains additional customary representations and warranties, covenants, indemnification and insurance and confidentiality provisions for agreements of its type. 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.

Unless terminated in accordance with its terms, 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.

Intellectual Property

We strive to protect the proprietary vaginal pH modulator gel technology both internationally and domestically. We seek and maintain patents intended to cover our product candidates, and their methods of use, as well as any other inventions that are commercially important to the development of our business. We endeavor to properly file patent applications for new inventions we believe may have commercial value. We also may rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend on our ability, in part: to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; to defend and enforce our patents and other intellectual property rights; and to preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We will also rely on continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

As of February 10, 2023, we owned or had exclusive license to approximately 49 issued patents and allowed applications in the United States and other countries and jurisdictions, and had approximately 22 patent applications pending in the United States 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):

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

We solely own several patent application families relating to the composition and therapeutic use of our vaginal pH modulator gel, which, upon issue, would expire at the earliest in 2033. We also have the Rush License IP, which provides general protection for our vaginal pH modulator platform. Our vaginal pH modulator platform could be eligible for regulatory extensions to at least 2026 in the United States and in certain European jurisdictions, if granted by those regulatory bodies. Rush University has submitted a patent term extension (PTE) application requesting a five-year PTE for the U.S. patent and has received two Orders Granting Interim Extension (OGIE), which have extended the expiration of the U.S. patent by two years to 2023. We believe that our licensed and solely owned non-hormonal birth control gel patents and pending patent applications,

combined with our substantial know-how in this field, will continue to provide opportunities for us to establish a significant barrier to competitor entry into the market.

In addition to patents, we rely, and expect to rely, on trade secrets and know-how to develop and maintain our competitive positions. For example, certain aspects of the composition, manufacturing, and use of Phexxi are protected by unpatented trade secrets and know-how. Although trade secrets and know-how can be difficult to protect, we seek to protect our proprietary technology and processes, in part, through confidentiality agreements with our employees, consultants, scientific advisors, collaborators, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for these incidents. In addition, our trade secrets and know-how may otherwise become known or may be independently discovered by competitors. To the extent our consultants, contractors or collaborators use intellectual property owned by third parties in their work for us, disputes may arise as to the rights in related or resulting intellectual property, including trade secret, know-how and inventions.

Trademark Basics and Strategy

We own or have rights to various trademarks, copyrights and trade names used in our business, including Evofem, Phexxi and Femidence. All of our logos and trademarks appearing in this Annual Report are the property of Evofem Biosciences, Inc. All other third-party trademarks appearing in this Annual Report are the property of their respective holders. Our use or display of other parties' trademarks, trade dress, or products in this Annual Report is not intended to, and does not, imply a relationship with, or endorsement or sponsorship of us, by the trademark, trade dress, or product owner.

Government Regulation and Product Approval

The research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of our products are subject to extensive regulation by governmental authorities in the United States and other countries. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory requirements, require the expenditure of substantial time and financial resources.

In the United States, the FDA regulates drugs and other medical products under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations. Failure to comply with the applicable United States requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending New Drug Applications (NDAs), warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

Drug Development and FDA Review and Approval Process

Our product candidates may not be marketed in the United States until the product has received FDA approval. The steps to be completed before a drug may be marketed in the United States include:

a. completion of preclinical laboratory tests, animal studies, and formulation studies, performed in accordance with the FDA's Good Laboratory Practice (GLP) regulations;

b. submission to the FDA of an Investigational New Drug (IND) application to permit human clinical testing of the therapeutic candidate;

c. approval by an independent institutional review board (IRB) or ethics committee at each clinical trial site before each clinical trial may be initiated;

d. completion of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, current good clinical practices (cGCPs), and other clinical-trial related regulations to establish the safety and efficacy of the investigational drug for each proposed indication;

e. submission to the FDA of an NDA for marketing approval, including payment of application user fees;

f. satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice (cGMP) regulations;

g. satisfactory completion of FDA bioresearch monitoring inspections of selected investigational sites at which the drug product was subject to clinical trials to assess compliance with cGCP regulations; and

h. FDA review and approval of the NDA, including satisfactory completion of an FDA advisory committee review of the product candidate, where appropriate or if applicable, prior to any commercial marketing or sale of the product in the United States.

Before testing any drug product candidate, including our product candidates, in humans, the product candidate must undergo rigorous preclinical testing. The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational product to humans, and must become effective before human clinical trials may begin.

Preclinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after an IND for an investigational drug candidate is submitted to the FDA and human clinical trials have been initiated.

The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials in the United States may begin and is required to be updated annually. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Clinical holds also may be imposed by the FDA at any time before or during studies due to safety concerns or non-compliance. We currently have two active INDs on file with the FDA: one for EVO100 for the prevention of urogenital chlamydia and urogenital gonorrhea, and one for our BV product candidate (EVO200).

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. The trial protocol and informed consent information for trial subjects in clinical trials must also be approved by an IRB for each institution where the trials will be conducted, and each IRB must monitor the trial until completion; an IRB may halt a trial under its jurisdiction for safety reasons. Trial subjects must sign an informed consent form before participating in a clinical trial. Clinical testing also must satisfy extensive good clinical practice regulations and regulations for informed consent and privacy of individually identifiable information.

Clinical trials necessary for product approval are typically conducted in three sequential phases, although the phases may overlap.

a. ***Phase 1:*** The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

b. ***Phase 2:*** This phase involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

c. ***Phase 3:*** Larger clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population, often at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow up. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

In addition, information about certain clinical trials, including details of the protocol and study results, must be submitted within specific timeframes to the National Institutes of Health for public dissemination on the ClinicalTrials.gov data registry. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical trials, together with detailed information relating to the product's chemistry, manufacturing, and controls and proposed labeling, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. An NDA must be accompanied by payment of a significant user fee to the FDA (for example, for the fiscal year ending December 31, 2023, this application fee exceeds $3.2 million). Annual program fees are also assessed on each sponsor of an approved NDA after a drug's approval. Section 505(b)(1) and Section 505(b)(2) of the FDCA are the provisions governing the type of NDAs that may be submitted under the FDCA. Section 505(b)(1) is the traditional pathway for new chemical entities when no other new drug containing the same active pharmaceutical ingredient or active moiety, which is the molecule or ion responsible for the action of the drug substance, has been approved by the FDA. As an alternate pathway to FDA approval for new or improved formulations of previously approved products, a company may file a Section 505(b)(2) NDA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

During the 60 days after submission, the FDA reviews any NDA submitted to ensure that it is sufficiently complete for substantive review before the FDA accepts the NDA for filing. The FDA may request additional information rather than accept the NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has agreed to certain performance goals in the review of NDAs. For most applications involving first-in-kind molecular entities, FDA has ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with priority review. Priority review can be applied to drugs intended to treat a serious condition and that the FDA determines offer major advances in treatment by providing a significant improvement in safety or effectiveness, or that provide a treatment where no adequate therapy exists. Even if the NDA is filed by the FDA, companies cannot be sure that any approval will be granted on a timely basis, if at all. Moreover, the FDA does not always meet its PDUFA goal dates, and the review process for both standard and priority new drug applications may be extended by FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA may also refer the application to an appropriate advisory committee, typically a panel of independent clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee, but it typically considers such recommendations when making final decisions on marketing approval. The FDA also may require submission of a risk evaluation and mitigation strategy or "REMS" plan if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the drug or biological product. The REMS plan could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS plan is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve an NDA without a REMS, if required.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCPs. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMP requirements is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. On the basis of the FDA's evaluation of the NDA and information, including the results of the inspection of the manufacturing facilities, it issues either an approval letter or a Complete Response Letter, or CRL. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with the submission of additional information responding to the deficiencies identified in a prior CRL, however, the FDA ultimately may decide that a new drug application does not satisfy the regulatory criteria for approval.

When issued, an NDA approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications as described in the application. Further, depending on the specific risk(s) to be addressed, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling, require that post-approval trials, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the drug. Moreover, the FDA may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs. Once granted, product approvals may be withdrawn if compliance with regulatory requirements is not maintained or problems are identified following initial marketing or any time thereafter, and certain types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements in the United States

Following approval of a new product or indication, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, and complying with promotion and advertising requirements, which include restrictions on promoting approved drugs for unapproved uses or patient populations (known as "off-label use"). Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA. Prescription drug promotional materials also must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the approved drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the applicant to develop additional data or conduct additional preclinical studies or clinical trials.

Any limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur while the product is on the market.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing facilities for our product and product candidates must meet cGMP requirements and satisfy the FDA or comparable foreign regulatory authorities' satisfaction before any product candidate is approved and our commercial products can be manufactured. Evofem relies, and expects to continue to rely, on third parties for the production of clinical and commercial quantities of its products and product candidates in accordance with cGMPs. These manufacturers must also comply with cGMPs that require, among other things, quality control and quality assurance, the maintenance of records and documentation, and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or combination products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMPs, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including recall.

After approval of a drug is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information, or imposition of additional post-market surveillance or clinical trials to assess new safety risks. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on investigational or post-approval clinical trials;

- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act (PDMA), which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. More recently, the Drug Supply Chain Security Act (DSCSA), was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products. The DSCSA mandates phased-in resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that is expected to culminate in November 2023. On February 4, 2022, FDA announced the availability of the proposed rule "National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers" (Docket No. FDA-2020-N-1663) as required by the Drug Supply Chain Security Act (DSCSA). The proposed rule, when finalized, would provide greater assurance that supply chain participants are sufficiently vetted and qualified to distribute prescription drugs, further strengthening the supply chain. On May 24, 2022, FDA extended the comment period for the proposed Rule to September 6, 2022, to allow interested stakeholders additional time to submit comments. As of the date of this annual report, the FDA had not provided a subsequent update on the proposed rule.

From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations will be changed or what the impact of such changes, if any, may be.

Hatch-Waxman Act and Marketing Exclusivity

Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Amendments) to the Federal Food, Drug, and Cosmetic Act (FDCA), Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute and also enacted Section 505(b)(2) of the FDCA. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application (ANDA), to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing conducted for a drug product previously approved under an NDA, known as the reference listed drug (RLD). Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. In contrast, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A Section 505(b)(2) applicant may eliminate the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously-approved product is scientifically appropriate. Unlike the ANDA pathway used by developers of bioequivalent versions of innovator drugs, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies; for example, they may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. The FDA may then approve the new product for all or some of the label indications for which the RLD has been approved, or for any new indication sought by the Section 505(b)(2) applicant, as applicable.

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant’s product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. The Orange Book listing for the Phexxi vaginal gel NDA includes two patents covering the product’s composition of matter and its method of use in prevention of pregnancy. Except for patents covering methods of use for which the follow-on applicant is not seeking approval, the applicant is required to certify to the FDA concerning any patents listed in the Orange Book for the RLD, when an ANDA applicant submits its application to the FDA. To the extent the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, such an applicant is also required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, an ANDA or 505(b)(2) applicant for a follow-on drug product with respect to each patent must certify that: (i) the required patent information has not been filed by the original applicant; (ii) the listed patent already has expired; (iii) the listed patent has not expired, but will expire on a specified date and approval is sought after patent expiration; or (iv) the listed patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the new product.

If a Paragraph I or II certification is filed, the FDA may make approval of the application effective immediately upon completion of its review. If a Paragraph III certification is filed, the approval may be made effective on the patent expiration date specified in the application, although a tentative approval may be issued before that time. If an application contains a Paragraph IV certification, a series of events will be triggered, the outcome of which will determine the effective date of approval of the ANDA or 505(b)(2) application.

A certification that the new product will not infringe the RLD's listed patents or that such patents are invalid is called a Paragraph IV certification. If the follow-on applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders for the RLD once the applicant's NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the follow-on applicant's ANDA or 505(b)(2) NDA will not be subject to the 30-month stay.

In addition, under the Hatch-Waxman Amendments, the FDA may not approve an ANDA or 505(b)(2) NDA until any applicable period of non-patent exclusivity for the referenced RLD has expired. These market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a drug containing a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of marketing exclusivity for a NDA, 505(b)(2) NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving follow-on applications for drugs containing the original active agent. Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA. However, an applicant submitting a traditional NDA would be required to either conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. The three-year new product exclusivity for the Phexxi NDA expires on May 22, 2023. The product's intellectual property also 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); these patents are expected to protect Phexxi into 2033.

Designation of and Exclusivity for Qualified Infectious Disease Products

In 2012 as part of the Food Drug Administration Safety and Innovation Act, Congress passed legislation known as the Generating Antibiotic Incentives Now Act (GAIN Act), which amended the FDCA to encourage the development of antibacterial and antifungal drug products that treat pathogens that cause serious and life-threatening infections. The law grants an additional five years of marketing exclusivity upon the approval of an NDA for a drug product previously designated by FDA as a QIDP. As a result, if applicable to a designated QIDP, upon approval the periods of five-year new chemical entity exclusivity and three-year new clinical investigation exclusivity would become ten years and eight years, respectively.

A QIDP is defined in the GAIN Act to mean "an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by: (1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens;" or (2) certain "qualifying pathogens." A "qualifying pathogen" is a pathogen that has the potential to pose a serious threat to public health (e.g., resistant gram positive pathogens, multi-drug resistant gram negative bacteria, multi-drug resistant tuberculosis and *Clostridium difficile*) and that is included in a list established and maintained by FDA. A drug sponsor may request FDA to designate its product as a QIDP any time before the submission of an NDA for that indication. FDA must make a QIDP determination within 60 days of the designation request. A product designated as a QIDP

may be granted priority review by FDA upon submission and can also qualify for "Fast Track" status, described further below. We have received two QIDP designations from the FDA for EVO100 for the prevention of urogenital infection in women with both chlamydia and gonorrhea and one for EVO200 for BV.

Fast Track and Priority Review Designations

The FDA is authorized to designate certain products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include Fast Track designation and priority review designation.

To be eligible for a Fast Track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast Track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the NDA for a Fast Track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the NDA. Fast Track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging in the clinical trial process. A product candidate designated as a QIDP is eligible for Fast Track designation under the provisions of the GAIN Act, but the NDA sponsor must specifically request Fast Track designation from the agency as with non-infectious disease product candidates. Fast Track designation may be requested concurrent with or at any time after the QIDP designation. In addition, although QIDP designation may be requested prior to submission of an Investigational New Drug Application (IND), a request for Fast Track designation may only be made concurrently with, or any time after, submission of an IND.

The FDA also may designate a product for priority review if it is a drug or biologic that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the marketing application is submitted, on a case- by-case basis, whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months for an original new molecular entity NDA from the date of filing. Although the FDA automatically gives priority review designation to the first application submitted for a specific drug product and indication for which a QIDP designation was granted, a subsequent application from the same sponsor for the same product and indication will receive priority review designation only if it otherwise meets the criteria for priority review.

Finally, even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, Fast Track designation and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

We have received two Fast Track designations from the FDA for EVO100 for the prevention of urogenital chlamydia and gonorrhea infection in women.

Patent Term Restoration in the United States

Depending upon the timing, duration and specifics of FDA approval of our drug candidates, some of our U.S. patents may be eligible for limited PTE under other provisions of the Hatch-Waxman Amendments. These PTEs permit a patent restoration term of up to five years as compensation for any patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The United States Patent and Trademark Office (USPTO) in consultation with the FDA, reviews and approves the application for any PTE or restoration.

Other United States Governmental Regulations and Environmental Matters

If we establish international operations, we will be subject to compliance with the United States Foreign Corrupt Practices Act of 1977, as amended (the FCPA), which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate to obtain or retain business or to otherwise influence a person working in an official capacity. We also may be implicated under the FCPA for activities by our partners, collaborators, contract research organizations, vendors or other agents.

Importantly, United States authorities that enforce the FCPA, including the Department of Justice, deem most health care professionals and other employees of foreign hospitals, clinics, research facilities and medical schools in countries with public health care or public education systems to be "foreign officials" under the FCPA. If and when we interact with foreign health care professionals and researchers in testing and marketing our products abroad, we must have policies and procedures in place sufficient to prevent us and agents acting on our behalf from providing any bribe, gift or gratuity, including excessive or lavish meals, travel or entertainment in connection with marketing our products and services or securing required permits and approvals such as those needed to initiate clinical trials in foreign jurisdictions. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the maintenance of books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and the development and maintenance of an adequate system of internal accounting controls for international operations.

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import and export and use and disposal of hazardous or potentially hazardous substances used in connection with our research work are or may be applicable to our activities. Certain agreements involving exclusive license rights, if any, or acquisitions, if any, may be subject to national or supranational antitrust regulatory control, the effect of which cannot be predicted. The extent of government regulation, which might result from future legislation or administrative action, cannot accurately be predicted.

Review and Approval of Drug Products in the European Union

In addition to regulations in the United States, we are and will be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and future commercial sales and distribution of our products, if approved in those markets.

We must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of a product in those countries. Moreover, the time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others. As of January 31, 2020, the United Kingdom (UK) is no longer a member state of the European Union (EU), and therefore a separate marketing authorization application (MAA) and approval will be required to market a medicinal product in the UK.

We are currently assessing the optimal regulatory legal basis for the Phexxi MAA in the EU and the UK. As in the United States, medicinal products can be marketed in the EU only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the United States, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls.

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the EU has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of an EU member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent ethics committee has issued a favorable opinion. Clinical trial applications must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents. In April 2014, the new Clinical Trials Regulation, Regulation EU No 536/2014 (Clinical Trials Regulation) was adopted and it came into application on January 31, 2022. The Clinical Trials Regulation will be directly applicable in all the EU member states, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the EU will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more

than three years from the day on which the Clinical Trials Regulation becomes applicable, the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure via a single entry point; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU member states in which an application for authorization of a clinical trial has been submitted. Part II is assessed separately by each EU member state concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU member state. However, overall related timelines will be defined by the Clinical Trials Regulation.

To obtain marketing approval of a drug in the EU, an applicant must submit an MAA either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU member states, Iceland, Lichtenstein and Norway. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of certain diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use (CHMP). Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is of 150 days, excluding stop-clocks.

The decentralized procedure is available to applicants who wish to market a product in specific EU member states where such product has not received marketing approval in any EU member states before. The decentralized procedure provides for an applicant to apply to one-member state to assess the application (the reference member state) and specifically list other member states in which it wishes to obtain approval (concerned member states). Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labelling and package leaflet, to the reference member state and each concerned member state. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application which is then reviewed and approved commented on by the concerned member states. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

In the EU, only products for which marketing authorizations have been granted may be promoted. A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause). Even if authorized to be marketed in the EU, prescription-only medicines may only be promoted to health care professionals, not the general public. All promotion should be in accordance with the particulars listed in the summary of product characteristics. Promotional materials must also comply with various laws, and codes of conduct developed by pharmaceutical industry bodies in the EU which govern (among other things) the training of sales staff, promotional claims and their justification, comparative advertising, misleading advertising, endorsements, and (where permitted) advertising to the general public. Failure to comply with these requirements could lead to the imposition of penalties by the competent authorities of the EU member states. The penalties could include warnings, orders to discontinue the promotion of the drug product, seizure of promotional materials, fines and possible imprisonment.

EU Regulatory Exclusivity

In the EU, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Rest of the World Regulation

For other countries outside of the EU and the United States, such as countries in Eastern Europe, Latin America, Asia, or Africa, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from jurisdiction to jurisdiction. Additionally, the clinical trials must be conducted in accordance with cGCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Other U.S. Health Care Laws and Regulations

We must comply with various U.S. federal and state laws, rules and regulations pertaining to health care fraud and abuse, including anti-kickback laws. HCPs and third-party payers play a primary role in the recommendation and prescription of drug products and medical devices. Our current and future arrangements with health care professionals, principal investigators, consultants, third-party payers and customers may expose us to broadly applicable fraud and abuse and other health care laws and regulations. Such restrictions under applicable federal and state health care laws and regulations, include but are not limited to the following:

Anti-Kickback Statute – the Federal Anti-Kickback Statute, among other things, prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federally funded health care programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate the statute in order to have committed a violation. In addition, the government may assert that a claim that includes items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Civil and Criminal False Claims Laws – the federal civil and criminal false claims laws, including the federal False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.

Health Insurance Portability and Accountability Act of 1996 – the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits, among other things, individuals or entities from executing a scheme to defraud any health care benefit program or making any false statements relating to health care matters; as in the case of the Federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate the statute in order to have committed a violation. Additionally, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and its implementing regulations impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization, on entities subject to the law, such as certain HCPs, health plans, and health care clearinghouses and their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information.

False Statements Statute – the federal False Statements Statutes prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement to the federal government, including executive or administrative agencies.

Sunshine Act – the federal transparency or "sunshine" requirements of the ACA requires certain manufacturers of drugs, devices, biologics and medical supplies to annually report to the Department of Health and Human Services (the DHHS) information related to payments and other transfers of value made to physicians, teaching hospitals and certain advanced non-

physician health care practitioners, as well as ownership and investment interests held by physicians and their immediate family members.

State Transparency Laws – some U.S. state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to HCPs and other HCPs or marketing expenditures; some state laws require pharmaceutical companies to implement compliance programs and to track and report gifts, compensation and other remuneration provided to physicians, in addition to requiring drug manufacturers to report information related to payments to physicians and other HCPs or marketing expenditures and pricing information; and some state and local laws require the registration of pharmaceutical sales representatives.

State and Foreign Regulatory Concerns – there are analogous State and foreign laws and regulations, such as State Anti-Kickback and False Claims laws, which may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payers, including private insurers. State and foreign laws also govern the privacy and security of health and personal information. These laws differ from each other in significant ways and may conflict, while applying simultaneously with HIPAA, thus complicating compliance efforts.

The scope and enforcement of these laws is uncertain and subject to rapid change. Notably, in November 2020, DHHS finalized significant changes to the regulations implementing the Anti-Kickback Statute, as well as the civil monetary penalty rules regarding beneficiary inducements, with the goal of offering the health care industry more flexibility and reducing the regulatory burden associated with those fraud and abuse laws, particularly with respect to value-based arrangements among industry participants. Regulatory authorities might challenge our current or future activities under these laws, regulations, and safe harbors. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. In addition, efforts to ensure that our business arrangements with third parties will comply with these laws will involve substantial costs. Any investigation of us or the third parties with whom we contract, regardless of the outcome, would be costly and time consuming. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, debarment under the FDCA, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

Health Care Reform and Potential Changes to Laws and Regulations

In the United States and some foreign jurisdictions, there have been, and continue to be, legislative and regulatory changes both enacted and proposed related to the health care system, which could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted. For example, in December 2016, the 21st Century Cures Act (Cures Act), was passed by Congress and signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and devices and to spur innovation, but its ultimate implementation is uncertain. In addition, in August 2017, the FDA Reauthorization Act was signed into law, which reauthorized the FDA's user fee programs and included additional drug and device provisions that build on the Cures Act. A subsequent FDA reauthorization package was finalized by Congress on September 30, 2022, and several other FDA-related changes are being proposed in Congress, including several within a "Cures 2.0" bill that is likely to have bipartisan support. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; and established a Center for Medicare Innovation at the U.S. Centers for Medicare and Medicaid Services (CMS) to test innovative payment and service delivery

models to lower Medicare and Medicaid spending. As another example, the 2021 Consolidated Appropriations Act, signed into law on December 27, 2020, incorporated extensive health care provisions and amendments to existing laws, including a requirement that all manufacturers of drug products covered under Medicare Part B report the product's average sales price (ASP) to DHHS beginning on January 1, 2022, subject to enforcement via civil money penalties.

Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA, and as a result certain sections of the ACA have not been fully implemented or effectively repealed. However, following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court upheld the ACA when it dismissed a legal challenge to the ACA's constitutionality. Further legislative and regulatory changes under the ACA remain possible, although the new federal administration under President Biden has signaled that it plans to build on the ACA and expand the number of people who are eligible for health insurance subsidies under it. It is unknown what form any such changes or any law would take, and how or whether it may affect the pharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, such as changes allowing the federal government to directly negotiate drug prices, and changes stemming from other health care reform measures, especially with regard to health care access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the United States.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2030 unless additional congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), which was signed into law on March 27, 2020, and was designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation. The suspension was subsequently extended through March 31, 2022, with a reduction of the suspension to 1% sequester through June 30, 2022. On July 1, 2022 the Medicare sequester increased to 2%.

As another example, on December 20, 2019, President Trump signed the Further Consolidated Appropriations Act for 2020 into law (P.L. 116-94) that includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (the CREATES Act). The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products to deny generic product developers access to samples of brand products. Because generic product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic product developers will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown. Other new laws may result in additional reductions in Medicare and other health care funding, which could have an adverse effect on customers for our approved product and, accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny in the United States of manufacturers' pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. DHHS has solicited feedback on various measures intended to lower drug prices and reduce the out-of-pocket costs of drugs and has implemented others under its existing authority. For example, in 2020, the FDA finalized a rulemaking to establish a system whereby state governmental entities could lawfully import and distribute prescription drugs sourced from Canada. More recently, in July 2021, President Biden issued a sweeping executive order on promoting competition in the American economy that includes several mandates pertaining to the pharmaceutical and health care insurance industries. Among other things, the executive order directs the FDA to work towards implementing a system for importing drugs from Canada (following on the Trump administration notice-and-comment rulemaking on Canadian drug importation that was finalized in October 2020). The Biden order also called on DHHS to release a comprehensive plan to combat high prescription drug prices, and it includes several directives regarding the Federal Trade Commission's oversight of potentially anticompetitive practices within the pharmaceutical industry. The drug pricing plan released by DHHS in September 2021 in response to the executive order makes clear that the Biden Administration supports aggressive action to address rising drug prices, including allowing DHHS to negotiate the cost of Medicare Part B and D drugs, but such significant changes will require either new legislation to be passed by Congress or time-consuming administrative actions.

Coverage, Pricing, and Reimbursement

Sales of Evofem's products approved for marketing by the FDA and foreign regulatory authorities depend, in part, on the extent to which such products will be covered by third-party payers, such as government health programs, commercial insurance and managed care organizations. In the United States, no uniform policy of coverage and reimbursement for drug or biological products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of Evofem's FDA-approved products will be made on a payer-by-payer basis. Prescriptions generated through the Phexxi telehealth platform may be subject to additional payer requirements. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our approved products to each payer separately, with no assurance that coverage and adequate reimbursement will be obtained.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, and mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the DHHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price (AMP), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Congress has expressed its intention to repeal or repeal and replace the ACA. If that is done, many if not all of the provisions of the ACA may no longer apply to prescription drugs.

The marketability of any products for which Evofem has or will receive regulatory approval for commercial sale may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement. An increasing emphasis on cost containment measures in the United States has increased, and Evofem expects will continue to increase, the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of our product candidate to currently available therapies (so called health technology assessment) in order to obtain reimbursement or pricing approval. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of Evofem's approved drug products. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

Corporate Information

Effective April 1, 2023, our corporate headquarters are located at 7770 Regents Rd, Suite 113-618, San Diego, CA 92122-1967, and our telephone number is (858) 550-1900. Our website is located at www.evofem.com. Our Annual Report, Annual Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act) will be made available free of charge on our website as soon as reasonably practicable after we electronically file these materials with, or furnish it to, the Securities and Exchange Commission (SEC) on their website located at www.sec.gov. The contents of our website are not incorporated into this Annual Report, and our reference to the URL for our website is intended to be an inactive textual reference only. The information contained on, or that can be accessed through, our website is not a part of this Annual Report.

Employees

As of April 7, 2023, we had a total of 35 full-time employees and two part-time employees. We also engage consultants and contract workers on an as-needed basis. We believe that relations with our employees and consultants are good.

Item 1A. Risk Factors.

Summary of Risk Factors

The risk factors described below are a summary of the principal risk factors associated with an investment in Evofem. These are not the only risks we face. You should carefully consider the following risk factors, together with all of the other information included in this Annual report, including the financial statements and related notes, when deciding to invest in us. You should be aware that the occurrence of any of the events described in this Risk Factors section and elsewhere in this Annual Report could have a material adverse effect on our business, financial position, results of operations and cash flows and the trading price of our securities could decline and you could lose all or part of your investment.

Risks Related to Our Financial Condition and Capital Requirements

- We received a Notice of Default on the Baker Bros. Purchase Agreement.
- We are currently over 90 days past due on a significant amount of vendor obligations, including pursuant to previous lease agreements. We may not be able to refinance, extend or repay our substantial indebtedness owed to our secured and unsecured lenders, which would have a material adverse effect on our financial condition and ability to continue as a going concern.
- We have incurred significant losses and negative cash flows since our inception and anticipate we will continue to incur significant losses and negative cash flow for the foreseeable future.
- We must raise significant additional funds to finance our operations and to remain a going concern. If we are unable to raise additional capital when needed or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our business initiatives.
- We have a limited number of shares of common stock available for future issuance which could adversely affect our ability to raise capital or consummate strategic transactions.

Risks Related to Potential Bankruptcy

- We are subject to risks and uncertainties associated with potential bankruptcy proceedings including a long and protracted restructuring.
- Our 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 our business to fail.
- We face competition from other medical device, biotechnology and biopharmaceutical companies and our operating results will suffer if we are unable to compete effectively.
- Phexxi may not gain sufficient market acceptance among physicians, patients or the medical community, thereby limiting our potential to generate revenue, which will undermine our future growth prospects.
- The commercial success of Phexxi or any future approved products will depend in significant measure on the label claims that the FDA or other regulatory authorities approve for those products.
- We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely affect our business.
- The proportion of the contraceptive market that is made up of generic products continues to increase, making introduction of a branded contraceptive difficult and expensive.

Risks Related to the Development of Our Product Candidates

- Our inability to develop our vaginal pH modulator for additional indications could have an adverse effect on our business and our ability to successfully market Phexxi for the prevention of pregnancy.
- Indemnity claims from lawsuits or damages against our clinical trial sites could cause us to incur substantial liabilities and to limit commercialization of Phexxi and any other product candidates we may develop.

- Clinical trials are costly, time consuming and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Risks Related to Regulatory Approval of Our Product Candidates

- If our clinical trials fail to satisfactorily demonstrate the safety and efficacy of our product candidates to the FDA and other comparable foreign regulators, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Even though we have received approval from the FDA in the United States to market Phexxi for the prevention of pregnancy, we may fail to receive similar approval outside the United States.
- We have not paid our Fiscal Year 2023 PDUFA Invoice for Phexxi to the FDA and the balance due continues to incur interest, penalties and may apply retroactively. We cannot submit any new applications or supplements until paid.

Risks Related to Our Post-Marketing Legal and Regulatory Compliance

- Developments after a product reaches the market may adversely affect sales of the product.
- Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of Phexxi. If we are unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage, a material liability claim could adversely affect our financial condition.
- If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial condition or results of operations.

Risks Related to Our Intellectual Property

- Our rights to develop and commercialize Phexxi are subject, in part, to the terms and conditions of licenses granted to us by third parties. The patent protection and patent prosecution of Phexxi is dependent on third parties.
- If we are unable to obtain and maintain patent protection for Phexxi or other proprietary technologies we may develop, or if the scope of the patent protection we have or will obtain is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to our products and technology, and our ability to successfully commercialize Phexxi, our product candidates and other proprietary technologies we may develop may be adversely affected.
- We may not be able to protect our intellectual property and proprietary rights throughout the world.
- Issued patents covering Phexxi and other proprietary technologies we may develop could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.
- If we do not obtain patent term extensions (PTE) for our products or product candidates, our business may be materially harmed.
- The patent protection and patent prosecution for our product candidates are dependent on third parties, including Rush University.
- If an event of default occurs under our issued and outstanding secured convertible notes issued pursuant to the Baker Bros. Purchase Agreement, the note holders could take possession of all assets owned by us, including any directly owned intellectual property.
- If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.
- We may be subject to claims that our employees have wrongfully used or disclosed or wrongfully use alleged trade secrets of their former employers.
- We may not be successful in obtaining necessary rights to any product candidate we may develop through acquisitions and in-licenses.
- Some intellectual property that we have 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 our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Risks Related to Our Reliance on Third Parties

- Our 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 our business and our ability to market Phexxi and develop and market our product candidates, and our business could be substantially harmed.
- We have no significant internal distribution capabilities. We intend to engage third-party distributors for distribution of products outside the United States, if approved, and have engaged additional third-party wholesale distributors for the distribution of Phexxi in the United States. Our inability to identify, or enter into an agreement with, any such third-party distributor would likely have a material adverse effect on our business and operations.

Risks Related to Our Commercialization of Health Care Products

- Changes in health care 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 we are successful in obtaining regulatory approval to market other product candidates in the United States, 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.
- Health care legislative reform measures may have a negative impact on our business and results of operations.
- Our business may be adversely affected by unfavorable macroeconomic conditions, including the COVID-19 pandemic.

Risks Related to Our Business Operations

- We will need to expand the size of our organization, and we may experience difficulties in managing this growth or be unable to successfully commercialize Phexxi, develop any product candidates or otherwise implement our business plan.

Risks Related to Our Common and Preferred Stock

- Our management has identified material weakness in our internal controls and procedures.
- Our shares of common stock have been delisted from the Nasdaq Capital Market which has and could result in, among other things, a decline in the price of our common stock and less liquidity for holders of shares of our common stock.
- Our stock price is and may continue to be volatile.
- There may not be an active, liquid trading market for our equity securities.
- Because our Common Stock is subject to the "penny stock" rules, brokers cannot generally solicit the purchase of our Common Stock, which adversely affects its liquidity and market price.
- Because, until a reverse split is effectuated, we do not have sufficient authorized capital on a fully diluted basis, the excess outstanding capital exposes us to liability, and we will need to increase our authorized capital, effectuate a reverse split or obtain effective waivers from derivative securityholders.
- We may not obtain requisite shareholder approval to approve an increase in the authorized, reverse split or other corporate action relating to the common stock when and if needed.
- If approved, a reverse stock split may decrease the liquidity of our common stock.
- A reverse stock split may lead to a decrease in our overall market capitalization.
- Our common stock could be further diluted as the result of the issuance of additional shares of common stock, convertible securities, warrants or options.
- We are and may continue to be subject to short-selling strategies.
- Our business could be negatively affected as a result of the actions of activist stockholders.
- We may become a defendant in one or more stockholder derivative or class-action litigation(s), and any such future lawsuit(s) may adversely affect our business, financial condition, results of operations and cash flows.

Risks Related to Our Financial Condition and Capital Requirements

We are currently in Default of the Securities Purchase and Security Agreement with Baker Brothers.

On March 7, 2023, Baker Bros. Advisors, LP (the Designated Agent) provided a Notice of Event of Default and Reservation of Rights (the Notice of Default) relating to the Securities Purchase and Security Agreement dated April 23, 2020, and subsequently amended (SPA), by and amount the Company, Designated Agent, the Guarantors and Baker Purchasers. The Notice of Default claims that the Company has failed to maintain the "Required Reserve Amount" as required by Section 2.7 of the Third Amendment to the Securities Purchase Agreement and Section 8.1(e) of the SPA. The Designated Agent claims such failure constitutes an immediate Event of Default pursuant to Section 9.1(e) of the SPA. The Designated Agent, at the direction of the Baker Purchasers, has accelerated repayment of the outstanding balance payable and elected its remedies pursuant to Section 5.07(b) of the Securities Purchase Agreement. As a result, approximately $92.8 million representing two times the sum of the outstanding balance and all accrued and unpaid interest thereon and all other amounts due under the SPA and other documents is due and payable within three business days of receipt of the Notice of Default. The failure to cure the default or otherwise settle or resolve, could have a significant negative financial impact on the Company, could result in litigation, and could result in the assets of the company being seized, attached or otherwise utilized to satisfy the debt.

We are currently over 90 days past due on a significant amount of vendor obligations. We may not be able to refinance, extend or repay our substantial indebtedness owed to our secured and unsecured lenders, which would have a material adverse effect on our financial condition and ability to continue as a going concern.

As of April 7, 2023, we have approximately $19.3 million in accounts payable with approximately $14.1 million that is over 90 days past due (not including the Baker Notes described herein). If we are unable to repay these amounts, as well as our existing debt obligations at maturity, and we are otherwise unable to extend the maturity dates or refinance these obligations, we would be in default. We cannot provide any assurances that we will be able to raise the necessary amount of capital to repay these obligations or that we will be able to extend the maturity dates or otherwise refinance these obligations. Upon a default, our secured lenders would have the right to exercise their rights and remedies to collect, which would include foreclosing on our assets. Accordingly, a default would have a material adverse effect on our business, and we would likely be forced to seek bankruptcy protection.

Our audited financial statements included a statement that there is a substantial doubt about our ability to continue as a going concern and a continuation of negative financial trends could result in our inability to continue as a going concern.

Our management has determined that there is a substantial doubt about our ability to continue as a going concern over the next 12 months from the estimated filing date of April 27, 2023. Our independent auditors have included a "going concern" explanatory paragraph in their report on our financial statements as of and for the year ended December 31, 2022 as filed in this Annual Report on Form 10-K. The reaction of investors to the inclusion of a going concern statement by our independent auditors, and our potential inability to continue as a going concern, could materially adversely affect the price of our common stock.

Additionally, if our operating results fail to improve we could violate additional debt covenants, our liquidity could be further adversely impacted and we may need to seek additional sources of funding. There is no assurance that we will be able to raise additional capital to fund our operations or that debt or equity financing will be available in sufficient amounts or on acceptable terms. If our operating results fail to improve, then our financial condition could render us unable to continue as a going concern.

We have incurred significant losses and negative cash flows since our inception and anticipate we will continue to incur significant losses and negative cash flow for the foreseeable future.

We have incurred yearly losses and negative cash flows since our inception, including net losses of $76.7 million and $205.2 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $938.7 million. Negative cash flows from our operations are expected to continue for the foreseeable future. To date, we have devoted substantially all our financial resources to the development and commercialization of Phexxi for hormone-free contraception and to the development of EVO100 for the prevention of chlamydia and gonorrhea and our other product candidates, as well as providing general and administrative support for our operations. Our utilization of cash has historically been highly dependent on these development programs and the commercialization of Phexxi in the United States. In October 2022, we discontinued development of EVO100 for the prevention of chlamydia and gonorrhea and have no plans to advance clinical development of this program or to significantly invest in other clinical programs or product candidates for the foreseeable future. We plan to allocate capital to fund our continued commercialization efforts. Our cash expenses will also continue to be dependent on the terms and conditions of our contracts with service providers and any license partners.

To date, we have financed our operations primarily through the sale of equity securities, notes, warrants, convertible notes, convertible preferred stock and through other debt arrangements. The amount of our future net losses will depend, in large part, on our ability to generate revenue from the sale of Phexxi, the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations or grants which may be particularly challenging or impossible in light of market conditions, especially in light of the ongoing COVID-19 pandemic. The commercialization and development of biopharmaceutical products involves a substantial degree of risk.

We expect to continue to incur significant operating expenses and to continue to incur significant losses for the foreseeable future as we:

- incur sales, marketing, and distribution costs to commercialize Phexxi, including media and digital promotional campaigns;
- incur costs associated with the commercial manufacturing of Phexxi;
- implement post-approval changes and process improvements to manufacturing;
- seek regulatory and marketing approvals for Phexxi outside the United States and reimbursement for Phexxi or any product candidates we may choose to develop in the future;
- continue our efforts to identify, assess, acquire, and/or develop other product candidates;
- make milestone, royalty or other payments under third-party license agreements;
- seek to maintain, protect, and expand our intellectual property portfolio; and
- seek to attract and retain skilled personnel.

Due in part to circumstances related to the COVID-19 pandemic, we delayed the commercial launch of Phexxi from June 2020 until September 2020. The COVID-19 pandemic led to slower than forecasted uptake of Phexxi due to reduced access to medical offices and HCPs as well as changes in sexual behavior among consumers, particularly during periods of lockdown and the emergence of variant strains of the virus. Should we experience any further delays or encounter issues with the commercialization, some of which may result in part due to the ongoing COVID-19 pandemic, we may incur significant additional expenses.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Due to the recurring losses, negative cash flows from operating activities since inception, and net working capital at December 31, 2022, the report of our independent registered public accountant on our financial statements as of and for the years ended December 31, 2022 and 2021 filed with this Annual Report on Form 10-K for the year ended December 31, 2022 includes explanatory language describing the existence of substantial doubt about our ability to continue as a going concern. In addition, our management has further determined that there is a substantial doubt about our ability to continue as a going concern over the next 12 months from the estimated filing date of April 27, 2023.

Although we have generated revenue from product sales, we may never be profitable. Our operating results may differ from any guidance we may announce.

Our current business is substantially dependent on the commercial success of Phexxi. The commercial launch of Phexxi took place on September 8, 2020, and although we have generated revenue from sales of Phexxi, we may never achieve or sustain profitability. Our ability to generate revenue and achieve and sustain profitability depends on our ability, alone or with strategic collaborators, to successfully commercialize Phexxi and, to a lesser extent, any future products we may license or develop and commercialize. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including, but not limited to:

- the rate and degree of market acceptance for Phexxi and any other product candidates that may be approved in the future;
- the effectiveness of our commercialization strategy for Phexxi and any other product candidates that may be approved in the future, either directly or with one or more distribution partners, including the effectiveness of our sales force, the Phexxi telehealth platform, media and digital campaigns, and contracted tele-sales vendor;
- reimbursement and pricing for Phexxi and any other approved product candidates in amounts that support profitability;
- successfully competing against other contraceptive products;
- manufacturing Phexxi and establishing and maintaining supply and manufacturing relationships with third parties that are commercially feasible, as well as complying with applicable regulatory requirements and meeting our supply needs in sufficient quantities to meet market demand for Phexxi;

- our ability to adapt in a dynamic and challenging pandemic environment;
- obtaining regulatory approval of Phexxi in territories outside of the United States;
- manufacturing any investigational product(s), should we choose to advance their clinical development, funding and successfully completing clinical development, and obtaining regulatory approval;
- protecting, maintaining and enforcing our intellectual property rights, including patents, trade secrets and know-how;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter; and
- attracting, hiring and retaining qualified personnel.

From time to time, we may provide guidance as to our anticipated future performance and certain unit shipment information, prescription and prescriber statistics, website and search statistics and other metrics. We may fail to achieve the performance described in any such guidance, and any information or metrics we may provide may be not be indicative of future results. In addition, we provide co-pay assistance to commercially insured patients with an approved Phexxi prescription and utilize a sample program to promote demand for Phexxi. The co-pay program reduces the amount of profit we realize per unit sold, however it is a value program to patients that we aim to continue in 2023. Because of the expense to run the program, we will look to modify the business rules surrounding the co-pay program in the future, particularly as payers increasingly cover Phexxi at $0 co-pay to comply with HRSA guidelines; compliance is mandated beginning January 1, 2023 and enforcement action is anticipated. If we are not able to generate sufficient revenue from product sales of Phexxi, the revenue from product sales of Phexxi is not sufficiently profitable, we fail to meet our guidance, or our information or metrics is not indicative of our future results of operations, this could materially and adversely affect our business results of operations, the price of our common stock, our financial condition and our ability to raise additional capital.

We will need to raise significant additional funds to finance our operations, including the commercialization of Phexxi, and to remain a going concern. If we are unable to raise additional capital when needed or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our business initiatives or to cease our operations entirely.

We have incurred significant losses and negative cash flows since our inception. We believe our existing capital resources as of April 7, 2023 are sufficient to fund our planned operations into the third quarter of 2023. Our ability to raise additional funds will depend, in part, on our ability to successfully commercialize Phexxi in the United States. If, for whatever reason, we are unsuccessful in these efforts, it may make any necessary debt, equity or alternative financing more difficult, more costly and more dilutive. Attempting to secure additional financing will divert our management from our day-to-day activities, which may adversely affect our ability to commercialize Phexxi. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Furthermore, the global credit and financial markets have experienced extreme volatility and disruptions in recent history, particularly for life science companies. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. If we are unable to raise additional funds when needed or on acceptable terms, we may be unable to continue commercializing Phexxi as a contraceptive. In addition, we may be required to delay, scale back or eliminate some or all of our business initiatives or be forced to cease operations entirely. To the extent we raise additional capital through the sale of equity, convertible debt or other securities convertible into equity, the ownership interest of our stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Future debt financings, if available at all, would likely involve agreements with additional covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions or declaring dividends. If we raise additional funds through strategic collaborations, alternative non-dilutive financing, such as royalty-based financing, or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or future revenue streams or grant licenses on terms that are not favorable to us.

Moreover, if we are unable to continue as a going concern, we may be forced to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. Given the amounts currently owed pursuant to the Adjuvant Notes, the Baker Notes and other debt arrangements, holders of our common stock may not receive value for their shares in the event of a liquidation.

We have certain obligations pursuant to our issued and outstanding promissory notes, convertible notes and related note purchase agreements, and our failure to comply with these obligations could have a material adverse effect on our business, financial condition or results of operations.

In April 2020, we entered into a Securities Purchase and Securities Agreement (the "Baker Bros. Purchase Agreement") with certain institutional investors and their designated agent pursuant to which we issued and sold secured convertible promissory notes in an aggregate principal amount of $25.0 million and warrants to purchase shares of our common stock. In November 2021, we entered into the first amendment to the Baker Bros. Purchase Agreement which extends the affirmative covenant to achieve $100.0 million in cumulative net sales of Phexxi by June 30, 2022 to June 30, 2023. On March 7, 2023, Baker Bros. Advisors, LP (the Designated Agent) provided a Notice of Event of Default and Reservation of Rights (the Notice of Default) relating to the Baker Bros. Purchase Agreement.

