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, 2021

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.)**
12400 High Bluff Drive, Suite 600 San Diego, CA	**92130**
(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	The Nasdaq Stock Market LLC (Nasdaq Capital Market)
Series A Preferred Stock Purchase Rights, par value $0.0001 per share	N/A	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

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. ☐

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 $172,915,009 as of June 30, 2021, 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 February 28, 2022, was 167,783,009.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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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 sections entitled "Business," "Risk Factors," and "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 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;
- 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;
- 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 continue as a going concern;
- our ability to maintain the listing of shares of our common stock on the Nasdaq Capital Market, including the results or potential results of any hearing;
- our ability to comply with the provisions and requirements of our debt arrangements;
- the impacts of the ongoing pandemic related to a novel strain of a virus named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus), which causes coronavirus disease 2019 (COVID-19), 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 United States (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 Phexxi for prevention of urogenital transmission of *Chlamydia trachomatis* infection (chlamydia) and *Neisseria gonorrhoeae* infection (gonorrhea) in women, and any other product candidate we may seek to develop;
- the success, cost and timing of our clinical trials;
- our top-line or initial clinical trial data, which are subject to adjustment and revision;
- 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 in the conduct of our clinical trials and for the manufacture of Phexxi and our product candidates;
- 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. We have included important factors in the cautionary statements included in this Annual Report, particularly in the section entitled "*Risk Factors*," which we believe could cause our actual results to 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.

To date, only one of our products, Phexxi vaginal gel, has been approved by the FDA for marketing in the United States. Our other current clinical programs and product candidates are investigational and have not been submitted to or approved by the FDA, and 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.

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 on Form 10-K includes our trademarks, trade names and service marks, including "Phexxi®," 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, including hormone-free, woman-controlled contraception and protection from certain sexually transmitted infections (STIs).

Our first commercial product, Phexxi, was approved by the FDA on May 22, 2020 and 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.

We are evaluating Phexxi for two potential new indications: the prevention of chlamydia and the prevention of gonorrhea in women. These are two of the most pervasive STIs in the United States. The Centers for Disease Control and Prevention (CDC) estimates that four million new chlamydia infections and 1.6 million new cases of gonorrhea occurred in 2018 alone. The number of reported cases is lower than the estimated total number because almost 60% of women infected with chlamydia have no symptoms. This is a concern because chlamydia and gonorrhea have been reported to be responsible for one-third to half of pelvic inflammatory disease (PID) cases. PID can cause serious, long-term problems including infertility, ectopic pregnancy, and chronic pelvic pain.

Currently, there are no FDA-approved prescription products for the prevention of either of these dangerous infections. In October 2020, we initiated our confirmatory Phase 3 clinical trial of Phexxi for these potential indications (EVOGUARD). We expect top-line results from EVOGUARD in the second half of 2022.

The FDA has designated Phexxi, using the investigational name EVO100, (EVO100) as a Qualified Infectious Disease Product (QIDP) for the prevention of urogenital chlamydia infection and the prevention of urogenital gonorrhea infection in women. QIDP designation provides several important potential advantages to a future drug product, including possible priority review of its marketing application, and a longer period of marketing exclusivity under the FDA statutes. The FDA has also granted Fast Track designations to EVO100 for both potential new indications.

EVO200 vaginal gel (EVO200), our investigational candidate for the reduction of recurrent bacterial vaginosis (BV), uses the same proprietary vaginal pH modulator platform as Phexxi. EVO200 has been designated a QIDP by the FDA for this indication. 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.

Phexxi, EVO200, and other product candidates in development share similar non-hormonal, acid-buffering, bioadhesive properties. However, they are designed differently to target viral and bacterial pathogens while playing an integral role to the survival of healthy bacteria in the vagina, enabling women to achieve better sexual and reproductive health.

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.

Our Strategy

Key elements of our strategy include:

- ***Successfully commercialize Phexxi***. 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 continuing the clinical development of our vaginal pH modulator platform, including our Phase 3 program

evaluating the potential of Phexxi to prevent chlamydia and gonorrhea in women and the development of additional product candidates.

- ***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 $7.35 billion in 2020 and is expected to reach approximately $9.6 billion by 2027 with a compound annual growth rate of 4.2% year-over-year between 2020 and 2027.