In October 2020, we entered into a Securities Purchase Agreement (the "Adjuvant Purchase Agreement") pursuant to which we issued and sold to certain institutional investors unsecured convertible promissory notes in an aggregate principal amount of $25.0 million. On April 4, 2022, we entered into the first amendment to the Adjuvant Purchase Agreement (the "First Adjuvant Amendment"). The First Adjuvant Amendment extended, effective as of the date on which we achieved the Qualified Financing Threshold upon the closing of the May 2022 Public Offering, the affirmative covenant to achieve $100.0 million in cumulative net sales of Phexxi by June 30, 2022 to June 30, 2023. The First Adjuvant Amendment also provided for an adjustment to the conversion price of the Adjuvant Notes such that the conversion price for these Notes, effective as of the reverse stock split the conversion price will now be the lesser of (i) $5.4279 and (ii) 100% of the lowest price per share of common stock (or with respect to securities convertible into common stock, 100% of the applicable conversion price) sold in any equity financing until we have met the Qualified Financing Threshold.

In January 2022, we entered into a Securities Purchase Agreement (the "2022 Purchase Agreement") with certain institutional investors pursuant to which we issued warrants and unsecured subordinate promissory notes with an original principal amount of $5.8 million (the "January 2022 Notes"). In March 2022, we entered into a Securities Purchase Agreement (the "March 2022 Purchase Agreement") with certain institutional investors pursuant to which we issued warrants and unsecured subordinate promissory notes with an original principal amount of $7.45 million (the "March 2022 Notes"; collectively with the Baker Bros. Notes, the Adjuvant Notes and the January 2022 Notes, the "Notes").

These debt arrangements limit our ability to incur debt, merge, or declare dividends and, in certain circumstances, and with respect to the January 2022 Notes and March 2022 Notes, the holders may require us to redeem outstanding amounts out of gross proceeds raised in certain subsequent offerings which could mean money raised in these offerings would not ultimately be able to be used to fund our ongoing operations. The Baker Notes are secured by substantially all of our assets, and we are currently in default. Our failure to make payments as due under any of the Notes could be an event of default under all of the Notes. Events of default under these arrangements could also include, but are not limited to, a material breach of representations, our failure to comply with our obligation to convert convertible notes, our failure to perform or observe, and in certain instances, cure, certain covenants, including, but not limited to, covenants requiring us to maintain the listing of shares of our common stock on the OTCQB and, assuming no further amendment of current terms, to achieve cumulative net sales of Phexxi of at least $100.0 million by June 30, 2023. In the event of a default and depending on the terms of each Note, a holder of the Notes may be entitled to redemption premiums, treble amounts and other remedies described in their respective agreements. Any default could materially and adversely impact our business, results of operations and financial condition, as well as increase our need to raise additional capital, cause us to cease our operations entirely and may result in the holders of our common stock not receiving any value for their investment.

On December 20, 2022, we entered into a securities purchase agreement (SPA), with certain investors (the "Investors") providing for the sale and issuance of senior secured convertible notes due in the aggregate original principal amount of $2,307,692,31 (the Notes), warrants to purchase an aggregate 46,153,847 shares of common stock (Warrants) and an aggregate 70 shares of Series D Preferred Stock (the Preferred Shares) (collectively, the Offering). The Offering closed on December 21, 2022 (the Closing Date) and as a result, we issued an aggregate $2,307,692 in aggregate principal amount of Notes and the Warrants to purchase 46,153,847 shares of common stock. Each Investor shall paid approximately $650 for each $1,000 of principal amount of Notes, Preferred Shares and Warrants. Our net proceeds from the Offering, after deducting offering expenses were approximately $1,250,000.

On December 19, 2022, we entered into the First Amendment to Forbearance Agreement (the Amendment) effective as of December 15, 2022 (the Amendment Effective Date) to amend certain provisions of the of the Secured Creditor Forbearance Agreement dated September 15, 2022. The Amendment revises the Secured Creditor Forbearance Agreement to (i) amend the Fifth Recital Clause to clarify that the Purchasers consent to any additional indebtedness *pari passu*, but nor senior to that of the Purchases, in an amount not to exceed $5,000,000, and (ii) strike and entirely replace Section 4 to clarify the terms of the Purchasers' consent to Interim Financing (as defined therein). No other revisions were made to the Secured Creditor Forbearance Agreement, including the requirement under Section 5. Agreement to Forbear where the Forbearance Termination Event means, among other things, the first date after December 31, 2022 on which our total cash falls below $1,000,000.

A failure to comply with these obligations, triggering additional events of default, or other breach could have a material adverse effect on our business, financial condition or results of our operations.

We have a limited number of shares of common stock available for future issuance which could adversely affect our ability to raise capital or consummate strategic transactions.

We are currently authorized to issue 500,000,000 shares of common stock under our amended and restated certificate of incorporation. As of April 7, 2023 we have issued 215,961,346 shares of common stock and approximately 23.5 billion shares of common stock were committed for issuance giving effect to the assumed exercise of all outstanding warrants, options, purchase rights and the assumed conversion of all issued and outstanding convertible notes. The conversion prices of the Adjuvant Convertible Notes (as amended) and Baker Convertible Notes may also be subject to adjustment depending on the

price of issuances in future financings as described above. These adjustments would further increase the numbers of shares of common stock to be reserved as a result of these adjustments. Due to the limited number of authorized shares common stock available for future issuance, we may not able to raise additional equity capital or complete a merger or other business combination unless we increase the number of shares we are authorized to issue. We would need to seek stockholder approval to increase the number of our authorized shares of Common Stock, and we can provide no assurance that we would succeed in amending our amended and restated certificate of incorporation to increase the number of shares of Common Stock we are authorized to issue which could negatively impact our business, prospects and results of operations.

Use of net operating loss carryforwards may be limited and U.S. federal income tax reform could adversely affect us.

Our ability to utilize our net operating loss (NOL) carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes. Corresponding rules may apply under state tax laws. Even if there is no limitation on utilization of our NOL carryforwards as the result of an ownership change, the utilization of NOL carryforwards may be limited by other applicable laws. Pursuant to the TCJA passed in December 2017, carryforwards originating from a loss incurred in a year after 2017 are limited and may reduce taxable income in any post-2020 year by no more than 80% of the pre-NOL taxable income in such year. The Coronavirus Aid, Relief and Economic Security Act (the CARES Act) temporarily suspended this 80% taxable income limitation, allowing an NOL carryforward to fully offset taxable income in tax years beginning before January 1, 2021. Additional legislation or regulation which could affect our tax burden could be enacted by any governmental authority. We cannot predict the timing or extent of such tax-related developments which could have a negative impact on our financial results, including a potential increase in federal corporate tax rates generally. We cannot estimate how the changes in tax law from this legislation will affect our tax liability in future years, but we have recorded a valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits from those assets. We have established a full valuation allowance for our deferred tax assets due to uncertainties as to their utilization. While we use our best judgment in attempting to quantify and reserve for our tax obligations. A challenge by a taxing authority, our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax-related assumptions may cause actual results to deviate from previous estimates.

Risks Related to Potential Bankruptcy

Given our current financial condition, we have considered and continue to consider filing for bankruptcy protection. While we have not initiated bankruptcy proceedings, we caution that trading in our securities is highly speculative and poses substantial risks relating to the potential of bankruptcy proceedings. Trading prices for our securities may bear little or no relationship to the actual recovery, if any, by holders of our securities in Bankruptcy proceedings, if any.

We are subject to risks and uncertainties associated with potential bankruptcy proceedings.

Our operations and ability to develop and execute our business plan, our financial condition, our liquidity and our continuation as a going concern, are subject to risks and uncertainties associated potential or actual bankruptcy. These risks include the following:

- our ability to prosecute, confirm and consummate a plan of reorganization with respect to the Chapter 11 proceedings;
- the high costs of bankruptcy proceedings and related fees;
- our ability to obtain sufficient financing to allow us to emerge from bankruptcy and execute our business plan post emergence;
- our ability to maintain our current relationships with or attract new suppliers, service providers, customers, employees, and other third parties;
- our ability to maintain contracts that are critical to our operations;
- our ability to execute our business plan in the current depressed commodity price environment;
- our ability to attract, motivate and retain key employees;
- the ability of third parties to seek and obtain court approval to terminate contracts and other agreements with us or make other third-party motions in the proceedings;
- the ability of third parties to seek and obtain court approval to convert Chapter 11 proceedings to Chapter 7 proceedings, if applicable; and
- the actions and decisions of our creditors and other third parties who have interests in proceedings that may be inconsistent with our plans.

Delays in filing for or moving forward with the proceedings increase the risks of our being unable to reorganize our business and emerge from bankruptcy and increase our costs associated with the bankruptcy process.

These risks and uncertainties could affect our business and operations in various ways. For example, negative events associated with either Chapter 11 or Chapter 7 proceedings could adversely affect our relationships with our suppliers, service providers, customers, employees, and other third parties, which in turn could adversely affect our operations and financial condition. Also, we need the prior approval of the Bankruptcy Court for transactions outside the ordinary course of business, which may limit our ability to respond timely to certain events, take advantage of certain opportunities or pursue our business strategies. Because of the risks and uncertainties associated with potential proceedings, we cannot accurately predict or quantify the ultimate impact that events that may occur during the proceedings will have on our business, financial condition and results of operations.

Our businesses could suffer from a long and protracted restructuring.

Our future results could be dependent upon the successful confirmation and implementation of a bankruptcy plan or other alternative restructuring transaction, including a sale of all or substantially all of our assets. A long period of operations under Bankruptcy Court protection could have a material adverse effect on our business, financial condition, results of operations and liquidity. Failure to obtain confirmation of a Chapter 11 plan or approval and consummation of an alternative restructuring transaction in a timely manner may harm our ability to obtain financing to fund our operations, and there is a significant risk that the value of our securities and assets would be substantially eroded to the detriment of all stakeholders. If a Chapter 11 plan that complies with the applicable provisions of the Bankruptcy Code cannot be agreed upon, it is possible that we would have to liquidate our assets, in which case it is likely that holders of claims would receive substantially less favorable treatment than they would receive if we were to emerge as a viable, reorganized entity.

If filed, for as long as bankruptcy proceedings continue, we will be required to incur substantial costs for professional fees and other expenses associated with the administration of the Chapter 11 or Chapter 7 proceedings. Chapter 11 proceedings may also require us to seek debtor-in-possession financing to fund operations. If we are unable to obtain such financing on favorable terms or at all, our chances of successfully reorganizing our business may be seriously jeopardized, the likelihood that we instead will be required to liquidate our assets may be enhanced, and, as a result, any securities in us could become further devalued or become worthless.

In the event we decide to initiate bankruptcy proceedings, there can be no assurance that we will successfully reorganize and emerge from Chapter 11 proceedings or, if we do successfully reorganize, as to when we would emerge from the Chapter 11 proceedings. Even after a Chapter 11 plan is confirmed and implemented, our operating results may be adversely affected by the possible reluctance of prospective lenders, suppliers and other counterparties to do business with a company that recently emerged from bankruptcy proceedings.

In certain instances, a Chapter 11 case may be converted to a case under Chapter 7 of the Bankruptcy Code.

We have not yet filed for bankruptcy and therefore have not yet decided upon Chapter 11 or Chapter 7. However, should we choose to pursue Chapter 11, upon a showing of cause, the Bankruptcy Court may convert our Chapter 11 case to a case under Chapter 7 of the Bankruptcy Code. In such event, a Chapter 7 trustee would be appointed or elected to liquidate our assets for distribution in accordance with the priorities established by the Bankruptcy Code. We believe that liquidation under Chapter 7 would result in significantly smaller distributions being made to our creditors because of (i) the likelihood that the assets would have to be sold or otherwise disposed of in a distressed fashion over a short period of time rather than in a controlled manner and as a going concern, (ii) additional administrative expenses involved in the appointment of a Chapter 7 trustee, and (iii) additional expenses and claims, some of which would be entitled to priority, that would be generated during the liquidation and from the rejection of leases and other executory contracts in connection with a cessation of operations.

If we choose to file under Chapter 11, we may be subject to claims that will not be discharged in the bankruptcy proceedings, which could have a material adverse effect on our financial condition and results of operations.

The Bankruptcy Code provides that the confirmation of a plan of reorganization discharges a debtor from substantially all debts arising prior to confirmation. With few exceptions, all claims that arose prior to confirmation of the plan of reorganization (i) would be subject to compromise and/or treatment under the plan of reorganization and/or (ii) would be discharged in accordance with the Bankruptcy Code and the terms of the plan of reorganization. Any claims not ultimately discharged through a plan of reorganization could be asserted against the reorganized entities and may have an adverse effect on our financial condition and results of operations on a post-reorganization basis.

Our financial results may be volatile and may not reflect historical trends.

During bankruptcy proceedings, we expect our financial results to continue to be volatile as asset impairments, asset dispositions, restructuring activities and expenses, contract terminations and rejections, and claims assessments occur, which

may significantly impact our consolidated financial statements. As a result, our historical financial performance is likely not indicative of our financial performance after the date of the bankruptcy filing.

In addition, if we emerge from Chapter 11, the amounts reported in subsequent consolidated financial statements may materially change relative to historical consolidated financial statements, including as a result of revisions to our operating plans pursuant to a plan of reorganization. We also may be required to adopt fresh start accounting, in which case our assets and liabilities will be recorded at fair value as of the fresh start reporting date, which may differ materially from the recorded values of assets and liabilities on our consolidated balance sheets. Our financial results after the application of fresh start accounting also may be different from historical trends.

Risks Related to Commercialization of Phexxi and Any Other Approved Product Candidates

Our success will depend heavily on whether we can successfully commercialize our only commercially available product, Phexxi, for prevention of pregnancy. Failure to successfully commercialize Phexxi for the prevention of pregnancy would likely cause our business to fail.

Our overall success will rely heavily on the commercial success of Phexxi vaginal gel for prevention of pregnancy. Failure to successfully commercialize Phexxi for the prevention of pregnancy would likely cause our business to fail. There are numerous examples of failures to meet high expectations of market potential for new product launches in the health care space, including by pharmaceutical companies with more experience and resources than us. If the commercialization of Phexxi is unsuccessful or perceived as disappointing, our stock price could decline significantly.

If we are unable to establish and maintain effective internal sales and marketing capabilities, or enter into agreements with third parties to market and sell Phexxi, our ability to generate revenue would be adversely affected.

Although our employees may have previously marketed, commercialized and sold other pharmaceutical products, including contraceptives, while employed at other companies, we have limited experience selling and marketing Phexxi. We may face difficulties recruiting and hiring sales representatives and otherwise obtaining these marketing capabilities. Any failure or delay in the timely development of our internal commercialization capabilities could adversely impact the potential for commercial success of Phexxi.

If we are unable to effectively train and equip our sales force, our ability to successfully commercialize Phexxi will be harmed.

We may not be able to maintain the requisite sales force to market Phexxi. Even if we are able to maintain the requisite sales force, Phexxi is a newly marketed drug with a new mechanism of action as a vaginal pH modulator and, therefore, none of the members of our sales force has extensive experience promoting Phexxi. We expect to continue to expend significant time and resources to train our sales consultants in marketing Phexxi. In addition, we must train our sales force to ensure that an appropriate and compliant message about Phexxi is being delivered. If we are unable to effectively train our sales force and equip them with compliant and effective materials, including medical and sales literature to help them appropriately inform and educate physicians regarding the potential benefits of Phexxi, our efforts to successfully commercialize Phexxi could be put in jeopardy, which would negatively impact our ability to generate product revenues.

Our use of social media platforms to market and promote a prescription product, e.g. Phexxi, presents risks and operational challenges.

We believe that our customer base and potential patient populations for Phexxi are active on social media, and we have engaged and intend to continue to engage through those platforms to elevate our national marketing presence in direct-to-consumer marketing. Social media practices in the pharmaceutical, biotechnology and medical device industries are evolving, which creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media platforms to comment on the effectiveness of, or adverse experiences with, our product, which could result in regulatory reporting obligations or the need for us to conduct an investigation. The use of influencers and patient ambassadors to promote Phexxi also may be subject to federal truth-in-advertising laws enforced by the Federal Trade Commission (FTC), as well as comparable state consumer protection laws, and we are responsible for training those influencers on the compliant messages they can deliver to consumers about Phexxi. Any actual or perceived non-compliance by our influencers and patient ambassadors with those requirements could lead to an investigation by the FTC or a comparable state agency or could lead to allegations of misleading advertising by private plaintiffs. In addition, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us or our product on any social networking website. If any of these events were to occur or we otherwise fail to comply with any applicable regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business such as reputational damage.

We face competition from other medical device, biotechnology and biopharmaceutical companies and our operating results will suffer if we are unable to compete effectively.

The medical device, biotechnology and biopharmaceutical industries, and the women's health sector, are intensely competitive. Significant competition among various contraceptive products already exists. Existing products have name recognition, are marketed by companies with established commercial infrastructures, and are marketed with greater financial, technical and personnel resources than we have. To compete and gain market share, any new product must demonstrate advantages in efficacy, convenience, tolerability or safety, among other things. In addition, new products developed by others could emerge as competitors to Phexxi. These products could potentially offer an alternative form of non-hormonal contraception that is more convenient, is more effective and/or provides protection over longer periods of time as compared to Phexxi. We also compete with these organizations to recruit management, scientists, and sales and marketing and clinical development personnel. Any failure to attract and retain such personnel could negatively affect our level of expertise and our ability to execute our business plan. We also face competition in connection with identifying and engaging in strategic transactions and, should we choose to advance the clinical development of our product candidates, in establishing clinical trial sites and enrolling subjects for clinical trials and funding those trials. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

Our potential competitors include large, well-established pharmaceutical companies and specialty pharmaceutical companies who have significantly more resources than Evofem. These companies include Merck & Co., Inc., Allergan PLC, Pfizer Inc., Bayer AG, Johnson & Johnson, CooperSurgical Inc. and Mylan Inc. Additionally, several generic manufacturers currently market and continue to introduce new generic contraceptives.

Phexxi and any other approved products may not gain sufficient market acceptance among physicians, patients or the medical community, thereby limiting our potential to generate revenue, which will undermine our future growth prospects.

Even though Phexxi has been approved by the FDA for commercial sale for the prevention of pregnancy, and even if any of our other product candidates are approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any new product by physicians, patients and the medical community will depend on a number of factors, including:

- demonstrated evidence of efficacy and safety and potential advantages compared to competing products;
- perceptions by the medical community, physicians, and patients, regarding the safety and effectiveness of the product and the willingness of the target patient population to try it and of physicians to prescribe it;
- relative convenience and ease of administration compared to other products approved for the same indication;
- the regulatory label requirements for the product, including any potential restrictions on use or precautionary statements;
- sufficient third-party insurance coverage and adequate reimbursement;
- the willingness of wholesalers and pharmacies to stock the products;
- the prevalence and severity of any adverse side effects;
- the ability to sufficiently educate physicians with respect to the product's safety and efficacy; and
- availability of alternative products and the cost-effectiveness of our product relative to competing products.

If any approved product that we may license, develop or sell, including Phexxi, does not provide a benefit over currently available options, that product is unlikely to achieve market acceptance, and we will not generate sufficient revenues to achieve profitability.

The telehealth market is immature and unpredictable, and if it does not develop, if it develops more slowly than we expect, if it encounters negative publicity over privacy issues, if it fails to engage sufficient numbers of providers, or if limitations on reimbursement or new state law regulatory requirements impede our ability to implement our telehealth platform, the growth of our business will be harmed.

We operate a telehealth platform where women can directly meet with HCPs to determine their eligibility for Phexxi and potentially have prescriptions written. The telehealth market is relatively new and unproven, and it is uncertain whether it will achieve and sustain high levels of demand, consumer acceptance and market adoption. Our success will depend to a substantial extent on the willingness of women to use our telehealth platform. Negative publicity concerning our telehealth solution or the telehealth industry as a whole could limit market acceptance of the Phexxi telehealth platform. Additionally, telehealth laws are rapidly changing, especially in light of the COVID-19 pandemic and attendant public health emergency. Many states loosened telehealth restrictions to facilitate remote care, but these changes are typically by executive order and are intended to be temporary for the duration of the public health emergency. There is no guarantee that telehealth will be permitted in the same way in the future. Changes by state professional licensing boards to the standards of care or other requirements

governing the practice of telehealth, including imposition of new requirements for prescriptions from state and federal regulatory bodies, could impact the success of our telehealth solution. Similarly, individual and health care industry concerns or negative publicity regarding patient confidentiality and privacy in the context of telehealth could limit market acceptance of our platform. If any of these events occurs, it could have a material adverse effect on our business, financial condition or results of operations.

The success of Phexxi will depend on the availability of competitive products and women's preferences, in addition to the market's acceptance of our new form contraception.

The commercial success of Phexxi will depend upon the contraceptive market as well as market acceptance of Phexxi as a new form of prevention of pregnancy, a vaginal pH modulator. Risks related to market acceptance include, among other things:

- minimum acceptable contraceptive efficacy rates and the related regulatory label requirements, including any potential restrictions on use or precautionary statements;
- perceived safety differences of hormonal and/or non-hormonal contraceptive options;
- changing women's preferences;
- the effect of the Affordable Care Act (ACA) on pharmaceutical coverage, reimbursement and pricing, and the coverage of preventable services (including contraception under certain conditions); and
- new generic contraceptive options including the possibility of a future potential generic version of Phexxi.

For example, the pregnancy rate for typical use of Phexxi in the FDA-approved label is higher than many other forms of contraceptives, and we cannot be certain that the associated risk of unintended pregnancy will not deter adoption of Phexxi as a method of pregnancy prevention. In addition, Phexxi's label contains a warning related to use by women with a history of recurrent urinary tract infections, which could limit the willingness of HCPs to prescribe or certain women to use Phexxi. These risks could reduce the market potential for Phexxi or any future contraceptive product we may seek to develop, and place pressure on our business, financial condition, results of operations and prospects.

The commercial success of Phexxi and/or any future approved products will depend in significant measure on the label claims that the FDA or other regulatory authorities approve for those products.

The commercial success of Phexxi vaginal gel and/or future approved products, if any, will depend in significant measure upon the prescribing information and the patient-directed labeling describing the product's features, benefits and risks.

We are required to submit all revisions to approved product labeling for Phexxi as part of a supplemental NDA to the FDA for review and approval. In addition, the FDA must review and approve proposed labeling for any of our product candidates as part of the NDA pre-market review process. Failure to achieve approval from the FDA or other regulatory authorities of product labeling containing certain types of information on features or benefits will prevent or substantially limit our advertising and promotion of such features in order to differentiate our product candidates from those products already existing in the market. This failure would have a material adverse impact on our business, financial condition, results of operations and prospects.

The FDA and other regulatory agencies actively enforce laws and regulations prohibiting the promotion of off-label uses for prescription drugs and medical devices. If we are found or alleged to have improperly promoted our commercial product for off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products such as Phexxi. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. Promotional labeling for Phexxi, and for any other of our products that may receive marketing approval, must be submitted to FDA at the time of first use. The agency actively solicits reports from health care professionals about improper drug manufacturer promotional claims or activities. If we are found to have promoted Phexxi for any off-label use, we may become subject to significant liability and potentially reputational harm. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of Phexxi or any of our product candidates, if approved in the future, to ensure compliance with these legal and regulatory requirements, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely affect our business.

Any name we intend to use for our current or future product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of our proposed product names, we may be required to adopt alternative names for our product candidates. If we adopt alternative names, we would lose any goodwill or brand recognition developed for previously used names and marks, as well as the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize the product.

If we suffer negative publicity concerning the safety or efficacy of Phexxi or our product candidates in development, our reputation and the commercialization of Phexxi could be harmed and we may be forced to cease development of such product candidates.

If concerns should arise about the actual or anticipated clinical outcomes regarding the safety or efficacy of any of our current or future product candidates, such concerns could adversely affect the market's perception of these candidates. Such concerns could lead to a decline in investors' expectations, adverse effects on our results of operations and a decline in the price of our common stock.

We rely, and expect to continue to rely, on market research conducted internally and on our behalf to evaluate the potential commercial acceptance of Phexxi for the prevention of pregnancy, and any other future product candidates.

We have contracted with and expect to continue to perform market research and to contract with third parties to perform research on our behalf. These research findings may not be indicative or predictive of actual or overall market acceptance and any future market research may not be indicative of the acceptance for Phexxi for contraception or any future product candidates we may develop. Moreover, our internal and external research that have informed our views with respect to our sales and marketing strategy, payer coverage, pricing and reimbursement with respect to Phexxi may prove to be incorrect. For example, we believe that women that are most likely to use Phexxi as their primary method of preventing pregnancy are those who are unwilling to use hormone-based contraceptives and are unsatisfied with other commercially available non-hormonal alternatives. If our market research has overestimated the size of this population or the willingness of these women to try Phexxi, the commercialization of Phexxi may be less successful than we or others expect.

There can be no assurance on the accuracy or completeness of certain facts, forecasts and other statistics obtained from various government publications, market data providers and other independent third-party sources, including industry expert reports, contained in this Annual Report or other statements we may make from time to time.

Certain facts, forecasts and other statistics contained herein and that we may discuss from time to time have been derived from various government publications, market data providers and other third-party sources. While we have no reason to believe that this information is false or misleading or that any fact has been omitted that would render this information false or misleading, we cannot guarantee the accuracy and completeness of this information. While we have taken reasonable care to ensure that these facts, forecasts and other statistics have been accurately reproduced from their respective sources, these facts, forecasts and other statistics have not been independently verified by us, our directors, advisers or any other parties and none of us make any representation as to the accuracy or completeness of such information. Due to possibly flawed or ineffective collection methods or discrepancies between published information and market practice and other problems, the facts, forecasts and statistics contained herein may be inaccurate or may not be comparable to information produced by other parties. Therefore, you should give consideration as to how much weight or importance you should attach to or place on these facts, forecasts or statistics and in all cases, but particularly with respect to market size, this information should not be unduly relied upon.

The proportion of the contraceptive market that is made up of generic products continues to increase, making the introduction of a branded contraceptive difficult and expensive.

The proportion of the U.S. market that is made up of generic products has been increasing over time. This trend is occurring in the women's health segment as well, where many of the most popular oral contraceptive pills brands have experienced genericization. Assuming this trend continues, it may be more challenging to introduce Phexxi, or any future approved contraceptive product candidate we may develop as a branded contraceptive, at a price that will maximize our revenue and profits. Also, there may be additional marketing costs to introduce Phexxi in order to overcome the trend towards generics and to gain access to reimbursement by payers. If we are unable to introduce any future approved product candidate at a price that is commensurate with that of current branded products, or if we are unable to gain reimbursement from payers for Phexxi, or if patients are unwilling to pay any price differential between Phexxi and a generic contraceptive product, our revenues will

be limited. We are currently covering the cost of Phexxi for the first month for women with commercial insurance whose health plans do not reimburse for Phexxi or whose health plans require a co-pay for Phexxi, and we are covering the cost of subsequent refills of Phexxi at a $25 co-pay for these women if their co-pay is above that amount with a cap of $650 annual benefit to each patient. However, we cannot be certain that these initiatives will be successful in overcoming general inclinations of physicians and their patients to avoid branded contraceptives and these initiatives may become prohibitively expensive. If we choose to curtail our co-pay programs, demand for Phexxi may decrease. In addition, if health care plans do not add Phexxi to their covered formularies within the timelines we expect or impose more restrictive co-pay than we expect, our costs of providing these incentive programs will increase beyond our expectations and reduce our product margins and net revenues from sales of Phexxi.

Our business has been adversely affected and could continue to be materially and adversely affected in the future by the ongoing COVID-19 pandemic.

Any outbreak or pandemic of a contagious disease, such as COVID-19 and its variants, or other adverse public health developments, could have a material and adverse effect on our operations, results of operations and financial condition. The COVID-19 pandemic led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures, as well as adverse impacts on health care resources, facilities and providers, in California, across the United States and in other countries. A number of health care systems have had to restructure operations to prioritize caring for COVID-19 patients and limit or cease other activities. The severe burden on health care systems caused by this pandemic has impaired the ability of physicians to diagnose and treat patients with non-COVID-19 related conditions, including routine women's health visits, and impaired the ability of many clinical research sites to continue existing studies, start new studies, enroll new patients and monitor patients in clinical trials. The COVID-19 pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses, commerce and commercial spending, as significant reductions in business related activities have occurred, unemployment has risen, supply chains have been disrupted, and certain manufacturing and clinical development activities have been curtailed or suspended. The continued impact of COVID-19 on our operations or those of our third-party partners and suppliers will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the ultimate duration of the pandemic, additional or modified government actions, the success of ongoing vaccination efforts, the emergence, prevalence and strength of variant strains, actions taken to contain or treat the disease as well as the continued impact on local, regional, national and international markets, among others.

Our business has been adversely affected by the COVID-19 pandemic. In response to the pandemic and in accordance with direction from state and local government authorities, we took precautionary measures in 2020 and 2021 intended to help minimize the risk of the virus to our employees, including temporarily requiring most employees to work remotely (which in turn increases the threat to our cyber security and data accessibility, and communication matters) and suspending all non-essential travel worldwide for our employees. We are heavily reliant on our employees to perform the day to day operation of our business, and to the extent multiple employees are unavailable at the same time due to an outbreak or to personal illness, our ability to complete these day to day operations may be impaired. Further, the COVID-19 pandemic has already affected and will likely continue to affect our commercialization activities for Phexxi. For example, in light of the COVID-19 pandemic, particularly the restrictions on physician interactions, we made the strategic decision to delay the commercial launch of Phexxi from June 2020 to September 2020. In light of the COVID-19 pandemic, we also made the decision to reduce our target initial internal sales force and rely more on telehealth for marketing, including the Phexxi telehealth platform. Nevertheless, the restrictions on in person contact have limited the ability of our sales representatives to meet with HCPs in person and have also significantly reduced the number of visits by patients to physician offices. These factors may continue to slow the rate of adoption of Phexxi. The public health response to the COVID-19 pandemic included universal recommendations for social distancing, individual and household quarantines, and clinic visits for health emergencies only. With respect to our clinical development efforts, the completion of enrollment in our Phase 3 *EVOGUARD* clinical trial evaluating EVO100 for the prevention of chlamydia and gonorrhea in women was delayed due in part due to challenges related to COVID-19 and the Omicron variant. We also believe changes in clinical site operations, subject behavior and actions including deviations from following the clinical study protocol requirements related to STI acquisition, detection, and prevention contributed to the outcome of *EVOGUARD*, which did not achieve its endpoints. As and if COVID-19 and its variants continue to affect individuals, businesses and industries, economies and markets around the globe, we and our third party partners and suppliers may experience further effects on our business and results of operations stemming directly or indirectly from the pandemic, some of which could severely impact our business, results of operations and financial condition.

Risks Related to the Development of Our Product Candidates

Our inability to develop our vaginal pH modulator for additional indications could have an adverse effect on our business and our ability to successfully market Phexxi for the prevention of pregnancy.

We believe our vaginal pH modulator gel may be useful in certain indications outside of the prevention of pregnancy. In August 2019, we completed the Phase 2B/3 *AMPREVENCE* clinical trial to evaluate EVO100 for the prevention of

urogenital chlamydia in women and for the prevention of urogenital gonorrhea in women. *AMPREVENCE* results demonstrated that the trial met both its primary and secondary endpoints, with women receiving EVO100 experiencing a relative risk reduction for chlamydia and gonorrhea infection of 50% and 78%, respectively, compared to women receiving placebo.

On October 11, 2022 we announced that the completed Phase 3 *EVOGUARD* clinical trial evaluating EVO100 for the prevention of chlamydia and gonorrhea did not achieve its endpoints. As a result of this outcome, together with limited financial resources, we discontinued further investment this clinical program. This trial failure could impede our ability to market Phexxi for the prevention of pregnancy. Lastly, if we do not obtain regulatory approvals for additional indications for Phexxi, there will likely be a material adverse effect on our business, results of operations or our financial condition.

Indemnity claims from lawsuits or damages against our clinical trial sites could cause us to incur substantial liabilities and to limit commercialization of Phexxi and any other product candidates we may develop.

In connection with our clinical trials, our third-party investigators and clinical trial sites face inherent risk of liability exposure from patients enrolled in our clinical trials. We have entered into indemnification agreements with each of our clinical trial sites obligating us to defend the sites against third-party claims or reimburse the sites should they incur certain costs or liability in connection with our clinical trials.

We currently carry product liability insurance with policy limits we believe are customary for similarly situated companies and adequate to provide us with coverage for foreseeable risks. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or is in excess of the limits of our insurance coverage.

If we or our clinical trial sites cannot successfully defend against product liability or other health related claims, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims and/or litigation may result in decreased demand for Phexxi and any other product candidates we may develop, injury to our reputation, negative media attention and the diversion of our management's time and attention from our product development and commercialization efforts to address claim related matters.

The success of our business is also expected to depend in part upon our ability to identify, license, discover, develop or commercialize additional product candidates. Failure to identify additional product candidates would have a negative impact on our business and operations.

Although a substantial amount of our effort will focus on the commercialization of Phexxi for the prevention of pregnancy, the success of our business is also expected to depend in part upon our ability to identify, license, discover, develop or commercialize additional product candidates. We are seeking to license, or otherwise obtain, product and technology rights to a variety of products and product candidates in the field of women's health, but there can be no assurance we will be able to do so, or do so on favorable terms. There are risks, uncertainties and costs associated with identifying, licensing and advancing product candidates through successful clinical development. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development and commercialization for a number of reasons, including but not limited to the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our clinical development program such that a product may become unreasonable to continue to develop;
- research and development programs are quite costly, and we may be unable to obtain the financing and resources to initiate, conduct or complete them;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and,

- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payers.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license, partner, discover, develop or commercialize additional product candidates, which could have a material adverse effect on our business, financial condition or results of operations. Moreover, even if we were able to obtain the rights to additional product candidates, there can be no assurance these candidates will ever be advanced successfully through clinical development.

Clinical trials are costly, time consuming and inherently risky, and may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Clinical development is expensive, time consuming and involves significant risk. We cannot guarantee any clinical trials will be conducted as planned or completed on schedule, if at all. In addition, certain of our product candidates have been targeted toward the prevention of STIs. It may be especially difficult to recruit patients to participate in our clinical trials when doing so may require patients to refrain from using other methods of infection prevention. A failure of one or more clinical trials can occur at any stage of development. Events that may prevent successful or timely completion of clinical development include, but are not limited to:

- inability to obtain the funding necessary to initiate or complete any clinical trial;
- inability to generate satisfactory preclinical, toxicology or other *in vivo* or *in vitro* data or to develop diagnostics capable of supporting the initiation or continuation of clinical trials;
- delays in reaching agreement on acceptable terms with clinical research organizations (CROs) and clinical trial sites and principal investigators, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays or failure in obtaining required institutional review board (IRB) approval at each clinical trial site;
- failure to obtain or delays in obtaining authorization from regulatory authorities to conduct or begin a clinical trial;
- delays in recruiting or failure to recruit sufficient eligible patients in our clinical trials;
- failure to manufacture clinical trial scale quantities of our product candidate;
- failure by clinical sites, CROs or other third parties to adhere to clinical trial requirements or protocols;
- failure by clinical sites, CROs or other third parties to perform in accordance with the good clinical practices requirements of the FDA, applicable laws or applicable foreign regulatory requirements;
- patients withdrawing from our clinical trials;
- adverse events or other issues of concern significant enough for an IRB to suspend or terminate a clinical trial or for the FDA, or comparable foreign regulatory authority, to put an IND or comparable foreign clinical trial application on clinical hold;
- occurrence of adverse events associated with our product candidates that may make it more difficult to recruit subjects or cause other material delays in the clinical programs;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical trials of our product candidates;
- negative or inconclusive results from our clinical trials that may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development programs in other ongoing or planned indications for a product candidate; and
- delays in reaching agreement on acceptable terms with third-party manufacturers and the time for manufacture of sufficient quantities of our product candidates for use in clinical trials.

In addition to the possible events described above, our clinical trials may also be impacted by matters beyond our control. For example, conditions and circumstances surrounding the ongoing COVID-19 pandemic delayed enrollment in our Phase 3 *EVOGUARD* trial and may, in future, again make it difficult for us and our third-party service providers to recruit, enroll, retain and monitor patients in these trials, disrupt the necessary logistic and manufacturing activities related to our clinical trials, require us to adjust our trial protocols, lead to a failure to collect in a timely manner key data necessary to support trial endpoints or otherwise compromise our ability to collect reliable data, result in delays in related communications and activities with the FDA or other comparable regulatory organizations and may affect our clinical trials in ways we may not presently predict.

Any inability to successfully complete clinical development and obtain regulatory approval for one or more of our product candidates could result in additional costs to us or impair our ability to generate revenue. In addition, if we make

manufacturing or formulation changes to our product candidates, we may need to conduct additional non-clinical studies and/or clinical trials to show the results obtained from such new formulation or manufacturing process are consistent with previous results obtained. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow competitors to develop and bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Due in part to our limited financial resources, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our product candidates and we may be unable to pursue and complete the clinical trials we would like to pursue and complete.

We have limited financial and technical resources to determine the indications on which we should focus the development efforts for our product candidates and any future candidates we may choose to develop. Due to our limited available financial resources, we may be required to curtail clinical development programs and activities that might otherwise have led to more rapid progress of our product candidates, or product candidates we may in the future choose to develop, through the regulatory and development processes. We may make incorrect determinations regarding the indications and clinical trials on which to focus our available resources. The decisions to allocate our research, management and financial resources towards particular indications may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate development programs may also cause us to miss valuable opportunities.

Risks Related to Regulatory Approval of Our Product Candidates

We are required to obtain regulatory approval prior to marketing or commercializing any of our product candidates and we also must obtain regulatory approval from international authorities should we elect to commercialize Phexxi outside of the United States. To obtain regulatory approval, we must complete our preclinical studies and clinical trials in compliance with the regulatory approval requirements of the FDA and any applicable and comparable foreign regulators. If our clinical trials fail to satisfactorily demonstrate the safety and efficacy of our product candidates to the FDA and other comparable foreign regulators, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

With the exception of Phexxi vaginal gel for the prevention of pregnancy, which has been approved by the FDA for U.S. marketing and patient use, we are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Comparable foreign regulatory authorities impose similar restrictions, and we do not have marketing approval for Phexxi in any country outside of the United States except Nigeria, where it is approved and may potentially be launched as Femidence. We may never receive such approvals, and we may need to complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of our product candidates in other populations before we may be able to obtain these approvals.

Any inability to complete preclinical and clinical development successfully could result in additional costs to us and impair our ability to generate revenues. Moreover, if (i) we are required to conduct additional clinical trials or other nonclinical testing of our product candidates beyond the trials and testing we currently contemplate, (ii) we are unable to successfully complete clinical trials of our product candidates or other testing, (iii) the results of these clinical trials or tests are unfavorable, uncertain or are only modestly favorable or (iv) there are unacceptable safety concerns associated with our product candidates, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements; or
- be required to remove the product from the market after obtaining marketing approval.

Even if we complete the necessary clinical trials for our product candidates, the marketing approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the commercialization of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required marketing approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

To date, we have not received approval from the FDA or regulatory authorities in other jurisdictions to market any of our product candidates, with the exception of Phexxi vaginal gel, which is approved by FDA for the prevention of pregnancy and, as Femidence, by the National Agency for Food and Drug Administration and Control of Nigeria. Despite the experience of our management team in completing successful regulatory filings for other companies, we have only submitted one NDA to

date for Phexxi as a contraceptive product and four regulatory submissions to foreign regulatory authorities, so we have limited experience in filing and supporting the applications necessary to obtain marketing approvals for our product candidates. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication in the relevant patient population to establish the product candidate's safety and effectiveness for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Regulatory authorities may determine that our unapproved product candidates or any potential future product candidate is not effective, is only moderately effective or has undesirable or unintended side effects, toxicities, safety profiles or other characteristics that preclude us from obtaining marketing approval for the product or that limit or restrict its commercial use.

The process of obtaining marketing approvals is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical studies, clinical trials or other trials. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Currently, we are listed on the FDA's list of companies in arrears for non-payment of its annual fees under PDUFA and as such, any drug application or supplement submitted by us will be considered incomplete and will not be accepted for consideration until all fees due and payable are paid.

From time to time, we may report top-line data from our clinical trials. These top-line data may differ from complete trial results once additional data are received and evaluated by the FDA or comparable foreign regulatory authorities.

Top-line data are based on a preliminary analysis of currently available efficacy and safety data, and therefore these results are subject to change, either by us or the FDA (or comparable foreign regulatory authorities), following a comprehensive review of the more extensive data we expect to receive when the full data set becomes available. Top-line data are based on important assumptions, estimations, calculations and information currently available to us. As a result, the top-line results may differ from the full data, or different conclusions or considerations may qualify these top-line results, once the complete data have been received and fully evaluated. If these initial data analyses differ from the results of the full data analyses, in a manner not favorable to the development of our product candidates, our business, financial condition, results of operations, prospects and, ultimately, the value of our common stock could be adversely affected.

Even though we have received approval from the FDA in the United States to market Phexxi for the prevention of pregnancy, and, as Femidence, by the National Agency for Food and Drug Administration and Control of Nigeria, we may fail to receive similar approval in other territories outside the United States.

To market a new product outside the United States, we must obtain separate marketing approvals in each jurisdiction and comply with numerous and varying regulatory requirements of other countries, including clinical trials, commercial sales, pricing manufacture distribution and safety requirements. The time required to obtain approval in other countries might differ from, and be longer than, that required to obtain FDA approval. The marketing approval process in other countries may include all the risks associated with obtaining FDA approval in the United States, as well as other risks. In addition, in many countries outside the United States, a new product must receive pricing and reimbursement approval prior to commercialization. This can result in substantial delays in these countries. Additionally, the product labeling requirements outside the United States are different and may be inconsistent with the United States labeling requirements, negatively affecting our ability to market our products in countries outside the United States.

In addition, if we are unable to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of marketing approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. In such an event, our ability to market to our full target market will be reduced and our ability to realize the full market potential of Phexxi will be harmed, which could have a materially adverse effect on our business, financial condition, results of operations and prospects.

The discontinuation of further investment in the development of Phexxi as a preventative of chlamydia and gonorrhea infection in women could have a material adverse effect on our ability to generate additional revenues.

The ability to market the additional use of Phexxi as a preventative measure for chlamydia and gonorrhea infection in women would have given us the ability to increase our revenues and thus profits from sales for that purpose. After the Phase 3 *EVOGUARD* clinical trial did not achieve its endpoints, and due to a lack of financial resources, we discontinued further investment in this program. This change may have a negative effect on our stock price and our financial condition overall.

If we are unable to take full advantage of regulatory programs designed to expedite drug development or provide other incentives, our development programs may be adversely impacted.

There are a number of incentive programs administered by the FDA and other regulatory bodies to facilitate development of drugs in areas of unmet medical need. Phexxi may not qualify for or maintain designations under these or other incentive programs under any of the FDA's existing or future programs to expedite drug development in areas of unmet medical need. Our inability to fully take advantage of these incentive programs may require us to run larger trials, incur delays, lose opportunities that may not otherwise be available to us, lose marketing exclusivity for which we would otherwise be eligible and incur greater expense in the development of our product candidates.

We have not paid our Fiscal Year 2023 PDUFA Invoice to the FDA and cannot submit any application or supplements to the FDA, and the amount payable continues to accrue interest and penalties.

We have not paid our Fiscal Year 2023 PDUFA Invoice for Phexxi to the FDA in the amount of $0.4 million with an original due date of November 7, 2022, and grace period through December 6, 2022. Beyond this date, interest and penalties have begun to be applied retroactively to the original due date of October 7, 2022. The most recent reminder payment correspondence from the FDA was received on March 17, 2023, and states that we are currently on the arrears list. As a result, any drug application or supplement we submit will be considered incomplete and will not be accepted for consideration for filing until all fees, interest and penalties are paid.

Risks Related to Our Post-Marketing Legal and Regulatory Compliance

Even though we have obtained FDA approval for Phexxi for prevention of pregnancy, we will remain subject to ongoing regulatory requirements.

Even though Phexxi vaginal gel has been approved by the FDA for the prevention of pregnancy we are and will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing clinical trials and submission of safety, efficacy and other post-approval information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

In addition, manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring quality control and manufacturing procedures conform to cGMP regulations and corresponding foreign regulatory manufacturing requirements. Accordingly, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA submission to the FDA or any other type of domestic or foreign MAA.

Any regulatory approvals we receive for Phexxi, or for any other product candidates we may seek to develop, may be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance.

If a regulatory agency discovers previously unknown problems with Phexxi or a future product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or it disagrees with the promotion, marketing or labeling of a product, the regulatory agency may impose restrictions on that product or on us, including requiring withdrawal of the product from the market. If we are unable to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;

- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- require a product recall.

Any government investigation of alleged violations of law would require us to expend significant time and resources in response and could generate adverse publicity. Any inability to comply with ongoing regulatory requirements may significantly and adversely affect our ability to develop and commercialize our products and the value of our business and our operating results would be adversely affected.

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

Even though Phexxi has been approved in the United States for the prevention of pregnancy and even assuming any of our other product candidates were to be approved, certain developments may decrease market demand for our products, including the following:

- the re-review of products that are already marketed;
- new scientific information and evolution of scientific theories;
- the recall or loss of marketing approval of products that are already marketed;
- changing government standards or public expectations regarding safety, efficacy or labeling changes; and
- greater examination of advertising and promotion.

In the past, clinical trials and post-marketing surveillance of certain marketed drugs have raised concerns that have led to recalls, withdrawals or addition of restrictive labeling of marketed products. If previously unknown side effects are discovered with one of the active ingredients in, or if there is an increase in negative publicity regarding known side effects related to Phexxi or any of our product candidates following marketing approval, this could significantly reduce demand for the product or require us to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of Phexxi for the prevention of pregnancy. If we are unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage, a material liability claim could adversely affect our financial condition.

We face an inherent risk of product liability exposure in commercializing Phexxi for the prevention of pregnancy and other product candidates we may seek to develop or commercialize. If serious adverse events or undesirable side effects occur during or following the commercialization of Phexxi, or during the clinical investigation or post marketing of Phexxi or our other product candidates, the following events could occur which would materially and adversely affect our business:

- regulatory authorities may require the addition of specific warnings or contraindications to product labeling or the issuance of alerts to physicians, pharmacies and the general public;
- we may be required to change the way Phexxi or our other product candidates are administered or to revise the labeling of Phexxi or our other product candidates;
- we may be subject to promotional and marketing limitations on Phexxi and our product candidates;
- sales of Phexxi and our other approved products, if any, may decrease significantly;
- regulatory authorities may require us to take Phexxi or, should any of our other product candidates be approved, our other approved products off the market;
- IRBs may suspend or terminate our clinical trials;
- regulatory authorities may impose a clinical hold, which could result in substantial delays and adversely impact our ability to continue development of our product candidates;
- we may be required to conduct additional clinical trials with more patients or over longer periods of time than anticipated;
- we may be required to implement risk evaluation and mitigation strategies (REMS), which could result in substantial cost increases and have a negative impact on our ability to commercialize Phexxi or our other approved products, if any;
- we may be required to limit the patients who can receive Phexxi or our product candidates;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of Phexxi or our other product candidates, or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from Phexxi or our other product candidates. Serious adverse events or side effects could require Phexxi to be taken off the market, may require them to be packaged with safety warnings or may otherwise limit our sales.

Further, if we cannot successfully defend ourselves against these product liability claims, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in decreased demand for Phexxi or other product candidates we may seek to develop, injury to our reputation, negative media attention and the diversion of our management's time and attention from our product development and commercialization efforts to address claim related matters.

We will need to maintain liability insurance coverage as we continue to commercialize Phexxi and conduct clinical trials for our product candidates. This insurance may become increasingly expensive and difficult to procure. In the future, this insurance may not be available to us at all or may only be available at a very high cost and, if available, may not be adequate to cover all liabilities we may incur. In addition, while we have increased our liability insurance coverage in connection with the commercialization of Phexxi, we cannot be certain our coverage limits will be sufficient to cover liability claims we may face. We will also need to increase liability coverage if any other product candidate we may seek to develop is approved. If we are not able to obtain and maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise, our business could be harmed, possibly materially.

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

Our research and development activities and our third-party manufacturer's and suppliers' activities may involve the controlled storage, use, and disposal of hazardous materials. We and our manufacturer and supplier, and our potential future manufacturers and suppliers, are and will be subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use may be stored at our and our current and potential future manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations; environmental damage resulting in costly clean-up; and liabilities under applicable laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe the safety procedures utilized by us and our current third-party manufacturers for handling and disposing of materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of specified materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

Risks Related to Our Intellectual Property

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

We are reliant upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the commercialization of Phexxi. For example, the Rush License Agreement includes intellectual property rights to Phexxi. This agreement requires us, as a condition to the maintenance of our license and other rights, to make milestone and royalty payments and satisfy certain performance obligations. As of December 22, 2022, we are current on all such obligations, financial and otherwise, and, pursuant to the Rush License Agreement, we have obtained a waiver of any potential claim of breach based on any provisions requiring us to timely exploit the licensed patent or make minimum royalty payments.

In addition, with respect to Phexxi, Rush University has the right, in certain instances, to control the defense against any infringement litigation arising from the manufacture or development (but not the sale) of Phexxi. While the Rush License Agreement requires Rush University to indemnify us for certain losses arising from these claims, this indemnification may not be sufficient to adequately compensate us for any related losses or the potential loss of our ability to manufacture and develop Phexxi. In general, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and

prospects. Moreover, if disputes over intellectual property we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidate, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

If we are unable to obtain and maintain patent protection for Phexxi for the prevention of pregnancy, or other proprietary technologies we may develop, or if the scope of the patent protection we have or will obtain is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to our products and technology, and our ability to successfully commercialize our product candidates, and other proprietary technologies we may develop may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our products, product candidates and other proprietary technologies we may develop. We seek to protect our proprietary position by in-licensing intellectual property and filing patent applications in the United States and abroad relating to Phexxi and other proprietary technologies we may develop. If we or our licensors are unable to obtain or maintain patent protection with respect to Phexxi and other proprietary technologies we may develop, our business, financial condition, results of operations, and prospects could be materially harmed.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties. Our pending and issued patent claims for Phexxi are not broad, and it is possible that a competitor may seek to make modifications to their product in an effort to design around our patent claims and avoid infringement. Furthermore, if any such competitor or third party is able to demonstrate bioequivalence without infringing our patents, then such a competitor or third party would then be able to introduce a competitive generic product onto the market once any available regulatory exclusivity has expired. The FDA has broad discretion in determining whether a potential competitive product demonstrates bioequivalence; we are not able to predict the extent to which a competitor or third party might be able to demonstrate bioequivalence without infringing our patents.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible we will be unsuccessful in our efforts to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

The patent position of biotechnology and biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our owned or in-licensed pending and future patent applications may not result in patents being issued which protect Phexxi and other product candidates or proprietary technologies that we may seek to develop or which effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents we own or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether Phexxi and

other proprietary technology will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We or our licensors may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings or other similar proceedings challenging our owned or licensed patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our owned or in-licensed patent rights, allow third parties to commercialize generic versions of our products, product candidates and other proprietary technologies we may develop and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our licensor's priority of invention or other features of patentability with respect to our owned or in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates and other proprietary technologies we may develop. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

In addition, given the amount of time required for the commercialization, development, testing, and regulatory review of our products and product candidates, patents protecting such products and product candidates might expire before or shortly after such products or product candidates are fully commercialized. The patent rights licensed to us under the Rush University License expire in 2023. If we are unable to obtain extensions of the patent rights, these patent rights will no longer protect Phexxi, and we will be relying solely on our directly owned patent formulas and patent application families for patent protection for Phexxi. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned and in-licensed patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, and defending patents on our products, product candidates and other proprietary technologies we may develop in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technology in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, some jurisdictions, such as Europe, Japan, and China, may have a higher standard for patentability than in the United States, including for example the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in United States and other jurisdictions.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any,

may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-United States government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the America Invents Act) enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we do could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to Phexxi and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in

unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

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

If we or one of our licensors initiated legal proceedings against a third party to enforce a patent covering Phexxi or other proprietary technologies we may develop, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of our owned or in-licensed patents before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover Phexxi and other proprietary technologies we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates and other proprietary technologies we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

If we do not obtain a Patent Term Extension (PTE) for our products or product candidates, our business may be materially harmed.

One or more of our owned or in-licensed U.S. patents covers Phexxi for the prevention of pregnancy, and depending upon the timing, duration and specifics of any FDA marketing approval of any other product candidate we may develop, our patents may be eligible for limited PTE under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a PTE of up to 5 years as compensation for patent term lost during the FDA regulatory review process. A PTE cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate (SPC). Further, if the FDA determines that the Phexxi does not represent the first permitted commercial marketing or use of the product, or the active ingredients, we may fail to satisfy applicable requirements which could materially harm us and our operations.

In 2020, Rush University submitted a PTE application for the U.S. patent which we licensed from them, requesting a five-year PTE to 2026. Two Orders Granting Interim Extension (OGIEs) were received from the USPTO, extending the expiration of this patent to 2023. A third request for interim patent term extension was filed on December 7, 2022. If granted, the expiration of this patent would be extended to 2024. However, we may not be granted a full five-year PTE for this patent or any similar extension outside the United States, such as SPC for the European patents, because of, for example, our inability to exercise due diligence during the testing phase or regulatory review process, our inability to apply within applicable deadlines, our inability to apply prior to expiration of relevant patents, or if we are otherwise unable to satisfy applicable requirements. Moreover, the applicable time or the scope of patent protection afforded could be less than our or Rush University's request. If we or Rush University are unable to obtain PTE, or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

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

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our products and product candidates, there may be times, such as with respect to our agreement with Rush University, when the filing and prosecution activities for patents relating to our products or product candidates are controlled by our licensors or collaboration partners. If any of our current or future licensing or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our products or product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize Phexxi for the prevention of pregnancy may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to

and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

If an event of default continues and remains uncured under our issued and outstanding secured convertible notes issued pursuant to the Baker Bros. Purchase Agreement, the note holders could take possession of all assets owned by us, including any directly owned intellectual property.

On March 7, 2023, Baker Bros. Advisors, LP (the Designated Agent) provided a Notice of Event of Default and Reservation of Rights (the Notice of Default) relating to the Securities Purchase and Security Agreement dated April 23, 2020, and subsequently amended (SPA), by and among Evofem, Designated Agent, the Guarantors and Baker Purchasers. The Notice of Default claims that the Company has failed to maintain the "Required Reserve Amount" as required by Section 2.7 of the Third Amendment to the Securities Purchase Agreement and Section 8.1(e) of the SPA. The Designated Agent claims such failure constitutes an immediate Event of Default pursuant to Section 9.1(e) of the SPA. The Designated Agent, at the direction of the Baker Purchasers, has accelerated repayment of the outstanding balance payable and elected its remedies pursuant to Section 5.07(b) of the Securities Purchase Agreement. As a result, approximately $92.8 million, representing two times the sum of the outstanding balance and all accrued and unpaid interest thereon and all other amounts due under the SPA and other documents, is due and payable within three business days of receipt of the Notice of Default. We disagree with the Designated Agent's claims and have invited the Designated Agent to reconsider and rescinded its Notice of Default and request for payment, for which no formal request for payment has yet been made. Given our current inability to pay any amounts due under the Baker Bros. Purchase Agreement or under the convertible notes, the designated agent of these note holders has the right to take possession of all of our assets and/or pursue any available legal remedies against us.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our products or product candidates and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensor's ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products, product candidates and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking and maintaining patents for Phexxi and other proprietary technologies we may develop, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. With respect to Phexxi, we consider trade secrets and know-how to be one of our important sources of intellectual property. Trade secrets and know-how can be difficult to protect. In particular, our trade secrets and know-how in connection with Phexxi and other proprietary technology we may develop over time may be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel with scientific positions in academic and industry.

We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing our

products and product candidates. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, it may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to a product candidate and other proprietary technologies we may develop. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have no knowledge of any claims against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. To date, none of our employees have been subject to such claim.

We may be at risk that our former employees may wrongfully use or disclose our trade secrets.

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants, and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee, former employee, consultant, former consultant or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

We may not be successful in obtaining necessary rights to any product candidate we may develop through acquisitions and in-licenses.

We currently have rights to intellectual property covering Phexxi. Other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. To avoid infringing these third-party patents, we may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders. However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for Phexxi and other proprietary technologies we may develop. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow it to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development or commercialization of the relevant program, product or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable

intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that it regards as its own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Third-party claims of intellectual property infringement, induced intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the development and commercialization of our products, product candidates and other proprietary technologies we may develop.

The contraceptive market is competitive and dynamic. Due to the significant research and development activities that are taking place by several companies in this field, including us and our competitors, the intellectual property landscape is in flux, and it may remain uncertain in the future. There may be significant intellectual property related litigation and proceedings relating to our owned and in-licensed and other third-party intellectual property and proprietary rights in the future.

Our commercial success depends in part on our and our collaborators' ability to avoid infringing, inducing infringement, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and biopharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we intend to commercialize Phexxi and in which we are developing other proprietary technologies. As the biotechnology and biopharmaceutical industries expand and more patents are issued, the risk increases that our product candidate may give rise to claims of infringement of the patent rights of others. We cannot assure you that Phexxi and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are commercializing or developing our products or product candidates, might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our products, product candidates and other proprietary technologies we may develop, could be found to be infringed by our products or product candidate. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our products or product candidate may infringe.

Third parties may currently have patents or obtain patents in the future and may claim that use of our technology or the manufacture, use or sale of our product candidates infringes upon these patents. In the event a third party claims we infringed their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our technology, products or product candidates. In this case, the holders of such patents may be able to block our ability to commercialize the applicable product candidate or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our products, product candidates or technology or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing our infringing products or technology. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technology, which may be impossible or require substantial time and monetary expenditure. In that event,

we would be unable to further develop and commercialize our product, product candidates or technology, which could harm our business significantly. Further, we cannot predict whether any required license would be available at all or whether we would be available on commercially reasonable terms. In the event we could not obtain a license, we may be unable to further develop our product, product candidates and commercialize our product and product candidates, if approved, which could harm our business significantly. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations such as the commercialization of Phexxi, if, as a result of actual or threatened patent infringement claims, we are unable to enter licenses on acceptable terms.

Engaging in litigation defending us against third parties alleging infringement of patent and other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

In the ordinary course, we have been and again may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming, and unsuccessful.

Competitors or other third parties may infringe our patents or the patents of our licensing partners. We have and may again be required to defend against claims of infringement or otherwise engage in legal action to protect our intellectual property. Any commercial success we may achieve with Phexxi for the prevention of pregnancy may incentivize third parties to challenge or infringe our intellectual property. In addition, our patents or the patents of our licensing partners also may become involved in inventorship, priority or validity disputes. To counter or defend against these claims is expensive and time consuming. In an infringement proceeding, a court may decide a patent owned or in-licensed by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds our owned and in-licensed patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. These litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Some intellectual property that we have 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 our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Intellectual property rights we have licensed or may in the future license are generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current product or our current or future product candidates pursuant to the Bayh-Dole Act of 1980 (Bayh-Dole Act) and implementing regulations. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us or our licensors to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. These time limits have recently been changed by regulation, and may change in the future. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that

any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names have in the ordinary course of our business been challenged and may again be challenged by third parties. These trademarks and trade names may also be infringed, circumvented or may not be registered with the USPTO or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we have proposed to use with our product or product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, we may be subject to potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names or that allege we have infringed on their trademarks and trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights or to defend ourselves in suits related to our trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our products or product candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technology without infringing our owned or licensed intellectual property rights;
- it is possible that our current or future pending owned or licensed patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and

- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Our Reliance on Third Parties

Our 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 our business and our ability to develop and market our products or product candidates, and our business could be substantially harmed.

We have a small number of employees and no internal manufacturing capability. Our management does not expect to manufacture any products and expects to rely solely on third parties to manufacture our products, including our FDA-approved commercial product Phexxi, and as such we will be subject to inherent uncertainties related to product safety, availability and security. We currently have only one contract manufacturer for drug product, DPT Laboratories, Ltd. (DPT), with whom we entered into a supply and manufacturing agreement in November 2019 (the "Manufacturing Agreement"). Pursuant to the Manufacturing Agreement, subject only to a supply failure, we are obligated to purchase all of our requirements with respect to Phexxi from DPT. We expect to rely on DPT to increase the manufacturing of Phexxi in amounts needed to support commercialization. If DPT does not perform as agreed or is unable to increase manufacturing of Phexxi as needed to support commercialization, including as a result of being adversely affected by COVID-19, or terminates our agreement, we will be required to replace them as our manufacturer, and we may be unable to do so on a timely basis, on similar terms or at all. Furthermore, we have only a single source of supply for some of the key raw materials and components of Phexxi, and while we believe we would be able to obtain supplies through alternative sources if needed, alternate sources of supply may not be readily available and alternate sources of supply may also be affected by COVID-19.

Moreover, we do not control the manufacturing processes for the production of Phexxi, which must be made in accordance with relevant regulations including, among other things, quality control, quality assurance, compliance with cGMP and the maintenance of records and documentation. In the future, it is possible that our suppliers or manufacturers may fail to comply with FDA regulations, the requirements of other regulatory bodies or our own requirements, any of which would result in suspension or prevention of commercialization and/or manufacturing of our products or product candidates, including Phexxi; suspension of ongoing research; disqualification of data or other enforcement actions such as product recall, injunctions, civil penalties or criminal prosecutions against us. Furthermore, we may be unable to replace any supplier or manufacturer with an alternate supplier or manufacturer on a commercially reasonable or timely basis, or at all.

If we were to experience an unexpected loss of supply of, or if any supplier or manufacturer were unable to meet our demand for Phexxi or our product candidates, we could experience delays in research, planned clinical trials and/or commercialization. We might be unable to find alternative suppliers or manufacturers with FDA approval, of acceptable quality, and that are able to supply products/ingredients in the appropriate volumes and at an acceptable cost. The long transition periods necessary to switch manufacturers and suppliers would significantly delay our timelines, including our commercialization timeline, which would materially adversely affect our business, financial conditions, results of operations and prospects.

In addition, our reliance on DPT, and potential future third-party manufacturers, exposes us to the following additional risks:

- we may be unable to identify other manufacturers on acceptable terms or at all;
- our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- DPT and potential future third-party manufacturers may not be able to execute our manufacturing procedures appropriately;
- our future third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;
- manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding state agencies to ensure strict compliance with cGMPs and other government regulations and corresponding foreign standards, and we do not have control over third-party manufacturers' compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product or product candidates; and,

- our third-party manufacturers could breach or terminate their agreements with us.

Each of these risks could impact the continued availability of Phexxi or could result in higher costs or deprive us of potential product revenue and, should we resume research and development activities, could delay our clinical trials, the approval of our product candidates by the FDA or the commercialization of our product candidates. In addition, we rely on third parties to perform release testing on our products and product candidates prior to delivery to patients. If these tests are not appropriately conducted and test data are not reliable, patients could be put at risk of serious harm, which could result in product liability suits.

The manufacture of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, timely availability of raw materials, lot consistency, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product or product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period to investigate and remedy the contamination. We cannot be assured that any stability or other issues relating to the manufacture of our products or product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidates to patients in clinical trials would be jeopardized and our ability to distribute any approved products would be harmed. Any delay or interruption in the supply of clinical trial supplies, could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. There is no assurance that our manufacturer will be successful in establishing a larger-scale commercial manufacturing process for Phexxi or other product candidates that achieves our objectives for manufacturing capacity and cost of goods. There is no assurance that our manufacturers will be able to manufacture or continue to manufacture any approved products, including Phexxi, to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. Any delay or failure in the production of any approved products would impair our ability to commercialize and obtain revenue from these products. These circumstances would materially harm our business, results of operations, financial conditions and prospects.

We have no significant internal distribution capabilities. We intend to engage third-party distributors for distribution of products outside the United States, if approved, and have engaged additional third-party wholesale distributors for the distribution of Phexxi in the United States. Our inability to identify, or enter into an agreement with, any such third-party distributor, would likely have a material adverse effect on our business and operations.

If we are unable to engage additional wholesale distributors and/or maintain our relationship with our wholesale distributors within the United States for Phexxi, our domestic commercialization activities may be disrupted. If we are able to identify and enter into a strategic relationship with one or more third party collaborators for the development of Phexxi outside of the United States, we intend to work with that third party or third parties to obtain marketing approval for Phexxi in each relevant jurisdiction and to enter into distribution agreements with such third party or parties for distribution of Phexxi in each relevant jurisdiction outside the United States. We cannot guarantee that we will be able to enter into any such additional wholesale distribution agreements on commercially reasonable terms, or at all, or that we will be able to identify any third party collaborators for the development and commercialization of Phexxi outside the United States or that we will be able to enter into any such distribution agreement with any such third party for the distribution of Phexxi outside the United States. For our current distribution agreements and for any future distribution agreements we may enter into, we would be subject to uncertainties related to such distribution services, including the quality of such distribution services. For example, distributors may not have the capacity to supply sufficient product if demand increases rapidly. Further, we would be dependent on the distributors to ensure that the distribution process accords with applicable foreign and U.S. regulations, which include, among other things, compliance with current good documentation practices, the maintenance of certain records, and compliance with other regulations, including, without limitation, the Foreign Corrupt Practices Act (FCPA) and the Drug Supply Chain Security Act (DSCSA) in the United States. Failure to comply with these requirements could result in significant remedial action, including enforcement action requiring distributors to implement physical changes or improvements to their facilities, suspension of distribution or recall product. Additionally, any failure by us to forecast demand for finished product, including Phexxi, and failure by us to ensure our distributors have appropriate capacity to distribute such quantities of finished product, could result in an interruption in the supply of certain products and a decline in sales of that product. If we grant any such third-party distributor the right to manufacture any applicable product, we would also be subject to the risk factors set forth above with respect to third-party manufacturing of our product as well as the requirement to have any such additional manufacturer pre-approved by FDA or other relevant regulatory authorities. Further, third-party distributors may not perform as agreed or may terminate their agreements with us. Any significant problem or disruption that our distributors experience, including any disruption resulting from the COVID-19 pandemic, could delay or interrupt our sale of products in the applicable jurisdiction until the applicable distributor cures the problem or until we identify and negotiate an acceptable agreement with an alternative

distributor, if one is available. Due to the global nature of the COVID-19 pandemic, we may be unable to find any alternative distributor. Any failure or delay in distributing products would likely have a negative impact on our business and operations.

We rely and intend to rely on third parties for the execution of our development programs for our product candidates and for the delivery of telehealth services through the Phexxi telehealth platform. Failure of these third parties to provide services of a suitable quality, in accordance with applicable regulations and within acceptable time frames may cause the delay or failure of our development programs.

We employ a business model that relies on the outsourcing of certain functions, tests and services to CROs, medical institutions and other specialist providers, including, without limitation, the conduct, management and monitoring of our ongoing and planned clinical trials. As a result, we rely on these third parties for, among other things, quality assurance, clinical monitoring, clinical data management and regulatory expertise. We also intend to engage a CRO for all future clinical trial requirements needed to file for regulatory approvals. There is no assurance that such organizations or individuals will be able to provide the functions, tests or services as agreed upon, or to the requisite quality. We will rely on the efforts of these organizations and individuals and could suffer significant delays in the development of our product or processes should they fail to perform as expected.

There is also no assurance that these third parties will not make errors in, or simply fail to be effective in, the design, management or retention of our data or data systems. Any failures by such third parties could lead to a loss of data or data integrity, which in turn could lead to delays in clinical development and obtaining regulatory approval. Third parties may not pass FDA or other regulatory audits, which could delay or prohibit regulatory approval. In addition, the cost of such services could significantly increase over time. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, regulatory approval of our current or any future product candidates may be delayed, prevented or cost significantly more than expected, all which would have a material adverse effect on our business, financial conditions, results of operations and prospects.

The Phexxi telehealth platform is designed to provide physicians with on-demand educational support, and to remove certain barriers to women's access to Phexxi by removing the need for an in-office visit. With the Phexxi telehealth platform, women can directly meet with an HCP to determine their eligibility for a Phexxi prescription and potentially have it written by the HCP, filled, and mailed directly to them by a third-party pharmacy. These telehealth platform services are not core to our business of developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health. These services are also subject to complex federal and state laws and regulations and professional practice standards, and we do not have the resources to provide these telehealth services internally. Any pharmacy that fills Phexxi prescriptions will be fully independent from us. We do not control or own or possess any ownership stake in any pharmacy that we expect may fill prescriptions for Phexxi or in any telehealth service provider. All prescriptions will be routed through our independent third-party telehealth service providers. If our telehealth service providers fail to perform or fail to perform in compliance with applicable laws, regulations and standards of care, our business, financial condition, commercial launch of Phexxi and results of operation would be adversely affected.

If we are unable to enter into or maintain strategic relationships or collaborations with respect to Phexxi for the prevention of pregnancy or for our future product candidates, or if we are unable to realize the potential benefits from such collaborations, our business, financial condition, commercialization prospects and results of operation may be materially adversely affected.

We do not presently expect to commercialize Phexxi, assuming international marketing approval is obtained, outside of the United States unless we enter into a strategic relationship or collaboration with a third party. If we are successful in identifying and in-licensing the rights to additional product candidates, our expected strategy with respect to the development of any such future product candidates is to supplement internal efforts with third-party collaborations. We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming arrangements to negotiate and document.

Our success in entering into a definitive agreement for any collaboration will depend upon, among other things, our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design and outcomes of the clinical trials, the collaborator's history of regulatory compliance, the likelihood of approval by regulatory authorities, the potential market for the product, the costs and complexities of manufacturing and delivering such products to customers, the potential of competing products, the strength of the intellectual property and industry and market conditions generally. The collaborator may also consider alternative products or technologies for similar indications that may be available to collaborate on with one of our competitors and whether such collaboration could be more attractive than the one with us for our products or product candidates.

Any potential collaboration agreement into which we might enter may call for licensing or cross-licensing of potentially blocking patents, know-how or other intellectual property. Due to the potential overlap of data, know-how and intellectual property rights, there can be no assurance that one of our collaborators will not dispute our right to use, license or distribute such data, know-how or other intellectual property rights, and this may potentially lead to disputes, liability or termination of the collaboration.

We may also be restricted under existing and future collaboration agreements from entering into agreements on certain terms with other potential collaborators and may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If that were to occur, we may have to curtail the development of a particular product, reduce or delay our development program, delay commercialization, reduce the scope of sales or marketing activities, or increase expenditures and undertake development or commercialization activities at our own expense. If we elect to fund development or commercialization activities on our own, we will need to obtain additional capital, which may not be available to us on acceptable terms or at all. Absent sufficient funds, we may not be able to commercialize a product candidate. If we enter into a collaboration agreement regarding a product or product candidate, we could be subject to, among other things, the following risks, each of which may materially harm our business, commercialization prospects and financial condition:

- we may not be able to control the amount and timing of resources that the collaborator devotes to the product development program;
- we may experience financial difficulties and thus not commit sufficient financial resources to the product development program;
- we may be required to relinquish important rights to the collaborator such as marketing, distribution and intellectual property rights;
- a collaborator could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors;
- a collaborator could terminate the agreement either for convenience, if permitted, or for our breach; or
- business combinations or significant changes in a collaborator's business strategy may adversely affect our willingness to complete our obligations under any arrangement.

As a result, a collaboration may not result in the successful development or commercialization of our product or product candidates. In addition, actions taken by a collaborator within its licensed territory, many of which we may not be able to control, could negatively impact our development or commercialization of the product or product candidate in the United States.

We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we must perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we periodically enter into or will enter into manufacturing, distribution, wholesale, academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, including the Rush License Agreement, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sublicensees' exercise of rights under the agreement. With respect to collaboration agreements, we may have to indemnify our collaborators from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right owned by a third party. With respect to consultants, we indemnify them from claims arising from performance of their services in accordance with legal and contractual requirements.

If our obligations under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

Risks Related to Our Commercialization of Health Care Products

Phexxi and any other approved product may face follow-on competition sooner than anticipated.

Although Phexxi vaginal gel is FDA-approved for commercialization in the United States, it and any of our product candidates that may achieve regulatory approval in the future may face competition from generic products earlier or more

aggressively than anticipated, depending upon how well such approved products perform in the United States prescription drug market. In addition to creating the 505(b)(2) NDA pathway, the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) authorized the FDA to approve generic drugs that are the same as drugs previously approved for marketing under the NDA provisions of the statute pursuant to an Abbreviated New Drug Application (ANDA). An ANDA relies on the preclinical and clinical testing conducted for a previously approved reference listed drug (RLD) and must demonstrate to the FDA that the generic drug product is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug and also that it is "bioequivalent" to the RLD. The FDA is prohibited by statute from approving an ANDA when certain marketing or data exclusivity protections apply to the RLD. If any such competitor or third party is able to demonstrate bioequivalence without infringing our patents, then this competitor or third party may then be able to introduce a competing generic product onto the market.

Phexxi is indicated for the prevention of pregnancy and has been granted three (3) years of data exclusivity that expires on May 22, 2023, and it has been designated as an RLD by the FDA. As such, the three-year exclusivity period should block FDA from approving either a subsequent ANDA or 505(b)(2) NDA that relies in whole or in part on our protected clinical data. We cannot predict the interest of potential follow-on competitors in the future Phexxi market, whether someone will attempt to invalidate our period of exclusivity or otherwise force the FDA to take other actions, or how quickly others may seek to come to market with competing products after the three-year data exclusivity period ends. Future product candidates may also receive marketing exclusivity under the FDCA after approval that may similarly be subject to challenge or uncertainty.

If the FDA approves generic versions of our products, it could negatively impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on our investments in those product candidates.

Changes in health care 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. Our management expects our success will be dependent on the willingness or ability of patients to pay out-of-pocket for Phexxi should they not be able to obtain third-party reimbursement or should such reimbursement be limited.

We cannot be certain that third-party reimbursement will remain available for Phexxi vaginal gel for the prevention of pregnancy, or if reimbursement is available, that the amount of any such reimbursement would not change. We provide a financial assistance program for Phexxi patients to offset any co-pay or patient out of pocket costs, but we do not know if this program will be successful in increasing market acceptance or that such program will not prove to be prohibitively costly. Demand for Phexxi may decrease if we elect to discontinue our co-pay programs. The ACA and subsequent regulations enacted by the U.S. Department of Health and Human Services (DHHS) require, under certain conditions, health plans to provide coverage for women's preventive care, including all forms of FDA-cleared or FDA-approved contraception, without imposing any cost sharing on the plan beneficiary. These regulations ensure that women who wish to use an approved form of contraception may request it from their doctors and their health insurance plan must cover all costs associated with such products, under certain conditions. In January 2022, the DHHS, Department of Labor, and Treasury Department jointly issued guidance on implementation of this ACA mandate, among other things. The recently issued federal guidance makes clear that all FDA-approved or cleared contraceptive products that are determined by an individual's medical provider to be medically appropriate for such individual must be covered without-cost sharing, regardless of whether the product is specifically identified in the FDA's Birth Control Guide.

However, certain members of Congress and other stakeholders may attempt to repeal or repeal and replace the ACA and corresponding regulations, as more fully described below, which could eliminate the requirement for health plans to cover women's preventive care without cost sharing. Even if the ACA is not repealed, the DHHS regulations to specifically enforce the preventive health coverage mandate could be repealed or modified; for example, the Trump administration in 2017 altered the mandate to allow certain employers and insurers to opt-out of birth control coverage for religious or moral reasons, which was partially upheld by the Supreme Court in July 2020. The DHHS, Department of Labor, and Treasury Department are expected to initiate rulemaking in 2022 that would amend existing regulations to account for recent litigation. We cannot predict the timing or impact of any future rulemaking or changes in the law. Any repeal or elimination of the preventive care coverage rules would mean that women seeking to use prescribed forms of contraceptives may have to pay some portion of the cost for such products out-of-pocket, which could deter some women from using prescription contraceptive products, such as Phexxi, at all. We expect that health care reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that may be charged for Phexxi or any of our product candidates, if approved. Even if we obtain coverage for any approved products, the resulting reimbursement payment rates might not be adequate or may require a co-pay that patients find unacceptably high. Patients are unlikely to use any products we may market unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of those products. As a result, we expect that our success, to some degree, will be dependent on the willingness of patients to pay out-of-pocket for Phexxi in the event that their third-party payer either does not cover and reimburse Phexxi or requires payment of a portion of Phexxi by the patient, thus increasing the patient's overall cost to use Phexxi. This could reduce market demand for Phexxi or any future product candidates we may seek to develop, if and when they receive FDA approval, which would have a material adverse effect on our business, financial conditions, and prospects.

We may also experience pressure from payers as well as state and federal government authorities concerning certain promotional approaches that we may implement such as our co-pay programs. Certain state and federal enforcement authorities and members of Congress have initiated inquiries about co-pay programs. Some state legislatures have been considering proposals that would restrict or ban co-pay coupons. For example, legislation was recently signed into law in California that would limit the use of co-pay coupons in cases where a lower cost generic drug is available and if individual ingredients in combination therapies are available over the counter at a lower cost. It is possible that similar legislation could be proposed and enacted in additional states. If we are unsuccessful with or discontinue our co-pay programs, or we are unable to secure adequate coverage from third-party payers, we may experience financial pressure which would have a material adverse effect on our business and make it difficult to commercialize successfully.

Despite FDA-approval for Phexxi and even if we are successful in obtaining regulatory approval to market other product candidates in the United States, revenues may be adversely affected if Phexxi or any other the product does not obtain coverage and adequate reimbursement from third-party payers in the United States.

Market acceptance and sales of Phexxi vaginal gel or any other product candidates that we may seek to commercialize will depend in part on the extent to which reimbursement for these products will be available from third-party payers, including government health administration authorities, managed care organizations and private health insurers. Third-party payers decide which therapies they will pay for and establish reimbursement levels. Third-party payers in the United States often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product or product candidates that we develop will be made on a payer-by-payer basis. One payer's determination to provide coverage for a drug does not assure that other payers will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payer's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved.

Third-party payers are increasingly challenging the prices charged for pharmaceutical and medical device products, including Phexxi. The U.S. government and other third-party payers are increasingly limiting both coverage and the level of reimbursement for new drugs and medical devices, in addition to questioning their safety and efficacy. Coverage decisions can depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. We may incur significant costs to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our future products, in addition to the costs required to obtain the necessary FDA marketing approvals. Third-party payer coverage may not be available to patients for Phexxi or any future product we may seek to commercialize. If third-party payers do not provide coverage and adequate reimbursement for Phexxi or our other product candidates, if approved, HCPs may not prescribe them or patients may ask their HCPs to prescribe competing products with more favorable reimbursement.

Managed care organizations and other private insurers frequently adopt their own payment or reimbursement reductions. Consolidation among managed care organizations has increased the negotiating power of these entities. Third-party payers increasingly employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. Failure to obtain timely or adequate pricing or formulary placement for Phexxi or any future product we may seek to commercialize, or obtaining such pricing or placement at unfavorable pricing levels, could materially adversely affect our business, financial conditions, results of operations and prospects.

The pharmaceutical and medical device industries are highly regulated and subject to various fraud and abuse, data privacy, transparency, and other health care laws, including, without limitation, the U.S. Federal Anti-Kickback Statute, the U.S. Federal False Claims Act and the FCPA.

HCPs and third-party payers play a primary role in the recommendation and prescription of drug products and medical devices that are granted marketing approval. Our current and future arrangements with health care professionals, principal investigators, consultants, third-party payers, customers and other organizations may expose us to broadly applicable fraud and abuse and other health care laws and regulations in the United States. These regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include, among others:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal health care program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws, including the False Claims Act, which can be enforced by private individuals through civil whistleblower or *qui tams* actions, and civil monetary penalty laws, which prohibit,

among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent;

- the Health Insurance Portability and Accountability Act (HIPAA) which, among other things, created new federal criminal statutes that prohibit executing a scheme to defraud any health care benefit program and making false statements relating to health care matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and its implementing regulations, which imposes certain requirements on certain covered HCPs, health plans, and health care clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of individually identifiable health information;
- the Physician Payments Sunshine Act, enacted as part of the ACA, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to payments and other transfers of value to physicians, as defined by such law, teaching hospitals, and certain advanced non-physician health care practitioners and ownership and investment interests held by physicians and their immediate family members; and,
- foreign and state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to HCPs and other potential referral sources; state laws that require product manufacturers to report information related to payments and other transfers of value to physicians and other HCPs or marketing expenditures; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and which may conflict, thus complicating compliance efforts.

The scope and enforcement of these laws and regulations is uncertain and subject to rapid change. Notably, in November 2020, DHHS finalized significant changes to the regulations implementing the Anti-Kickback Statute, as well as the civil monetary penalty rules regarding beneficiary inducements, with the goal of offering the health care industry more flexibility and reducing the regulatory burden associated with those fraud and abuse laws, particularly with respect to value-based arrangements among industry participants. Regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. These risks may be increased where there are evolving interpretations of applicable regulatory requirements, such as those applicable to manufacturer co-pay programs. Pharmaceutical manufacturer co-pay programs, including pharmaceutical manufacturer donations to patient assistance programs offered by charitable foundations, are the subject of ongoing litigation, enforcement actions and settlements (involving other manufacturers and to which we are not a party) and evolving interpretations of applicable regulatory requirements and certain state laws, and any change in the regulatory or enforcement environment regarding such programs could impact our ability to offer such programs. In addition, efforts to ensure that our business arrangements with third parties will comply with these laws will involve substantial costs. Any investigation of us or the third parties with whom we contract, regardless of the outcome, would be costly and time consuming. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, imprisonment, disgorgement of profits, possible exclusion and debarment from participation in Medicare, Medicaid and other federal health care programs, debarment under the FDCA, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

Health care legislative reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product or product candidates for which we obtain marketing approval.

Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and/or expanding access. In the

United States, the pharmaceutical industry has been a focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, Congress passed the ACA, which substantially changed the way health care is financed by both the government and private insurers, and significantly impacts the United States pharmaceutical industry. As another example, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020 incorporated extensive health care provisions and amendments to existing laws, including a requirement that all manufacturers of drug products covered under Medicare Part B report the product's Average Sales Price (ASP) to DHHS beginning on January 1, 2022, subject to enforcement via civil money penalties.

There remain judicial and Congressional challenges to certain aspects of the ACA, and as a result certain sections of the ACA have not been fully implemented or effectively repealed. However, following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court upheld the ACA when it dismissed a legal challenge to the ACA's constitutionality. Further legislative and regulatory changes under the ACA remain possible, although the new federal administration under President Biden has signaled that it plans to build on the ACA and expand the number of people who are eligible for health insurance subsidies under it. It is unknown what form any such changes or any law would take, and how or whether it may affect the biopharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, such as changes allowing the federal government to directly negotiate drug prices, and changes stemming from other health care reform measures, especially with regard to health care access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the U.S.

Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In addition, CMS published a final rule that would give states greater flexibility, effective January 1, 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

The uncertainty around the future of the ACA, and in particular the impact to reimbursement levels, may lead to uncertainty or delay in the purchasing decisions of our customers, which may in turn negatively impact our product sales. If there are not adequate reimbursement levels, our business and results of operations could be adversely affected.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2030 unless additional Congressional action is taken. However, the Medicare sequester reductions under the Budget Control Act of 2011 will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic, pursuant to provisions of the CARES Act which also extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation. The suspension was subsequently extended through March 31, 2022, with a reduction of the suspension to 1% sequester through June 30, 2022.

In addition, in 2013, the Drug Supply Chain Security Act (DSCSA) enacted imposed obligations on manufacturers of pharmaceutical products related to product tracking and tracing. On December 20, 2019, President Trump signed the Further Consolidated Appropriations Act for 2020 into law (P.L. 116-94) that includes a piece of bipartisan legislation called the CREATES Act. The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. The CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic and biosimilar product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown. Other legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are unsure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or whether such changes will have any impact on our business.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices considering the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, state legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases,

designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court unanimously held that federal law does not preempt the states' ability to regulate PBMs or other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area.

At the federal level, DHHS has solicited feedback on various measures intended to lower drug prices and reduce the out of pocket costs of drugs and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. In addition, in 2020, the FDA finalized a rulemaking to establish a system whereby state governmental entities could lawfully import and distribute prescription drugs sourced from Canada. The Biden Administration, which assumed control of the Executive Branch on January 20, 2021, has also indicated that lowering prescription drug prices is a priority. For example, in July 2021, President Biden issued a sweeping executive order on promoting competition in the American economy that includes several mandates pertaining to the pharmaceutical and health care insurance industries. Among other things, the executive order directs the FDA to work towards implementing a system for importing drugs from Canada (following on the Trump administration notice-and-comment rulemaking on Canadian drug importation finalized in October 2020). The Biden order also called on DHHS to release a comprehensive plan to combat high prescription drug prices, and it includes several directives regarding the Federal Trade Commission's oversight of potentially anticompetitive practices within the pharmaceutical industry. The drug pricing plan released by DHHS in September 2021 in response to the executive order makes clear that the Biden Administration supports aggressive action to address rising drug prices, including allowing DHHS to negotiate the cost of Medicare Part B and D drugs, but such significant changes will require either new legislation to be passed by Congress or time-consuming administrative actions. The implementation of cost containment measures or other health care reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Current and future health care legislation could have a significant impact on our business. There is uncertainty with respect to the impact these changes, if any, may have, and any changes likely will take time to unfold. In addition, it is possible that additional governmental action is taken to address the COVID-19 pandemic. Any additional federal or state health care reform measures could limit the amounts that third-party payers will pay for health care products and services, and, in turn, could significantly reduce the projected value of certain development projects and reduce our profitability.

We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage.

We and our third-party service providers are subject to laws and regulations covering data privacy and the protection of personal information including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the United States, we and our third-party service providers may be subject to state security breach notification laws, state health information privacy laws and federal and state consumer protections laws which impose requirements for the collection, use, disclosure and transmission of personal information. These laws overlap and often conflict and each of these laws are subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and our third-party service providers. In particular, our Phexxi telehealth platform and our online, digital and media marketing strategies are required to comply with these laws and regulations. If we fail to comply with applicable laws and regulations, we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain information that is protected by HIPAA (protected health information) from a covered entity or business associate in a manner that is not authorized or permitted by HIPAA or for aiding and abetting a violation of HIPAA.

The regulatory environment surrounding information security, data collection, and privacy is increasingly demanding. We are subject to numerous U.S. federal and state laws and regulations governing the protection of health, personal information, and financial information of our customers, clinical subjects, clinical investigators, employees, and vendors/business contacts. For example, California has implemented the California Confidentiality of Medical Information Act that imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information, and California has recently adopted the CCPA, which went into effect in January of 2020. The CCPA mirrors a number of the key provisions of the EU General Data Protection Regulation (GDPR) described below. The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. Additionally, a new privacy law, the California Privacy Rights Act (CPRA), was a ballot measure approved by California voters in the election on November 3, 2020, and certain provisions are effective as of January 1, 2022 with full effectiveness as of January 1, 2023. The CPRA modifies and expands the CCPA significantly, and among other things, creates the California Privacy Protection Agency with full administrative power, authority and jurisdiction to implement and enforce CCPA. CPRA transferred rulemaking authority from the California attorney General to the California Privacy Protection Agency effective July 1, 2021 with final CPRA regulations due by July 1, 2022. CPRA enforcement will begin July 1, 2023. The CCPA creates the potential for further uncertainty, additional costs and expenses in our efforts to comply with California privacy requirements and additional potential

for harm and liability for failure to comply. Virginia and Colorado enacted similar data protection laws in 2021, and other U.S. states have proposals under consideration, increasing the regulatory compliance risk.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations.

On May 25, 2018, the GDPR went into effect, implementing a broad data protection framework that expanded the scope of EU data protection law, including to non-EU entities that process, or control the processing of, personal data relating to individuals located in the EU, including clinical trial data. The GDPR sets out a number of requirements that must be complied with when handling the personal data of EU based data subjects, including: providing expanded disclosures about how their personal data will be used; higher standards for organizations to demonstrate that they have obtained valid consent or have another legal basis in place to justify their data processing activities; the obligation to appoint data protection officers in certain circumstances; new rights for individuals to be "forgotten" and rights to data portability, as well as enhanced current rights (e.g. access requests); the principal of accountability and demonstrating compliance through policies, procedures, training and audit; and a new mandatory data breach regime. In particular, medical or health data, genetic data and biometric data where the latter is used to uniquely identify an individual are all classified as "special category" data under the GDPR and afford greater protection and require additional compliance obligations. Further, EU member states have a broad right to impose additional conditions—including restrictions—on these data categories. This is because the GDPR allows EU member states to derogate from the requirements of the GDPR mainly in regard to specific processing situations (including special category data and processing for scientific or statistical purposes). As the EU states continue to reframe their national legislation to harmonize with the GDPR, we will need to monitor compliance with all relevant EU member states' laws and regulations, including where permitted derogation from the GDPR are introduced.

We will also be subject to evolving EU laws on data export if we transfer data outside the EU to ourselves or third parties. The GDPR only permits exports of data outside the EU where there is a suitable data transfer solution in place to safeguard personal data (e.g. the EU Commission approved Standard Contractual Clauses). On July 16, 2020, the Court of Justice of the EU (CJEU) issued a landmark opinion in the case Maximilian Schrems vs. Facebook (Case C-311/18) (Schrems II). This decision calls into question certain data transfer mechanisms as between the EU member states and the US. The CJEU is the highest court in Europe and the Schrems II decision heightens the burden on data importers to assess U.S. national security laws on their business future actions of EU data protection authorities are difficult to predict at the early date. Consequently, there is some risk of any data transfers from the EU being halted. If we have to rely on third parties to carry out services for us, including processing personal data on our behalf, we are required under GDPR to enter into contractual arrangements to help ensure that these third parties only process such data according to our instructions and have sufficient security measures in place. Any security breach or non-compliance with our contractual terms or breach of applicable law by such third parties could result in enforcement actions, litigation, fines and penalties or adverse publicity and could cause customers to lose trust in us, which would have an adverse impact on our reputation and business. Any contractual arrangements requiring the processing of personal data from the EU to us in the United States will require greater scrutiny and assessments as required under Schrems II and may have an adverse impact on cross-border transfers of personal data or increase costs of compliance. The GDPR provides an enforcement authority to impose large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. We will be subject to GDPR when we have a EU presence or "establishment" (e.g. EU based subsidiary or operations), when conducting clinical trials with EU based data subjects, whether the trials are conducted directly by us or through a vendor or partner, or offering approved products or services to EU based data subjects, regardless of whether involving a EU based subsidiary or operations.