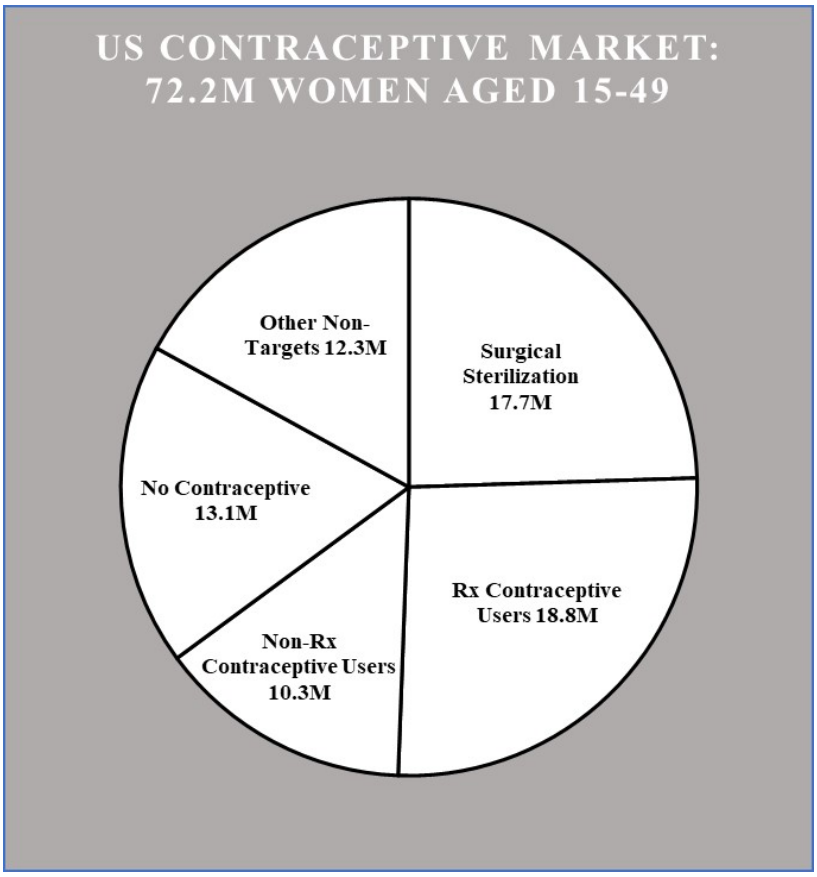
Current contraceptive options include:

- 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), which 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;
- 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, 13.1 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 18.8 million women in the United States use prescription birth control methods, which are predominantly hormone-based with the sole exception of the copper IUD.

U.S. Contraceptive Market



Source: Daniels K, Abma JC. Current contraceptive status among women aged 15-49: United States, 2015-2017. NCHS Data Brief. 2018; 327: 1-14.

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. As such, women using contraception consider the most appropriate methods for their purposes and intended use. According to the United Nations, in 2017, model-based estimates indicated that approximately 75% of women of reproductive age (18 to 49) worldwide required some form of family planning.

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 over the last couple of 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 do not have 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 there are 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.

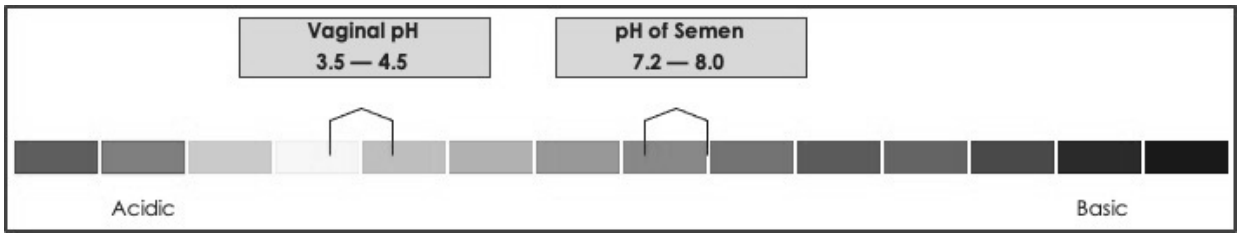
Product Class	Non-Hormonal	No Systemic Side Effects	Non-invasive	Convenient
Vaginal pH Modulator (i.e. Phexxi)	ü	ü	ü	ü
28 Day OCs			ü	
Extended Regimen OCs			ü	
Hormone Releasing IUDs				ü
Copper IUD	ü	ü		ü
Implant				ü
Vaginal Ring			ü	ü
Transdermal Patch			ü	