Applicable data privacy and data protection laws may conflict with each other, and by complying with the laws or regulations of one jurisdiction, we may find that we are violating the laws or regulations of another jurisdiction. Despite our efforts, we may not have fully complied in the past and may not in the future. If we become liable under laws or regulations applicable to us, we may be required to pay significant fines and penalties, our reputation may be harmed, and we may be forced to change the way we operate. That could require us to incur significant expenses, which could significantly affect our business.

Our business may be adversely affected by unfavorable macroeconomic conditions, including the COVID-19 pandemic.

Various macroeconomic factors could adversely affect our business, our results of operations and our financial condition, including changes in inflation, interest rates and foreign currency exchange rates and overall economic conditions and uncertainties, including those resulting from political instability (including workforce uncertainty), trade disputes between nations and the current and future conditions in the global financial markets. For example, if inflation or other factors were to significantly increase our business costs, we may be unable to pass through price increases to patients. The cost of importing similar products from foreign markets may affect our sales in any domestic market.

In addition, U.S. and global financial markets have experienced disruption due to various macroeconomic and geopolitical events. These include, but are not limited to, rising inflation, rising interest rates, the risk of a recession and other ongoing global conflicts. For example, on March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. At the time of the closure we held assets in an account with SVB, however we were able to retrieve such funds and move them to other institutions, and as of the date of this Annual Report, we do not have funds in an SVB account. On March 12, 2023, the FDIC announced that Signature Bank was closed and that the FDIC was appointed as receiver. On March 13, 2023, the FDIC announced that all of SVB's deposits and substantially all of its assets had been transferred to a newly created, full-service FDIC-operated bridge bank, SVBB. SVBB assumed all loans that were previously held by SVB. On March 27, 2023, First-Citizens Bank & Trust Company assumed all of SVBB's customer deposits and certain other liabilities and acquired substantially all of SVBB's loans and certain other assets from the FDIC. While we have had full access to the assets and were able to successfully protect them since March 13, 2023, we may be impacted by other disruptions to the U.S. banking system caused by the recent developments involving SVB, including potential delays in our ability to transfer funds and potential delays in making payments to vendors while new banking relationships are established. We cannot predict at this time to what extent our or our collaborators, employees, suppliers, contract manufacturers and/or vendors could be negatively impacted by these and other macroeconomic and geopolitical events.

Interest rates and the ability to access credit markets could also adversely affect the ability of patients, payers and distributors to purchase, pay for and effectively distribute our product if, and when approved. Similarly, these macroeconomic factors could affect the ability of our current or potential future third-party manufacturers, sole source or single source suppliers, licensors or licensees to remain in business, or otherwise manufacture or supply our product candidate. Failure by any of them to remain in business could affect our ability to manufacture Phexxi or any of our future product candidates.

The COVID-19 pandemic may continue to affect the macroeconomic factors and the credit markets in a manner that is detrimental to our business. Moreover, some physician offices appear to be negatively impacted by restrictions on elective procedures and office visits related to the pandemic. To the extent physician offices are again closed or visits are again reduced, patients could be less likely to be prescribed Phexxi. Even with our planned telehealth efforts through efforts such as the Phexxi telehealth platform, we may not be able to effectively commercialize Phexxi for the prevention of pregnancy as a result of our reduced sales force, any reduction in physician office visits and other circumstances related to the COVID-19 pandemic. The pandemic may continue to adversely affect us and our business in manner we may be unable to reliably predict or quantify.

Also, as a result of the current geopolitical tensions and conflict between Russia and Ukraine, and the recent invasion by Russia of Ukraine, the governments of the United States, European Union, Japan and other jurisdictions have recently announced the imposition of sanctions on certain industry sectors and parties in Russia and the regions of Donetsk and Luhansk, as well as enhanced export controls on certain products and industries. These and any additional sanctions and export controls, as well as any counter responses by the governments of Russia or other jurisdictions, could adversely affect, directly or indirectly, the global supply chain, with negative implications on the availability and prices of raw materials, energy prices, and our customers, as well as the global financial markets and financial services industry.

Risks Related to Our Business Operations

As we mature and expand our sales and marketing infrastructure, we will need to expand the size of our organization. If we experience difficulties in managing this growth or are unable to attract and retain management and other key personnel, we may be unable to successfully commercialize our products, develop any product candidates or otherwise implement our business plan.

As of April 7, 2023, we had a total of 35 full-time employees and two part-time employees. In addition, we use third-party consultants to assist with finance, including regulatory filings, sales, marketing and market access research and programs, as well as general and administrative activities. As our development and commercialization plans and strategies continue to develop, we expect that we will expand the size of our employee base for managerial, operational, sales, marketing, financial, regulatory affairs and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, management may have to divert a disproportionate amount of its attention away from day-to-day activities and devote a substantial amount of time to managing these growth activities, which would lead to disruptions in our operations. We cannot provide assurance that we will be able to retain adequate staffing levels to run our operations and/or to accomplish all the objectives that we otherwise would seek to accomplish, or that our staffing levels may turn out to be too robust for our actual business activity.

Our ability to compete in the highly competitive pharmaceutical industry depends upon our ability to attract and retain highly qualified managerial and key personnel. We are highly dependent on our senior management, and the loss of the services of any members of our senior management team could impede, delay or prevent the development and commercialization of our product or product candidates, hurt our ability to raise additional funds and negatively impact our ability to implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely

basis or at all, and our business could be harmed as a result. We do not maintain "key man" insurance policies on the lives of these individuals.

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, medical device, biopharmaceutical and other businesses, particularly in the San Diego area where we are headquartered. As a result, we may be required to expend significant financial resources in our employee recruitment and retention efforts, including the grant of significant equity incentive awards which would be dilutive to stockholders. Many of the other companies within the contraceptive industry with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives or if we are not able to effectively manage any future growth, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

Our current or future employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with legal requirements or regulatory standards.

We may become exposed to the risk of employees, independent contractors, principal investigators, consultants, suppliers, commercial partners or vendors engaging in fraud or other misconduct. Misconduct by employees, independent contractors, principal investigators, consultants, suppliers, commercial partners and vendors could include intentional conduct such as failures: (i) to comply with FDA or other regulators' regulations; (ii) to provide accurate information to such regulators; or (iii) to comply with manufacturing standards established by us and/or required by law. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws, regulations and industry guidance intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by current or future employees, independent contractors, principal investigators, consultants, suppliers, commercial partners and vendors could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory or civil sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees, independent contractors, principal investigators, consultants, suppliers, commercial partners and vendors, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending or asserting our rights, those actions could have a significant adverse impact on our business and we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

We may be vulnerable to disruption, damage and financial obligations as a result of information technology system failures, cybersecurity breaches, loss of data or other disruptions that could compromise our proprietary information or other sensitive information.

Despite the implementation of security measures and internal policies and controls, any of the internal computer systems belonging to us or our third-party service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, malicious attack, human error, and telecommunication and electrical failure. Cybersecurity risks continue to increase for our industry, including for our third party vendors, who may hold some of our data, and the proliferation of new technologies and the increased sophistication and activities of the actors behind such attacks present risks for compromised or lost data, which could result in substantial costs and harm to our reputation. Any system failure, accident, security breach or data breach that causes interruptions in our own or in third-party service vendors' operations could result in a material disruption of our commercialization or product development programs. For example, the loss of clinical study data from future clinical trials could result in liability, delays in our or our partners' regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. Further, our information technology and other internal infrastructure systems, including firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure, which could disrupt our operations. In addition, our commercialization of Phexxi is partially reliant on the use of the Phexxi telehealth platform and our other digital or media marketing strategies. We are in turn reliant on third parties and limited internal resources to ensure the Phexxi telehealth platform and these other digital and marketing resources function appropriately. Our commercialization of Phexxi may be adversely affected to the extent the Phexxi telehealth platform and our other online marketing resources do not work properly or are disrupted. To the extent any disruption or security breach results in a loss or damage to our data or applications, sensitive information or inappropriate disclosure of confidential or proprietary information, we may incur resulting liability and reputation damage, our product development programs and competitive position may be adversely affected and the further commercialization or development of our products may be delayed. Furthermore, we may incur additional costs to remedy the damage caused by these disruptions or security breaches and these costs could be significant.

The United States federal and various state and foreign governments have adopted or proposed requirements regarding the collection, distribution, use, security, and storage of personally identifiable information and other data relating to individuals, and federal and state consumer protection laws are being applied to enforce regulations related to the collection, use, and dissemination of data. Some of these federal, state and foreign government requirements include obligations of companies to notify individuals and others of security breaches involving health information or particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Even though we may have contractual protections with such vendors, contractors, or other organizations, notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers.

The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated or remote areas of the world. For example, there may be an increased risk of cybersecurity attacks by state actors due to the current conflict between Russia and Ukraine. Recently, Russian ransomware gangs have threatened to increase hacking activity against critical infrastructure of any nation or organization that retaliates against Moscow for its invasion of Ukraine. Any such increase in such attacks on our third-party provider or other systems could adversely affect our network systems or other operations. We may not be able to address these techniques proactively or implement adequate preventative measures. There can be no assurance that we will promptly detect any such disruption or security breach, if at all. If our computer systems are compromised, we could be subject to fines, damages, reputational harm, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business, in addition to possibly requiring substantial expenditures of resources to remedy. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, require us to comply with federal and/or state breach notification laws and foreign law equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. In addition, the loss of data from clinical trials for our drug or biologic candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce data and a cybersecurity breach could adversely affect our reputation and could result in other negative consequences, including disruption of our internal operations, increased cyber security protection costs, lost revenues or litigation. Despite precautionary measures to prevent unanticipated problems that could affect our IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business.

Any such security breach may compromise information stored on our networks and may result in significant data losses or theft of our intellectual property or proprietary business information, it may also subject us to significant fines, penalties or liabilities for any noncompliance with certain privacy and security laws. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches. A cybersecurity breach could adversely affect our reputation and could result in other negative consequences, including disruption of our internal operations, increased cybersecurity protection costs, lost revenue or litigation.

We expect to continue to incur increased costs as a result of operating as a public company and our management will be required to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, we incur and expect to continue to incur additional significant legal, accounting and other expenses in relation to our status as a public reporting company. Now that we are no longer an emerging growth company, we expect these expenses will further increase. We may need to hire additional accounting, finance and other personnel in connection with our continuing efforts to comply with the requirements of being a public company, and our management and other personnel will need to continue to devote a substantial amount of time towards maintaining compliance with these requirements. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and the OTC Markets have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

While we remain a smaller reporting company and have revenues of less than $100 million per year, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If and when we are required to achieve compliance with regulatory auditor attestation report requirements within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. As described herein, we have identified one or more material weaknesses. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Loss of 39 employees during the 2022 RIF and 11 employees during the March 2023 RIF and the inability to attract and retain qualified key management personnel would impair our ability to implement our business plan.

Our success largely depends on the continued service of key management, advisors and other specialized personnel, including Saundra Pelletier our Chief Executive Officer, who is employed at-will and for whom we do not have "key man" insurance coverage. On October 10, 2022 Alex Fitzpatrick, our General Counsel and Secretary, tendered his resignation effective October 14, 2022 and his position as General Counsel has not been filled, but rather we have hired outside counsel to perform those duties. On March, 3, 2023 Justin J. File, our Chief Financial Officer tendered his resignation effective April 3, 2023. On March 6, 2023, our Board of Directors appointed Albert Altro as Interim Chief Financial Officer and on April 13, 2023, our Board of Directors appointed Ivy Zhang as Chief Financial Officer and Secretary.

As a result of the RIF in the fourth quarter of 2022, we reduced our workforce by 39 employees. As a result of the RIF in the first quarter of 2023, we further reduced our workforce by 11 employees. The loss of one or more members of our management team or other key employees or advisors could delay our commercialization efforts and could also have a material and adverse effect on our business, financial condition, results of operations and prospects. Our future success will depend in large part on our continued ability to attract and retain other highly qualified management personnel, as well as personnel with expertise in women's health care, drug development, governmental regulation and commercialization. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations (many of whom have substantially greater financial resources than us), and we might not be able to attract or retain these key employees on conditions that are economically acceptable. Our inability to attract and retain these key employees could prevent us from achieving our objectives and implementing our business strategy, which could have a material adverse effect on our business and prospects.

In connection with the two RIFs, and/or the departure of key personnel, we may be subject to certain separation payments, legal actions or other claims.

As a result of the RIFs in the fourth quarter of 2022 and first quarter of 2023, we reduced our workforce by 39 and 11 employees, respectively. Also, on March 3, 2023, Justin J. File, our Chief Financial Officer, tendered his resignation effective April 3, 2023. We are and may continue to be responsible for the payment of all earned and unpaid wages, vacation, bonuses and other forms of compensation due to certain employees. Our failure to pay such may result in claims being filed against us and us being subject to further penalties for any violations. The failure to successfully remediate any such disputes or pay any amounts payable could negatively impact our business, financial conditions, results of operations and prospects.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the FCPA, the U.S. domestic bribery statute contained in 18 United States Code (U.S.C.) § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

We or the third parties upon whom we depend may be adversely affected by earthquakes, medical epidemics or pandemics, or other natural disasters. These natural disasters may be exacerbated by the effects of climate change.

Our principal offices are located in our facilities in San Diego, California. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics or pandemics, power shortage, telecommunication failure or other natural or man-made accidents or incidents, including the COVID-19 pandemic, that results in us being unable to fully utilize our facilities, effects the ability of our employees working remotely to communicate with us and our systems, or that

affects the operations of our third party manufacturers, distributors, service providers or consultants may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. These natural events may become worse over time due to the ongoing effects of climate change. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Common Stock

Our shares of common stock have been delisted from the Nasdaq Capital Market which have and could result in, among other things, a decline in the price of our common stock and less liquidity for holders of shares of our common stock.

Our common stock was listed on the Nasdaq Capital Market, but as a result of our failure to maintain a minimum $1.00 per share bid price requirement for continued inclusion on the Nasdaq Capital Market pursuant to the Bid Price Requirement, on October 27, 2022, we were delisted. Since July 12, 2021, the closing bid price for our common stock has been below $1.00 per share. On August 23, 2021, we received a deficiency letter from the Staff of Nasdaq notifying us, that, for the preceding 30 consecutive trading days, the closing bid price for shares of our common stock was below the minimum $1.00 per share requirement and that we had failed to comply with the Bid Price Requirement. In accordance with Nasdaq rules, we were provided until the Compliance Date to regain compliance with the Bid Price Requirement. We did not evidence compliance with the Bid Price Requirement by the Compliance Date and, as a result, the Staff of Nasdaq notified us on February 22, 2022 that shares of our common stock were subject to delisting unless we timely requested a hearing before the Nasdaq Hearings Panel. On October 27, 2022, the Nasdaq Stock Market, LLC filed the Notification of Removal From Listing and Registration Under 12(b) of the Securities Exchange Act of 1934 with the SEC.

Delisting from the Nasdaq Capital Market has made trading our common stock more difficult for investors, potentially leading to declines in our share price and liquidity. Other possible consequences could include: a default under our Notes, an adverse effecting on our ability to obtain equity financing at acceptable terms or at all, a negative effect on the common stock trading volume, price, and an increase in the stock volatility, and a possible loss of confidence by shareholders, employees, and business partners. As noted above, in the event of a default under our Notes, holders of our common stock may not receive the value of their investment.

Our stock price is and may continue to be volatile.

Our Common Stock is currently quoted for public trading on the OTCQB under the symbol "EVFM". The market price for our common stock is volatile and may continue to fluctuate significantly in response to a number of factors, many of which we cannot control, such as quarterly fluctuations in financial results, the timing and our ability to advance the development of our product candidates or changes in securities analysts' recommendations, any of which could cause the price of our common stock to fluctuate substantially. Each of these factors, among others, could harm your investment in our securities and could result in your being unable to resell any of our securities that you purchase at a price equal to or above the price you paid.

In addition, the stock market in general and the market for biopharmaceutical companies in particular, have experienced extreme volatility that has often been unrelated to companies operating performance. The market price for our common stock may be influenced by many factors, including:

- the delisting of our common stock from Nasdaq;
- failure to cure the delinquency and file all future required filings in a timely fashion;
- the loss of key personnel;
- the results of our efforts to commercialize Phexxi or any other approved products;
- failure or discontinuation of any of our research programs;
- the results of our efforts to discover, develop, acquire or in-license product candidates or products, if any; actual or anticipated results from, and any delays in, any future clinical trials, as well as results of regulatory reviews relating to the approval of any product candidates we may choose to develop;
- the level of expenses related to any product candidates that we may choose to develop or clinical development programs we may choose to pursue;
- commencement or termination of any collaboration or licensing arrangement;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technology;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures and capital commitments;
- additions or departures of key scientific or management personnel;
- variations in our financial results or those of companies that are perceived to be similar to us;

- new products, product candidates or new uses for existing products introduced or announced by our competitors, and the timing of these introductions or announcements;
- results of clinical trials of product candidates of our competitors;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies, wars, terrorism and political unrest, outbreak of disease (e.g., the COVID-19 pandemic), boycotts and other business restrictions;
- regulatory or legal developments in the United States and other countries;
- changes in the structure of health care payment systems;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts and related debt and equity issuances;
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock;
- stockholder activism;
- any stockholder derivative actions; and
- other factors described in this "Risk Factors" section.

Between January 1, 2021 and December 31, 2021, the closing sales price of our common stock reported on the Nasdaq Capital Market ranged between $0.37 and $4.88 per share. Upon being listed on the OTCQB Marketplace on October 10, 2022 the closing sales price started at $0.17, was $0.07 as of December 23, 2022, and was $0.02 as of April 7, 2023. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, following periods of volatility in companies' stock prices, securities class-action litigation has often been instituted against such companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

There may not be an active, liquid trading market for our equity securities.

Our common stock trades exclusively on the OTCQB Marketplace. Trading volumes on the OTCQB Marketplace can fluctuate significantly, which could make it difficult for investors to execute transactions in our securities and could cause declines or volatility in the prices of our equity securities.

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

The SEC has adopted regulations which generally define "penny stock" to be an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. The market price of our Common Stock on the OTCQB Marketplace is presently less than $5.00 per share and therefore we are considered a "penny stock" company according to SEC rules. Further, we do not expect our stock price to rise above $5.00 in the foreseeable future. The "penny stock" designation requires any broker-dealer selling our securities to disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules limit the ability of broker-dealers to solicit purchases of our Common Stock and therefore reduce the liquidity of the public market for our shares.

Moreover, as a result of apparent regulatory pressure from the SEC and the Financial Industry Regulatory Authority (FINRA), a growing number of broker-dealers decline to permit investors to purchase and sell or otherwise make it difficult to sell shares of penny stocks. The "penny stock" designation may have a depressive effect upon our Common Stock price.

Because we do not have sufficient authorized capital on a fully diluted basis, the excess outstanding capital exposes us to liability, and we will need to increase our authorized capital, effectuate a reverse split or obtain effective waivers from derivative securityholders.

As of December 31, 2022, and April 7, 2023, our authorized capital consists of 500,000,000 shares of common stock and 5,000,000 shares of Preferred Stock. As of December 31, 2022, of the authorized common stock, 123,098,285 shares were issued and outstanding and 3,082,369,072 shares were reserved for issuance under pending conversions of convertible notes, purchase rights, warrants and all other derivatives. As of April 7, 2023, of the authorized common stock, 215,961,346 shares were issued and outstanding and approximately 23.5 billion shares were reserved for issuance under pending conversions of convertible notes, rights, warrants and all other derivatives. As such, our fully diluted capital structure is presently well above

the amount of common stock we are authorized to issue. Therefore, until we either increase our authorized common stock, effectuate a reverse split, or obtain waivers from the holders of the outstanding derivative securities both and with respect to their rights to an adequate reserve from which to receive the shares of common stock which underlie their respective securities, we are exposed to the risk of liability arising from the excess fully diluted capitalization. In addition to the dilutive effect any exercises of the derivative securities would have, in the event we are unable to obtain the requisite approvals or waivers, or we are delayed in those efforts, the Company and your investment in us would be at risk.

We may not obtain requisite approval to approve an increase in the authorized, reverse split or other corporate action relating to the common stock.

On March 15, 2023, we held a Special Meeting of our Stockholders wherein stockholders approved a reverse split of the outstanding shares of our common stock at a ratio of not less than 1-for-20 and not more than 1-for-125 at any time on or prior to March 15, 2024, with the exact ratio to be set at a whole number within such range by our board of directors. We have not yet effectuated the reverse split. Given the current ownership structure of our common stock, it is possible that any future proposals made to the shareholders of our common stock may not pass or be approved. To approve an increase in the authorized common stock or a reverse split of the common stock, we will need a majority of the then outstanding shares of common stock to not only vote but vote in the affirmative. Since no one person or group own a majority of the currently issued and outstanding shares of common stock, we cannot guarantee that we could obtain requisite shareholder approval to effectuate a reverse split, an increase in the authorized number of common shares, or other corporate action that could benefit us and your investment. Additionally, we cannot guarantee approval by FINRA, SEC or any other governmental or regulatory agency needed to effectuate a corporate action.

A reverse stock split may decrease the liquidity of our common stock.

Although our board of directors believes that an increase in the market price of our common stock could encourage interest in our common stock and possibly promote greater liquidity for our stockholders, such liquidity could also be adversely affected by the reduced number of shares outstanding after the reverse stock split. The reduction in the number of outstanding shares may lead to reduced trading and a smaller number of market makers for our common stock.

A reverse stock split may lead to a decrease in our overall market capitalization.

Should the market price of our common stock decline after a reverse stock split, the percentage decline may be greater, due to the smaller number of shares outstanding, than it would have been prior to the reverse stock split. A reverse stock split is often viewed negatively by the market and, consequently, can lead to a decrease in our overall market capitalization. If the per share market price does not increase in proportion to the reverse stock split ratio, then our value, as measured by our stock capitalization, will be reduced. In some cases, the per-share stock price of companies that have effected reverse stock splits subsequently declined back to pre-reverse split levels and, accordingly, it cannot be assured that the total market value of our common stock will remain the same after the reverse stock split is effected, or that a reverse stock split will not have an adverse effect on our stock price due to the reduced number of shares outstanding after a reverse stock split.

Our common stock could be further diluted as the result of the issuance of additional shares of common stock, convertible securities, warrants or options.

In the past, we have issued common stock, convertible securities (such as convertible notes) and warrants in order to raise capital. We have also issued common stock as compensation for services and incentive compensation for our employees, directors and certain vendors. We have shares of common stock reserved for issuance upon the exercise of certain of these securities and may increase the shares reserved for these purposes in the future. Our issuance of additional common stock, convertible securities, options and warrants could affect the rights of our stockholders, could reduce the market price of our common stock or could result in adjustments to exercise prices of outstanding warrants (resulting in these securities becoming exercisable for, as the case may be, a greater number of shares of our common stock), or could obligate us to issue additional shares of common stock to certain of our stockholders.

A significant portion of our total outstanding shares of common stock may be sold into the public market at any point, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Future issuances of our securities may cause additional reduction in the percentage interests of our current stockholders in the voting power, liquidation value, our book and market value, and in any future earnings. As of April 7, 2023, 2023, there were approximately 0.6 million shares of our common stock subject to outstanding options which have been registered on registration statements on Form S-8. Furthermore, as of April 7, 2023, there were an aggregate of approximately 23.5 billion shares subject to outstanding warrants to purchase our common stock, reserved for issuance upon conversion of our

issued and outstanding convertible notes, and outstanding purchase rights. We have granted (or are required to grant) certain of our security holders registration rights pursuant to our agreements with these holders, including agreements requiring us to register for resale the shares of our common stock issued upon the conversion or exercise of our convertible notes and related warrants.

The issuance or resale of our common stock issued to our security holders upon conversion of convertible notes or upon exercise of our warrants or options could cause the market price of our common stock to decline. In addition, the increase in the number of issued shares of our common stock issuable upon conversion of our convertible notes or upon exercise of our warrants may have an incidental anti-takeover effect in that these additional shares could be used to dilute the stock ownership of parties seeking to obtain control of us. The resulting increased number of issued shares could discourage the possibility of, or render more difficult, certain mergers, tender offers, proxy contests or other change of control or ownership transactions.

We are and may continue to be subject to short selling strategies.

Short sellers of our stock may be manipulative and may attempt to drive down the market price of shares of our Common Stock. Short selling is the practice of selling securities that the seller does not own but rather has, borrowed from a third party with the intention of buying identical securities back at a later date to return to the lender. The short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is therefore in the short seller's best interests for the price of the stock to decline, many short sellers (sometime known as "disclosed shorts") publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects to create negative market momentum and generate profits for themselves after selling a stock short. Although traditionally these disclosed shorts were limited in their ability to access mainstream business media or to otherwise create negative market rumors, the rise of the Internet and technological advancements regarding document creation, videotaping and publication by weblog (blogging) have allowed many disclosed shorts to publicly attack a company's credibility, strategy and veracity by means of so-called "research reports" that mimic the type of investment analysis performed by large Wall Street firms and independent research analysts. These short attacks have, in the past, led to selling of shares in the market, on occasion in large scale and broad base. Issuers who have limited trading volumes and are susceptible to higher volatility levels than large-cap stocks, can be particularly vulnerable to such short seller attacks. These short seller publications are not regulated by any governmental, self-regulatory organization or other official authority in the United States, are not subject to certification requirements imposed by the SEC and, accordingly, the opinions they express may be based on distortions or omissions of actual facts or, in some cases, fabrications of facts. In light of the limited risks involved in publishing such information, and the enormous profit that can be made from running a successful short attack, unless the short sellers become subject to significant penalties, it is more likely than not that disclosed short sellers will continue to issue such reports.

Significant short selling of a company's stock creates an incentive for market participants to reduce the value of that company's common stock. Short selling may lead to the placement of sell orders by short sellers without commensurate buy orders because the shares borrowed by short sellers do not have to be returned by any fixed period of time. If a significant market for short selling our common stock develops, the market price of our common stock could be significantly depressed.

Continued failure to remediate current material weaknesses and establish and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and stock price.

As a publicly traded company, we are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which requires management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of controls over financial reporting. As discussed below, we have identified internal control weaknesses, and need to undertake various actions, such as implementing new internal controls, new systems and procedures and hiring additional accounting or internal audit staff, which could increase our operating expenses. In addition, we may identify additional deficiencies in our internal control over financial reporting as part of that process.

In addition, if we are unable to resolve internal control deficiencies in a timely manner, investors could lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected.

We identified material weaknesses in our internal control over financial reporting as of December 31, 2022 and these or other material weaknesses could continue to materially impair our ability to report accurate financial information in a timely manner.

Item 9A our Annual Report on Form 10-K, as filed with the Securities and Exchange Commission on April 27, 2023 our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as

of December 31, 2022 and identified material weaknesses in our internal control environment, risk assessment, control activities, monitoring activities and information and communication and therefore did not maintain effective internal control over financial reporting or effective disclosure controls and procedures as of that date. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis and/or that requisite regulatory filings will be filed on a timely basis. During the course of preparing our consolidated financial statements and other financial data for the year ended December 31, 2022, we have concluded that we have material weaknesses in each of the following areas:

Control Environment- control deficiencies constituting material weaknesses, either individually or in the aggregate, relating to:(i) an insufficient number of personnel with an appropriate level of experience to create the proper environment for effective internal control over financial reporting and to ensure that (a) there were adequate processes for oversight, (b) there was accountability for the performance of internal control over financial reporting responsibilities, and (c) corrective activities were appropriately applied, prioritized, and implemented in a timely manner, and (ii) oversight processes and procedures that guide individuals in applying internal control over financial reporting were not adequate such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

Risk Assessment - control deficiencies constituting material weaknesses, either individually or in the aggregate, relating to: (i) identifying and assessing risks relating to external financial reporting objectives; (ii) identifying and analyzing risks to achieve these objectives, and (iii) identifying and assessing changes in the business model and leadership that could impact the system of internal controls.

Control Activities - control deficiencies constituting material weaknesses, either individually or in the aggregate, relating to: (i) providing evidence of performance, (ii) providing appropriate segregation of duties, or (iii) operation at a level of precision to identify all potentially material errors.

Monitoring activities - control deficiencies constituting material weaknesses, either individually or in the aggregate, relating to: (i) assessing results of deficiencies; (ii) communicating internal control deficiencies in a timely manner to the board of directors; or (iii) taking corrective actions timely.

Information and communication- control deficiencies constituting material weaknesses, either individually or in the aggregate, relating to: (i) obtaining, generating, and using relevant quality information to support the function of internal control; or (ii) communicating internal control information with the board of directors in a timely manner.

We believe that the material weaknesses described in Item 9A resulted in the failure to prevent or detect these issues. As a result of these material weaknesses, we were unable to timely file our quarterly report on Form 10-Q for the three months ended September 30, 2022 and the Form 10-K for the year-ended December 31, 2022.

We are taking steps to remediate these material weaknesses. However, the remedial measures we are taking may not be adequate to prevent additional misstatements or avoid other control deficiencies or material weaknesses with respect to our control environments, risk assessment, control activities, monitoring activities and/or information and communication or any other matters. The effectiveness of our internal control over financial reporting is subject to various inherent limitations, including judgments used in decision making, the nature and complexity of the transactions we undertake, assumptions about the likelihood of future events, the level of adequate qualified personnel, the soundness of our systems, the adequacy of training and experience, the possibility of human error, cost limitations and the risk of fraud. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions and the risk that the degree of compliance with policies or procedures may deteriorate over time. Because of these limitations, there can be no assurance that any system of internal control over financial reporting will be successful in preventing all errors or fraud or in making all material information known in a timely manner to the appropriate levels of management. As a result, our financial statements may contain one or more material misstatements and may not be available on a timely basis or we may discover additional material weaknesses related to control environments, risk assessment, control activities, monitoring activities and/or information and communication or other matters, any of which could cause investors to lose confidence in us and lead to, among other things, unanticipated legal, accounting and other expenses, delays in filing required financial disclosures, enforcement actions by government authorities, fines, penalties, the delisting of our securities, a decline in the prices of our securities, liabilities arising from stockholder litigation and defaults under our various debt obligations.

We are a "smaller reporting company", and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a "smaller reporting company" under SEC regulations. For so long as we remain a smaller reporting company, we will be permitted to and intend to rely on exemptions from certain disclosure requirements applicable to other public companies that are not smaller reporting companies. These exemptions include:

- for so long as we remain a smaller reporting company with annual revenues of less than $100 million per year and a public float value as of our most recently completed second fiscal quarter of less than $700 million, not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting; and
- reduced disclosure obligations regarding executive compensation.

We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the price of our common stock price may be more volatile.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future; capital appreciation, if any, will be your sole source of gain as a holder of our common stock.

We have never declared or paid cash dividends on shares of our common stock. As noted above, we are also restricted from paying dividends pursuant to our debt arrangements. Except as may be required to redeem our issued and outstanding promissory notes or shares of Series B-2 Convertible Preferred Stock, we currently plan to retain all our future earnings, if any, and any cash received through future financings to finance the growth and development of our business. Accordingly, capital appreciation, if any, of our common stock will be the sole source of gain for our common stockholders for the foreseeable future.

Provisions in our amended and restated certificate of incorporation, our bylaws or Delaware law might discourage, delay or prevent a change in control of the Company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our amended and restated certificate of incorporation, our bylaws or Delaware law may discourage, delay or prevent a merger, acquisition or other change in control stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions might frustrate or prevent any attempts by our stockholders to replace or remove the current management by making it more difficult for our stockholders to replace members of our board of directors. These provisions include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- prohibiting our stockholders from calling a special meeting of stockholders or acting by written consent other than unanimous written consent;
- permitting our board of directors to issue additional shares of our preferred stock, with such rights, preferences and privileges as they may designate, including the right to approve an acquisition or other changes in control;
- establishing an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- providing that our directors may be removed only for cause;
- providing that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- requiring the approval of our board of directors or the holders of a supermajority of our outstanding shares of capital stock to amend our bylaws and certain provisions of our certificate of incorporation.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provides that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities, or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnities, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

If securities analysts cease publishing research or reports about our business, or if they publish negative evaluations of our common stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports industry or financial analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts covering our business downgrade their evaluations of our common stock, the price of our common stock could decline. In addition, if one or more of these analysts cease coverage or cease regularly publishing reports on our business, we could lose visibility in the financial markets, which in turn could cause our common stock price or trading volume to decline.

Our business could be negatively affected as a result of the actions of activist stockholders.

It is possible that one or more of our stockholders may publicly voice opposition to our financing strategy and/or certain aspects of our corporate governance and strategy, or undertake a proxy contest to reconstitute our board. Proxy contests have been waged against many companies in the biopharmaceutical industry over the last several years. If faced with a proxy contest or other type of stockholder activism, we may not be able to respond successfully to the contest or other type of activism which would be disruptive to our business. Even if we are successful, our reputation and/or business could be adversely affected by a proxy contest or other form of stockholder activism because:

- responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees;
- perceived uncertainties as to our company and future strategic direction may result in the loss of potential financing, acquisitions, collaboration, in-licensing or other business opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and
- if individuals are elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

Any or all of these activities could cause our stock price to decline or experience periods of volatility, and could be particularly problematic as our company seeks to transition to a commercial enterprise in a challenging environment.

We may become a defendant in one or more stockholder derivative or class-action litigations, and any such future lawsuit may adversely affect our business, financial condition, results of operations and cash flows.

We and certain of our officers and directors may become defendants in one or more future stockholder derivative actions or other class-action lawsuits. These lawsuits would divert our management's attention and resources from our ordinary business operations, and we would likely incur significant expenses associated with their defense (including, without limitation, substantial attorneys' fees and other fees of professional advisors and potential obligations to indemnify current and former officers and directors who are or may become parties to such actions). If these lawsuits do arise, we may be required to pay material damages, consent to injunctions on future conduct and/or suffer other penalties, remedies or sanctions. In addition, any

such future stockholder lawsuits could adversely impact our reputation and/or to launch and commercialize Phexxi, thereby harming our ability to generate revenue. Accordingly, the ultimate resolution of these matters could have a material adverse effect on our business, financial condition, results of operation and cash flow and, consequently, could negatively impact the trading price of our common stock.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Effective April 1, 2023, our corporate headquarters are now virtual and are located at 7770 Regents Rd, Suite 113-618, San Diego, California. We maintain this address for mail service.

We also continue to be obligated under a lease for our former offices at 12400 High Bluff Drive, Suite 600, San Diego, CA., where we lease approximately 33,290 square fee of office space. This existing lease will expire on September 30, 2025, unless terminated sooner.

We believe that our existing facilities are adequate for our current needs.

Item 3. Legal Proceedings.

From time to time we may be involved in various actual and threatened legal proceedings, claims, investigations and government inquiries arising in the ordinary course of our business, including intellectual property, securities, stockholder derivative claims, employment, governance, workplace culture, contractual rights, false or misleading advertising, or other legal claims relating to our products and operations. Any proceedings, claims or inquiries involving us, whether successful or not, may be time consuming, result in costly litigation, unfavorable outcomes, increased costs of business, may require us to change our business practices or products, require significant amount of management's time, may harm our reputation or otherwise harm our business and future financial results.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock began trading on the Nasdaq Global Market on November 20, 2014 under the ticker symbol "NEOT" and corporate name Neothetics, Inc. (Neothetics). Prior to November 20, 2014, there was no public market for our common stock. On January 17, 2018, we completed a merger (the Merger) with privately-held Evofem Biosciences Operations, Inc. (Private Evofem) where Private Evofem survived as our wholly owned subsidiary. In connection with the Merger, we changed our name from "Neothetics, Inc." to "Evofem Biosciences, Inc." and changed the ticker symbol for our common stock to "EVFM." Shares of our common stock began trading on the Nasdaq Capital Market (Nasdaq) under the ticker symbol EVFM on January 18, 2018.

On August 11, 2022, our stock was suspended from trading on the Nasdaq due to noncompliance with its minimum bid price requirement. On October 26 2022, our common stock was formally delisted from Nasdaq. The delisting of our shares from Nasdaq makes our common stock less liquid and makes it more difficult for us to raise funds when and as needed to fund operations. Our common stock began trading on the OTCQB® Venture Market (the OTCQB) of the OTC Markets Group, Inc., a centralized electronic quotation service for over-the-counter securities, effective October 3, 2022 under the symbol "EVFM."

Holders of Common Stock

As of April 7, 2023, there were 215,961,346 shares of our common stock outstanding and 61 holders of record of our common stock. This number was derived from our stockholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

Recent Sales of Unregistered Securities

During the quarter ended December 31, 2022, we did not issue any securities that were not registered under the Securities Act of 1933, as amended, that were not reported on a Current Report on Form 8-K.

Dividend Policy

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

Equity Compensation Plan Information

Information about our equity compensation plans is incorporated herein by reference to Part III, Item 12 of this Annual Report.

Issuer Repurchases of Equity Securities

For the quarter ended December 31, 2022, we did not repurchase any equity securities.

Item 6. [RESERVED]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis is set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

We are a San Diego-based commercial-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health. Our first commercial product, Phexxi, was approved by the FDA on May 22, 2020. It is the first and only FDA-approved, hormone-free, woman-controlled, on-demand prescription contraceptive gel for women. We commercially launched Phexxi in September 2020 in the United States. We intend to commercialize Phexxi in all other global markets through partnerships or licensing agreements

Recent Developments

On February 10, 2023, Jenny Yip notified Evofem Biosciences, Inc., a Delaware corporation (the Company), of her resignation as member of the Company's board of directors (the Board), effective immediately. Ms. Yip's resignation is not the result of any dispute or disagreement with the Company on any matter relating to the Company's operations, policies or practices

In February, March and April 2023, we entered into securities purchase agreements with certain investors providing for the sale and issuance of senior secured convertible notes (collectively, the 2023 SPAs). The 2023 SPAs included (i) convertible promissory notes with aggregate original principal amounts of approximately $1.4 million, $0.6 million, $0.5 million and $0.8 million, respectively (the 2023 Notes), and (ii) warrants to purchase an aggregate 69,230,769, 30,000,000, 26,923,077 and 76,923,077 shares of common stock, respectively (the 2023 Warrants and collectively, the 2023 Offerings). The 2023 Offerings closed on February 17, 2023 (the February 2023 Closing), March 13, 2023 March 20, 2023 (the March 2023 Closing) and April 5, 2023 (the April 2023 Closing), respectively, with net proceeds to the Company, after deducting offering expenses, of approximately $0.7 million, $0.3 million, $0.3 million, and $0.5 million, respectively. The 2023 SPAs also included a Registration Rights Agreement requiring us to register the common stock underlying the 2023 Notes and 2023 Warrants within the timeframes specified therein.

Upon the April 2023 Closing, the conversion and strike prices, as applicable, of the Baker Notes, Baker Warrants, the May 2022 Common Warrants, the June 2022 Baker Warrants, the Adjuvant Notes, the December 2022 Notes and Warrants, and the Notes and Warrants in the February and March 2023 Closing reset to $0.0065 per share, accordingly. Additionally, the Company's outstanding Purchase Rights increased by approximately 3.1 billion since December 31, 2022.

On March 7, 2023, Baker Bros. Advisors, LP (the Designated Agent) provided a Notice of Event of Default and Reservation of Rights (the Notice of Default) relating to the Securities Purchase and Security Agreement dated April 23, 2020, and subsequently amended (SPA), by and amount we, Designated Agent, the Guarantors and Baker Purchasers. The Notice of Default claims that the Company has failed to maintain the "Required Reserve Amount" as required by Section 2.7 of the Third Amendment to the Securities Purchase Agreement and Section 8.1(e) of the SPA. The Designated Agent claims such failure constitutes an immediate Event of Default pursuant to Section 9.1(e) of the SPA. The Designated Agent, at the direction of the Baker Purchasers, has accelerated repayment of the outstanding balance payable and elected its remedies pursuant to Section 5.07(b) of the Securities Purchase Agreement. As a result, approximately $92.8 million representing two times the sum of the outstanding balance and all accrued and unpaid interest thereon and all other amounts due under the SPA and other documents is due and payable within three business days of receipt of the Notice of Default. We disagree with the Designated Agent's claims and have invited the Designated Agent to reconsider and rescinded its Notice of Default and request for payment, for which no formal request for payment has yet been made. We will explore all available options in resolving this matter.

On March 15, 2023, we held a Special Meeting of Stockholders in which our stockholders approved an amendment to our Certificate of Incorporation to effectuate a reverse stock split of the outstanding shares of our common stock by a ratio of not less than 1-for-20 and not more than 1-for-125 at any time on or prior to March 15, 2024, with the exact ratio to be set at a whole number within such range by our board of directors (the 2023 Reverse Stock Split).

On March 20, 2023 our Board of Directors approved a reduction in force (the March 2023 RIF) intended to conserve our current cash resources and manage operating expenses. We reduced our current workforce, resulting in an overall 39% reduction of payroll expenses including (i) salary cuts for certain employees, (ii) elimination of eight office and management

positions including the elimination of the Chief Commercial Officer role effective March 17, 2023; and (iii) reduction of the Chief Executive Officer's salary by 40%. We expect annualized future cost savings from the reduction in force to be approximately $4.3 million, which we intend to use to support our operations.

In connection with the March 2023 RIF, we estimate we will incur aggregate charges of approximately $0.1 million primarily consisting of notice period and severance payments, employee benefits and related costs, which charges were incurred in the first quarter of 2023. We expect the reduction in force associated with the March 2023 RIF will be complete by the end of the second quarter of 2023.

On March 7, 2023, Baker Bros. Advisors, LP (the Designated Agent) provided a Notice of Event of Default and Reservation of Rights (the Notice of Default) relating to the Securities Purchase and Security Agreement dated April 23, 2020, and subsequently amended (SPA), by and amount the Company, Designated Agent, the Guarantors and Baker Purchasers. The Notice of Default claims that the Company has failed to maintain the "Required Reserve Amount" as required by Section 2.7 of the Third Amendment to the Securities Purchase Agreement and Section 8.1(e) of the SPA. The Designated Agent claims such failure constitutes an immediate Event of Default pursuant to Section 9.1(e) of the SPA. The Designated Agent, at the direction of the Baker Purchasers, has accelerated repayment of the outstanding balance payable and elected its remedies pursuant to Section 5.07(b) of the Securities Purchase Agreement. As a result, approximately $92.8 million representing two times the sum of the outstanding balance and all accrued and unpaid interest thereon and all other amounts due under the SPA and other documents is due and payable within three business days of receipt of the Notice of Default. The Company disagrees with the Designated Agent's claims and has invited the Designated Agent to reconsider and rescinded its Notice of Default and request for payment, for which no formal request for payment has yet been made. The Company will explore all available options in resolving this matter.

On April 24, 2023, Gillian Greer, PhD., notified the Company of her resignation as member of the Company's board of directors (the Board), effective immediately. Dr. Greer's resignation is not the result of any dispute or disagreement with the Company on any matter relating to the Company's operations, policies or practices.

Phexxi as a Contraceptive; Commercial Strategies

In September 2020, we commercially launched Phexxi. Our sales force promotes Phexxi directly to obstetrician/gynecologists and their affiliated health professionals, who collectively write the majority of prescriptions for contraceptive products. Our sales force comprises approximately 16 regional sales representatives, three business managers and a VP of sales, supported by a self-guided virtual health care provider (HCP) learning platform. Additionally, we offer women direct access to Phexxi via our telehealth platform. Using the platform, women can directly meet with an HCP to determine their eligibility for a Phexxi prescription and, if eligible, have the prescription written by the HCP, filled, and mailed directly to them by a third party pharmacy.

Our comprehensive commercial strategy for Phexxi includes marketing and product awareness campaigns targeting women of reproductive potential in the U.S., including the approximately 23 million women who are not using hormonal contraception and the approximately 18.8 million women who are using a prescription contraceptive, some of whom, particularly pill users, may be ready to move to an FDA-approved, non-invasive hormone-free contraceptive, as well as certain identified target HCP segments. In addition to marketing and product awareness campaigns, our commercial strategy includes payer outreach and execution of our consumer digital and media strategy.

According to our post-commercial launch market research, HCPs indicated they would recommend Phexxi to approximately 60% of patients who are currently using natural contraceptive methods, approximately 58% of patients who are currently using over-the-counter contraceptive products and approximately 26% of patients who are currently using prescription contraception or methods requiring an HCP to perform a procedure. Additional research into the demographics of more than 1,300 women who are using Phexxi revealed that 60% of Phexxi users are between the ages of 18 to 34 years of age. Among the subset of Phexxi users for whom prior contraceptive data is available (n=413), 39% of women who had recently started Phexxi switched over from either an oral contraceptive, hormone patch/ring, or long-acting reversible contraception.

On February 14, 2021, we launched a direct-to-consumer advertising campaign, known as "Get Phexxi," designed to increase awareness and educate women on the benefits of Phexxi. The campaign highlights some of the struggles women face when choosing among the many available methods of contraception, including the lack of control with condoms, daily use of the pill, and abstinence required for cycle tracking.

On September 9, 2021, we launched a national brand ambassador campaign called "House Rules" designed to broaden awareness and drive uptake of Phexxi. The House Rules campaign significantly raised our target audience awareness of Phexxi, while also driving women to their HCP to request a trial. More importantly, it also helped increase new HCPs recommending and prescribing Phexxi.

We continue working to increase the number of lives covered and to gain a preferred formulary position for Phexxi. We gained coverage for 32.5 million lives in 2022 and added 16.3 million lives in the first quarter of 2023. Coverage includes 60% of commercial lives, including 16.4 million lives covered at no out-of-pocket cost as of February 10, 2023 and approximately 13.7 million lives covered under our December 2020 contract award from the U.S. Department of Veterans Affairs. As of February 2023, the Phexxi approved claims rate increased to 80%.

On January 1, 2021, as a result of our participation in the Medicaid National Drug Rebate Program, the U.S. Medicaid population gained access to Phexxi. Medicaid provides health coverage to approximately 68 million members, including approximately 16.8 million women between 19 to 49 years of age.

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."

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, like Phexxi, prescribed by healthcare providers.

As a result, to comply with these Guidelines, payers are increasingly covering Phexxi by:

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

While highly favorable to Phexxi, the updated HSRA Guidelines remove the impetus for the FDA to update its Birth Control Guide (the Guide) to include methods that were approved by the FDA after the development of the Guide more than a decade ago, including the vaginal pH modulator (Phexxi). We believe there is still merit to the Guide being current and accurate, and continue to work with the FDA's Office of Women's Health to update the Guide.

The Guide was developed and is used as an educational tool by many obstetrician/gynecologists to assist in counseling patients on their contraceptive options and to help them find the method that best suits their needs. Methods not on the current, outdated Guide may be underrepresented in these contraceptive counseling dialogues. We therefore believe the Guide should include all FDA-approved methods of birth control.

Further, even though the FDA Guide was intended as an educational tool, certain insurers have used it to block coverage of methods not included on the Guide. While this is explicitly prohibited by the current HSRA Guidelines, and there has been considerable progress since January 1, 2023, two notable plans continue to flout the law.

With the FDA not yet moving to update its Guide, in 2022 Evofem developed and introduced a new educational chart that provides high-level information about birth control methods that are currently available to women in the United States, adding new categories including vaginal pH modulator. This new educational tool has been extremely well received and has had a positive impact with HCPs and patients alike.

Research and Development

Our pipeline includes programs to evaluate vaginal pH modulators and other new product candidates for a variety of women's health concerns, including those listed below. These programs are on currently hold as we focus resources on activities intended to increase Phexxi revenues.

EVO100 for the Prevention of Chlamydia and Gonorrhea

Until October 2022, we were evaluating EVO100 for the prevention of urogenital chlamydia and gonorrhea in women. Chlamydia and gonorrhea are among the many bacterial and viral pathogens that require a higher pH environment to thrive. in 2018, the CDC reported that infections with these two sexually transmitted pathogens cost the U.S. healthcare system $1 billion, in aggregate direct and indirect costs. There are no FDA-approved drugs to prevent these sexually transmitted diseases (STIs), and we believe there is a clear need for new prophylactics given the rising incidence and increasing antibiotic resistance of gonorrhea. We therefore advanced our program to investigate the potential for EVO100 to prevent vaginal infection with these two common pathogens.

Our Phase 2B/3 trial (*AMPREVENCE*) achieved its primary and secondary endpoints, demonstrating statistically significant reductions in chlamydia and gonorrhea infections of 50% and 78%, respectively, in women receiving EVO100 vs.

placebo. Based on these highly positive clinical outcomes we initiated a Phase 3 clinical trial (*EVOGUARD*) to evaluate EVO100 for these potential indications in 2020. This randomized, placebo-controlled clinical trial enrolled 1,903 women with a prior chlamydia or gonorrhea infection who were at risk for future infection.

On October 11, 2022, we reported that *EVOGUARD* did not meet its primary efficacy endpoint. We believe COVID-19 related changes in clinical site operations, subject behavior and actions including deviations from following the clinical study protocol requirements related to STI acquisition, detection, and prevention contributed to this outcome. The product safety profile was consistent with what has been observed in prior clinical trials, and only two women (0.1%) in the study discontinued due to adverse events. We believe there is a path forward for EVO100 and may in the future conduct a new Phase 3 clinical trial of EVO100 for these potential indications. However, due to financial constraints, we discontinued investment in this clinical program in October 2022.

EVO200 Vaginal pH Modulator for Bacterial Vaginosis

Our investigational candidate for the reduction of recurrent bacterial vaginosis (BV), EVO200 vaginal gel, uses the same proprietary vaginal pH modulator platform as Phexxi. In a Phase 1 dose-finding trial for this indication, the highest dose formulation of the study drug demonstrated reduced vaginal pH for up to seven days following a single administration. We may decide to pursue further development of EVO200 in the future. The FDA has designed EVO200 as a Qualified Infectious Disease Product (QIDP) for this indication, which provides several important potential advantages including, but not limited to, longer market exclusivity.

Multipurpose Prevention Technology Candidate for HIV Prevention

In December 2021, we launched a collaboration with Orion Biotechnology Canada Ltd. (Orion) to evaluate the compatibility and stability of Orion's novel CCR5 antagonist, OB-002, in Phexxi with the goal of developing a Multipurpose Prevention Technology (MPT) product candidate for indications including the prevention of HIV in women. Assuming positive preclinical results, Evofem and Orion will seek government and philanthropic funding for subsequent clinical trials of any resulting MPT vaginal gel product candidate.

Financial Operations Overview

Net Product Sales

Our revenue recognition is based on unit shipments from our third-party logistics warehouse to our customers, which consist of wholesale distributors, retail pharmacies, telehealth companies Twentyeight Health (formerly SimpleHealth) and the Pill Club, and a mail-order specialty pharmacy. We have recognized net product sales in the United States since the commercial launch of Phexxi in September 2020. The year ended December 31, 2022 was our second full year of product sales.

For the year ended December 31, 2022, there was an approximate 26% increase in shipments to wholesale distributors and pharmacies compared to the year ended December 31, 2021. The increase in shipments coupled with improvements in gross to net adjustments drove an increase in net product sales of approximately 104%. Phexxi outperformed the newer branded contraceptive market and the launch of our House Rules campaign in September 2021 has increased Phexxi awareness, consideration, and prescriptions. Gross revenues, as discussed in Note 3- Revenue, were adjusted for variable consideration, including our patient support programs.

We intend to out-license commercialization rights for Phexxi to one or more pharmaceutical companies or other qualified potential partners for countries or regions outside of the United States. We are currently in discussion with potential partners for various geographies. We cannot forecast when or if these arrangements will be secured, the structure or potential amount of revenues from these arrangements, whether upfront, milestone-related or related to future Phexxi sales (assuming approval of Phexxi for commercial sale outside of the United States) or to what degree these arrangements would affect our development plans, future revenues and overall capital requirements.

In October 2021, we submitted the registration for our hormone-free contraceptive vaginal gel to the Mexican Regulatory Agency Comisión Federal para la Protección contra Riesgos Sanitarios. In addition to submitting for registration in Mexico, we have 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.

Cost of Goods Sold

Inventory costs include all purchased materials, direct labor and manufacturing overhead. In addition, we are obligated to pay quarterly royalty payments pursuant to our license agreement with Rush University, in amounts equal to a single-digit percentage of the gross amounts we receive on a quarterly basis, less certain deductions incurred in the quarter based on a sliding scale. We are 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 in a given year. A minimum annual royalty amount of $100,000 was first required for the annual period commencing on January 1, 2021. Such royalty costs were $1.1 million and $0.2 million for the years ended December 31, 2022 and 2021, respectively, and was included in the costs of goods sold in the consolidated financial statements.

Operating Expenses

Research and Development Expenses

Our research and development expenses primarily consist of costs associated with the continuous improvements related to Phexxi commercialization efforts. These expenses include:

- continuous improvements of manufacturing and analytical efficiency;
- on-going product characterization and process optimization;
- alternative raw material evaluation to secure an uninterrupted supply chain and reduce cost of goods sold;
- employee-related expenses, including salaries, benefits, travel and noncash stock-based compensation expense; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment, and research and other supplies.

In 2022 and 2021 research and development expenses also included costs associated with the clinical development of EVO100 for the prevention of chlamydia and gonorrhea, including:

- external development expenses incurred under arrangements with third parties, such as fees paid to clinical research organizations (CROs) relating to our clinical trials, costs of acquiring and evaluating clinical trial data such as investigator grants, patient screening fees, laboratory work and statistical compilation and analysis, and fees paid to consultants;
- costs to acquire, develop and manufacture clinical trial materials, including fees paid to contract manufacturers;
- costs related to compliance with drug development regulatory requirements;

We expense internal and third-party research and development expenses as incurred. The following table summarizes research and development expenses by product candidate (in thousands):

	Years Ended December 31,	
	2022	**2021**
Allocated third-party development expenses:		
Phexxi for prevention of chlamydia/gonorrhea- Phase 3 *(EVOGUARD)*	$ 17,374	$ 23,779
Unallocated internal research and development expenses:		
Noncash stock-based compensation expenses	553	1,357
Payroll and related expenses	3,820	4,967
Outside services costs	1,240	1,696
Other	2,045	1,330
Total unallocated internal research and development expenses	7,658	9,350
Total research and development expenses	**$ 25,032**	**$ 33,129**

Costs for our clinical development programs and clinical trials in general are very difficult to predict and may vary significantly between clinical trials and over the life of a program owing to the following:

- the phase of development of the product candidate;
- the number of patients participating in the trial;
- per patient trial costs;
- the number of sites included in the trial;
- the length of time and level of marketing required to enroll eligible patients;
- the number of doses patients receive;

- potential additional safety monitoring or other trials requested by regulatory agencies; and
- the efficacy and safety profile of the product candidate.

We anticipate that we will determine which programs and/or product candidates to pursue, if any, as well as the most appropriate funding allocations for each program and/or product candidate, on an ongoing basis in response to the outcomes of pre-clinical and clinical trials, regulatory developments, and our ongoing assessments of the commercial potential of each program and/or product candidate.

Research and development expenses decreased slightly in 2022 compared to 2021 primarily due to the completion of *EVOGUARD* program in the fourth quarter of 2022. As previously noted, we have discontinued this program and therefore expect a significant reduction in clinical trial expense in 2023 versus 2022 levels.

Selling and Marketing Expenses

Our selling and marketing expenses consist primarily of Phexxi commercialization costs, including direct to consumer (DTC) and HCP advertising, the Phexxi telehealth platform, our sample program, training, salaries, benefits, travel, noncash stock-based compensation expense, and other related costs for our employees and consultants.

In connection with our overall cost reduction strategy, our selling and marketing expenses decreased significantly in 2022 compared to 2021 due to reductions in media and marketing activities related to ongoing Phexxi promotional strategies.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries, benefits, travel, business development expenses, investor and public relations expenses, noncash stock-based compensation, and other related costs for our employees and consultants performing executive, administrative, finance, legal and human resource functions. Other general and administrative expenses include facility-related costs not otherwise included in research and development or selling and marketing, and professional fees for accounting, auditing, tax and legal fees, and other costs associated with obtaining and maintaining our patent portfolio.

Our general and administrative expenses increased in 2022 compared to 2021 primarily due to increased general legal expenses and recruiting and financing related fees.

Other Income (Expense)

Other income (expense) consists primarily of interest expense and the change in fair value of financial instruments issued in various capital raise transactions. The change in fair value of financial instruments was recognized as a result of mark-to-market adjustments for those financial instruments.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles (GAAP) in the United States. The preparation of consolidated financial statements requires us to make use of estimates, assumptions and judgments that affect the reported amounts of assets, expenses, and liabilities, as well as the disclosure of contingent liabilities on the date of the consolidated financial statements. Management bases its estimates, assumptions, and judgments on historical experience and on various other factors it believes to be reasonable under the circumstances. Different estimates, assumptions and judgments may change the estimate used in the preparation of our consolidated financial statements, which, in turn, could materially change our results from those reported. Management evaluates its use of estimates, assumptions, and judgments on an ongoing basis. However, if our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may have a material adverse effect on our consolidated statements of operations, liquidity, and financial condition. We believe the following critical accounting policies involve significant areas where management applies estimates, assumptions, and judgments in the preparation of our consolidated financial statements. See Note 2- Summary of Significant Accounting Policies.

Revenue Recognition and Trade Accounts Receivable

We recognize revenue from the sale of its product Phexxi in accordance with ASC 606, *Revenue from Contracts with Customers* (ASC 606). The provisions of ASC 606 require the following steps to determine revenue recognition: (1) Identify the contract(s) with a customer; (2) Identify the performance obligations in the contract; (3) Determine the transaction price; (4) Allocate the transaction price to the performance obligations in the contract; (5) Recognize revenue when (or as) the entity satisfies a performance obligation.

In accordance with ASC 606, we recognize revenue when its performance obligation is satisfied by transferring control of the product to a customer. Per our contracts with customers, control of the product is transferred upon the conveyance of title, which occurs when the product is sold to and received by a customer. Our customers consist of wholesale distributors, retail pharmacies, and a mail-order specialty pharmacy. Payment terms vary by customer, but typically range from 31 to 66 days and include prompt pay discounts. Trade accounts receivable due to us from contracts with its customers are stated separately in the balance sheet, net of various allowances as described in the Trade Accounts Receivable policy in Note 2- Summary of Significant Accounting Policies.

The amount of revenue we recognize is equal to the amount of consideration which is expected to be received from the sale of product to its customers. Revenue is only recognized when it is probable that a significant reversal will not occur in future periods. To determine the amount of revenue to recognize, we assess both the likelihood and magnitude of any such potential reversal of revenue.

Phexxi is sold to customers at the wholesale acquisition cost. However, we record product revenue, net of estimates for applicable variable consideration.

Revenue recognition is subject to uncertainty due to the variable consideration estimates that are required to be made by management. These estimates include chargebacks, rebates and patient support programs. Management must estimate and accrue for these amounts primarily by estimating the portion of product in the distribution supply channel at the reporting date that will be sold through to an entity or end user that will result in a variable consideration expense. To accomplish this, management relies on historical sales data showing the amount of various end-user consumer types, inventory reports from the wholesale distributors and mail-order specialty pharmacy, and other relevant data reports. The recorded variable consideration is directly sensitive to the estimated inputs made by management that are used in the calculation. The total balance for variable considerations was $2.7 million and $2.3 million, as of December 31, 2022 and 2021, respectively.

Clinical Trial Accruals

As part of the process of preparing our financial statements, we are required to estimate expenses resulting from our obligations under contracts with vendors, CROs and consultants and under clinical site agreements relating to conducting our clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

Our objective is to reflect the appropriate clinical trial expenses in our consolidated financial statements by recording those expenses in the period in which services are performed and efforts are expended. We account for these expenses according to the progress of the clinical trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through financial models and discussions with applicable personnel and outside service providers as to the progress of clinical trials.

During a clinical trial, we adjust the clinical expense recognition if actual results differ from estimates. We make estimates of accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. Our clinical trial accruals are partially dependent upon accurate reporting by CROs and other third-party vendors. Although we do not expect estimates to differ materially from actual amounts, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low for any reporting period. For the years ended December 31, 2022 and 2021 there were no material adjustments to our prior period estimates of accrued expenses for clinical trials.

Fair Value of the Baker Notes

We elected the fair value option under ASC 825, Financial Instruments, for the Baker Notes issued pursuant to that certain Baker Bros. Purchase Agreement with the Baker Purchasers, and Baker Bros. Advisors LP, as designated agent, dated April 23, 2020, as they are qualified financial instruments and are, in whole, classified as liabilities. Under the fair value option, we recognized the hybrid debt instrument at fair value inclusive of embedded features. Through June 30, 2022, the fair value of the Baker Notes issued, and the change in fair value of the Baker Notes at the reporting date, were determined using a Monte Carlo simulation-based model. The Monte Carlo simulation was used to take into account several embedded features and factors, including the future value of our common stock, a potential change of control event, the probability of meeting certain debt covenants, the maturity term of the Baker Notes, the probability of an event of voluntary conversion of the Baker Notes, the probability of the failure to meet the affirmative covenant to achieve $100.0 million in cumulative net sales of Phexxi by June 30, 2023, and the probability of exercise of the put right and the probability of exercise of our call right. The Baker Notes are re-valued as of each reporting date. For the second half of 2022, the fair value of the Baker Notes was determined by estimating the fair value of the Market Value of Invested Capital (“MVIC”) of the Company. This was estimated using forms of the cost and market approaches. In the Cost approach, an adjusted net asset value method was used to determine the net

recoverable value of the Company, including an estimate of the fair of the Company's intellectual property. The estimated fair value of the Company's intellectual property was valued using a relief from royalty method which required management to make significant estimates and assumptions related to forecasts of future revenue, and the selection of the royalty and discount rates. If the resulting fair value is not estimated as greater than the contractual payout. the fair value of the Baker Notes then becomes our MVIC available for distribution.

The fair value of the Baker Notes was $39.3 million and $81.7 million, as of December 31, 2022 and 2021, respectively.

Fair Value of Stock Options and Warrants

Upon the issuance of the options and warrants, they are initially measured at fair value and reviewed for the appropriate classification (liability or equity). Options and warrants determined to require liability accounting are subsequently re-measured with changes in fair value being recognized as a component of other income (expense), net in the consolidated statements of operations. Options and warrants are value using an option pricing model based on the applicable assumptions, which include the exercise price of the warrants, time to expiration, expected volatility of our peer group, risk-free interest rate, and expected dividends. We re-evaluate the classification of its options and warrants at each balance sheet to determine the proper balance sheet classification for them. The assumptions used in the OPM are considered level 3 assumptions and include, but are not limited to, the market value of invested capital, our cumulative equity value as a proxy for the exercise price, the expected term the purchase rights will be held prior to exercise and a risk-free interest rate, and probability of change of control events.

Fair Value of Purchase Rights

The fair value of the rights granted to the Baker Purchasers to optionally purchase from us up to $10.0 million of Baker Notes, as described in Note 5- Debt at the Baker Purchasers' discretion at any time prior to us receiving at least $100.0 million in aggregate gross proceeds from one or more sales of equity securities issued in connection with the Baker Bros. Purchase Agreement, as described in Note 5- Debt, and the change in fair value of the Baker Purchasers' option to purchase from us up to $10.0 million of Baker Notes upon exercise of such rights, was determined as the maximum of (i) the fair value of rights to purchase the additional $10.0 million Baker Notes and (ii) the fair value of the shares of on as-if converted basis, which was determined by the lattice model. Initially, the fair value of purchase rights was valued using a Geske option-pricing model. The Geske model was based on the applicable assumptions, including the underlying stock price, warrant exercise price, the exercise price of the rights to purchase the warrants, the term of the warrants, the term of the rights to purchase the warrants, expected volatility of our peer group, risk-free interest rate and expected dividends. For the second half of 2022, the fair value of the purchase rights were valued using an option pricing model (OPM), like a Black-Scholes Merton with changes in the fair value being recorded in the consolidated statements of operations. The assumptions used in the OPM are considered level 3 assumptions and include, but are not limited to, the market value of invested capital, our cumulative equity value as a proxy for the exercise price, the expected term the purchase rights will be held prior to exercise and a risk-free interest rate and probability of change of control events.

Inventories

Inventories, consisting of purchased materials, direct labor and manufacturing overheads, are stated at the lower of cost or net realizable value. Cost is determined on a first-in, first-out basis. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. At each balance sheet date, we evaluate ending inventories for excess quantities, obsolescence, or shelf-life expiration. The evaluation includes an analysis of our current and future strategic plans, anticipated future sales, the price projections of future demand, and the remaining shelf life of goods on hand. To the extent that we determine there are excess or obsolete inventory or quantities with a shelf life that is too near its expiration for us to reasonably expect that it can sell those products prior to their expiration, we adjust the carrying value to estimated net realizable value in accordance with the first-in, first-out inventory costing method.

Results of Operations

Year Ended December 31, 2022 Compared to Year Ended December 31, 2021 (in thousands):

Net Product Sales

	Year Ended December 31,		2022 vs. 2021	
	2022	2021	$ Change	% Change
Product sales, net	$ 16,837	8,244	$ 8,593	104%

The increase in net product sales was primarily due to continued growth in ex-factory Phexxi unit sales and an increase in net sales from the impact of Phexxi promotional strategies and gross-to-net initiatives implemented in 2022.

Cost of Goods Sold

	Year Ended December 31,		2022 vs. 2021	
	2022	2021	$ Change	% Change
Cost of goods sold	$ 4,415	4,055	$ 360	9%

The increase in cost of goods sold was primarily due to increase in royalty costs associated with the growth in Phexxi net sales, partially offset by the reversal of excess & obsolete inventory reserve recorded in 2021.

Research and Development Expenses

	Year Ended December 31,		2022 vs. 2021	
	2022	2021	$ Change	% Change
Research and development	$ 25,032	33,129	$ (8,097)	(24)%

The decrease in research and development expenses was primarily due to a $7.2 million decrease in clinical trial costs associated with *EVOGUARD*, a $1.1 million decrease in payroll and related expenses due to reduced headcount, and a $0.8 million decrease in noncash stock-based compensation. These decreases were partially offset by a $1.1 million increase in facilities and other research and development related activities.

Selling and Marketing Expenses

	Year Ended December 31,		2022 vs. 2021	
	2022	2021	$ Change	% Change
Selling and marketing	$ 43,951	113,152	(69,201)	(61)%

The decrease in selling and marketing expenses was primarily due to a $61.0 million decrease in media and marketing costs related to ongoing promotional strategies, a $6.3 million decrease in payroll and related expenses due to reduced headcount, $1.6 million in the Phexxi sample program, and a $1.3 million decrease in facilities costs. These aggregated decreases were partially offset by a $2.0 million increase in noncash stock-based compensation.

General and Administrative Expenses

	Year Ended December 31,		2022 vs. 2021	
	2022	2021	$ Change	% Change
General and administrative	$ 27,563	24,709	$ 2,854	12 %

The increase in general and administrative expenses was primarily due to a $7.7 million increase in legal, corporate, and financing related expenses. This increase was partially offset by a decrease of $3.4 million in noncash stock-based compensation expense and a $1.4 million decrease in payroll related expenses due to reduced headcount.

Total Other Expense, Net

	Year Ended December 31,		2022 vs. 2021	
	2022	2021	$ Change	% Change
Total other expense, net	$ 7,470	$ (38,374)	$ 45,844	(119)%

Total other expense, net, for the year ended December 31, 2022, primarily due to gains of: $92.2 million from the change in fair value of the liability classified warrants issued in 2022, and $2.5 million from the partial extinguishment of the Adjuvant Notes, as described in Note 5- Debt. These gains were partially offset by losses of: $73.0 million recorded upon issuance of financial instruments, primarily from the June 2022 Baker Warrants, $10.3 million from the change in the fair value of the May Notes as a result of mark-to-market adjustments and $2.0 million from the change in fair value of the Baker Notes as a result of mark-to-market adjustments unrelated to changes in credit risk, and $2.2 million in interest expense related to the Adjuvant Notes.

Total other expense, net, for the year ended December 31, 2021 primarily included $4.7 million in interest expense related to the Baker Notes and the Adjuvant Notes as described in Note 5- Debt and a $33.7 million recorded loss as a result of mark-to-market adjustments including the recorded loss from the change in fair value of the Baker Notes and the recorded gain from the change in fair value of the derivative liability

Liquidity and Capital Resources

Overview

As of December 31, 2022, we had a working capital deficit of $81.1 million and an accumulated deficit of $938.7 million. We have financed our operations to date primarily through the issuance of preferred stock, common stock and warrants, cash received from private placement transactions, the issuance of convertible notes and, to a lesser extent, product sales. As of December 31, 2022, we had approximately $2.8 million in cash and cash equivalents, and $0.9 million in restricted cash available for use from the Adjuvant Notes (as defined in Note 5- Debt). Our cash and cash equivalents include amounts held in checking accounts.

We have incurred losses and negative cash flows from operating activities since inception. During the year ended December 31, 2022, we received gross proceeds of $11.5 million from the sale of notes and warrants in three registered direct offerings, net proceeds of $7.4 million from the sale and issuance of common stock pursuant to the Stock Purchase Agreement, net proceeds of $18.1 million upon the sale and issuance of common stock and warrants from the May 2022 Public Offering, and $25.2 million from the exercise of common warrants.

We aim to reach operational earnings before interest, taxes, depreciation, amortization (EBITDA) break even on a normalized basis by year-end 2023 and anticipate that we will continue to restructure our trade payables with extended terms and to attempt to cure existing defaults. We have implemented measures, including headcount reductions in November 2022 and March 2023, to right size our cost structure with projected revenues. For 2023, we expect research and development expenses to decrease significantly primarily due to the completion of *EVOGUARD* and discontinuation of this clinical program in October 2022; selling and marketing expenses to decrease significantly due to reductions in media and marketing activities related to ongoing Phexxi promotional strategies; and general and administrative expenses to decrease slightly due to reductions in headcount partially offset by increased professional and consulting expenses.

Despite the letter of default, our senior lenders have not yet taken additional actions in accordance with their contractual rights. If we can cure existing defaults, we currently expect our liquidity resources as of December 31, 2022, together with the net proceeds from the 2023 Offerings, defined below, cost reductions, restructuring of outstanding account payable and liquidity tactics to be sufficient to fund our planned operations into the third quarter of 2023. We expect, once the 2023 Reverse Stock Split is effectuated, to be back in compliance under the terms of the Baker Notes. As of December 31, 2022, our significant commitments include the Baker Notes, as described in Note 5- Debt, our office lease, fleet leases, and our supply and manufacturing agreement with our Phexxi manufacturer, as described in Note 8- Commitments and Contingencies. The purpose of these commitments is to further the commercialization of Phexxi. We expect to fund these commitments through debt and equity issuances and product sales.

Our management is currently evaluating different strategies to obtain the required funding for our operations. These strategies may include, but are not limited to: public and private placements of equity and/or debt, licensing and/or collaboration arrangements and strategic alternatives with third parties, corporate restructuring, or other potential funding from third parties. Our ability to secure funding is subject to numerous risks and uncertainties, including the impact of the COVID-19 pandemic, geopolitical turmoil related to the ongoing hostilities in Ukraine and economic uncertainty related to rising inflation

and disruptions in the global supply chain. As a result, there can be no assurance that these funding efforts will be successful. Our ability to raise additional funds, and the terms on which those funds may be raised, will be dependent, in part, on how successful the commercialization of Phexxi is, the success of our cost reduction and gross-to-net improvement efforts, the accuracy of our estimates regarding cash needed to fund our operations, our ability to comply with the terms of our debt arrangements, and whether we are able to gain revenue traction prior to raising additional funds.

If we are not able to obtain required additional funding when and as needed, through equity financings or other means, or if we are unable to obtain funding on terms favorable to us, the shortfall in funds raised, or such unfavorable terms, will likely have a material adverse effect on our operations and strategic plan for future growth. If we cannot successfully raise the funding necessary to implement our current and ongoing liquidity tactics or as necessary to comply with obligations pursuant to our debt arrangements (including any acceleration of those obligations), we may be forced to make further reductions in spending, expand on our extended payment terms with suppliers, liquidate assets where possible, suspend or curtail planned programs, and/or cease operations entirely. Any of these developments would materially and adversely affect our financial condition and business prospects and could even cause us to be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and, in doing so, we may receive less than the value at which those assets are carried on our financial statements. Any of these developments would materially and adversely affect the price of our stock and the value of an investment in our stock. As a result, our financial statements include explanatory disclosures expressing substantial doubt about our ability to continue as a going concern.

The opinion of our independent registered public accounting firm on our audited financial statements as of and for the years ended December 31, 2022 and 2021 contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern. Future reports on our financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. Our audited consolidated financial statements as of and for the years ended December 31, 2022 and 2021 included in this Annual Report do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue our operations.

2023 Equity Financings

In February, March and April 2023, we entered into securities purchase agreements with certain investors providing for the sale and issuance of senior secured convertible notes (collectively, the 2023 SPAs). The 2023 SPAs included (i) convertible promissory notes with aggregate original principal amounts of approximately $1.4 million, $0.6 million, $0.5 million and $0.8 million, respectively (the 2023 Notes), and (ii) warrants to purchase an aggregate 69,230,769, 30,000,000, 26,923,077 and 76,923,077 shares of common stock, respectively (the 2023 Warrants and collectively, the 2023 Offerings). The 2023 Offerings closed on February 17, 2023 (the February 2023 Closing), March 13, 2023 and March 20, 2023 (the March 2023 Closings) and April 5, 2023 (the April 2023 Closing), respectively, with net proceeds to the Company, after deducting offering expenses, of approximately $0.7 million, $0.3 million, $0.3 million, and $0.5 million, respectively. The 2023 SPAs also included a Registration Rights Agreement requiring us to register the common stock underlying the 2023 Notes and 2023 Warrants within the time frames specified therein.

Upon the April 2023 Closing, the conversion and strike prices, as applicable, of the Baker Notes, Baker Warrants, the May 2022 Common Warrants, the June 2022 Baker Warrants, the Adjuvant Notes, the December 2022 Notes and Warrants, and the Notes and Warrants in the February and March 2023 Closing reset to $0.0065 per share, accordingly. Additionally, the Company’s outstanding Purchase Rights increased by approximately 3.1 billion since December 31, 2022.

2022 Debt and Equity Financings

As described in Note 5- Debt, we received net proceeds of $10.0 million, before issuance costs, from the sale of notes and warrants in two registered direct offerings in the first quarter of 2022. These notes were then exchanged for the May 2022 Notes during the May 2022 Exchange transaction, as defined in Note 5- Debt, which were subsequently exchanged for Purchase Rights during the debt restructuring in September 2022 with a total outstanding balance of $21.8 million immediately prior to the restructuring.

As described in Note 10 - Stockholders' Equity (Deficit), we received net proceeds of $18.1 million upon the sale and issuance of common stock and warrants from an underwritten public offering in May 2022, net proceeds of $7.4 million from the sale and issuance of common stock pursuant to the Stock Purchase Agreement, and $25.2 million from the exercise of common warrants.

As described in Note 5- Debt, we received gross proceeds of $2.3 million, before issuance costs, from the sale of notes, warrants and non-convertible Series D preferred stock in the December 2022.

2021 Equity Financings

As described in Note 10- Stockholders' Equity (Deficit), we received proceeds of approximately $28.0 million, net of underwriting discounts, from a public offering in March 2021, upon the issuance of 1,142,857 shares of our common stock, and approximately $4.2 million, net of underwriting discounts, from the issuance of 171,428 shares of common stock upon exercise of the underwriters' overallotment option in April 2021.

As described in Note 10- Stockholders' Equity (Deficit), we received proceeds of approximately $46.8 million, net of underwriting discounts and fees, from a public offering in May 2021, upon the issuance of 3,333,333 shares of common stock and common warrants to purchase 3,333,333 shares of common stock. We received approximately $2.4 million and $0.1 million, both net of underwriting discounts, from the issuance of 169,852 shares of common stock and 500,000 common warrants, respectively, upon exercise of the underwriter's overallotment option in May 2021.

As described in Note 10- Stockholders' Equity (Deficit), we received proceeds of approximately $9.6 million, net of offering expenses, from a registered direct offering in October 2021, upon the issuance of 5,000 shares of Series B-1 Convertible Preferred Stock and 5,000 shares of Series B-2 Convertible Preferred Stock.

Summary Statements of Cash Flows

The following table sets forth a summary of the net cash flow activity for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,		2022 vs. 2021	
	2022	2021	$ Change	% Change
Net cash, cash equivalents and restricted cash used in operating activities	$ (70,410)	$ (146,667)	$ 76,257	(52)%
Net cash, cash equivalents and restricted cash used in investing activities	(341)	(2,689)	2,348	(87)%
Net cash, cash equivalents and restricted cash provided by financing activities	61,939	90,693	(28,754)	(32)%
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (8,812)	$ (58,663)	$ 49,851	(85)%

Cash Flows from Operating Activities. During the years ended December 31, 2022 and 2021, the primary use of cash, cash equivalents and restricted cash was to fund commercialization of our lead product Phexxi, to fund the Phase 3 clinical trial to evaluate EVO100 for the prevention of chlamydia and gonorrhea, and to support selling and marketing and general and administrative operations.

Cash Flows from Investing Activities. During the year ended December 31, 2022, the change in net cash, cash equivalents and restricted cash used in investing activities was primarily due to $0.3 million in purchases of property and equipment. During the year ended December 31, 2021, the change in net cash, cash equivalents and restricted cash used in investing activities was primarily due to $2.9 million in purchases of property and equipment, offset by a $0.3 million cash inflow from the sale of Softcup line of business.

Cash Flows from Financing Activities. During the year ended December 31, 2022, the primary source of cash, cash equivalents and restricted cash was provided from the issuance of 22,665,000 shares of common stock, warrants to purchase 71,000,000 shares of common stock and pre-funded warrants to purchase 12,835,000 shares of common stock for net proceeds of $24.9 million; the issuance of 35,314,846 shares of our common stock for net proceeds of $25.2 million from the exercise of common warrants; and the issuance of 1,964,272 shares of common stock for net proceeds of $7.4 million and net proceeds of $11.5 million from the sale of term notes and warrants, net of original issue discount when applicable.

During the year ended December 31, 2021, the primary source of cash, cash equivalents and restricted cash was provided from the issuance of 4,817,470 shares of common stock and 500,000 shares of common warrants for proceeds of approximately $81.5 million, net of underwriting discounts, the issuance of 30,708 shares of our common stock under the 2019 Employee Stock Purchase Plan (ESPP) with proceeds of approximately $0.3 million, the issuance of 10,599 shares of common stock from the exercise of common warrants for proceeds of approximately $0.2 million, the issuance of 5,000 shares of Series B-1 Convertible Preferred Stock and 5,000 shares of Series B-2 Convertible Preferred Stock for proceeds of approximately $9.6 million, net of offering expenses, offset by $0.3 million in payments of tax withholdings related to vesting of restricted stock awards and $1.0 million in payments for financing issuance costs.

Operating and Capital Expenditure Requirements

Our specific future operating and capital expense requirements are difficult to forecast. However, we can anticipate the general types of expenses and areas in which they might occur in 2023 as follows: we expect research and development expenses to decrease significantly due to the completion of the *EVOGUARD* trial and discontinuation of the program developing EVO100; selling and marketing expenses to decrease significantly; and general and administrative expenses to increase slightly due to the reasons stated under the Operating Expenses section above.

Contractual Obligations and Commitments

Operating Leases

On December 31, 2022, operating lease ROU assets and lease liabilities were $4.4 million and $5.4 million, respectively, and were $5.4 million and $6.8 million, respectively, on December 31, 2021. See Note 8- Commitments and Contingencies for more detailed discussions on leases and financial statements information under ASC 842, *Leases.*

Other Contractual Commitments

As described in Note 8- Commitments and Contingencies, in November 2019, the Company entered into a supply and manufacturing agreement with a third-party to manufacture Phexxi, with potential to manufacture other product candidates in accordance with all applicable current good manufacturing practice regulations, pursuant to which the Company has certain minimum purchase commitments based on the forecasted product sales. The amounts purchased under the supply and manufacturing agreement were $1.0 million and $3.0 million for the years ended December 31, 2022 and 2021, respectively.

Intellectual Property Rights

As described in Note 8- Commitments and Contingencies, royalty costs owed to Rush University pursuant to the Rush License Agreement were $1.1 million and $0.2 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022 and 2021, approximately $0.6 million and $31,000 were included in accrued expenses in the consolidated balance sheets.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a "smaller reporting company" as defined in Rule 12(b) of the Exchange Act, we are not required to provide the information required by this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements and the report of our independent registered public accounting firm required pursuant to this item are included in this Annual Report on Form 10-K beginning on page F-1.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of the end of the period covered by this Annual Report, or December 31, 2022, our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, our disclosure controls and procedures were not effective as of December 31, 2022 due to the identified material weaknesses in our internal control over financial reporting as discussed below.

Notwithstanding the conclusion by our principal executive officer and principal financial officer that our disclosure controls and procedures as of December 31, 2022 were not effective and the material weaknesses identified in our internal controls over financial reporting described below, management believes that the consolidated financial statements and related financial information included in this Annual Report on Form 10-K fairly present in all material respects our financial condition, results of operations and cash flows as of the dates presented, and for the periods ended on such dates, in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). Our management, under the supervision and with the participation of our principal executive officer and principal financial officer, conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2022, based on the framework and criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("the COSO framework"). Based on this assessment, management concluded that, as of December 31, 2022, our internal control over financial reporting was not effective due to the existence of material weaknesses described below.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of our annual or interim financial statements would not be prevented or detected on a timely basis.

Our management identified material weaknesses in the Company's internal control over financial reporting primarily related to limited finance and accounting staffing levels that are not commensurate with the Company's complexity and its financial accounting and reporting requirements. The Company has had several organization changes, including the resignation of the some of its named executives, including the principal financial officer. Turnover of these key management positions of the Company led the financial reporting staff to rely increasingly on outsourced service providers and specialists, without adequate resources to monitor and operate internal controls of financial reporting.

Based on the above, the Company did not fully implement components of the COSO framework, including elements of the control environment, risk assessment, control activities, information and communication, and monitoring activities components.

Remediation Activities:

Management is continuing to evaluate the material weaknesses discussed above and is in the process of implementing its remediation plan, which includes the hiring of additional resources. However, we cannot provide assurance as to when our

remediation efforts will be complete and the material weaknesses cannot be considered remediated until the applicable controls have operated for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses.

This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting because that requirement under Section 404 of the Sarbanes-Oxley Act of 2002 was permanently removed for smaller reporting company filers pursuant to the provisions of Section 989G(a) set forth in the Dodd-Frank Wall Street Reform and Consumer Protection Act enacted into federal law in July 2010.

Changes in Internal Control over Financial Reporting

Except for the remediation activities described in the preceding paragraphs, there were no changes in our internal control over financial reporting that occurred during our quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Internal Controls

Management recognizes that a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item is incorporated herein by reference to our definitive proxy statement for our 2023 Annual General Meeting to be filed with the United States Securities and Exchange Commission.

Item 11. Executive Compensation.

The information required under this item is incorporated herein by reference to our definitive proxy statement for our 2023 Annual General Meeting to be filed with the United States Securities and Exchange Commission.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required under this item is incorporated herein by reference to our definitive proxy statement for our 2023 Annual General Meeting to be filed with the United States Securities and Exchange Commission.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required under this item is incorporated herein by reference to our definitive proxy statement for our 2023 Annual General Meeting to be filed with the United States Securities and Exchange Commission.

Item 14. Principal Accounting Fees and Services.

The information required under this item is incorporated herein by reference to our definitive proxy statement for our 2023 Annual General Meeting to be filed with the United States Securities and Exchange Commission.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Documents filed as part of this Annual Report

1. Financial Statements.

The Report of Independent Registered Public Accounting Firm, the financial statements and the notes to the financial statements listed above are set forth beginning on page F-1, immediately following the signature pages of this Annual Report.

2. Financial Statement Schedules.

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. Exhibits Required to Be Filed by Item 601 of Regulation S-K.

A list of exhibits is set forth on the following page and is incorporated herein by reference.

EXHIBIT INDEX

Exhibit No.	Exhibit Title	Filed Herewith	Incorporated by Reference		
			Form	File No.	Date Filed
3.1	Amended and Restated Certificate of Incorporation		10-Q	001-36754	5/10/2022
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation		8-K	001-36754	5/5/2022
3.3	Amended and Restated Bylaws of the Registrant.		8-K	001-36754	1/17/2018
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock		8-K	001-36754	3/24/2022
3.5	Certificate of Designation of Series D Preferred Shares		8-K	001-36754	12/21/2022
4.1	Form of Warrant.		8-K	001-36754	1/13/2022
4.2^^	Form of Senior Subordinated Note.		8-K	001-36754	1/13/2022
4.3^^	Form of Warrant.		8-K	001-36754	3/1/2022
4.4	Form of Senior Subordinated Note.		8-K	001-36754	3/1/2022
4.5^^	Form of Senior Subordinated Note.		8-K	001-36754	5/5/2022
4.6^^	Form of Senior Subordinated Note.		8-K	001-36754	5/5/2022
4.7	Form of Warrant.		8-K	001-36754	5/5/2022
4.8^^	Form of Pre-Funded Warrant		8-K	001-36754	5/23/2022
4.9^^	Form of Warrant[1]		8-K	001-36754	5/23/2022
10.1^^	Securities Purchase Agreement, dated as of January 13, 2022, by and amount Evofem Biosciences, Inc. and each investor listed therein.		8-K	001-36754	1/13/2022
10.2^^	Common Stock Purchase Agreement, dated as of February 15, 2022, by and between Evofem Biosciences, Inc. Seven Knotts, LLC.		8-K	001-36754	2/16/2022
10.3^^	Securities Purchase Agreement, dated as of March 1, 2022, by and amount Evofem Biosciences, Inc. and each investor listed therein.		8-K	001-36754	3/1/2022
10.4	Form of Exchange Agreement		8-K	001-36754	3/24/2022
10.5	Second Amendment to Securities Purchase and Security Agreement, dated as of April 23, 2020, by and among Evofem Biosciences, Inc., certain affiliates of Baker Bros. Advisors L.P. as purchases, and Baker Bros. Advisors LP. as designated agent.		8-K	001-36754	3/21/2022
10.6	First Amendment to Securities Purchase Agreement, dated as of October 14, 2020, by and among Evofem Biosciences, Inc. Adjuvant Global Health Technology Fund, L.P. and Adjuvant Global Health Technology Fund, DE LP.		8-K	001-36754	4/7/2022
10.7	Form of Amendment and Exchange Agreement		8-K	001-36754	5/5/2022
10.8	Form of Amendment and Exchange Agreement		8-K	001-36754	5/5/2022
10.9	Form of Amendment and Exchange Agreement		8-K	001-36754	5/5/2022
10.1	Office Sublease dated as of May 27, 2022 by and between Evofem Biosciences, Inc. and AMN Healthcare, Inc.		10-Q	001-36754	8/12/2022
10.11	Forbearance Agreement, dated as of September 15, 2022, by and among Evofem Biosciences, Inc. and certain institutional investors.		8-K	001-36754	9/16/2022
10.12	Forbearance Agreement, dated as of September 15, 2022, by and among Evofem Biosciences, Inc., Adjuvant Global Health Technology Fund, LP, and Adjuvant Global Health Technology Fund, DE, LP.		8-K	001-36754	9/16/2022
10.13	Subordination Agreement, dated as of September 15, 2022, by and among Global Health Technology Fund, LP, Adjuvant Global Health Technology Fund, DE, LP, and certain institutional investors and their designated agent.		8-K	001-36754	9/16/2022

1

10.14	Form of Investor Exchange Agreement.	8-K	001-36754	9/16/2022
10.15	Form of Adjuvant Exchange Agreement.	8-K	001-36754	9/16/2022
10.16	Form of Right.	8-K	001-36754	9/16/2022
10.17	Third Amendment to Securities Purchase and Security Agreement, dated as of September 15, 2022, by and among Evofem Biosciences, Inc., certain institutional investor and their designated agent.	8-K	001-36754	9/16/2022
10.18	Second Amendment to Securities Purchase Agreement, dated as of September 15, 2022, by and among Evofem Biosciences, Inc., Adjuvant Global Health Technology Fund, LP, and Adjuvant Global Health Technology Fund, DE, LP.	8-K	001-36754	9/16/2022
10.19	Form of Securities Purchase Agreement	8-K	001-36754	12/21/2022
10.20	Form of Senior Secured Convertible Note	8-K	001-36754	12/21/2022
10.21	Form of Warrant	8-K	001-36754	12/21/2022
10.22	Form of Registration Rights Agreement	8-K	001-36754	12/21/2022
10.23	First Amendment to Forbearance Agreement	8-K	001-36754	12/21/2022
10.24Δ	Amended and Restated 2007 Stock Plan, as amended.	S-1/A	333-199449	11/10/2014
10.25Δ	Form of Stock Option Agreement under 2007 Stock Plan.	10-K	001-36754	3/04/2021
10.26Δ	Evofem Biosciences, Inc. Amended and Restated 2014 Equity Incentive Plan.	10-K	001-36754	3/04/2021
10.27Δ	Form of Stock Option Agreement under Amended and Restated 2014 Equity Incentive Plan.	S-1/A	333-199449	11/10/2014
10.28Δ	Form of Restricted Stock Units Agreement under the Amended and Restated 2014 Equity Incentive Plan.	S-1/A	333-199449	11/10/2014
10.29Δ	Form of Restricted Stock Agreement under the Amended and Restated 2014 Equity Incentive Plan.	S-1/A	333-199449	11/10/2014
10.30Δ	Form of Notice of Grant of Restricted Stock Units under the Amended and Restated 2014 Equity Incentive Plan.	S-1/A	333-199449	11/10/2014
10.31Δ	Form of Notice of Grant of Restricted Stock under the Amended and Restated 2014 Equity Incentive Plan.	S-1/A	333-199449	11/10/2014
10.32Δ	Form of Notice of Grant of Stock Option under the Amended and Restated 2014 Equity Incentive Plan.	S-1/A	333-199449	11/10/2014
10.33Δ	2014 Employee Stock Purchase Plan.	S-1/A	333-199449	11/10/2014
10.34Δ	Evofem Biosciences Operations, Inc. Amended and Restated 2012 Equity Incentive Plan.	S-4	333-221592	11/15/2017
10.35Δ	Form of Notice of Option Grant and Option Agreement under the Evofem Biosciences Operations, Inc. Amended and Restated 2012 Equity Incentive Plan.	S-4	333-221592	11/15/2017
10.36Δ	Form of Notice of Grant of Restricted Stock Award under the Evofem Biosciences Operations, Inc. Amended and Restated 2012 Equity Incentive Plan.	S-4	333-221592	11/15/2017
10.37Δ	Evofem Biosciences, Inc. Incentive Recoupment Policy	10-K	001-36754	3/04/2021
10.38Δ	Amended and Restated Non-Employee Director Compensation Policy (to be effective April 1, 2022).	10-K	001-36754	3/10/2022
10.39Δ	Severance Agreement, dated as of April 27, 2015, by and between Evofem Biosciences Operations, Inc. and Saundra Pelletier.	S-4	333-221592	11/15/2017
10.40Δ	Offer Letter, dated as of April 15, 2015, by and between Evofem Biosciences Operations, Inc. and Kelly Culwell, M.D.	S-4	333-221592	11/15/2017
10.41Δ	Offer Letter, dated as of October 16, 2014, by and between Evofem Biosciences Operations, Inc. and Saundra Pelletier.	S-4	333-221592	11/15/2017
10.42Δ	Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers.	S-1	333-199449	10/17/2017

10.43Δ	Executive Employment Agreement, dated as of July 2, 2018, by and between the Registrant and Saundra Pelletier.		8-K	001-36754	7/03/2018
10.44Δ	Executive Employment Agreement, dated as of July 2, 2018, by and between the Registrant and Kelly Culwell, M.D.		8-K	001-36754	7/03/2018
21.1	List of Registrant Subsidiaries	X			
23.1	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.	X			
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
**101.INS†	XBRL Instance Document	X			
**101.SCH†	XBRL Taxonomy Extension Schema Document	X			
**101.CAL†	XBRL Taxonomy Extension Calculation Linkbase Document	X			
**101.DEF†	XBRL Definition Linkbase Document	X			
**101.LAB†	XBRL Taxonomy Extension Labels Linkbase Document	X			
**101.PRE†	XBRL Taxonomy Extension Presentation Linkbase Document	X			
**104	Cover Page Interactive Date File	X			

Δ Management Compensation Plan or arrangement.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, as amended.