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), bioadhesive and viscosity-retaining properties to provide effective acidification of the male ejaculate in the vagina and to form a long-lasting layer of gel over the vaginal and cervical surfaces. 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, 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 EU, APAC, and 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 and our product candidates. In September 2020, we commercially launched Phexxi, with a sales force promoting Phexxi directly to obstetricians/gynecologists and their affiliated health professionals, who collectively write the majority of prescriptions for contraceptive products. Our sales force currently comprises approximately 57 regional sales representatives and eight business managers, supported by a self-guided virtual HCP learning platform. Additionally, we offer women direct access to Phexxi via our telehealth platform where 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.

Our comprehensive commercial strategy for Phexxi includes marketing and product awareness campaigns 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. In addition to marketing and product awareness campaigns, our commercial strategy includes payer outreach and execution of our consumer digital and media strategy.

These efforts are complemented by multi-channel marketing campaigns to raise brand awareness, including direct-to-consumer (DTC) and health care professional campaigns. These key initiatives are supported by advertising campaigns encompassing social media, print and digital media, paid search initiatives, and public relations efforts.

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

On September 9, 2021, we launched a national campaign featuring brand ambassador and Emmy Award-winning celebrity Annie Murphy, known as the House Rules campaign (House Rules), designed to broaden awareness and drive uptake of Phexxi. The House Rules campaign has significantly increased our target audience awareness of Phexxi, driven women to request a trial from their HCPs and driven significant increases in new HCPs recommending and prescribing Phexxi. Through December 31, 2021, the House Rules DTC campaign has impacted key metrics. The number of ex-factory units sent to distributors grew each quarter in 2021 and totaled 89,163 for the year. The largest growth occurred in the fourth quarter, with an increase in ex-factory units sent to distributors of 73% in Phexxi units shipped compared to the third quarter. This growth in the fourth quarter was propelled by over 22,600 new patients starting Phexxi, a 56% increase as compared to the third quarter. Ex-factory growth was further driven by a significant growth in refills (over 9,700 refill prescriptions, a 111% increase compared to the third quarter).

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 and will continue to be 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, which on an annualized basis is comparable to the average annual cost of other branded contraception products. As of October 1, 2021, Phexxi is priced at $294.00 per box of 12 applicators, which when annualized is comparable to all other contraceptives commercially available today.

Phexxi is classified in the databases and pricing compendia of Medi-Span and First Databank, two major drug information databases that payers consult for pricing and product information, as the first and only "Vaginal pH Modulator."

Third-party Payers

Market acceptance and sales of Phexxi and our other product candidates, assuming approval, will depend in part on the extent to which reimbursement for these products will be 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 both health plans and PBMs to secure additional formulary positioning for Phexxi.

We continue working to increase the number of lives covered and to gain preferred formulary position for Phexxi. As of December 2021, IQVIA, a leading healthcare data science company, reports that approximately 80% of Phexxi prescriptions are being approved either by payers or through Evofem patient support programs. We have coverage for approximately 55% of U.S. commercial lives, including approximately nine million lives covered at no out-of-pocket cost and approximately 13.7 million lives covered under our December 2020 contract award from the U.S. Department of Veterans Affairs.

We are also participating in government programs that include 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.

In January 2022, the Health Resources and Services Administration (HRSA) and the U.S. Department of Labor separately issued updated guidance related to contraceptive access. The new guidance specifies that most insurers and PBMs

must provide coverage with no out-of-pocket costs to women, for FDA-approved contraceptive products, like Phexxi, prescribed by health care providers.

Under the HRSA Women's Preventive Services Guidelines, 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. The full range of contraceptives is clarified to include those currently listed in the FDA's Birth Control Guide and any additional contraceptives approved, granted, or cleared by the FDA. The HSRA guidelines take effect in plan year 2023, with earlier adoption allowed.