^ The schedules and exhibits to the Merger Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.

^^ Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the SEC.

* Furnished herewith. This certification is being furnished solely to accompany this Annual Report pursuant to 18 U.S.C. 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation by reference language in such filing.

** The financial information of Evofem Biosciences, Inc. Annual Report on Form 10-K for the year ended December 31, 2022 filed on April 27, 2023 formatted in iXBRL (Inline Extensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) Parenthetical Data to the Consolidated Balance Sheets, (iii) the Consolidated Statements of Operations, (iv) the Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit, (v) the Consolidated Statements of Cash Flows, and (vi) Notes to Consolidated Financial Statements, is furnished electronically herewith.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned hereunto duly authorized.

EVOFEM BIOSCIENCES, INC.

April 27, 2023

By: /s/ Saundra Pelletier
Name: Saundra Pelletier
Title: *President, Chief Executive Officer and Interim Chairperson of the Board*

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Saundra Pelletier Saundra Pelletier	President, Chief Executive Officer and Interim Chairperson of the Board (*Principal Executive Officer*)	April 27, 2023
/s/ Ivy Zhang Ivy Zhang	Chief Financial Officer and Secretary (*Principal Financial Officer and Principal Accounting Officer*)	April 27, 2023
/s/ Kim P. Kamdar, Ph.D. Kim P. Kamdar, Ph.D.	Director	April 27, 2023
/s/ Tony O'Brien Tony O'Brien	Director	April 27, 2023
/s/ Colin Rutherford Colin Rutherford	Director	April 27, 2023
/s/ Lisa Rarick, M.D. Lisa Rarick, M.D.	Director	April 27, 2023

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Evofem Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Evofem Biosciences, Inc. and subsidiaries (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive operations, convertible and redeemable preferred stock and stockholders' deficit and cash flows, for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses, negative cash flows from operations since inception and has received a notice of default for its convertible notes, and does not have sufficient capital to repay such obligations, which are now currently due. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Debt and Fair Value of Financial Instruments — Refer to Notes 5 and 7 to the financial statements

Critical Audit Matter Description

In April 2020, the Company entered into a Securities Purchase and Security Agreement with certain affiliates of Baker Bros. Advisors LP, as purchasers, pursuant to which the Company agreed to issue and sell senior secured promissory notes (the "Baker Notes") in an aggregate principal amount of up to $25.0 million. The Baker Notes were issued and sold in two separate closings in April and June 2020 and remain outstanding at December 31, 2022. The Company elected the fair value option under ASC 825, Financial Instruments ("ASC 825") and recognized the hybrid debt instrument at fair value inclusive of the embedded features. The fair value of the Baker Notes was determined by estimating the fair value of the Market Value of Invested Capital of the Company. This was estimated using forms of the cost and market approaches. In the Cost approach, an

adjusted net asset value method was used to determine the net recoverable value of the Company, including an estimate of the fair value of the Company's intellectual property. The estimated fair value of the Company's intellectual property was valued using a relief from royalty method which required management to make significant estimates and assumptions related to forecasts of future revenue, and the selection of the royalty and discount rates. As of December 31, 2022, the Company recorded the fair value of the Baker Notes at $39.4 million.

We identified the Company's estimate of the fair value for the Baker Notes as a critical audit matter due to the significant estimates and assumptions made by management related to forecasts of future revenue, and the selection of the royalty and discount rates to determine the fair value of the Company's intellectual property. This required a high degree of auditor judgment and an increased extent of effort, including the need to involve our fair value specialists, when performing audit procedures to evaluate the reasonableness of management's forecasts of future revenue and the selection of the royalty and discount rates for the intellectual property.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the Company's determination of the fair value of the Baker Notes included the following, among others:

- We evaluated management's ability to accurately forecast future revenue by comparing actual revenues to management's historical forecasts.
- We evaluated the reasonableness of management's forecasts of future revenue by comparing the forecasts to (1) historical results, (2) internal communications to management and the Board of Directors, and (3) the overall estimated market size.
- With the assistance of fair value specialists, we evaluated the reasonableness of the royalty and discount rates by (1) testing the underlying source information and mathematical accuracy of the calculations (2) developing a range of independent estimates and comparing those to the discount rates selected by management and (3) understanding the facts and circumstances around the selected royalty rate.

/s/ Deloitte & Touche LLP

San Diego, CA
April 27, 2023

We have served as the Company's auditor since 2015.

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(In thousands, except par value and share data)

	December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 2,769	$ 7,732
Restricted cash	1,207	5,056
Trade accounts receivable, net	1,126	6,449
Inventories	5,379	7,674
Prepaid and other current assets	2,218	3,229
Total current assets	12,699	30,140
Property and equipment, net	3,940	5,774
Operating lease right-of-use assets	4,406	5,395
Other noncurrent assets	4,118	1,203
Total assets	$ 25,163	$ 42,512
Liabilities, convertible and redeemable preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 14,984	$ 10,316
Convertible notes payable - carried at fair value (Note 5)	39,416	81,717
Convertible notes payable - Adjuvant (Note 5)	26,268	27,209
Accrued expenses	4,124	8,370
Accrued compensation	2,175	4,653
Operating lease liabilities – current	2,311	2,332
Derivative liabilities	1,676	202
Other current liabilities	2,876	2,864
Total current liabilities	93,830	137,663
Operating lease liabilities – noncurrent	3,133	4,424
Total liabilities	96,963	142,087
Commitments and contingencies (Note 8)		
Convertible and redeemable preferred stock, $0.0001 par value		
Series B-1 convertible preferred stock, no shares issued and outstanding as of December 31, 2022 and 2021	—	—
Series B-2 convertible preferred stock, no shares and 5,000 shares issued and outstanding at December 31, 2022 and 2021, respectively	—	4,740
Stockholders' deficit		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized; no equity-classified preferred stock issued and outstanding at December 31, 2022 and 2021	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized; 123,098,285 and 10,833,308 shares issued and outstanding at December 31, 2022 and 2021, respectively	12	16
Additional paid-in capital	817,355	751,260
Accumulated other comprehensive income	49,527	5,089
Accumulated deficit	(938,694)	(860,680)
Total stockholders' deficit	(71,800)	(104,315)
Total liabilities, convertible and redeemable preferred stock and stockholders' deficit	$ 25,163	$ 42,512

See accompanying notes to the consolidated financial statements.

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)

	Years Ended December 31,	
	2022	**2021**
Product sales, net	$ 16,837	$ 8,244
Operating expenses:		
Cost of goods sold	4,415	4,055
Research and development	25,032	33,129
Selling and marketing	43,951	113,152
General and administrative	27,563	24,709
Total operating expenses	100,961	175,045
Loss from operations	(84,124)	(166,801)
Other income (expense):		
Interest income	85	15
Other expense	(2,087)	(4,732)
Gain on issuance of financial instruments, net	(72,993)	—
Change in fair value of financial instruments	82,465	(33,657)
Total other income (expense), net	7,470	(38,374)
Loss before income tax	(76,654)	(205,175)
Income tax expense	(44)	(17)
Net loss	(76,698)	(205,192)
Series B-1 and B-2 convertible preferred stock deemed dividends	(1,316)	(1,047)
Net loss attributable to common stockholders	$ (78,014)	$ (206,239)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.34)	$ (23.63)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	58,248,079	8,727,253

See accompanying notes to the consolidated financial statements.

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE OPERATIONS

(In thousands, except share and per share data)

	Years Ended December 31	
	2022	**2021**
Net loss	$ (76,698)	$ (205,192)
Other comprehensive income:		
Change in fair value of financial instruments attributed to credit risk change	44,438	5,089
Comprehensive loss	$ (32,260)	$ (200,103)

See accompanying notes to consolidated financial statements.

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CONVERTIBLE AND REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) (In thousands, except share data)

	Series B Convertible and Redeemable Preferred Stock		Series C Convertible and Redeemable Preferred Stock		Stockholders' Equity (Deficit)					
					Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2020	—	$ —	—	—	5,423,387	$ 1	$ 656,834	$ —	$ (655,488)	$ 1,347
Issuance of common stock in connection with the March 2021 and May 2021 Public Offering (see Note 10)	—	—	—	—	4,817,470	—	80,799	—	—	80,799
Issuance of common stock - ESPP	—	—	—	—	30,708	—	297	—	—	297
Issuance of common stock upon cash exercise of warrants	—	—	—	—	10,599	—	159	—	—	159
Issuance of series B-1and B-2 convertible preferred stock deemed dividends	10,000	9,081	—	—	—	—	—	—	—	—
Conversion of series B-1 convertible preferred stock	(5,000)	(4,631)	—	—	529,100	—	5,662	—	—	5,662
Deemed dividends on series B-1 and B-2 convertible preferred stock	—	290	—	—	—	—	(1,047)	—	—	(1,047)
Restricted stock awards issued	—	—	—	—	118,498	—	—	—	—	—
Restricted stock awards cancelled	—	—	—	—	(71,588)	—	—	—	—	—
Shares withheld to cover taxes related to vesting of restricted stock awards	—	—	—	—	(24,866)	—	(327)	—	—	(327)
Change in fair value of financial instruments attributed to credit risk change	—	—	—	—	—	—	—	5,089	—	5,089
Stock-based compensation	—	—	—	—	—	—	8,898	—	—	8,898
Net loss	—	—	—	—	—	—	—	—	(205,192)	(205,192)
Balance at December 31, 2021	**5,000**	**$ 4,740**	**—**	**$ —**	**10,833,308**	**$ 1**	**$ 751,275**	**$ 5,089**	**$ (860,680)**	**$ (104,315)**

	Series B Convertible and Redeemable Preferred Stock		Series C Convertible and Redeemable Preferred Stock		Stockholders' Equity (Deficit)					
					Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Issuance of common stock - Stock Purchase Agreement (Note 10)	—	$ —	—	$ —	2,092,430	$ —	7,953	$ —	$ —	7,953
Issuance of common stock - May 2022 Public Offering (see Note 10)	—	—	—	—	22,665,000	2	1,237	—	—	1,239
Issuance of common stock upon cash exercise of warrants and pre-funded warrants	—	—	—	—	48,149,846	5	41,927	—	—	41,932
Issuance of common stock - ESPP	—	—	—	—	75,169	—	20	—	—	20
Issuance of common stock - a360 Media	—	—	—	—	6,738,544	1	3,407	—	—	3,408
Issuance of common stock upon noncash exercise of Purchase Rights	—	—	—	—	32,586,530	3	1,002	—	—	1,005
Conversion of series B-2 convertible preferred stock (see Note 10)	(1,200)	(1,143)	—	(72)	293,496	—	1,251	—	—	1,251
Exchange of series B-2 convertible preferred stock (see Note 10)	(1,700)	(1,616)	1,700	1,616	—	—	—	—	—	—
Convertible preferred stock deemed dividends	—	118	—	84	—	—	(81)	—	—	(81)
Restricted stock awards issued	—	—	—	—	157,333	—	—	—	—	—
Restricted stock awards cancelled	—	—	—	—	(157,328)	—	—	—	—	—
May 2022 exchange transaction	(2,100)	(2,099)	(1,700)	(1,628)	(325,002)	—	3,655	—	(1,316)	2,339
Cash repurchase of fractional common stock after the reverse stock split	—	—	—	—	(11,041)	—	(18)	—	—	(18)
Issuance of December 2022 Notes (see Note 5)	—	—	—	—	—	—	1,344	—	—	1,344
Change in fair value of financial instruments attributed to credit risk change	—	—	—	—	—	—	—	44,438	—	44,438
Modification of Baker Warrants (see Note 5)	—	—	—	—	—	—	1,070	—	—	1,070
Stock-based compensation	—	—	—	—	—	—	3,313	—	—	3,313
Net loss	—	—	—	—	—	—	—	—	(76,698)	(76,698)
Balance at December 31, 2022	**—**	**$ —**	**—**	**$ —**	**123,098,285**	**$ 12**	**$ 817,355**	**$ 49,527**	**$ (938,694)**	**$ (71,800)**

See accompanying notes to the consolidated financial statements.

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (76,698)	$ (205,192)
Adjustments to reconcile net loss to net cash, cash equivalents and restricted cash used in operating activities:		
Loss on issuance of financial instruments	72,993	—
Change in fair value of financial instruments	(82,465)	33,657
Stock-based compensation	3,313	8,898
Depreciation	1,015	1,023
Noncash lease expenses	1,031	1,404
Noncash interest expenses	2,176	2,665
Noncash inventory reserve	(300)	300
Noncash instrument exchange expense	514	—
Loss on disposal of property and equipment	926	—
Financial instrument modification expense	1,067	—
Changes in operating assets and liabilities:		
Accounts receivable	5,323	(5,382)
Inventories	1,566	(21)
Prepaid and other assets	2,593	13,882
Accounts payable	4,474	(4)
Accrued expenses and other liabilities	(4,106)	5,471
Accrued compensation	(2,478)	(1,861)
Operating lease liabilities	(1,354)	(1,507)
Net cash, cash equivalents and restricted cash used in operating activities	(70,410)	(146,667)
Cash flows from investing activities:		
Proceeds from sale of Softcup line of business	—	250
Purchases of property and equipment	(341)	(2,939)
Maturities of short-term investments	—	—
Net cash, cash equivalents and restricted cash (used in) provided by investing activities	(341)	(2,689)
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants, net of discounts and commissions - public offerings	24,882	81,534
Proceeds from issuance of common stock - exercise of warrants	25,211	159
Proceeds from issuance of common stock, net of commissions - ATM transactions	7,438	—
Proceeds from issuance of common stock - ESPP and exercise of stock options	20	297
Proceeds from issuance of preferred stock - registered direct offering	—	10,000
Payments under term notes	(5,892)	—
Borrowings under convertible notes	11,500	—
Cash repurchase of fractional common stock after the reverse stock split	(18)	—
Cash paid for financing costs	(1,202)	(970)
Payments of tax withholdings related to vesting of restricted stock awards	—	(327)
Net cash, cash equivalents and restricted cash provided by financing activities	61,939	90,693
Net change in cash, cash equivalents and restricted cash	(8,812)	(58,663)
Cash, cash equivalents and restricted cash, beginning of period	13,588	72,251
Cash, cash equivalents and restricted cash, end of period	$ 4,776	$ 13,588
Supplemental cash flow information:		
Cash paid for interest	$ 698	1,389
Cash paid for taxes	$ 26	$ 11
Supplemental disclosure of noncash investing and financing activities:		
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	$ 476
Conversion of series B-2 and B-1, respectively, convertible preferred stock to common stock	$ 1,187	$ 1,032
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	$ —
Issuance of common stock from exercise of Purchase Rights	$ 1,007	$ —

See accompanying notes to the consolidated financial statements.

1. Description of Business and Basis of Presentation

Description of Business

Evofem is a San Diego-based, commercial-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health.

The Company's first commercial product, Phexxi® (lactic acid, citric acid, and potassium bitartrate) vaginal gel (Phexxi), was approved by the Food and Drug Administration (FDA) on May 22, 2020 and is the first and only FDA-approved, hormone-free, woman-controlled, on-demand prescription contraceptive gel for women. The Company commercially launched Phexxi in September 2020.

Until October 2022, the Company was developing EVO100 for the prevention of urogenital chlamydia and gonorrhea in women. Based on the positive, statistically significant outcomes of a Phase 2B/3 trial (AMPREVENCE), the Company initiated a Phase 3 clinical trial (EVOGUARD) to evaluate EVO100 for these potential indications in 2020. On October 11, 2022, the Company reported that EVOGUARD did not achieve its efficacy endpoints. The Company has discontinued investment in this development program. We remain focused on continuing to meet the unmet contraceptive need of millions of women with Phexxi.

Basis of Presentation and Principles of Consolidation

The Company prepared the consolidated financial statements in accordance with accounting principles generally accepted in the United States (GAAP) and the rules and regulations of the Securities and Exchange Commission (SEC) related to annual reports on Form 10-K. The Company's financial statements are presented on a consolidated basis, which include the accounts of the Company and its wholly-owned subsidiaries. Intercompany accounts and transactions have been eliminated in consolidation.

Risks, Uncertainties and Going Concern

The Company is susceptible to risks and uncertainties associated with the COVID-19 pandemic, which is affecting its employees, customers, communities, and business operations, as well as the U.S. and global economies and financial markets.

Any disruptions in the commercialization of Phexxi and/or its supply chain could have a material adverse effect on its business, results of operations and financial condition. The full extent to which the ongoing COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and/or financial condition will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19, the success of ongoing COVID-19 vaccination efforts, the emergence, prevalence and strength of variant strains, actions taken to contain or treat the disease, as well as the economic impact on local, regional, national and international markets. The COVID-19 pandemic slowed the Company's ability to generate product sales of Phexxi due to reduced access to medical offices and HCPs.

The consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities, in the normal course of business, and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty.

The Company's principal operations have been related to research and development, including the development of Phexxi, and to its commercially related sales and marketing efforts. Additional activities have included raising capital, recruiting personnel and establishing and maintaining a corporate infrastructure to support a commercial product. The Company has incurred operating losses and negative cash flows from operating activities since inception. As of December 31, 2022, the Company had cash and cash equivalents of $2.8 million and $0.9 million in restricted cash from the Adjuvant Notes (as defined in Note 5- Debt) that is available for use, a working capital deficit of $81.1 million and an accumulated deficit of $938.7 million.

In October 2022, the Company reported that EVOGUARD did not achieve its efficacy endpoints. The Company has discontinued investment in this development program. In March 2023, the Company received a Notice of Event of Default and Reservation of Rights (the Notice of Default) from Baker Bros claiming that the Company has failed to maintain the required shares reserved amount per the Third Baker Amendment as defined in Note 5- Debt. In addition, the Notice of Default resulted in a cross default under all outstanding debt.

Management's plans to meet its cash flow needs in the next 12 months include generating recurring product revenue, restructuring its current payables, curing the event of default under its debt arrangements, and obtaining additional funding such as through the issuance of its capital stock, non-dilutive financings, or through collaborations or partnerships with other companies, including license agreements for Phexxi in foreign markets.

The Company's common stock began trading on the OTCQB® Venture Market (the OTCQB) of the OTC Markets Group, Inc., a centralized electronic quotation service for over-the-counter securities, effective October 3, 2022 under the symbol "EVFM." While the Company's common stock was previously listed on the Nasdaq Capital Market (Nasdaq) under the symbol "EVFM", on August 11, 2022, it was suspended from trading on the Nasdaq due to noncompliance with the Nasdaq's minimum bid price requirement. On October 26, the Company's common stock was formally delisted from Nasdaq. The delisting of the Company's shares from Nasdaq makes shares of the Company's common stock less liquid and makes it more difficult for the Company to raise funds when and as needed to fund its operations.

The Company has recognized limited revenues since the launch of Phexxi in September 2020 and anticipates it will continue to incur net losses for the foreseeable future. According to management estimates, liquidity resources as of December 31, 2022 are not sufficient to maintain the Company's cash flow needs for the twelve months from the date of issuance of these consolidated financial statements.

If the Company is not able to obtain the required funding, through a significant increase in revenue, equity or debt financings, license agreements for Phexxi in foreign markets, or other means, or is unable to obtain funding on terms favorable to the Company, or if the event of default under its existing debt arrangements is not cured or there is another event of default affecting the notes payable, there will be a material adverse effect on commercialization and development operations, seek bankruptcy protection, and the Company's ability to execute its strategic development plan for future growth. If the Company cannot successfully raise additional funding and implement its strategic development plan, the Company may be forced to make further reductions in spending, including spending in connection with its commercialization activities, extend payment terms with suppliers, liquidate assets where possible at a potentially lower amount than as recorded in the consolidated financial statements, suspend or curtail planned operations or cease operations entirely. Any of these could materially and adversely affect the Company's liquidity, financial condition and business prospects, and the Company would not be able to continue as a going concern. The Company has concluded that these circumstances and the uncertainties associated with the Company's ability to obtain additional equity or debt financing on terms that are favorable to the Company, or at all, and otherwise succeed in its future operations raise substantial doubt about the Company's ability to continue as a going concern.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and the notes thereto.

Significant estimates affecting amounts reported or disclosed in the consolidated financial statements include, but are not limited to: the assumptions used in measuring the revenue gross-to-net variable consideration items; the trade accounts receivable credit loss reserve estimate; the discount rate used in estimating the fair value of the lease right-of-use (ROU) assets and lease liabilities; the assumptions used in estimating the fair value of convertible notes, warrants and purchase rights issued; the useful lives of property and equipment; the recoverability of long-lived assets; and clinical trial accruals; the assumptions used in estimating the fair value of stock-based compensation expense. These assumptions are more fully described in Note 3- Revenue, Note 5- Debt, Note 7- Fair Value of Financial Instruments, Note 8- Commitments and Contingencies, and Note 11- Stock-based Compensation. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances and adjusts when facts and circumstances dictate. The estimates are the basis for making

judgments about the carrying values of assets, liabilities and recorded expenses that are not readily apparent from other sources. As future events and their effects cannot be determined with precision, actual results may materially differ from those estimates or assumptions.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker, the Chief Executive Officer of the Company, in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and restricted cash. Deposits in the Company's checking, time deposit and investment accounts are maintained in federally insured financial institutions and are subject to federally insured limits or limits set by Securities Investor Protection Corporation. The Company invests in funds through a major U.S. bank and is exposed to credit risk in the event of default to the extent of amounts recorded on the consolidated balance sheets.

The Company has not experienced any losses in such accounts and believes it is not exposed to significant concentrations of credit risk on its cash, cash equivalents and restricted cash balances on amounts in excess of federally insured limits due to the financial position of the depository institutions in which these deposits are held. The Company's deposits were primarily held in Silicon Valley Bank prior to their closure by regulators, however, the Company was subsequently able to regain full access to all its deposits and moved these to a different financial institution.

The Company is also subject to credit risk related to its trade accounts receivable from product sales. Its customers are located in the United States and consist of wholesale distributors, retail pharmacies, and a mail-order specialty pharmacy. The Company extends credit to its customers in the normal course of business after evaluating their overall financial condition and evaluates the collectability of its accounts receivable by periodically reviewing the age of the receivables, the financial condition of its customers, and its past collection experience. Historically, the Company has not experienced any credit losses. As of December 31, 2022, based on the evaluation of these factors the Company did not record an allowance for doubtful accounts. Phexxi is distributed primarily through three major distributors and a mail-order pharmacy, who receive service fees calculated as a percentage of the gross sales, and fee per units shipped, respectively. These entities are not obligated to purchase any set number of units and distribute Phexxi on demand as orders are received. For the years ended December 31, 2022, and 2021, the Company's three largest customers combined made up approximately 77% and 75% of its gross product sales, respectively. As of December 31, 2022 and 2021, the Company's four largest customers combined made up 81% and the Company's three largest customers combined made up 75%, respectively, of its trade accounts receivable balance.

Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents consist of readily available cash in checking accounts and money market funds. Restricted cash consists of cash held in monthly time deposit accounts and letters of credit, which are collateral for the Company's credit cards, facility leases and fleet leases, as described in Note 8- Commitments and Contingencies. As of December 31, 2022, the Company maintained letters of credit of $0.8 million and $0.3 million for its office lease and fleet leases, respectively. Additionally, the remaining $0.9 million of the $25.0 million received from the issuance of Adjuvant Notes (as defined below) in the fourth quarter of 2020 is classified as restricted cash due to the Company's contractual obligation to use the funds for specific purposes. Refer to Note 14 – Subsequent Events for forfeiture of the $0.8 million letter of credit related to the office lease.

The following table provides a reconciliation of cash, cash equivalents and restricted cash, reported within the consolidated statements of cash flows (in thousands):

	Years Ended December 31,	
	2022	2021
Cash and cash equivalents	$ 2,769	$ 7,732
Restricted cash	1,207	5,056
Restricted cash included in other noncurrent assets	800	800
Total cash, cash equivalents and restricted cash presented in the consolidated statements of cash flows	$ 4,776	$ 13,588

Trade Accounts Receivable and Allowance

Trade accounts receivable are amounts owed to the Company by its customers for product that has been delivered. The trade accounts receivable are recorded at the invoice amount, less prompt pay and other discounts, chargebacks, and an allowance for credit losses, if any. The allowance for credit losses is the Company's estimate of losses over the life of the receivables. The Company determines the allowance for credit losses based on its historical payment information by customer and the analysis of the trade accounts receivable balance by customer segment. When the collectability of an invoice is no longer probable, the Company will create a reserve for that specific receivable. If a receivable is determined to be uncollectible, it is charged against the general credit loss reserve or the reserve for the specific receivable, if one exists.

Fair Value of Financial Instruments

The Company defines fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities that are required to be recorded at fair value, the Company considers the principal or most advantageous market in which to transact and the market-based risk. The Company applies fair value accounting for all assets and liabilities that are recognized or disclosed at fair value in the consolidated financial statements on a recurring basis.

The valuation of assets and liabilities are subject to fair value measurements using a three-tiered approach. Fair value measurement is classified and disclosed by the Company in one of the following three categories:

Level 1:	Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
Level 2:	Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability;
Level 3:	Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents, restricted cash, accounts payable, accrued expenses and accrued compensation approximate their fair values due to their short-term nature.

The Company believes that the Adjuvant Notes bear interest at a rate that approximates prevailing market rates for instruments with similar characteristics and, accordingly, the carrying value of the Adjuvant Note, as defined below, approximates fair value. The Company estimates the fair value of long-term debt utilizing an income approach. The Company uses a present value calculation to discount principal and interest payments and the final maturity payment on these liabilities using a discounted cash flow model based on observable inputs. The debt instrument is then discounted based on what the current market rates would be as of the reporting date. Based on the assumptions used to value these liabilities at fair value, the debt instrument is categorized as Level 2 in the fair value hierarchy.

Inventories

Inventories, consisting of purchased materials, direct labor and manufacturing overheads, are stated at the lower of cost, or net realizable value. Cost is determined on a first-in, first-out basis. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. At each balance sheet date, the Company evaluates ending inventories for excess quantities, obsolescence, or shelf-life expiration. The evaluation includes an analysis of the Company's current and future strategic plans, anticipated future sales, the price projections of future demand, and the remaining shelf life of goods on hand. To the extent that management determines there are excess or obsolete inventory or quantities with a shelf life that is too near its expiration for the Company to reasonably expect that it can sell those products prior to their expiration, the Company adjusts the carrying value to estimated net realizable value in accordance with the first-in, first-out inventory costing method.

Property and Equipment

Property and equipment generally consist of research equipment, computer equipment and software and office furniture. Property and equipment are recorded at cost and depreciated over the estimated useful lives of the assets (generally three to five years) using the straight-line method. Leasehold improvements are stated at cost and are amortized on a straight-line basis over the lesser of the remaining term of the related lease or the estimated useful lives of the assets. Repairs and maintenance costs are charged to expense as incurred and improvements and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the consolidated balance sheets and any resulting gain or loss is reflected in the consolidated statements of operations in the period realized.

Impairment of Long-lived Assets

The Company reviews property and equipment for impairment on an annual basis and whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. An impairment loss would be recognized when estimated future undiscounted cash flows relating to the asset or asset group are less than its carrying amount. An impairment loss is measured as the amount by which the carrying amount of an asset or asset group exceeds its fair value. The Company did not recognize an impairment loss related to long-lived assets during the years ended December 31, 2022 and 2021.

Clinical Trial Accruals

As part of the process of preparing the financial statements, the Company is required to estimate expenses resulting from obligations under contracts with vendors, clinical research organizations (CROs), consultants and under clinical site agreements relating to conducting clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

The Company's objective is to reflect the appropriate clinical trial expenses in our consolidated financial statements by recording those expenses in the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the clinical trial as measured by patient progression and the timing of various aspects of the trial. Management determines accrual estimates through financial models and discussions with applicable personnel and outside service providers as to the progress of clinical trials.

During a clinical trial, the Company adjusts the clinical expense recognition if actual results differ from its estimates. The Company makes estimates of accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. The Company's clinical trial accruals are partially dependent upon accurate reporting by CROs and other third-party vendors. The Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low for any period.

Fair Value of Warrants

Upon the issuance of the warrants, they are initially measured at fair value and reviewed for the appropriate classification (liability or equity). Warrants determined to require liability accounting are subsequently re-measured with changes in fair value being recognized as a component of other income (expense), net in the consolidated statements of operations. Warrants are value using an option pricing model based on the applicable assumptions, which include the exercise price of the warrants, time to expiration, expected volatility of our peer group, risk-free interest rate, and expected dividends. The Company re-evaluates the classification of its warrants at each balance sheet to determine the proper balance sheet classification for them. The assumptions used in the OPM are considered level 3 assumptions and include, but are not limited to, the market value of invested capital, our cumulative equity value as a proxy for the exercise price, the expected term the purchase rights will be held prior to exercise and a risk-free interest rate, and probability of change of control events.

Leases

The Company determines if an arrangement is a lease or implicitly contains a lease at inception based on the lease definition, and if the lease is classified as an operating lease or finance lease in accordance with ASC 842, *Leases* (ASC 842). Operating leases are included in operating lease ROU assets and operating lease liabilities in the Company's consolidated balance sheets. ROU assets represent the Company's right to use an underlying asset for the lease term. Lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at commencement date or the Adoption Date for existing leases based on the present value of lease payments over the lease term using an estimated discount rate.

For leases which do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at commencement date or the Adoption Date in determining the present value of lease payments over a similar term. In determining the estimated incremental borrowing rate, the Company considers a rate obtained from its primary banker for discussion purposes of a potential collateralized loan with a term similar to the lease term; the Company's historical borrowing capability in the market; and the Company's costs incurred for underwriting discounts and financing costs in its previous equity financings. For leases which have an implicit rate, the Company uses the rate implicit in the lease to determine the present value of the lease payments. The ROU assets also include any lease payments made and exclude lease incentives. For operating leases, lease expense is recognized on a straight-line basis over the lease term. Lease and non-lease components within a contract are generally accounted for separately. Short-term leases of 12 months or less, if any. are expensed as incurred which approximates the straight-line basis due to the short-term nature of the leases.

Operating lease ROU assets and lease liabilities were $4.4 million and $5.4 million on December 31, 2022, respectively, and were $5.4 million and $6.8 million on December 31, 2021, respectively. See Note 8 - Commitments and Contingencies for more detailed discussions on leases and financial statements information under ASC 842.

Revenue

The Company recognizes revenue from the sale of Phexxi in accordance with ASC 606, *Revenue from Contracts with Customers* (ASC 606). Revenue is recognized when the Company's performance obligation is satisfied by transferring control of the product to a customer. In accordance with the Company's contracts with customers, control of the product is transferred upon the conveyance of title, which occurs when the product is sold to and received by a customer. The amount of revenue recognized by the Company is equal to the amount of consideration that is expected to be received from the sale of product to its customers.

An estimate for variable consideration is made with each sale and is recorded in conjunction with the revenue being recognized. To calculate the variable consideration, the Company uses the expected value method. If the estimated amount is payable to a customer, it is recorded as a reduction to accounts receivable. If the estimated amount is payable to an entity other than a customer, it is recorded as a current liability.

Research and Development

Research and development expenses include costs associated with the Company's research and development activities, including, but not limited to, payroll and personnel-related expenses, stock-based compensation expense, materials, laboratory supplies, clinical studies, and outside services. Research and development costs are expensed as incurred, except when accounting for

nonrefundable advance payments for goods or services not yet received. These payments, if any, are capitalized at the time of payment and expensed as the related goods are delivered or the services are performed.

Advertising

Costs for producing advertising are expensed when incurred. Costs for communicating advertising, such as television commercial airtime and print media space, are recorded as prepaid expenses and then expensed when the advertisement occurs.

Patent Expenses

The Company expenses all costs incurred relating to patent applications, including, but not limited to, direct application fees and the legal and consulting expenses related to making such applications. Such costs are included in general and administrative expenses in the consolidated statements of operations.

Stock-based Compensation

Stock-based compensation expense for stock options issued to employees, non-employee directors and consultants is measured based on estimating the fair value of each stock option on the date of grant using the BSM option-pricing model.

The following table summarizes the Company's stock-based awards expensing policies for employees and non-employees:

	Employees and Nonemployee Consultants
Service only condition	Straight-line based on the grant date fair value
Performance criterion is probable of being met:	
Service criterion is complete	Recognize the grant date fair value of the award(s) once the performance criterion is considered probable of occurrence
Service criterion is not complete	Expense using an accelerated multiple-option approach[(1)] over the remaining requisite service period
Performance criterion is not probable of being met and:	No expense is recognized until the performance criterion is considered probable at which point expense is recognized using an accelerated multiple-option approach

(1) The accelerated multiple-option approach results in compensation expense being recognized for each separately vesting tranche of the award as though the award was in substance multiple awards and, therefore, results in accelerated expense recognition during the earlier vesting periods.

Fair Value of Stock Options

The fair value of stock options is determined using the BSM option-pricing model based on the applicable assumptions, which includes the exercise price of warrants, time to expiration, expected volatility of our peer group, risk-free interest rate and expected dividend. The Company records forfeitures when they occur.

Performance-based Awards

For performance-based RSAs (i) the fair value of the award is determined on the grant date, (ii) the Company assesses the probability of the individual milestone under the award being achieved, and (iii) the fair value of the shares subject to the milestone is expensed over the implicit service period commencing once management believes the performance criteria is probable of being met. If the performance-based RSAs are modified, the Company applies the share-based payment modification accounting in accordance with ASC 718, *Compensation-Stock Compensation* (ASC 718).

Income Taxes

The accounting guidance for uncertainty in income taxes prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities based on the technical merits of the position.

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial reporting and the tax reporting basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized. When the Company establishes or reduces the valuation allowance against its deferred tax assets, its provision for income taxes will increase or decrease, respectively, in the period such determination is made.

Net Loss per Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share calculation, potentially dilutive securities are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive and therefore, basic and diluted net loss per share were the same for all periods presented. Potentially dilutive securities excluded from the calculation of diluted net loss per share are summarized in the table below. Common shares were calculated for the Series B-2 Convertible Preferred Stock and the convertible debt using the if-converted method.

	Years Ended December 31,	
	2022	**2021**
Common stock to be purchased under the 2019 ESPP	—	33,910
Options to purchase common stock	709,119	708,329
Warrants to purchase common stock	256,545,987	4,517,807
Series B-2 convertible preferred stock	—	555,555
Purchase rights to purchase common stock	561,275,330	—
Convertible debt	2,263,210,550	1,192,167
Total	3,081,740,986	7,007,768

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, *Debt* (ASU No. 2020-06), removing, modifying, and adding certain disclosure requirements of ASC 470, *Debt with Conversion and Other Options*, and ASC 815, *Derivatives and Hedging - Contracts in Entity's Own Equity* (ASC 815). ASU No. 2020-06 will be effective for the Company beginning January 1, 2024 and early adoption is allowed. The adoption of ASU No. 2020-06 did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements — Not Yet Adopted

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or other standards setting bodies that are adopted as of the specified effective date. The Company believes the impact of recently issued standards and any issued but not yet effective standards will not have a material impact on its consolidated financial statements upon adoption.

3. Revenue

The Company recognizes revenue from the sale of Phexxi in accordance with ASC 606, *Revenue from Contracts with Customers* (ASC 606). The provisions of ASC 606 require the following steps to determine revenue recognition: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; (5) recognize revenue when (or as) the entity satisfies a performance obligation.

In accordance with ASC 606, the Company recognizes revenue when its performance obligation is satisfied by transferring control of the product to a customer. In accordance with the Company's contracts with customers, control of the product is transferred upon the conveyance of title, which occurs when the product is sold to and received by a customer. The Company's customers are located in the U.S. and consist of wholesale distributors, retail pharmacies, and a mail-order specialty pharmacy. Payment terms vary by customer, but typically range from 31 to 66 days and include prompt pay discounts. Trade accounts receivable due to the Company from contracts with its customers are stated separately in the balance sheet, net of various allowances as described in the Trade Accounts Receivable policy in Note 2- Summary of Significant Accounting Policies.

The amount of revenue recognized by the Company is equal to the amount of consideration that is expected to be received from the sale of product to its customers. Revenue is only recognized when the performance obligation is satisfied. To determine whether a significant reversal will occur in future periods, the Company assesses both the likelihood and magnitude of any such potential reversal of revenue.

Phexxi is sold to customers at the wholesale acquisition cost (WAC), or in some cases, at a discount to WAC. However, the Company records product revenue, net of reserves for applicable variable consideration. These types of variable consideration reduce revenue and include the following:

- Distribution services fees
- Prompt pay and other discounts
- Product returns
- Chargebacks
- Rebates
- Patient support programs, including our co-pay programs

An estimate for variable consideration is made with each sale and is recorded in conjunction with the revenue being recognized. To calculate the variable consideration, the Company uses the expected value method. If the estimated amount is payable to a customer, it is recorded as a reduction to accounts receivable. If the estimated amount is payable to an entity other than a customer, it is recorded as a current liability. An estimated amount of variable consideration may differ from the actual amount. At each balance sheet date, these provisions are analyzed and adjustments are made if necessary. Any adjustments made to these provisions would also affect net product revenue and earnings.

In accordance with ASC 606, the Company must make significant judgments to determine the estimate for certain variable consideration. For example, the Company must estimate the percentage of end-users that will obtain the product through public insurance, such as Medicaid, or through private commercial insurance. To determine these estimates, the Company relies on historical sales data showing the amount of various end-user consumer types, inventory reports from the wholesale distributors and mail-order specialty pharmacy, and other relevant data reports. Because Phexxi was launched in September 2020, this historical data is limited. Due to limits on historical data, the Company has also used trend analysis, industry data, and professional judgment in developing these estimates.

The specific considerations that the Company uses in estimating these amounts related to variable consideration are as follows:

Distribution services fees – The Company pays distribution service fees to its wholesale distributors and mail-order specialty pharmacy. These fees are a contractually fixed percentage of WAC and are calculated at the time of sale based on the purchase amount. The Company considers these fees to be separate from the customer's purchase of the product, therefore, they are recorded in other current liabilities on the consolidated balance sheet.

Prompt pay and other discounts – The Company incentivizes its customers to pay their invoices on time through prompt pay discounts. These discounts are an industry standard practice, and the Company offers a prompt pay discount to each wholesale distributor and retail pharmacy customer. The specific prompt pay terms vary by customer and are contractually fixed. Prompt pay discounts are typically taken by the Company's customers, so an estimate of the discount is recorded at the time of sale based on the purchase amount. Prompt pay discount estimates are recorded as contra trade accounts receivable on the consolidated balance sheet.

The Company may also give other discounts to its customers to incentivize purchases and promote customer loyalty. The terms of such discounts may vary by customer. These discounts reduce gross product revenue at the time the revenue is recognized.

Chargebacks – Certain government entities and covered entities (e.g. Veterans Administration, 340B covered entities) are able to purchase the product at a price discounted below WAC. The difference between the government or covered entity purchase price and the wholesale distributor purchase price of WAC will be charged back to the Company. The Company estimates the amount of each chargeback channel based on the expected number of claims in each channel and related chargeback that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Estimated chargebacks are recorded as contra trade accounts receivable on the consolidated balance sheet.

Rebates – The Company is subject to mandatory discount obligations under the Medicaid and Tricare programs. The rebate amounts for these programs are determined by statutory requirements or contractual arrangements. Rebates are owed after the product has been dispensed to an end user and the Company has been invoiced. Rebates for Medicaid and Tricare are typically invoiced in arrears. The Company estimates the amount in rebates based on the expected number of claims and related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Rebate estimates are recorded as other current liabilities on the consolidated balance sheet.

Patient support programs – One type of patient support program the Company offers is a co-pay program to commercially insured patients whose insurance requires a co-pay to be made when filling their prescription. This is a voluntary program that is intended to provide financial assistance to patients meeting certain eligibility requirements. The Company estimates the amount of financial assistance for these programs based on the expected number of claims and related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Patient support programs estimates are recorded as other current liabilities on the consolidated balance sheet.

Product returns – Customers have the right to return product that is within six months or less of the labeled expiration date or that is past the expiration date by no more than six months. Phexxi was commercially launched in September 2020 and there have been minimal returns as of December 31, 2022. The Company uses historical sales and return data to estimate future product returns. Product return estimates are recorded as other current liabilities on the consolidated balance sheet.

The variable considerations discussed above were recorded in the consolidated balance sheet and consisted of $0.1 million in contra trade accounts receivable as of both December 31, 2022 and 2021 and $2.6 million and $2.2 million in other current liabilities as of December 31, 2022 and 2021, respectively.

4. Inventories

The inventory costs include all purchased materials, direct labor and manufacturing overhead.

Inventories consist of the following (in thousands) for the period indicated:

	December 31,	
	2022	2021
Raw materials	$ 758	$ 574
Work in process[1]	4,142	1,712
Finished goods[2]	1,748	5,629
Total[3]	$ 6,648	$ 7,915

[1] The work in process balance represents all production costs incurred for partially completed goods, including inventory designated for relabeling.
[2] The finished goods balance as of December 31, 2021, includes $0.3 million inventory reserve for estimated obsolescence and excess inventory based upon assumptions about the future demand for Phexxi.
[3] A portion of the total inventory balance is included in other noncurrent assets.

5. Debt

Convertible Notes

Baker Bros. Notes

On April 23, 2020, the Company entered into a Securities Purchase and Security Agreement (the Baker Bros. Purchase Agreement) with certain affiliates of Baker Bros. Advisors LP, as purchasers (the Baker Purchasers), and Baker Bros. Advisors LP, as designated agent, pursuant to which the Company agreed to issue and sell to the Baker Purchasers (i) convertible senior secured promissory notes (the Baker Notes) in an aggregate principal amount of up to $25.0 million and (ii) warrants to purchase shares of common stock (the Baker Warrants) in a private placement.

At the initial closing date of April 24, 2020 (the Baker Initial Closing), the Company issued and sold Baker Notes with an aggregate principal amount of $15.0 million (the Baker First Closing Notes) and Baker Warrants exercisable for 204,918 shares of common stock.

Following the Baker Initial Closing, the Baker Purchasers had an option to purchase from the Company up to $10.0 million of Baker Notes (the Baker Purchase Rights) at the Baker Purchasers' discretion at any time prior to the Company receiving at least $100.0 million in aggregate gross proceeds from one or more sales of equity securities.

On June 5, 2020 (the Exercise Date), the Baker Purchasers exercised the Baker Purchase Rights. At the second closing date of June 9, 2020 (the Baker Second Closing), the Baker Purchasers acquired the remaining Baker Notes with an aggregate principal amount of $10.0 million and Baker Warrants exercisable for 136,612 shares of common stock. With the completion of the underwritten public offering in June 2020 the exercise price of the Baker Warrants was $36.60. The Baker Warrants have a five-year term with a cashless exercise provision and are immediately exercisable at any time from their respective issuance date.