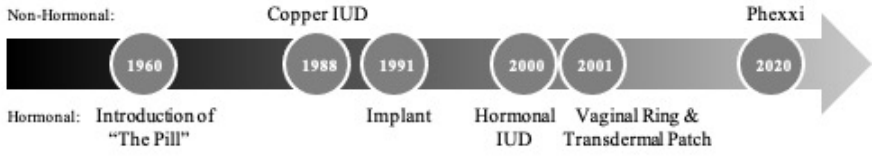
Under the U.S. Department of Labor's published tri-agency clarification regarding contraceptive coverage, plans are required to cover an FDA-approved, cleared, or granted contraceptive if a provider deems it medically necessary at $0 cost share, whether or not it is specifically identified in the current FDA Birth Control Guide. Additionally, plans cannot 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.

We believe these updates are a very significant step forward toward ensuring contraceptive access for all women at zero copay under the Affordable Care Act (ACA).

We continue to work with the FDA's Office of Women's Health to update its Birth Control Guide (Guide) to include a new category for vaginal pH modulators, as the current guide does not have a place for Phexxi due to its unique mechanism of action. While the HRSA and Department of Labor guidance are clear that plans are required to cover FDA- approved contraception at $0 cost share, whether or not it is specifically identified in the FDA Birth Control Guide, we believe there is still merit to the Guide being current and accurate. The Guide is used as an educational tool by obstetrician/gynecologists, and we therefore believe it should include all FDA-approved methods of birth control. To support this initiative, we have launched a grassroots coalition that shows the public's support of the need for updating the chart.

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 (LARC), comprising IUDs, implants, and injectables; and 3) OTC methods, dominated primarily by the male condom.

Prescription Contraception

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

OCs

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. OCs typically must be taken at the same time every day to be the most effective.

LARC

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. However, many women have opted against the IUD for fear of a bad insertion experience or having something in them (i.e. a “foreign body effect”). For other women who opt into the insertion procedure, many have decided to remove their IUD due to the hormonal and other side effects that they experience. Others have been deterred by the risks of IUDs brought to light by ongoing lawsuits.

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.

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.

Non-oral, Hormonal Contraceptives

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 by Merck & Co. was introduced to the market in 2001; however, 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. Users of the vaginal ring report the same incidence of hormone related side effects as those using oral hormonal contraception.

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

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

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 carry a black box warning label and have very limited utilization.

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 awaiting 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). In January 2022, we submitted registrations to the National Agency for Food and Drug Administration and Control in Nigeria and the Ethiopian Food and Drug Authority. These are the first tranche of several strategic regulatory submissions planned under Evofem's 2020 Global Health Agreement with Adjuvant Capital.

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, 2021, we estimated that we had manufactured inventory on hand to support approximately fifteen months of anticipated demand for Phexxi.

We are currently installing a second filling and packaging line at our manufacturer. We expect this line will be installed and qualified for manufacturing in 2022, thereby increasing our production capabilities to meet anticipated market demand for Phexxi.

Our Pipeline

Phexxi for STI Prevention

Our lead clinical program is evaluating Phexxi (using the investigational name EVO100) for the prevention of chlamydia and gonorrhea in women – the two most frequently reported bacterial infections in the United States. Currently, there are no FDA-approved prescription products for the prevention of either of these common STIs. The FDA has designated EVO100 (Phexxi) a Qualified Infectious Disease Product (QIDP) for the prevention of urogenital chlamydia infection and the prevention of urogenital gonorrhea infection in women. The FDA has also granted Fast Track designations to EVO100 (Phexxi) for both potential new indications.

According to the CDC, any sexually active person can be infected with chlamydia or gonorrhea. Despite the CDC recommendation for condom use to prevent STIs, U.S. rates of infection with chlamydia and gonorrhea climbed in 2019 for the sixth consecutive year. The CDC reported 1.8 million new cases of chlamydia in 2019, the most ever reported, and over 600,000 new cases of gonorrhea, also the highest reported. The number of reported cases is lower than the estimated total number because infected people are often unaware of, and do not seek treatment for, their infections. Almost 60% of women infected with chlamydia have no symptoms. Based on these reports, an estimated 78 million women 18-65 years of age who are sexually active in the United States could be at risk to contract these STIs.