The Baker Notes have a five-year term, with no pre-payment ability during the first three years. Interest on the unpaid principal balance of the Baker Notes (the Baker Outstanding Balance) accrues at 10.0% per annum with interest accrued during the first year from the two respective closing dates recognized as payment-in-kind. The effective interest rate for the period was 10.0%. Accrued interest beyond the first year of the respective closing dates are to be paid in arrears on a quarterly basis in cash or recognized as payment-in-kind, at the direction of the Baker Purchasers. The Baker Purchasers elected to have the accrued interest for the first quarter of 2021 paid-in-kind, and the accrued interest going forward to be paid in cash. Interest expense pertaining to the Baker Notes for the years ended December 31, 2021 was approximately $2.8 million. As of December 31, 2021, the accrued interest is recorded in the consolidated balance sheet in other current liabilities with a total balance of $0.7 million. As discussed below, with the amendment to the Baker Bros. Purchase Agreement, interest payments were paid-in kind. The Company accounts for the Baker notes under the

fair value method as described below and, therefore, the interest associated with the Baker Notes is included in the fair value determination. As of December 31, 2022, the Baker Notes could be converted into 1,400,966,828 shares of common stock.

The Baker Notes are callable by the Company on 10 days' written notice beginning on the third anniversary of the Baker Initial Closing. The call price will equal 100% of the Baker Outstanding Balance plus accrued and unpaid interest if the Company's common stock as measured using a 30-day volume weighted average price (VWAP) is greater than the benchmark price of $74.85 as stated in the Baker Bros. Purchase Agreement, or 110% of the Baker Outstanding Balance plus accrued and unpaid interest if the VWAP is less than such benchmark price. The Baker Purchasers also have the option to require the Company to repurchase all or any portion of the Baker Notes in cash upon the occurrence of certain events. In a repurchase event, as defined in the Baker Bros. Purchase Agreement, the repurchase price will equal 110% of the Baker Outstanding Balance plus accrued and unpaid interest. In an event of default or the Company's change of control, the repurchase price will equal to the sum of (x) three times of the Baker Outstanding Balance plus (y) the aggregate value of future interest that would have accrued (collectively, the Embedded Features of the Baker Notes), which was subsequently adjusted in an amendment to the Baker Notes on September 15, 2022, as further described below. The Baker Notes were convertible at any time at the option of the Baker Purchasers at the conversion price of $36.60 per share prior to the First Baker Amendment as defined below.

On November 20, 2021, the Company entered into the first amendment to the Baker Bros. Purchase Agreement (the First Baker Amendment), in which each Baker Purchaser shall have the right to convert all or any portion of the Baker Notes into Common Stock at a conversion price equal to the lesser of (a) $36.60 and (b) 115% of the lowest price per share of common stock (or, as applicable with respect to any equity securities convertible into common stock, 115% of the applicable conversion price) sold in one or more equity financings until the Company had met a qualified financing threshold, defined as one or more equity financings resulting in aggregate gross proceeds to the Company of at least $50.0 million (Financing Threshold).

The First Baker Amendment also extended, effective upon the Company's achievement of the Financing Threshold, the affirmative covenant to achieve $100.0 million in cumulative net sales of Phexxi by June 30, 2022 to June 30, 2023. Additionally per the First Baker Amendment, if in any equity financing closing on or prior to the date the Company has met the Financing Threshold, the Company was required to issue warrants to purchase capital stock of the Company (or other similar consideration), the Company was also required to issue to the Baker Purchasers an equivalent coverage of warrants (or other similar consideration) on the same terms as if the Baker Purchasers participated in the financing in an amount equal to the then outstanding principal of the Baker Notes held by the Baker Purchasers. In satisfaction of this requirement and in connection with the closing of the May 2022 Public Offering, the Company issued warrants to purchase 72,860,769 shares of the Company's common stock at an exercise price of $0.75 per share (the June 2022 Baker Warrants). As required by the terms of the First Baker Amendment, the June 2022 Baker Warrants have substantially the same terms as the warrants issued in the May 2022 Public Offering. Refer to Note 10 - Stockholders' Equity (Deficit) for further information. The exercise price of the initial Baker Warrants and the June 2022 Baker Warrants was reset to $0.21 per share along with the change of the conversion price per the Third Baker Amendment and further reset to $0.0325 per share with the December 2022 Notes issuance, both as discussed below.

On March 21, 2022, the Company entered into the second amendment to the Baker Bros. Purchase Agreement (the Second Baker Amendment), pursuant to which each Baker Purchaser now has the right to convert all or any portion of the Baker Notes into Common Stock at a conversion price equal to the lesser of (a) $5.8065 or (b) 100% of the lowest price per share of common stock (or as applicable with respect to any equity securities convertible into common stock, 100% of the applicable conversion price) sold in any equity financing until the Company has (i) met the qualified financing threshold by June 30, 2022, defined as a single underwritten financing resulting in aggregate gross proceeds to the Company of at least $20.0 million (Qualified Financing Threshold) and (ii) the disclosure of its top-line results from its *EVOGUARD* clinical trial (the Clinical Trial Milestone) by October 31, 2022. The Second Baker Amendment also provides that the exercise price of the Baker Warrants will equal the conversion price of the Baker Notes. The Company met the Qualified Financing Threshold upon the closing of the May 2022 Public Offering, and as of September 30, 2022, the conversion price and exercise price of the Baker Warrants was reset to $0.75. The Company achieved the Clinical Trial Milestone in October 2022. Also, with the achievement of the Qualified Financing Threshold and the Clinical Trial Milestone, the affirmative covenant to achieve $100.0 million in cumulative net sales of Phexxi was extended to June 30, 2023. The Baker Warrants were reset to $0.21 per share per the Third Baker Amendment and further reset to $0.0325 per share with the December 2022 Notes issuance, both as discussed below. Subsequent to December 31, 2022, the conversion and strike price adjusted to $0.0065, as discussed in Note 14 – Subsequent Events.

On September 15, 2022, the Company entered into the third amendment to the Baker Bros. Purchase Agreement (the Third Baker Amendment), pursuant to which the conversion was amended to equal to $0.21, subject to adjustment for certain dilutive Company equity issuance adjustments for a two-year period, removal of an interest make-whole payment due in certain circumstances,

and certain change of control and liquidation payment amounts were reduced from three times the outstanding amounts of the Baker Notes to two times the outstanding amounts. In addition, the Third Baker Amendment provides that the Company may make future interest payments to the Baker Purchasers in kind or in cash, at the Company's option. For the year ended December 31, 2022, the Company elected an in-kind interest payment and approximately $3.3 million was added to the outstanding principal balance.

The Company evaluated whether any of the Embedded Features required bifurcation as a separate component of equity. The Company elected the fair value option (FVO) under ASC 825, Financial Instruments (ASC 825), as the Baker Notes are qualified financial instruments and are, in whole, classified as liabilities. Under the FVO, the Company recognized the hybrid debt instrument at fair value, inclusive of the Embedded Features with changes in fair value related to changes in the Company's credit risk being recognized as a component of accumulated other comprehensive income in the consolidated balance sheets. All other changes in fair value were recognized in the consolidated statements of operations.

The Baker Notes contain various customary affirmative and negative covenants agreed to by the Company, including timely payment, in cash, of the quarterly interest payment and maintaining an active listing. On September 12, 2022, the Company received a default notice from the Baker Purchasers due to its failure of making the required payments of accrued interest for the first and second quarters of 2022 in the aggregate amount of $1.4 million and being delisted from Nasdaq. As a result of the cross-default provisions applicable to the Adjuvant Notes and the May 2022 Notes (both, as discussed below), the Company was also in default of these Notes. On September 15, 2022, the Company entered into a (i) Forbearance Agreement (the Secured Creditor Forbearance Agreement) with the Baker Purchasers, pursuant to which the Baker Purchasers agreed to forbear from exercising any of their rights and remedies during the Forbearance Period (as defined), but solely with respect to the specified events of default (Forbearance Termination Event) provided under the Secured Creditor Forbearance Agreement, which includes among other things, the first date after December 31, 2022, on which the Company's cash falls below $1.0 million. In exchange for the forbearance and the Third Baker Amendment, the Company agreed to adjust the aggregate principal balance of the Baker Notes to $44.2 million, which includes the delinquent interest payments of $1.4 million that the Baker Purchasers agreed to forego in cash, as well as an immaterial amount of legal fees incurred by the Baker Purchasers' counsel.

On December 19, 2022, the Company entered into the First Amendment to Forbearance Agreement (the Amendment) effective as of December 15, 2022 (the Amendment Effective Date) to amend certain provisions of the of the Secured Creditor Forbearance Agreement dated September 15, 2022. The Amendment revises the Secured Creditor Forbearance Agreement to (i) amend the Fifth Recital Clause to clarify that the Purchasers consent to any additional indebtedness *pari passu*, but not senior to that of the Purchasers, in an amount not to exceed $5.0 million, and (ii) strike and entirely replace Section 4 to clarify the terms of the Purchasers' consent to Interim Financing (as defined therein). No other revisions were made to the Secured Creditor Forbearance Agreements.

As described more fully in Note 14 – Subsequent Events, on March 7, 2023, the Company received a Notice of Event of Default and Reservation of Rights (the Notice of Default) from Baker Bros claiming that the Company has failed to maintain the required shares reserved amount per the Third Baker Amendment. As a result of the Notice of Default, approximately $92.8 million representing two times the sum of the outstanding balance and all accrued and unpaid interest thereon and all other amounts due under the SPA and other documents is due and payable within three business days of receipt of the Notice of Default. In addition, the Notice of Default resulted in a cross default under all outstanding debt.

During the year ended December 31, 2022, using the valuation methods discussed in Note 7- Fair Value of Financial Instruments, the Company recorded a gain of $42.4 million due to changes in fair value of the Baker Notes, of which $2.0 million is recorded in the consolidated statements of operations as a result of mark-to-market adjustments unrelated to instrument-specific credit losses and $44.4 million, recorded as a component of other comprehensive income due to changes in the underlying instrument-specific credit risk for the Baker Notes. Through June 30, 2023, the change in fair value attributed to the change in the underlying instrument-specific credit risk was determined by taking the difference between the fair value of the Baker Notes with and without the credit risk change and value of the collateral. For the second half of 2022, the fair value of the Baker Notes was determined by estimating the fair value of the Market Value of Invested Capital ("MVIC") of the Company. This was estimated using forms of the cost and market approaches. In the Cost approach, an adjusted net asset value method was used to determine the net recoverable value of the Company, including an estimate of the fair of the Company's intellectual property. The estimated fair value of the Company's intellectual property was valued using a relief from royalty method which required management to make significant estimates and assumptions related to forecasts of future revenue, and the selection of the royalty and discount rates. If the resulting fair value is not

estimated as greater than the contractual payout, the fair value of the Baker Notes then becomes the Company's MVIC available for distribution.

Adjuvant Notes

On October 14, 2020, the Company entered into a Securities Purchase Agreement (the Adjuvant Purchase Agreement) with Adjuvant Global Health Technology Fund, L.P., and Adjuvant Global Health Technology Fund DE, L.P. (together, the Adjuvant Purchasers), pursuant to which the Company sold unsecured convertible promissory notes (the Adjuvant Notes) in aggregate principal amount of $25.0 million.

The Adjuvant Notes have a five-year term, and in connection with certain Company change of control transactions, the Adjuvant Notes may be prepaid at the option of the Company or will become payable on the date of the consummation of a change of control transaction at the option of the Adjuvant Purchasers. The Adjuvant Notes have interest accruing at 7.5% per annum on a quarterly basis in arrears to the outstanding balance of the Adjuvant Notes and are recognized as payment-in-kind. The effective interest rate for the period was 7.7%.

Interest expense for the Adjuvant Notes consist of the following, and is included in short-term convertible notes payable on the consolidated balance sheet as of December 31, 2022 (in thousands):

	Years Ended December 31,	
	2022	**2021**
Coupon interest	$ 2,048	$ 1,959
Amortization of issuance costs	129	39
Total	$ 2,177	$ 1,998

The Adjuvant Notes are convertible, subject to customary 4.99% and 19.99% beneficial ownership limitations, into shares of the Company's common stock, par value $0.0001 per share, at any time at the option of the Adjuvant Purchasers at a conversion price of $54.75 per share. To the extent not previously prepaid or converted, the Adjuvant Notes will automatically convert into shares of the Company's common stock at a conversion price of $54.75 per share. In connection with certain Company change of control transactions, the Adjuvant Notes may be prepaid at the option of the Company or will become payable at the option of the Adjuvant Purchasers. To the extent not previously prepaid or converted, the Adjuvant Notes were originally automatically convertible into shares of the Company's common stock at a conversion price of $54.75 per share immediately following the earliest of the time at which the (i) 30-day value-weighted average price of the Company's common stock was $150.00 per share, or (ii) Company achieved cumulative net sales from the sales of Phexxi of $100.0 million, provided such net sales are achieved prior to July 1, 2022.

On April 4, 2022, the Company entered into the first amendment to the Adjuvant Purchase Agreement (the Adjuvant Amendment). The Adjuvant Amendment extended, effective as of the date the Company achieved the Qualified Financing Threshold upon the closing of the May 2022 Public Offering, the affirmative covenant to achieve $100.0 million in cumulative net sales of Phexxi by June 30, 2022 to June 30, 2023. The Adjuvant Amendment also provided for an adjustment to the conversion price of the Adjuvant Notes such that the conversion price (the Conversion Price) for these Notes, effective as of the reverse stock split the conversion price will now be the lesser of (i) $5.4279 and (ii) 100% of the lowest price per share of common stock (or with respect to securities convertible into common stock, 100% of the applicable conversion price) sold in any equity financing until the Company has met the Qualified Financing Threshold. In the second quarter of 2022 and upon the closing of the May 2022 Public Offering, the conversion price was reset to $0.75. Effective as of the Company's achievement of the Qualified Financing Threshold, the automatic conversion provisions in the Agreement were further amended to provide that the Adjuvant Notes will automatically convert into shares of the Company's common stock at the Conversion Price immediately following the earliest of the time at which the (i) 30-day value-weighted average price of the Company's common stock is $150.00 per share, or (ii) the Company achieves cumulative net sales from the sales of Phexxi of $100.0 million, provided such net sales are achieved prior to July 1, 2023.

The Adjuvant Notes contain various customary affirmative and negative covenants agreed to by the Company. On September 12, 2022, the Company was in default of the Adjuvant Notes due to the default with the Baker Notes under the cross-default provision. On September 15, 2022, the Company entered into a (i) Forbearance Agreement (the Adjuvant Forbearance Agreement) with the Adjuvant Purchasers, pursuant to which, the Adjuvant Purchasers agreed to forbear from exercising any of their rights and remedies

during the Forbearance Period as defined in therein, but solely with respect to the specified events of default provided under the Adjuvant Forbearance Agreement.

On September 15, 2022, the Company also entered into the second amendment to the Adjuvant Purchase Agreement (the Second Adjuvant Amendment), pursuant to which the conversion price per share was reduced to $0.21, subject to adjustment for certain dilutive Company equity issuance adjustments for a two-year period. In addition, the Company entered into an exchange agreement, pursuant to which the Adjuvant Purchasers agreed to exchange 10% of the outstanding amount of the Adjuvant Notes as of September 15, 2022 (or $2.9 million) for rights to receive 13,730,370 shares of common stock (Adjuvant Purchase Rights). The number of shares for each Adjuvant Purchase Right is initially fixed, but is subject to certain customary adjustments, and, until the second anniversary of issuance, adjustments for certain dilutive Company equity issuances. Refer to Note 10 - Stockholders' Equity (Deficit) for discussion regarding additional issuances of Purchase Rights under this provision. The Adjuvant Purchase Rights expire on June 28, 2027 and do not have an exercise price per share and, therefore, will not result in cash proceeds to the Company. As of December 31, 2022, all Adjuvant Purchase Rights remain outstanding. The conversion price of the Adjuvant Notes were further reset to $0.0325 per share with the December 2022 Notes issuance, as discussed below. Subsequent to December 31, 2022, the conversion price adjusted to $0.0065, as discussed in Note 14 – Subsequent Events.

The Adjuvant Notes are accounted for in accordance with authoritative guidance for convertible debt instruments and are classified as current liabilities in the consolidated balance sheet. The aggregate proceeds of $25.0 million was initially classified as restricted cash for financial reporting purposes due to contractual stipulations that specify the types of expenses the money can be spent on and how it must be allocated. Its conversion feature is required to be bifurcated as an embedded derivative due to the fact that the Company does not have sufficient number of shares reserved upon conversion. However, the fair value of such feature is immaterial as of December 31, 2022. As of December 31, 2022 and 2021, $0.9 million and $4.7 million in proceeds remained, which are included in restricted cash on the consolidated balance sheets. See Note 7- Fair Value of Financial Instruments for a description of the accounting treatment for the Adjuvant Purchase Rights.

Due to the execution of the Adjuvant Forbearance and the Second Adjuvant Amendment, the Company reviewed the Adjuvant Notes in accordance with Topics ASC 470-50 – *Modifications and Extinguishments* and ASC 470-60 – *Troubled Debt Restructurings by Debtors*. The Company concluded that although changes in the structure of the debt met certain qualitative factors to qualify as a troubled debt restructuring (TDR), the effective interest rate post changes was greater than the original effective interest rate and, therefore, failed the quantitative test to be a TDR. The Adjuvant Notes were evaluated in accordance with ASC 470-50 and were determined to have failed certain qualitative factors to qualify as a modification and, therefore, were accounted for as an extinguishment. The Company removed the old debt from its books and recorded the new, revised debt and concurrently recognized a gain of approximately $2.5 million upon extinguishment, included in change in fair value of financial instruments within the consolidated statements of operations.

As discussed above and described more fully in Note 14 – Subsequent Events, on March 7, 2023, the Company received a Notice of Event of Default and Reservation of Rights (the Notice of Default) from Baker Bros. resulting in a cross default under the all outstanding debt and as such, the Company was not in compliance with all applicable covenants as of the filing date of this Annual Report on Form 10-K, including the cross-default provisions addressed by the Secured Creditor Forbearance Agreement discussed above.

As of December 31, 2022 and 2021, the Adjuvant Notes are recorded in the consolidated balance sheet as short-term convertible notes payable with a total balance of $26.3 million and $27.2 million, respectively. As of December 31, 2022 and 2021, the balance is comprised of $22.3 million and $24.8 million, respectively, in principal, net of unamortized debt issuance costs, and $4.0 million and $2.4 million, respectively, in accrued interest.

As of December 31, 2022 and assuming the current conversion price of $0.0325 per share, the Adjuvant Notes could be converted into 815,987,312 shares of common stock.

Term Notes

January and March 2022 Notes

On January 13, 2022, the Company entered into a Securities Purchase Agreement (the January 2022 Purchase Agreement) with institutional investors (the January 2022 Notes Purchasers) pursuant to which the Company agreed to sell in a registered direct offering (i) unsecured 5.0% Senior Subordinated Notes due 2025 with an aggregate issue price of $5.9 million (the January 2022 Notes), which included an original issue discount of $0.9 million, and (ii) warrants (the January 2022 Warrants) to purchase up to 1,000,401 shares of the Company's common stock, $0.0001 par value per share. The January 2022 Warrants have an exercise price of $5.88 per share and were initially exercisable beginning on July 15, 2022 with a five-year term. Pursuant to the terms of the March 2022 Purchase Agreement (as defined below), the January 2022 Warrants became exercisable on March 1, 2022, as described in more detail below.

On March 1, 2022, the Company entered into a Securities Purchase Agreement (the March 2022 Purchase Agreement) with institutional investors (the March 2022 Notes Purchasers) pursuant to which the Company agreed to sell in a registered direct offering (i) unsecured 5.0% Senior Subordinated Notes due 2025 with an aggregate issue price of approximately $7.5 million (the March 2022 Notes), which included an original issue discount of approximately $2.5 million, and (ii) warrants (the March 2022 Warrants) to purchase up to 1,037,886 shares of the Company's common stock, $0.0001 par value per share. The March 2022 Warrants have an exercise price of $7.1805 per share and are immediately exercisable with a five-year term.

The January and March 2022 Notes carried an interest rate of 5% per annum, which was subject to increase to 18% upon an event of default. The January and March 2022 Notes were able to be prepaid, in whole or in part, at the Company's option together with all accrued and unpaid interest and fees as of the date of the repayment. The holders of the January and March 2022 Notes were able to require the Company to redeem their respective notes upon the occurrence of an event of default with a redemption premium of 25%. The holders of the January and March 2022 Notes were also able to require the Company to redeem their respective notes upon the occurrence of certain subsequent transactions.

Pursuant to the terms of the January and March 2022 Purchase Agreements, the Company agreed to certain restrictions on effecting variable rate transactions so long as the January and March 2022 Notes were outstanding. Also, pursuant to the terms of the January and March 2022 Purchase Agreements, the January and March 2022 Purchasers had certain rights to participate in subsequent issuances of the Company's securities, subject to certain exceptions.

The Company evaluated the January and March 2022 Notes to determine if any embedded components qualified as a derivative requiring bifurcation in accordance with ASC 815. The Company determined that the embedded put option and interest rate increase feature would both require bifurcation and separate accounting. Therefore, the Company elected to use the fair value option under ASC 825, *Financial Instruments* (ASC 825) for the January and March 2022 Notes inclusive of the embedded features.

The Company evaluated the January and March 2022 Warrants and determined that in accordance with ASC 815 the warrants should be recorded at fair value and classified as a derivative liability in the consolidated balance sheet. Both the January and March 2022 Notes and Warrants were marked-to-market at each reporting date.

Under the valuation methods as described in Note 7- Fair Value of Financial Instruments the Company recorded the following in the consolidated financial statements related to the January and March 2022 Notes and Warrants during the year ended December 31, 2022: (i) $0.2 million in notes at issuance; (ii) $10.6 million in warrants at issuance as a derivative liability; and (iii) a $0.9 million loss on issuance. During the year ended December 31, 2022, the Company recognized gains in fair value of financial instruments as a result of the mark-to-market adjustment on the January and March 2022 Warrants of $10.6 million.

On May 4, 2022, the January and March 2022 Notes were exchanged pursuant to the May 2022 Exchange, as defined below.

May 2022 Notes

On May 4, 2022, the Company entered into amendment and exchange agreements (the May 2022 Exchange) with the holder of issued and outstanding Series B-2 and C Preferred Stock, Seven Knots, and the January and March 2022 Notes Purchasers (collectively, the May 2022 Notes Purchasers), pursuant to which they agreed to exchange all of the January and March 2022 Notes, 2,100 shares of Series B-2 Convertible Preferred Stock, 1,700 shares of Series C Convertible Preferred Stock, and 533,333 shares of the Company's Common Stock for (i) new 5.0% Senior Subordinated Notes with an aggregate principal amount of $22.3 million (the May 2022 Notes), (ii) 208,333 new shares of Common Stock and (iii) new warrants to purchase up to 833,333 shares of Common

Stock (the May 2022 Warrants). The May 2022 Warrants have an exercise price of $2.4765 per share and were exercisable immediately with a five-year term. The 2,100 shares of Series B-2 Convertible Preferred Stock, 1,700 shares of Series C Convertible Preferred Stock, and 533,333 shares of the Company's Common Stock that were exchanged in the May 2022 Exchange were retired by the Company. All exchange transactions aforementioned were cashless.

The May 2022 Notes are substantially similar to the January and March 2022 Notes, except that (i) the maturity date of the May 2022 Notes was August 1, 2022 and (ii) the holders of the May 2022 Notes may require the Company to redeem or exchange up to 100% of the May 2022 Notes upon the occurrence of certain subsequent transactions (each, a Subsequent Transaction Optional Redemption). Pursuant to the terms of the May 2022 Notes and subject to certain conditions described in the May 2022 Notes, if the Company completed an underwritten public offering of at least $20 million complying with certain conditions (a Qualified Underwritten Offering) and the holder of the May 2022 Notes did not participate in the Qualified Underwritten Offering, then the holder would have forfeited their right to Subsequent Transaction Optional Redemption solely with respect to that Qualified Underwritten Offering and amounts that may have been due pursuant to the May 2022 Notes would not have been due and payable until the three-month anniversary of the Qualified Underwritten Offering.

The May 2022 Public Offering qualified as the Qualified Underwritten Offering and, in connection with the May 2022 Public Offering, the holders of the May 2022 Notes waived certain of their preemptive and redemption rights and the Company redeemed $5.9 million of the May 2022 Notes. The holders of the May 2022 Notes also waived the maturity date of the May 2022 Notes until October 31, 2022.

The May 2022 Notes contain various customary affirmative and negative covenants agreed to by the Company. The May 2022 Notes also include other customary events of default, which include the suspension of trading of shares of the Company's common stock on the Nasdaq Capital Market for a period of more than five trading days. On September 12, 2022, the Company was in default of the May Notes due to the default with the Baker Notes under the cross-default provision. As a result, the interest rate was increased to 18% for the duration of the default and the holders of the May 2022 Notes had the right to request redemption for 125% of the amounts then owed pursuant to the May 2022 Notes.

On September 15, 2022, the Company entered into exchange agreements with each of the May 2022 Notes Purchasers (the May 2022 Notes Exchange Agreements), pursuant to which the May 2022 Notes Purchasers agreed to exchange all outstanding balance of the May Notes as of September 15, 2022 using the higher interest rate and redemption premium aforementioned for purchase rights (the May Note Purchase Rights) to receive 104,029,723 shares of common stock. As a result, the May Notes are no longer outstanding as of December 31, 2022. The number of right shares for each May Note Purchase Right is initially fixed, but is subject to certain customary adjustments, and, until the second anniversary of issuance, adjustments for certain dilutive Company equity issuances, as further discussed in Note 10 - Stockholders' Equity (Deficit) and expire on June 28, 2027. The May 2022 Notes Purchasers also waived certain anti-dilution share adjustment provisions with respect to shares underlying the May 2022 Warrants.

The Company evaluated the May 2022 Notes and determined that in accordance with ASC 470 the notes should be accounted for as a modification of the January and March 2022 Notes. The Company further evaluated the May 2022 Notes to determine if any embedded components qualified as a derivative requiring bifurcation in accordance with ASC 815. The Company determined that the embedded put options and interest rate increase feature would all require bifurcation and separate accounting. Therefore, the Company elected to use the fair value option under ASC 825, *Financial Instruments* (ASC 825) for the May 2022 Notes inclusive of the embedded features.

The Company evaluated the May 2022 Warrants and determined that, in accordance with ASC 815, the warrants should be recorded at fair value and classified as a derivative liability in the consolidated balance sheet. Both the May 2022 Notes and Warrants are marked-to-market at each reporting date before the exchange as described above.

Under the valuation methods as described in Note 7- Fair Value of Financial Instruments, the Company recorded the following in the consolidated financial statements related to the May 2022 Notes and Warrants during the year ended December 31, 2022: (i) $22.3 million in notes at issuance; and (ii) $1.6 million in warrants at issuance as a derivative liability. During the year ended December 31, 2022, the Company recognized losses in fair value of financial instruments as a result of the mark-to-market adjustment on the May 2022 Notes of $10.3 million and gains in fair value of financial instruments as a result of the mark-to-market adjustment on the May 2022 Warrants of $1.6 million.

December 2022 Notes

On December 20, 2022, the Company entered into a Securities Purchase Agreement (the December 2022 Purchase Agreement), with certain investors (the December 2022 Notes Purchasers) pursuant to which the Company agreed to sell in a registered direct offering (i) unsecured 8.0% Senior Subordinated Notes due December 21, 2025 with an aggregate issue price of $2.3 million (the December 2022 Notes), which included an original issue discount of $0.8 million (ii) warrants (the December 2022 Warrants) to purchase up to 46,153,847 shares of the Company's common stock, $0.0001 par value per share, and (iii) an aggregate 70 shares of Series D Preferred Stock (the Preferred Shares) (collectively, the Offering). The Offering closed on December 21, 2022, with net proceeds to the Company from the Offering, after deducting offering expenses, of $1.25 million. The December 2022 Notes are convertible at $0.05, and the December 2022 Warrants have a strike price of $0.05. Upon the closing of the December 2022 Purchase Agreement, the conversion and strike price of the Baker Notes, the Baker Warrants, the June 2022 Baker Warrants, the Adjuvant Notes and the May Common Stock Warrants, as discussed in Note 10 - Stockholders' Equity (Deficit), reset to $0.0325 per share.

The December 2022 Notes interest rate is subject to increase to 12% upon an event of default and have no Company right to prepayment prior to maturity, however, the Company can redeem the respective notes at a redemption premium of 32.5%. The December 2022 Notes Purchasers can also require the Company to redeem their notes at the respective premium rate tied to the occurrence of certain subsequent transactions, as well as require the Company to redeem the December 2022 Notes in the event of subsequent placements (as defined). Also, pursuant to the terms of the December 2022 Purchase Agreement, the December 2022 Notes Purchasers have certain rights to participate in subsequent issuances of the Company's securities, subject to certain exceptions. Additionally, the December 2022 Notes conversion rate and warrant strike price are subject to adjustment upon the issuance of other securities (as defined) less than the stated conversion rate and strike price of $0.05. Subsequent to December 31, 2022, the conversion and strike price adjusted to $0.0065 as discussed in Note 14 – Subsequent Events.

The Company evaluated the December 2022 Notes and December 2022 Warrants, in accordance with ASC 480 – *Distinguishing Liabilities from Equity* and determined both were liability instruments. The December 2022 Notes were then evaluated in accordance the requirements of ASC 825, *Financial Instruments* (ASC 825) and concluded the Company was not precluded from electing the fair value option for the December 2022 Notes; as such the December 2022 Notes are carried at fair value in the consolidated balance sheets. Since the December 2022 Warrants are also required to be recorded as liabilities in the Company's consolidated balance sheets, they are also carried at fair value. Both the December 2022 Notes and Warrants are marked-to-market at each reporting date with changes in fair value of the December 2022 Notes and Warrants are recorded recognized in the consolidated statement of operations, unless the change is concluded to be related to changes in the Company's credit rating, in which case the change will be recognized as a component of accumulated other comprehensive income in the consolidated balance sheets.

Under the valuation methods as described in Note 7- Fair Value of Financial Instruments, the Company recorded the following in the consolidated financial statements related to the December 2022 Notes and Warrants during the year ended December 31, 2022: (i) $156,000 in convertible notes payable carried at fair value in the consolidated balance sheets, (ii) $143,000 in derivative liabilities for the warrants, and (iii) $1.3 million additional paid-in capital upon the issuance of financial instruments carried at fair value.

6. Balance Sheet Details

Prepaid and Other Current Assets

Prepaid and other current assets consist of the following (in thousands):

	December 31,	
	2022	2021
Insurance	$ 1,387	$ 1,144
Selling and marketing related costs	44	1,134
Manufacturing related costs	82	322
Other	705	629
Total	$ 2,218	$ 3,229

Property and Equipment, Net

Property and equipment, net, consists of the following (in thousands):

		December 31,	
	Useful Life	**2022**	**2021**
Research equipment	5 years	$ 653	$ 653
Computer equipment and software	3 years	639	619
Office furniture	5 years	881	881
Leasehold improvements	5 years or less	3,388	3,388
Construction in-process	—	1,568	2,407
		7,129	7,948
Less: accumulated depreciation		(3,189)	(2,174)
Total, net		$ 3,940	$ 5,774

Depreciation and amortization expense for property and equipment is disclosed in the consolidated statements of cash flows.

Other Noncurrent Assets

Other noncurrent assets consist of the following (in thousands):

	December 31,	
	2022	**2021**
Restricted cash included in noncurrent assets	$ 800	$ 800
Inventories, long-term	1,270	241
Prepaid directors & officers' insurance	1,717	109
Other	331	53
Total	$ 4,118	$ 1,203

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31,	
	2022	**2021**
Clinical trial related costs	$ 2,574	$ 5,294
Selling and marketing related costs	674	1,997
Legal and other professional fees	—	550
Manufacturing related costs	—	201
Other	876	328
Total	$ 4,124	$ 8,370

7. Fair Value of Financial Instruments

Fair Value of Financial Assets

The fair values of the Company's assets, including the money market funds, investments in marketable fixed income debt securities classified as cash and cash equivalents, restricted cash, and Flex Note receivable, measured on a recurring basis are summarized in the following tables, as applicable (in thousands):

	December 31, 2022	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds [1]	$ 2,612	$ 2,612	$ —	$ —
Total assets	$ 2,612	$ 2,612	$ —	$ —

	December 31, 2021	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds [1]	$ 11,176	$ 11,176	$ —	$ —
Total assets	$ 11,176	$ 11,176	$ —	$ —

[1] Included as a component of cash and cash equivalents and restricted cash on the consolidated balance sheet.

Fair Value of Financial Liabilities

The following table is a summary of the Company's convertible debt instruments as of December 31, 2022 and 2021, respectively (in thousands).

							Fair Value	
As of December 31, 2022	Principal Amount	Unamortized Issuance Costs	Accrued Interest	Redemption Amount	Amount Exchanged	Net Carrying Amount	Amount	Leveling
Baker Notes (1) (2)	$ 45,528	$ —	$ —	$ —	$ —	$ 45,528	$ 39,260	Level 3
Adjuvant Notes (3) (4)	22,500	(252)	4,020	—	—	26,268	—	N/A
May 2022 Notes (1)	16,376	—	1,101	4,369	(21,846)	—	—	N/A
Dec 2022 Notes (1)	2,308	—	—	—	—	2,308	156	Level 3

(1) These liabilities are/were carried at fair value in the consolidated balance sheets. As such, the principal and accrued interest was included in the determination of fair value. The related debt issuance costs were expensed.

(2) The Baker Notes principal amount includes $5.6 million of interest paid-in kind as of December 31, 2022.

(3) The Adjuvant Notes are recorded in the consolidated balance sheets at their net carrying amount which includes principal and accrued interest, net of unamortized issuance costs.

(4) The principal amount and accrued interest of the Adjuvant Notes are net of the 10% reduction in principal and interest of $2.5 million and $0.4 million, respectively, received in exchange for the issuance of Purchase Rights.

					Fair Value	
As of December 31, 2021	Principal Amount	Unamortized Issuance Costs	Accrued Interest	Net Carrying Amount	Amount	Leveling
Baker Notes (1) (2)	$ 27,323	$ —	$ 698	$ 28,021	$ 81,717	Level 3
Adjuvant Notes (3)	25,000	(146)	2,355	27,209	27,209	Level 3

(1) These liabilities are/were carried at fair value in the consolidated balance sheets. As such, the principal and accrued interest was included in the determination of fair value. The related debt issuance costs were expensed.

(2) The Baker Notes principal amount includes $2.3 million of interest paid-in kind as of December 31, 2021.

(3) The Adjuvant Notes are recorded in the consolidated balance sheets at their net carrying amount which includes principal and accrued interest, net of unamortized issuance costs.

The following tables summarize the Company's derivative liabilities as of December 31, 2022 and 2021 as discussed in Note 10- Stockholders' Equity (Deficit) (in thousands):

	Fair Value	
As of December 31, 2022[1]	**Amount**	**Leveling**
April and June 2020 Baker Warrants	$ 1	Level 3
May 2022 Public Offering Warrant	303	Level 3
June 2022 Baker Warrants	170	Level 3
December 2022 Warrants	107	Level 3
Purchase Rights	1,095	Level 3
Total Derivative Liabilities	$ 1,676	

(1) As of December 31, 2022, all warrants issued by the Company are subject to liability accounting due to potential settlement in cash, an insufficient number of authorized shares and other adjustment mechanics. However, warrants with an exercise price greater than $0.05 per share were considered to be significantly out of the money as of December 31, 2022 and therefore the value ascribed to those warrants was considered to be *de minimus* and is therefore excluded from the above table.

	Fair Value	
As of December 31, 2021	**Amount**	**Leveling**
Derivative Liabilities - Convertible Preferred Stock	$ 202	Level 3

Change in Fair Value of Level 3 Financial Liabilities

The Baker Warrants, as discussed in Note 5- Debt, were determined to be classified as liabilities. Therefore, they were stated at fair value at issuance and subject to mark-to-market adjustments at each reporting date until a subsequent event occurs that would change their classification. They were considered Level 3 instruments because the fair value measurement was based, in part, on significant inputs not observed in the market.

The following table summarizes the changes in Level 3 financial liabilities related to Term Notes, Baker Notes and December 2022 Notes measured at fair value on a recurring basis for the years ended December 31, 2022 (in thousands).

	Term Notes - January 2022 Notes	Term Notes - March 2022 Notes	Term Notes - May 2022 Notes	Baker First Closing Notes	Baker Second Closing Notes	December 2022 Notes	Total
Balance at December 31, 2021	$ —	$ —	$ —	$ 49,030	$ 32,687	**$ —**	**$ 81,717**
Balance at issuance	116	149	447	—	—	156	**868**
Debt repayment	—	—	(5,892)	—	—	—	**(5,892)**
Change in fair value presented in the Condensed Consolidated Statements of Operations	4	2	10,251	1,189	792	—	**12,238**
Change in fair value presented in the Statements of Comprehensive Operations				(26,663)	(17,775)	—	**(44,438)**
Exchange of notes (noncash)	(120)	(151)	(4,806)	—	—	—	**(5,077)**
Balance at December 31, 2022	$ —	$ —	$ —	$ 23,556	$ 15,704	$ 156	**$ 39,416**

The following table summarizes the changes in Level 3 financial liabilities related to Baker Notes measured at fair value on a recurring basis for the years ended December 31, 2021 (in thousands).

	Baker First Closing Notes	Baker Second Closing Notes	Total
Balance at December 31, 2020	$ 30,451	$ 20,301	$ 50,752
Initial liability at issuance	21,632	14,422	36,054
Change in fair value	(3,053)	(2,036)	(5,089)
Balance at December 31, 2021	$ 49,030	$ 32,687	$ 81,717

The following table summarizes the changes in Level 3 financial liabilities related to derivative liabilities measured at fair value on a recurring basis for the years ended December 31, 2022 (in thousands).

	Derivative Liability - Convertible Preferred Stock Conversion Feature	Derivative Liabilities Previously Classified as Equity Instruments	Derivative Liability - January 2022 Warrants	Derivative Liability - March 2022 Warrants	Derivative Liability - May 2022 Warrants	May 2022 Public Offering Common Warrants	May 2022 Public Offering Pre-Funded Warrants	June 2022 Baker Warrants	December 2022 Warrants	Purchase Rights	Derivative Liabilities Total
Balance at December 31, 2021	$ 202	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —	**$ 202**
Balance at issuance	—	—	4,562	6,025	1,613	18,074	4,633	70,238	107	6,284	111,536
Exercises	—	—	—	—	—	(12,086)	(4,633)	—	—	(1,007)	(17,726)
Change in fair value presented in the consolidated statements of operations	(83)	—	(4,562)	(6,025)	(1,613)	(5,685)	—	(70,068)	—	(4,182)	(92,218)
Conversion of series B-2 convertible preferred stock	(46)	—	—	—	—	—	—	—	—	—	(46)
Loss on re-valuation of derivative liabilities presented in the consolidated statement of operations.	—	1	—	—	—	—	—	—	—	—	1
May 2022 exchange transaction	(73)	—	—	—	—	—	—	—	—	—	(73)
Balance at December 31, 2022	$ —	$ 1	$ —	$ —	$ —	$ 303	$ —	$ 170	$ 107	$ 1,095	$ 1,676

The following table summarizes the changes in Level 3 financial liabilities related to derivative liabilities measured at fair value on a recurring basis for the year ended December 31, 2021 (in thousands):

	Derivative Liabilities
Beginning balance	$ —
Initial liability at issuance	550
Conversion of series B-1 convertible preferred stock	(275)
Change in fair value presented in the consolidated statements of operations	(73)
Ending balance	$ 202

Valuation Methodology

Baker Notes

Through June 30, 2022, the fair value of the Baker Notes issued, and the change in fair value of the Baker Notes at the reporting date, were determined using a Monte Carlo simulation-based model. The Monte Carlo simulation was used to take into account several embedded features and factors, including the future value of our common stock, a potential change of control event, the probability of meeting certain debt covenants, the maturity term of the Baker Notes, the probability of an event of voluntary conversion of the Baker Notes, the probability of the failure to meet the affirmative covenant to achieve $100.0 million in cumulative net sales of Phexxi by June 30, 2023, and the probability of exercise of the put right and the probability of exercise of our call right.

The fair value of the Baker Notes are subject to uncertainty due to the assumptions that are used in the Monte Carlo simulation-based model. These factors include but are not limited to the future value of the Company's common stock, the probability and timing of a potential change of control event, the probability of meeting certain debt covenants, the probability of an event of voluntary conversion of the Baker Notes, exercise of the put right, and exercise of the Company's call right. The fair value of the Baker Notes is sensitive to these estimated inputs made by management that are used in the calculation.

For the second half of 2022, the fair value of the Baker Notes issued as described in Note 5- Debt, and subsequent changes in fair value recorded at each reporting date, was determined by estimating the fair value of the Market Value of Invested Capital ("MVIC") of the Company. This was estimated using forms of the cost and market approaches. In the Cost approach, an adjusted net asset value method was used to determine the net recoverable value of the Company, including an estimate of the fair of the Company's intellectual property. The estimated fair value of the Company's intellectual property was valued using a relief from royalty method which required management to make significant estimates and assumptions related to forecasts of future revenue, and the selection of the royalty (3.5%) and discount (19.0%) rates. The guideline public company method served as another valuation indicator. In this form of the Market approach, comparable market revenue multiples were elected and applied to the Company's forward revenue forecast to ultimately derive a MVIC indication. If the resulting fair value from these approaches is not estimated as greater than the contractual payout, the fair value of the Baker Notes then becomes only the Company MVIC available for distribution to this first lien note holder.

January and March 2022 Notes

The fair value of the January and March 2022 Notes issued as described in Note 5- Debt, and subsequent changes in fair value recorded at each reporting date, were determined using a probability weighted expected return method (PWERM) model. PWERM was used to take into account several factors, including the future value of the Company's common stock, a potential change of control event, the probability of meeting certain debt covenants, the maturity term of the January and March 2022 Notes, exercise of the put right, and exercise of the Company's call right.

May 2022 Notes

The fair value of the May 2022 Notes issued as described in Note 5- Debt, and subsequent changes in fair value recorded at each reporting date, were determined using a PWERM model. PWERM was used to take into account several factors, including the future value of the Company's common stock, a potential change of control event, the probability of meeting certain debt covenants, the maturity term of the January and March 2022 Notes, exercise of the put right, and exercise of the Company's call right.

December 2022 Notes

The fair value of the December 2022 Notes issued as described in Note 5- Debt, were determined using an Black-Scholes option pricing model using typical inputs such as underlying market price of the Company's common stock, the conversion/strike price, time to maturity of the December 2022 Notes, guideline public company volatilities and a risk-free interest rate.

Purchase Rights

The Adjuvant Purchase Rights and the May Note Purchase Rights (collectively Purchase Rights) contain certain provisions that are outside the Company's control under which the holders can force settlement in cash; as such, the Purchase Rights are recorded as derivative liabilities in the consolidated balance sheets. The Purchase Rights are valued using an option pricing model (OPM), like a Black-Scholes Methodology with changes in the fair value being recorded in the consolidated statements of operations. The assumptions used in the OPM are considered level 3 assumptions and include, but are not limited to, the market value of invested capital, the cumulative equity value of the Company as a proxy for the exercise price and the expected term the Purchase Rights will be held prior to exercise and a risk-free interest rate.

Warrants

The warrants contain certain provisions, which are outside the Company's control, under which the holders can force settlement in cash, as such, the warrants are recorded as derivative liabilities in the consolidated balance sheets. In accordance with ASC 815 - *Derivatives and Hedging,* certain warrants previously classified as equity instruments were determined to be liability classified (the Reclassified Warrants) due to the Company having an insufficient number of authorized shares as of December 31, 2022. The Company will continue to re-evaluate the classification of its warrants at each balance sheet to determine the proper balance sheet classification for them. The warrants are valued using an OPM based on the applicable assumptions, which include the exercise price of the warrants, time to expiration, expected volatility of our peer group, risk-free interest rate, and expected dividends. The assumptions used in the OPM are considered level 3 assumptions and include, but are not limited to, the market value of invested

capital, the cumulative equity value of the Company as a proxy for the exercise price, the expected term the warrants will be held prior to exercise and a risk-free interest rate and probability of change of control event.

8. Commitments and Contingencies

Operating Leases

Fleet Lease

In December 2019, the Company and Enterprise FM Trust (the Lessor) entered into a Master Equity Lease Agreement whereby the Company leases vehicles to be delivered by the Lessor from time to time with various monthly costs depending on whether the vehicles are delivered for a term of 24 or 36 months, commencing on each corresponding delivery date. The leased vehicles are for use by eligible employees of the Company's commercial operations personnel. The Company maintains a letter of credit as collateral in favor of the Lessor, which was included in restricted cash in the consolidated balance sheet. As of December 31, 2022 and 2021, this letter of credit was $0.3 million. The Company determined that the leased vehicles are accounted for as operating leases under ASC 842. In September 2022, the Company extended the lease term for an additional 12 months for the vehicles with a term of 24 months. The Company determined that such extension is accounted for as a modification, for which the Company reassessed the lease classification and the incremental borrowing rate on the modification date and accounted for accordingly.