Chlamydia and gonorrhea have been reported to be responsible for one-third to one-half of pelvic inflammatory disease (PID) cases. PID can cause serious, long-term problems including infertility, ectopic pregnancy, and chronic pelvic pain. We believe this represents a significant unmet medical need, as well as a commercial opportunity.

In December 2020, the CDC updated its “Treatment Guidelines for Gonococcal Infection” due to the increasing resistance of gonorrhea and other organisms to treatment with the antibiotic azithromycin, which was the prior standard of care.

Phase 2B/3 Trial for STI Prevention

In 2019, we completed AMPREVENCE, a double-blinded, placebo-controlled Phase 2B/3 trial (AMPREVENCE) to evaluate the efficacy of Phexxi for the prevention of sexual transmission of chlamydia (primary endpoint) and gonorrhea (secondary endpoint). This trial enrolled 860 women, 18 to 45 years of age, at approximately 50 sites in the United States.

AMPREVENCE met both its primary and secondary endpoints of reducing the risk of chlamydia and gonorrhea infection, respectively, and demonstrated that Phexxi was generally safe and well tolerated. The infection rate of chlamydia among women who used Phexxi for the four-month study period was 4.9% (n=14/288) compared to 9.8% among those who used placebo for four months (n=28/287) (p=.024), a relative risk reduction of 50% in the primary endpoint. Among the reported cases of gonorrhea infection, the infection rate was 0.7% in the Phexxi arm (n=2/280), compared to 3.2% in the placebo arm (n=9/277) (p=.03), a relative risk reduction of 78% in the secondary endpoint. Phexxi was generally safe and well tolerated in this study population with the number of adverse events similar across both arms (7.2% for Phexxi and 7.5% for placebo) and no serious treatment-related adverse events reported.

Prior to the Phase 2B/3 trial, the FDA indicated that if AMPREVENCE met its primary endpoint, it could be considered as one of two pivotal trials required for approval of Phexxi for the prevention of chlamydia in women.

EVOGUARD

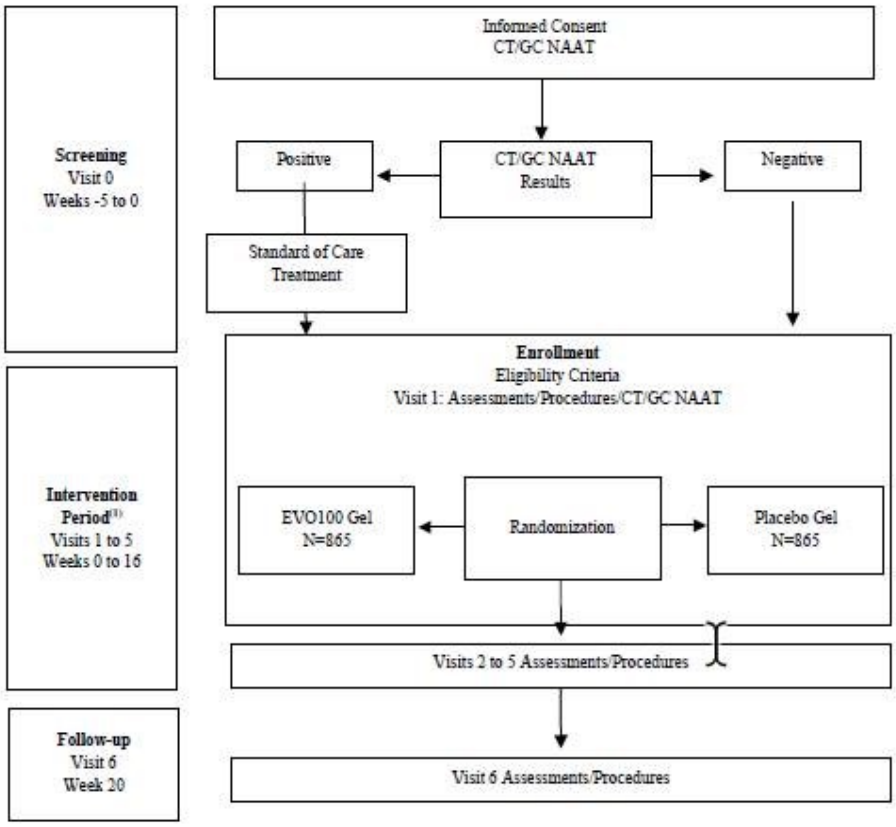
Based on the positive and statistically significant top-line results of our Phase 2B/3 AMPREVENCE trial, we initiated our Phase 3 *EVOGUARD* clinical trial in October 2020. We completed enrollment in March 2022 and expect to report top-line *EVOGUARD* results in the second half of 2022. Assuming positive results from the trial, we expect to submit a marketing application for Phexxi in the first half of 2023 with an anticipated FDA action date under the Prescription Drug User Fee Act in the second half of 2023. This is due to the potential for priority review afforded by the Fast Track Designation granted to EVO100 (Phexxi) by the FDA for the prevention of both chlamydia and gonorrhea. The FDA also designated EVO100 (Phexxi) a QIDP in 2022 for the prevention of urogenital chlamydia infection in women and in 2017 for the prevention of urogenital gonorrhea infection in women.