2020 Lease and the First Amendment

On October 3, 2019, the Company entered into an office lease for approximately 24,474 square feet (the Existing Premises) pursuant to a non-cancelable lease agreement (the 2020 Lease). The 2020 Lease commenced on April 1, 2020 and will expire on September 30, 2025, unless terminated earlier in accordance with its terms. The Company has a right to extend the term of the lease for an additional five years and does not anticipate exercising such extension. The Company provided the landlord with a $750,000 security deposit in the form of a letter of credit for the Existing Premises. On April 14, 2020, the Company entered into the first amendment to the 2020 Lease for an additional 8,816 rentable square feet of the same office location (the Expansion Premises), which commenced on September 1, 2020 and will expire on September 30, 2025. The Company provided an additional $50,000 in a letter of credit for the Expansion Premises. As of December 31, 2022 and 2021, restricted cash maintained as collateral for the Company's security deposit was $0.8 million. See default under lease agreement discussion within Note 14 – Subsequent Events for information regarding breach of the 2020 lease subsequent to December 31, 2022.

2022 Sublease

On May 27, 2022, the Company entered into a sublease agreement with AMN Healthcare, Inc. (AMN), pursuant to which the Company agreed to sublease 16,637 rentable square feet of the Existing Premises to AMN for a term commencing on June 15, 2022 and ending coterminous with the 2020 Lease on September 30, 2025, in exchange for the sum of approximately $87,000 per month, subject to an annual 3.5% increase each year. Gross sublease income was $0.6 million for the year ended December 31, 2022. Sublease income expected to be received from AMN is $1.0 million, $1.1 million and $0.9 million in each of the years ended December 31, 2023, 2024 and 2025, respectively.

		Year Ended December 31,	
Lease Cost (in thousands)	**Classification**	**2022**	**2021**
Operating lease expense	Research and development	$ 210	$ 499
Operating lease expense	Selling and marketing	886	1,012
Operating lease expense	General and administrative	597	827
Total		$ 1,693	$ 2,338

Lease Term and Discount Rate	**December 31, 2022**	**December 31, 2021**
Weighted Average Remaining Lease Term (in years)	2.68	3.58
Weighted Average Discount Rate	12 %	12 %

Maturity of Operating Lease Liabilities (in thousands)	Year Ended December 31
2023	$ 2,581
2024	2,360
2025	1,521
Total lease payments	6,462
Less: imputed interest	(1,018)
Total	$ 5,444

Other information (in thousands)	Year Ended December 31, 2022	Year Ended December 31, 2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash outflows in operating leases	$ 2,639	$ 2,426

Other Contractual Commitments

In November 2019, the Company entered into a supply and manufacturing agreement with a third-party to manufacture Phexxi, with potential to manufacture other product candidates in accordance with all applicable current good manufacturing practice regulations, pursuant to which the Company has certain minimum purchase commitments based on the forecasted product sales. The amounts purchased under the supply and manufacturing agreement were $1.0 million and $3.0 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, the $1.0 million remains unpaid.

Contingencies

From time to time the Company may be involved in various lawsuits, legal proceedings, or claims that arise in the ordinary course of business. On December 14, 2020, a trademark dispute captioned TherapeuticsMD, Inc. v Evofem Biosciences, Inc., filed in the United States District Court for the Southern District of Florida against the Company, alleging trademark infringement of certain trademarks owned by TherapeuticsMD under federal and state law (Case No. 9:20-cv-82296). On July 17, 2022, the Company settled the lawsuit with TherapeuticsMD, pursuant to which the Company agreed to rebrand its product by July 2024 to coincide with its marketing objectives.

As of December 31, 2022, there were no other claims or actions pending against the Company, which management believe has a probable, or reasonably possible, probability of an unfavorable outcome. However, the Company may receive trade payable demand letters from its vendors that could lead to potential litigation. As of December 31, 2022, approximately 56.7% of our trade payables were greater than 90 days past due.

Intellectual Property Rights

In 2014, the Company entered into an amended and restated license agreement (the Rush License Agreement) with Rush University Medical Center (Rush University) pursuant to which Rush University granted the Company an exclusive, worldwide license of certain patents and know-how related to its multipurpose vaginal pH modulator technology. Pursuant to the Rush License Agreement, the Company is obligated to pay to Rush University an earned royalty based upon a percentage of net sales in the range of mid-single digits. In September 2020, the Company entered into the first amendment to the Rush License Agreement, pursuant to which the Company is also obligated to pay a minimum annual royalty amount of $100,000 to the extent the earned royalties do not equal or exceed $100,000 commencing January 1, 2021. Such royalty costs, included in cost of goods sold, were $1.1 million and $0.2 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022 and 2021, approximately $0.6 million and immaterial were included in accrued expenses in the consolidated balance sheets.

9. Reduction in Force

On November 1, 2022, the Company's Board of Directors approved a reduction in force (RIF) intended to conserve the Company's current cash resources. The Company reduced the current workforce by 39 employees, of which 8 were in research and development, 30 were in sales and marketing and one was in general and administrative.

The Company estimated its aggregate pre-tax charges of approximately $0.4 million (of which $0.3 million was recorded within research and development expenses, $0.1 million, was recorded within sales and marketing expense and approximately $14,000 within general and administrative expenses), in connection with the reduction in force, primarily consisting of notice period and severance payments, employee benefits and related costs. The Company effected the reduction in force by the end of November 2022. These one-time charges were incurred primarily in the fourth quarter of 2022. As of December 31, 2022, any one-time charges not paid were considered to be *de minimus*. See Note 14 – Subsequent Events for additional RIF costs incurred subsequent to December 31, 2022.

10. Stockholders' Equity

Warrants

In April and June 2020, pursuant to the Baker Bros. Purchase Agreement, as discussed in Note 5- Debt, the Company issued in aggregate warrants to purchase up to 341,530 shares of the Company's common stock in a private placement at an exercise price of $36.60 per share. As discussed in Note 5- Debt, the Second Baker Amendment provides that the exercise price of the Baker Warrants will equal the conversion price of the Baker Notes. As discussed in Note 5- Debt, as of December 31, 2022, the exercise price of the Baker warrants was reset to $0.0325 per share and subsequent to year end was reset to $0.0065, as further discussed in Note 14 – Subsequent Events.

In January 2022, pursuant to the January 2022 Securities Purchase Agreement as discussed in Note 5- Debt, the Company issued warrants to purchase up to 1,000,401 shares of the Company's common stock in a registered direct offering at an exercise price of $5.88 per share. In March 2022, pursuant to the March 2022 Securities Purchase Agreement as discussed in Note 5- Debt, the Company issued warrants to purchase up to 1,037,886 shares of common stock in a registered direct offering at an exercise price of $7.18 per share.

In May 2022, pursuant to the exchange agreement as described in Note 5- Debt, the Company issued common warrants to purchase up to 833,333 shares of common stock at an exercise price of $2.4765 per share. The warrants have a five-year term and were exercisable beginning on May 4, 2022.

In May 2022, pursuant to the May 2022 Public Offering as described below, the Company issued common warrants to purchase up to 71,000,000 shares of common stock at an exercise price of $0.75 per share, and pre-funded warrants to purchase up to 12,835,000 shares of common stock at an exercise price of $0.001 per share. The warrants have a five-year term and were exercisable beginning May 24, 2022. The common warrants contain (and the pre-funded warrants contained) customary 4.99% and 19.99% limitations on exercise provisions. The exercise price and number of shares issuable upon exercise of the common warrants is subject to adjustment for certain dilutive issuances, stock splits and similar recapitalization transactions. As part of the debt restructuring in September 2022 as described Note 5- Debt, the exercise price of the common warrants was reset to $0.21 per share, and an additional 77,418,774 warrants were issued to holders of remaining unexercised warrants to reflect the dilutive adjustment resulting from the lower exercise price. Additionally, as part of the December 2022 Notes issuance as described in Note 5- Debt, the exercise price of the common warrants was reset to $0.0325 per share, and an additional 17,038,094 warrants were issued to holders of remaining unexercised warrants to reflect the dilutive adjustment resulting from the lower exercise price. No further adjustment to the holders of remaining unexercised warrants exists after the adjustment related to the December 2022 Notes issuance. During the second quarter of 2022, all pre-funded warrants were exercised for an immaterial amount of cash. During the year ended December 31, 2022, 35,314,846 shares of common warrants were exercised for total proceeds of $25.2 million. Subsequent to December 31, 2022, these warrants had their strike price reset to $0.0065, as discussed in Note 14 – Subsequent Events.

In June 2022, as required by the Second Baker Amendment, the Company issued the June 2022 Baker Warrants to purchase up to 72,860,769 shares of the Company's common stock, $0.0001 par value per share. The June 2022 Baker Warrants had an exercise

price of $0.75 per share at issuance and a five-year term and were exercisable beginning June 28, 2022. The June 2022 Baker Warrants also contain customary 4.99% and 19.99% limitations on exercise provisions. The exercise price and number of shares issuable upon exercise of the June 2022 Baker Warrants is subject to adjustment for certain dilutive issuances, stock splits and similar recapitalization transactions. As part of the debt restructuring in September 2022 as described Note 5- Debt, the exercise price of the June 2022 Baker Warrants was reset to $0.21 per share and then was further reset to $0.0325 per share upon the December 2022 Notes issuance. Subsequent to December 31, 2022, these warrants had their strike price reset to $0.0065, as discussed in Note 14 – Subsequent Events.

In December 2022, pursuant to the December 2022 Securities Purchase Agreement as discussed in Note 5- Debt, the Company issued warrants to purchase up to 46,153,847 shares of the Company's common stock in a registered direct offering at an exercise price of $0.05 per share. Subsequent to December 31, 2022, these warrants had their strike price reset to $0.0065, as discussed in Note 14 – Subsequent Events.

As of December 31, 2022, warrants to purchase up to 256,545,987 shares of the Company's common stock remain outstanding at a weighted average exercise price of $0.45 per share. All warrants issued by the Company are subject to liability accounting due to potential settlement in cash, an insufficient number of authorized shares and other adjustment mechanics. However, warrants with an exercise price greater than $0.05 per share were considered to be significantly out of the money as of December 31, 2022 and therefore the value ascribed to those warrants was considered to be *de minimus*. In accordance with ASC 815 - *Derivatives and Hedging,* certain warrants previously classified as equity instruments were determined to be liability classified (the Reclassified Warrants) due to the Company having an insufficient number of authorized shares as of December 31, 2022. The Company will continue to re-evaluate the classification of its warrants at each balance sheet to determine the proper balance sheet classification for them. The fair value of the warrants is included in derivative liabilities in the consolidated balance sheets. These warrants are summarized below:

Type of Warrants	Underlying Common Stock to be Purchased	Exercise Price	Issue Date	Exercise Period
Common Warrants	520	$ 55.35	June 11, 2014	June 11, 2014 to June 11, 2024
Common Warrants	56,578	$ 112.50	May 24, 2018	May 24, 2018 to May 24 2025
Common Warrants	12	$ 112.50	June 26, 2018	June 26, 2018 to June 26, 2025
Common Warrants	111,111	$ 95.70	April 11, 2019	October 11, 2019 to April 11, 2026
Common Warrants	185,185	$ 95.70	June 10, 2019	December 10, 2019 to June 10, 2026
Common Warrants	204,918	$ 0.0325	April 24, 2020	April 24, 2020 to April 24, 2025
Common Warrants	136,612	$ 0.0325	June 9, 2020	June 9, 2020 to June 9, 2025
Common Warrants	3,822,793	$ 15.00	May 20, 2021	May 20, 2021 to May 22, 2023
Common Warrants	1,000,401	$ 5.88	January 31, 2022	January 31, 2022 to March 1, 2027
Common Warrants	1,037,886	$ 7.1805	March 1, 2022	March 1, 2022 to March 1, 2027
Common Warrants	833,333	$ 2.4765	May 4, 2022	May 4, 2022 to May 4, 2027
Common Warrants	130,142,022	$ 0.0325	May 24, 2022	May 24, 2022 to May 24, 2027
Common Warrants	72,860,769	$ 0.0325	June 28, 2022	May 24, 2022 to June 28, 2027
Common Warrants	46,153,847	$ 0.05	December 21, 2022	December 21, 2022 to December 21, 2027
Total	**256,545,987**			

Convertible Preferred Stock

On October 12, 2021, the Company completed the initial closing of a registered direct offering with Keystone Capital Partners (Keystone Capital) (the Initial October 2021 Registered Direct Offering), whereby the Company issued 5,000 shares of Series B-1 Convertible Preferred Stock, par value $0.0001 per share, at a price of $1,000.00 per share. The Company received proceeds from the Initial October 2021 Registered Direct Offering of approximately $4.6 million, net of offering expenses. On October 26, 2021, the Company completed the additional closing of the October 2021 Registered Direct Offering (the Additional October 2021 Registered Direct Offering), whereby the Company issued 5,000 shares of Series B-2 Convertible Preferred Stock, par value $0.0001 per share, at

a price of $1,000.00 per share. The Company received proceeds from the Additional October 2021 Registered Direct Offering of approximately $5.0 million, net of offering expenses.

The Series B-1 and B-2 Convertible Preferred Stock were convertible into shares of common stock at any time at a conversion price per share of the greater of $9.00 (Fixed Conversion Price), or the price computed as the product of 0.85 multiplied by the arithmetic average of the closing sale prices of a share of the Company's common stock during the five consecutive trading-day period immediately preceding the conversion date (Variable Conversion Price). On October 12, 2021, Keystone Capital converted their 5,000 shares of B-1 Convertible Preferred Stock at a conversion price of $9.45 per share into 529,100 shares of the Company's common stock. Pursuant to the terms of the Series B-2 Convertible Preferred Stock, the Fixed Conversion Price was adjusted during the first quarter of 2022 for certain dilutive issuances. The adjustment period ended on April 25, 2022 and the Fixed Conversion Price was fixed at $2.66 from the sale of common stock pursuant to the Seven Knots Purchase Agreement. During March and April 2022, Keystone Capital converted their 1,200 shares of B-1 Convertible Preferred Stock at a conversion price of $4.70 per share into 293,496 shares of the Company's common stock. Pursuant to the terms of the Series B-2 Convertible Preferred Stock, the Fixed Conversion Price was adjusted during the first quarter of 2022 for certain dilutive issuances.

On March 24, 2022, the Company entered into an exchange agreement with the holder of its Series B-2 Convertible Preferred Stock, pursuant to which the holder agreed to exchange 1,700 shares of the Series B-2 Convertible Preferred Stock in consideration for 1,700 shares of the Company’s Series C Convertible Preferred Stock, par value $0.0001 per share, $1,000.00 per share stated value. Except with respect to voting provisions, the Series C and Series B-2 Preferred Stock had substantially similar terms.

On May 4, 2022, pursuant to the May 2022 Exchange, the remaining 2,100 shares of Series B-2 Convertible Preferred Stock and 1,700 shares of Series C Convertible Preferred Stock were exchanged for Senior Subordinated Notes with an aggregate principal amount of $4.8 million and warrants to purchase up to 833,333 shares of common stock.

The Company evaluated its convertible preferred stock to determine if an embedded component qualified as a derivative requiring bifurcation in accordance with ASC 815 *Derivative and Hedging*. The Company determined that the embedded conversion feature required bifurcation and needed to be accounted for separately as a free standing financial instrument. As a result, the fair value of the conversion feature is marked-to-market at each reporting date and is recorded on the consolidated balance sheet as a derivative liability. Changes in fair value are recognized on the consolidated income statement.

The Company also evaluated its convertible preferred stock and determined that it required mezzanine equity classification. The proceeds from the offering were first allocated to the fair value of the derivative liability and the remaining balance to the convertible preferred stock. The creation of the derivative liability resulted in a discount to the convertible preferred stock, at an amount equal to the fair value of the derivative liability at issuance. The discount is accreted through a deemed dividend which is recorded on the consolidated income statement. The entire discount to the Series B-1 Convertible Preferred Stock was accreted through a single deemed dividend when it was converted into common stock immediately after the initial closing. The Company elected to accrete the discount to the Series B-2 Convertible Preferred Stock over the four-year period from the issuance date to the date when the preferred stock becomes redeemable, and such accretion was immaterial for the year ended December 31, 2021. A deemed dividend for return of capital was also recorded as a result of the Series B-1 Convertible Preferred Stock conversion into common stock.

Under the valuation methods as described in Note 7- Fair Value of Financial Instruments, the Company recorded the following in the consolidated financial statements related to the convertible preferred stock issued in 2021: (i) an aggregate $9.6 million in convertible preferred stock, net of offering expenses, at issuance; (ii) an aggregate $0.5 million discount to the convertible preferred stock at issuance; (iii) an aggregate $0.5 million in derivative liabilities at issuance; (iv) a $0.8 million deemed dividend for return of capital as a result of the Series B-1 Convertible Preferred Stock conversion into common stock; (v) a $0.3 million deemed dividend for the accretion of the discount to the Series B-1 Convertible Preferred Stock upon conversion into common stock; and (vi) a $0.1 million gain in fair value of financial instruments as a result of the mark-to-market adjustment of the derivative liability at December 31, 2021. During the year ended December 31,2022, a loss of $0.1 million was recognized as a result of the mark-to-market adjustment of the derivative liability.

Effective December 15, 2021, the Company amended and restated its certificate of incorporation, under which the Company is currently authorized to issue up to 5,000,000 shares of preferred stock, $0.0001 par value per share.

Nonconvertible Preferred Stock

On December 16, 2022, the Company filed a Certificate of Designation of Series D Non-Convertible Preferred Stock, par value $0.0001 per share (the Series D Preferred Shares). An aggregate of 70 shares has been authorized, they are not convertible into shares of common stock, have limited voting rights equal to 1% of the total voting power of the then-outstanding shares of common stock entitled to vote per shares, are not entitled to dividends, and are required to be redeemed by us, once our shareholders have approved a reverse split, as described in the Certificate of Designation. All 70 shares of the Series D Preferred were subsequently issued in connection with the December 2022 Securities Purchase Agreement as discussed in in Note 5- Debt. Since the Series D Preferred Shares can only be settled in cash, they are recorded as a liability within accrued expenses in the consolidated balance sheets. The amount related to the liability is *de minimus.*

Common Stock

Effective January 17, 2018, the Company amended and restated its certificate of incorporation, under which the Company was authorized to issue up to 300,000,000 shares of common stock, $0.0001 par value per share. Effective December 15, 2021, the Company further amended its amended and restated certificate of incorporation to increase the number of authorized shares of common stock to 500,000,000 shares.

Public Offerings

In March 2021, the Company completed an underwritten public offering (the March 2021 Public Offering), whereby the Company issued 1,142,857 shares of common stock at a price to the public of $26.25 per share (the March 2021 Public Offering Price). The Company received proceeds from the March 2021 Public Offering of approximately $28.0 million, net of underwriting discounts. In addition, the Company granted the underwriters a 30 days overallotment option to purchase up to an additional 171,428 shares of its common stock at the March 2021 Public Offering Price, less applicable underwriting discounts. On April 6, 2021, the underwriters exercised their overallotment option in full and the Company received proceeds of approximately $4.2 million, net of underwriting discounts. The common stock issued in the March 2021 Public Offering were registered pursuant to a shelf registration statement on Form S-3 filed with the SEC on March 4, 2021 and declared effective on March 11, 2021.

In May 2021, the Company completed an underwritten public offering (the May 2021 Public Offering), whereby the Company issued 3,333,333 shares of common stock at a price to the public of $15.00 per share and common warrants to purchase 3,333,333 shares of common stock. The common warrants have an exercise price of $15.00 per share and can be exercised any time through May 22, 2023. The Company received proceeds from the May 2021 Public Offering of approximately $46.8 million, net of underwriting discounts and fees. In addition, the Company granted the underwriters a 30-day overallotment option to purchase up to an additional 500,000 shares of its common stock at $14.85 per share, less applicable underwriting discounts, and/or common warrants to purchase 500,000 shares of common stock, at $0.15 per warrant, less applicable underwriting discounts. On May 20, 2021, the underwriters exercised their overallotment option to purchase warrants in full and the Company received proceeds of approximately $0.1 million, net of underwriting discounts. On May 24, 2021, the underwriters exercised their overallotment option to purchase common stock and the Company issued an additional 169,852 shares of common stock and received proceeds of approximately $2.4 million, net of underwriting discounts. The common stock issued in the May 2021 Public Offering were registered pursuant to a shelf registration statement on Form S-3 filed with the SEC on March 4, 2021 and declared effective on March 11, 2021.

In May 2022, the Company completed an underwritten public offering (the May 2022 Public Offering), whereby the Company issued 22,665,000 shares of common stock and common warrants (the May Common Stock Warrants) to purchase 45,330,000 shares of common stock at a price to the public of $0.75. The common warrants have an exercise price of $0.75 per share, a five-year term, and were exercisable beginning on May 24, 2022. In the May 2022 Public Offering the Company also issued pre-funded warrants to purchase 12,835,000 shares of common stock and common warrants to purchase 25,670,000 shares of common stock at a price to the public of $0.749. The pre-funded warrants had an exercise price of $0.001 per share, were exercisable beginning on May 24, 2022 were fully exercised after completion of this offering. The Company received proceeds from the May 2022 Public Offering of $18.1 million, net of $5.9 million debt repayment, underwriting discounts and offering expenses. As discussed above, in Warrants, the May Common Stock Warrants were impacted by dilution adjustments and the strike price was reset to $0.0325 during the year ended December 31, 2022, with a further strike price reset to $0.0065, subsequent to December 31, 2022.

Common Stock Purchase Agreement

On February 15, 2022, the Company entered into a common stock purchase agreement (the Stock Purchase Agreement) with Seven Knots, LLC (Seven Knots), pursuant to which Seven Knots agreed to purchase from the Company up to $50.0 million in shares of the Company's common stock. Sales made to Seven Knots were at the Company's sole discretion, and the Company controlled the timing and amount of any and all sales. The price per share was based on the market price of the Company's common stock at the time of sale as computed under the Stock Purchase Agreement. As consideration for Seven Knots' commitment to purchase shares of common stock, the Company issued 128,172 shares of common stock to Seven Knots as commitment fee shares.

Sales of common stock to Seven Knots were subject to customary 4.99% and 19.99% beneficial ownership limitations. The Stock Purchase Agreement had a termination date of the earliest of March 1, 2024, or when Seven Knots has purchased from the Company $50.0 million in shares of the Company's common stock, or as otherwise determined by the Stock Purchase Agreement at the Company's option.

Effective May 18, 2022, the Company and Seven Knots elected to terminate the Stock Purchase Agreement without any penalty or additional cost to the Company. Prior to termination, the Company issued a total of 1,964,272 shares of common stock under the Stock Purchase Agreement for aggregate net proceeds of $7.4 million.

Unregistered shares

On June 8, 2022, the Company entered into an agreement for services with a360 Media, LLC (a360 Media), pursuant to which a360 Media will provide professional media support and advertising services in exchange for, at a360 Media's option, either (a) $860,119 in cash, or (b) 2,318,380 shares of the Company's common stock at a value of $0.371 per share. On July 18, 2022, the Company and a360 Media entered into a similar agreement for professional media support and advertising services in exchange for, at a360 Media's option, either (a) $1,409,858 in cash, or (b) 1,600,293 shares of the Company's common stock at a value of $0.881 per share. On August 15, 2022, the Company and a360 Media entered into a similar agreement for professional media support and advertising services in exchange for, at a360 Media's option, either (a) $1,142,048 in cash, or (b) 2,819,871 shares of the Company's common stock at a value of $0.405 per share. Pursuant to these three agreements, the company issued an aggregate 6,738,544 unregistered shares of the Company's common stock to a360 Media.

The Company evaluated the a360 Media agreement and determined that in accordance with ASC 480 *Distinguishing Liabilities from Equity* (ASC 480) and ASC 718 *Compensation-Stock Compensation* (ASC 718), the common stock issued to a360 should be equity classified and recorded as a prepaid asset in the consolidated balance sheet, which is then amortized to noncash stock-based compensation expense when services are received. During the year ended December 31, 2022, the Company recorded $3.4 million in stock-based compensation expense, which was recorded within sales and marketing expense in the consolidated statements of operations.

Purchase Rights

On September 15, 2022, the Company entered into certain exchange agreements with the Adjuvant Purchasers and the May 2022 Notes Purchasers to exchange, upon request, the Purchase Rights for an aggregate of 117,760,093 shares of the Company's common stock. The number of right shares for each Purchase Right is initially fixed at issuance, but is subject to certain customary adjustments, and, until the second anniversary of issuance, adjustments for certain dilutive Company equity issuances and expire on June 28, 2027. Refer to Note 7- Fair Value of Financial Instruments for the accounting treatment of the Purchase Rights. In connection with the December 2022 Notes issuance, the Company increased the number of outstanding Purchase Rights by 476,101,767. During the year ended December 31, 2022, the Company issued 32,586,530 shares of common stock upon the exercises of certain Purchase Rights. As of December 31, 2022, Purchase Rights related to the Adjuvant Purchase Rights and May Note Purchase Rights of 561,275,330 shares of the Company's common stock remained outstanding. Subsequent to December 31, 2022, the Purchase Rights had an additional dilution adjustment, as discussed in Note 14 - Subsequent Events.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance, on a one-for-one basis, is as follows in common equivalent shares as of December 31, 2022:

Common stock issuable upon the exercise of stock options outstanding	709,119
Common stock issuable upon the exercise of common stock warrants	256,545,987
Common stock issuance upon the exercise of purchase rights	561,275,330
Common stock available for future issuance under the 2019 ESPP	63,703
Common stock available for future issuance under the Amended and Restated 2014 Plan	498,727
Common stock available for future issuance under the Amended Inducement Plan	65,656
Common stock reserved for the conversion of convertible notes	2,263,210,550
Total common stock reserved for future issuance	3,082,369,072

11. Stock-based Compensation

Equity Incentive Plans

The following table summarizes stock-based compensation expense related to stock options, restricted stock awards (RSAs) and RSUs granted to employees, non-employee directors and consultants, and the 2019 ESPP (as defined below) included in the consolidated statements of operations as follows (in thousands):

	Years Ended December 31,	
	2022	2021
Research and development	$ 553	$ 1,357
Selling and marketing	497	1,870
General and administrative	2,263	5,671
Total	$ 3,313	$ 8,898

The 2012 Equity Incentive Plan (the 2012 Plan) provides for the issuance of RSAs, RSUs, or non-qualified and incentive common stock options to its employees, non-employee directors and consultants, from its authorized shares. In general, the options expire ten years from the date of grant and generally vest either (i) over a four-year period, with 25% exercisable at the end of one year from the employee's hire date and the balance vesting ratably thereafter or (ii) over a three-year period, with 25% exercisable at the grant date and the balance vesting ratably thereafter. No further awards may be issued under the 2012 Plan.

On September 15, 2014, the Company's board of directors adopted, and stockholders approved, the 2014 Equity Incentive Plan (the 2014 Plan), which was amended and restated on each of May 2018 and February 26, 2019 (the Amended and Restated 2014 Plan). Per the terms of the Amended and Restated 2014 Plan, the shares reserved will automatically increase on each January 1 through 2024, by an amount equal to the smaller of (i) 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31; or (ii) an amount determined by our board of directors.

On July 24, 2018, upon the recommendation by the Compensation Committee, the Company's board of directors adopted the Evofem Biosciences, Inc. 2018 Inducement Equity Incentive Plan (the Inducement Plan). Under the Inducement Plan, as amended, the number of authorized shares total 83,333 shares. The only persons eligible to receive awards under the Inducement Plan are individuals who satisfy the standards for inducement grant recipients under Nasdaq Marketplace Rule 5635(c)(4), generally, a person not previously an employee or director of the Company, or following a bona fide period of non-employment, as an inducement material to the individual's entering into employment with the Company.

Stock Options

The following table summarizes share option activity for the year ended December 31, 2022:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2021	708,329	$ 80.06	6.8	$ —
Granted	263,118	$ 6.44		
Exercised	—	$ —		
Cancelled	(262,328)	$ 54.81		
Outstanding as of December 31, 2022	709,119	$ 62.09	5.1	$ —
Options expected to vest as of December 31, 2022	709,119	$ 62.09	5.1	$ —
Options vested and exercisable as of December 31, 2022	498,530	$ 80.47	4.3	$ —

The following table summarizes certain information regarding stock options for the years ended December 31, 2022 and 2021 (in thousands, except per share data):

	2022	2021
Weighted average grant date fair value per share of options granted during the period	$ 5.16	$ 2.18
Cash received from options exercised during the period	$ —	$ —
Intrinsic value of options exercised during the period	$ —	$ —

As of December 31, 2022, unrecognized stock-based compensation expense for employee stock options was approximately $2.9 million, which the Company expects to recognize over a weighted-average remaining period of 2.2 years, assuming all unvested options become fully vested.

Summary of Assumptions

The fair value of noncash stock-based compensation for stock options granted to employees and non-employees was estimated on the date of grant using the Black-Scholes option pricing model based on the following weighted-average assumptions for options granted for the periods indicated.

	Years Ended December 31,	
	2022	2021
Expected volatility	102.5 %	101.1 %
Risk-free interest rate	2.0 %	0.7 %
Expected dividend yield	— %	— %
Expected term (years)	6.0	5.9

Expected volatility. The expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry.

Risk-free interest rate. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the stock option grants.

Expected dividend yield. The expected dividend yield assumption is based on the fact that the Company has never paid cash dividends and has no present intention to pay cash dividends.

Expected term. The expected term represents the period options are expected to be outstanding. Because the Company does not have historical exercise behavior, it determines the expected term assumption using the practical expedient as provided for under ASC 718, *Compensation-Stock Compensation* (ASC 718), which is the midpoint between the requisite service period and the contractual term of the option.

Restricted Stock Awards

The following table summarizes RSAs activity for the year ended December 31, 2022:

	Shares (RSAs)	Weighted Average Fair Value per Share
Unvested as of December 31, 2021	—	$ —
Granted	157,328	$ 7.34
Forfeited	(157,328)	$ 7.34
Released	—	$ —
Unvested as of December 31, 2022	—	$ —

Of the total RSAs granted during the years ended December 31, 2022 and 2021, no and 47,133 shares vested in accordance with the Company's achievement of the Performance-based RSAs milestones, respectively.

For the performance-based RSAs, (i) the fair value of the award is determined on the grant date; (ii) the Company assesses the probability of achieving each individual milestone associated with the award using reasonable assumptions based on the Company's operation performance towards each milestone; (iii) the fair value of the shares subject to the milestone is expensed over the implicit service period commencing once management believes the performance criteria is probable of being met; and (iv) the Company reassesses the probability of achieving each individual milestone at each reporting date, and any change in estimate is accounted for through a cumulative adjustment in the period when the change in estimate occurs. The non-performance based RSAs and RSUs are valued at the fair value on the grant date and the associated expenses will be recognized over the vesting period.

As of December 31, 2022, there was no unrecognized noncash stock-based compensation expense related to unvested RSAs.

Employee Stock Purchase Plan

On May 7, 2019, the board of directors approved a 2019 Employee Stock Purchase Plan (the 2019 ESPP), which was approved by stockholders at the 2019 annual meeting held on June 5, 2019. The 2019 ESPP initially authorized the issuance of 33,333 shares of common stock pursuant to purchase rights granted to employees. In addition, the number of shares available for issuance under the 2019 ESPP will increase on January 1 of each year until the first day of 2029, in an amount equal to the lesser of (i) 66,666 shares, (ii) 2% of the shares of common stock outstanding on December 31, or (iii) such lesser number of shares as is determined by the board of directors. This provision resulted in an additional 16,666 shares added to the total number of authorized shares on January 1, 2022. The 2019 ESPP is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended.

The 2019 ESPP enables eligible full-time and part-time employees to purchase shares of the Company's common stock through payroll deductions of between 1% and 15% of eligible compensation during an offering period. A new offering period begins around June 15 and December 15 of each year. At the last business day of each offering period, the accumulated contributions made during the offering period will be used to purchase shares. The purchase price is 85% of the lesser of the fair market value of the common stock on the first or the last business day of an offering period. The maximum number of shares of common stock that may be purchased by any participant during an offering period will be equal to $25,000 divided by the fair market value of the common stock on the first business day of an offering period. During the years ended December 31, 2022 and 2021, there were 75,169 and 30,709 shares of common stock purchased under the 2019 ESPP, respectively. In October 2022, the Board terminated the current offering period ending December 15, 2022, refunded all employee contributions, and suspended future offering periods.

The Company recognized $0.1 million and $0.3 million in noncash stock-based compensation expense related to the 2019 ESPP for the years ended December 31, 2022 and 2021, respectively. In October 2022, the Board terminated the current offering period ending December 15, 2022, refunded all employee contributions, and suspended future offering periods. As of December 31, 2022, the Company had no unrecognized noncash stock-based compensation expense related to the 2019 ESPP.

The fair value of shares to be issued to employees under the 2019 ESPP is estimated using a Black-Scholes option-pricing model at the grant date, which requires the use of subjective and complex assumptions, including (i) the expected stock price volatility, (ii) the calculation of the expected term of the award, (iii) the risk-free interest rate and (iv) the expected dividend yield. The following weighted average assumptions were used in the calculation of fair value of shares under the 2019 ESPP at the grant dates for the period indicated.

	Years Ended December 31,	
	2022	2021
Expected volatility	177.2 %	83.9 %
Risk-free interest rate	2.3 %	0.1 %
Expected dividend yield	— %	— %
Expected term (years)	0.5	0.5

12. Employee Benefits

The Company has a defined contribution 401(k) plan (401(k) Plan) for all qualifying employees. Employees are eligible to participate in the plan beginning on the first day of the month following their three-month anniversary of employment. Under the terms of the 401(k) Plan, employees may make voluntary contributions as a percent of their compensation. The Company makes a safe-harbor contribution of three percent (3.0%) of each employee's gross earnings, subject to Internal Revenue Service limitations. In the years ended December 31, 2022 and 2021, the Company made safe-harbor contributions of approximately $0.6 million and $0.8 million, respectively.

13. Income Taxes

The Company is subject to taxation in the United States and various states jurisdictions. Tax years since inception remain open to examination by the major taxing jurisdictions. The Company's consolidated pretax loss for the years ended December 31, 2022 and 2021 were generated by domestic as follows (in thousands). There are no consolidated pretax losses generated by foreign operations for the periods indicated.

	2022	2021
United States	$ (76,654)	$ (205,175)
Total	$ (76,654)	$ (205,175)

The income tax provision for the years ended December 31, 2022 and 2021 consisted of the following (in thousands):

	2022	2021
United States	$ —	$ —
State	(44)	(17)
Total current tax provision	(44)	(17)
Total deferred tax provision	—	—
Total	$ (44)	$ (17)

The reconciliation between the Company's effective tax rate on loss before income tax and the statutory tax rate for the years ended December 31, 2022 and 2021 was as follows:

	2022	2021
Statutory rate	21.00 %	21.00 %
State income tax, net of federal benefit	2.12 %	1.17 %
Nondeductible expenses	(0.41)%	(0.48)%
Equity-based expenses	(1.82)%	(0.70)%
Change in fair value of purchase rights	22.60 %	— %
Change in fair value of financial instruments	(20.00)%	(3.44)%
Return to provision	(0.47)%	(0.30)%
Tax credits	1.41 %	0.68 %
Uncertain tax positions	(0.39)%	(0.50)%
Change in valuation allowance	(24.11)%	(17.43)%
Effective tax rate	(0.07)%	— %

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company's net deferred tax assets arising from its taxable subsidiaries consisted of the following components as of December 31, 2022 and 2021 (in thousands):

	2022	2021
Deferred tax assets:		
Net loss carryforwards	$ 126,056	$ 112,891
Fixed assets and intangibles	338	423
Research and development capitalization	4,951	—
Research and development credits	6,136	5,233
Stock-based compensation	3,367	3,513
Other	2,247	2,726
Total deferred tax assets	143,095	124,786
Deferred tax liabilities		
Lease assets	(1,011)	(1,218)
Fixed assets	(113)	(101)
Other	(29)	—
Less: valuation allowance	(141,942)	(123,467)
Net deferred tax assets	$ —	$ —

In assessing the ability to realize deferred tax assets, management considers whether it is more likely than not that some portion or all the deferred tax assets will be realized. Generally, the ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Based on historical performance and future expectations, management has determined a valuation allowance is needed in respect to its ending deferred tax assets.

As of December 31, 2022, the Company had net operating loss (NOL) carryforwards for federal income tax purposes of approximately $548.9 million, which will begin to expire in 2029 if not utilized. As of December 31, 2022, the Company had NOL carryforwards in various states of approximately $212.8 million. The state carryforwards have varying expiration dates beginning in 2029.

As of December 31, 2022, the Company had federal and state research and development (R&D) tax credit carryforwards of approximately $6.2 million and $2.5 million, respectively. As of December 31, 2021, the Company had federal and state R&D tax credit carryforwards of approximately $5.1 million and $2.3 million, respectively. The federal R&D tax credits begin to expire in 2031, unless utilized, and the state credits do not expire.

For the tax years beginning on or after January 1, 2022, the Tax Cuts and Jobs Act of 2017 ("TCJA") eliminates the option to currently deduct research and development expenses and requires taxpayers to capitalize and amortize them over five years for research activities performed in the United States and 15 years for research activities performed outside the United States pursuant to IRC Section 174. Although Congress is considering legislation that would repeal or defer this capitalization and amortization requirement, it is not certain that this provision will be repealed or otherwise modified. If the requirement is not repealed or replaced, it will decrease our tax deduction for research and development expense in future years.

The following table summarized the activity related to the Company's gross unrecognized tax benefits as of December 31, 2022 and 2021 (in thousands):

	2022	2021
Balance at the beginning of the year	$ 2,679	$ 1,465
Adjustments related to prior year tax positions	5	813
Increases related to current year tax positions	304	401
Decreases due to statute of limitation expiration	—	—
Balance at end of year	$ 2,988	$ 2,679

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits, and uncertain income tax positions must meet a more likely than not recognition threshold to be recognized. The Company recognizes interest and penalties related to unrecognized tax benefits within the income tax expense line in the consolidated statements of operations. There were no accrued interest and penalties associated with unrecognized tax benefits as of December 31, 2022. The Company does not anticipate a significant change in its uncertain tax benefits over the next 12 months.

Management believes it is more likely than not that all significant tax positions taken to date would be sustained by the relevant taxing authorities. Furthermore, the Company has not recognized any tax benefits to date because the Company has established a full valuation allowance for its deferred tax assets due to uncertainties as to their ultimate realization.

Pursuant to Internal Revenue Code (IRC) sections 382 and 383, use of the Company's NOLs and R&D credit carryforwards may be limited if a cumulative change in ownership of more than 50.0% (by value) occurs within a rolling three-year period. The Company completed a formal Section 382 analysis through the period ending December 31, 2019, and determined they experienced ownership changes in 2010 and 2018. Accordingly, the Company has reduced its deferred tax asset for NOLs and R&D tax credits by the estimated impact of IRC sections 382 and 383 as of December 31, 2019. The Company has not completed a formal Section 382 analysis after the period ending December 31, 2019. Any future ownership changes could further impact the utilization of the NOLs and R&D tax credits, however given the full valuation allowance this would not result in an impact to the Company's tax expense.

14. Subsequent Events

Subsequent events were evaluated through the filing date of this Annual Report, April 27, 2023.

Additional Financings

In February, March and April 2023, the Company entered into securities purchase agreements with certain investors providing for the sale and issuance of senior secured convertible notes (collectively, the 2023 SPAs). The 2023 SPAs included (i) convertible promissory notes with aggregate original principal amounts of approximately $1.4 million, $0.6 million, $0.5 million and $0.8 million, respectively (the 2023 Notes), and (ii) warrants to purchase an aggregate 69,230,769, 30,000,000, 26,923,077 and

76,923,077 shares of common stock, respectively (the 2023 Warrants and collectively, the 2023 Offerings). The 2023 Offerings closed on February 17, 2023 (the February 2023 Closing), March 13, 2023, March 20, 2023 (the March 2023 Closing) and April 5, 2023 (the April 2023 Closing), respectively, with net proceeds to the Company, after deducting offering expenses, of approximately $0.7 million, $0.3 million, $0.3 million, and $0.5 million, respectively. The 2023 SPAs also included a Registration Rights Agreement that us to register the common stock underlying the 2023 Notes and 2023 Warrants within the timeframes specified therein. In addition, the Company issued warrants to purchase an aggregate 12,461,538 and 5,400,000 shares of common stock in February and March 2023 Closing to the placement agent.

Upon the April 2023 Closing, the conversion and strike prices, as applicable, of the Baker Notes, Baker Warrants, the May 2022 Common Warrants, the June 2022 Baker Warrants, the Adjuvant Notes, the December 2022 Notes and Warrants, and the Notes and Warrants in the February and March 2023 Closing reset to $0.0065 per share, accordingly. Additionally, the Company's outstanding Purchase Rights increased by approximately 3.1 billion since December 31, 2022.

Event of Default

On March 7, 2023, Baker Bros. Advisors, LP (the Designated Agent) provided a Notice of Event of Default and Reservation of Rights (the Notice of Default) relating to the Securities Purchase and Security Agreement dated April 23, 2020, and subsequently amended (SPA), by and amount the Company, Designated Agent, the Guarantors and Baker Purchasers. The Notice of Default claims that the Company has failed to maintain the "Required Reserve Amount" as required by Section 2.7 of the Third Amendment to the Securities Purchase Agreement and Section 8.1(e) of the SPA. The Designated Agent claims such failure constitutes an immediate Event of Default pursuant to Section 9.1(e) of the SPA. The Designated Agent, at the direction of the Baker Purchasers, has accelerated repayment of the outstanding balance payable and elected its remedies pursuant to Section 5.07(b) of the Securities Purchase Agreement. As a result, approximately $92.8 million representing two times the sum of the outstanding balance and all accrued and unpaid interest thereon and all other amounts due under the SPA and other documents is due and payable within three business days of receipt of the Notice of Default. As of the date of the filing of this Annual Report, the Baker Notes remain outstanding. The failure to cure the default or otherwise settle or resolve, could have a significant negative financial impact on the Company, could result in litigation, and could result in the assets of the company being seized, attached or otherwise utilized to satisfy the debt.

Proposed Reverse Stock Split

On March 15, 2023, the Company held a Special Meeting of its Stockholders in which the stockholders approved an amendment to the Company's Certificate of Incorporation to effectuate a reverse stock split of the outstanding shares of the Company's common stock by a ratio of not less than 1-for-20 and not more than 1-for-125 at any time on or prior to March 15, 2024, with the exact ratio to be set at a whole number within such range by the Company's board of directors. The Company expects the reverse stock split to be affected after the filing of this Annual Report.

Reduction in Force

On March 20, 2023 the Board of Directors of Evofem Biosciences, Inc. (the "Company") approved a reduction in force (RIF) intended to conserve the Company's current cash resources and manage operating expenses.

The Company estimates that it will incur aggregate pre-tax charges of approximately $0.1 million in connection with the reduction in force, primarily consisting of notice period and severance payments, employee benefits and related costs. The Company expects that the reduction in force will be complete by the end of the second quarter of 2023 and that these one-time charges will be incurred in the first quarter of 2023.

Default under Lease Agreement

On March 20 2023, the Company received a notice of default from its landlord, for failing to pay March 2023 rent timely resulting in a breach under the agreement. As a result, the Company's letter of credit in the amount of $0.8 million, in restricted cash, has been recovered by the landlord. As of the date of the filing of this Annual Report we are unable to estimate the amount of damages the landlord may seek, if any, as a result of the breech.

Exhibit 21.1

Subsidiaries of Evofem Biosciences, Inc.

Evofem Biosciences Operations, Inc.
Evofem, Inc.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333- 258321, 333-253881, 333-234769, 333-232303, 333-231126 and 333-230191 on Form S-3 and Registration Statement Nos. 333-200409, 333-203059, 333-225366, 333-226517, 333-231991, 333-231993, 333-237119, 333-237126, 333-238228, 333-252516 and 333-263422 on Form S-8 of our report dated April 27, 2023, relating to the financial statements of Evofem Biosciences, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2022.

/s/ DELOITTE & TOUCHE LLP

San Diego, California
April 27, 2023

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Saundra Pelletier, certify that:

1 I have reviewed this annual report on Form 10-K of Evofem Biosciences, Inc.;

2 Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3 Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4 The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5 The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 27, 20223

By: /s/ Saundra Pelletier

Saundra Pelletier

President, Chief Executive Officer, and Interim Chairperson of the Board

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ivy Zhang, certify that:

1 I have reviewed this annual report on Form 10-K of Evofem Biosciences, Inc.;

2 Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3 Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4 The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5 The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 27, 2023 By: /s/ Ivy Zhang

Ivy Zhang
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Evofem Biosciences, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Annual Report"), each of the undersigned officers of the Company, does hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of such officer's knowledge:

(1) The Annual Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 27, 2023 By: /s/ Saundra Pelletier

Saundra Pelletier
President, Chief Executive Officer, and Interim Chairperson of the Board
(Principal Executive Officer)

Date: April 27, 2023 By: /s/ Ivy Zhang

Ivy Zhang
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Evofem Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.