A summary of the *EVOGUARD* study and design is provided below.

EVOGUARD Study Design

EVOGUARD is a randomized, placebo-controlled clinical trial designed to enroll 1,730 women with a prior chlamydia or gonorrhea infection and who are at risk for future infections. Participants are enrolled for a 16-week interventional phase followed by a one-month follow-up period. The primary objective of this study is to evaluate the efficacy of Phexxi in the prevention of urogenital chlamydia and gonorrhea infections. The design of the study is illustrated in Figure 1.

Figure 1 Schematic Flow of Study Design



Abbreviations: CT = *Chlamydia trachomatis*, GC = *Neisseria gonorrhoeae*, NAAT = nucleic acid amplification test

(1)In the event a subject has CT or GC infection diagnosed at a local healthcare facility during the period between visits, the infection and treatment will be documented and every effort to obtain a medical record will be made.

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.

The FDA has designed EVO200 as a QIDP for this indication.

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. This collaboration will focus on determining compatibility and stability of OB-002 in Phexxi and is expected to yield results in the third quarter of 2022. Assuming positive preclinical results, Evofem and Orion will seek government and philanthropic funding for subsequent clinical trials of the MPT vaginal gel product candidate.

Thin Film Project

We have 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. Phase 2 of the project is planned for 2022, and the activities 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, 2021 were $0.2 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 28, 2022, we owned or had exclusive license to 41 issued patents and allowed applications in the United States and other countries and jurisdictions, and had 25 patent applications pending in the United States and other countries and jurisdictions. This includes two 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) following their submission to the FDA on June 3, 2020.

We 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. Further, 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 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 and Phexxi. 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 prevention of urogenital chlamydia, urogenital gonorrhea, and our BV product candidate (EVO200), and one for EVO100 (Phexxi) under which the ongoing Phase 3 clinical trial relating to prevention of chlamydia and gonorrhea *(EVOGUARD)* is being conducted.

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 ended December 31, 2021, this application fee exceeds $2.8 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 accompanying 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. 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. For example, FDA is expected to release proposed regulations in 2022 in order to amend the national standards for licensing of wholesale drug distributors by the states; establish new minimum standards for state licensing third-party logistics providers; and create a federal system for licensure for use in the absence of a State program, each of which is mandated by the DSCSA 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 Phexxi NDA is subject to this form of three-year new product exclusivity, which expires on May 22, 2023.

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 (Phexxi) for the prevention of urogenital infection in women with both chlamydia and gonorrhea.

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 (Phexxi) 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. Furthermore, the next FDA reauthorization package is currently being negotiated and is due to be finalized by Congress in 2022, while several other FDA-related changes are also being proposed in Congress, including 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.

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

Our corporate headquarters are located at 12400 High Bluff Drive, Suite 600, San Diego, California 92130, and our telephone number is (858) 550-1900. Our website is located at www.evofem.com. Our Annual Report, Quarterly 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 February 28, 2022, we had a total of 119 employees, all of which are full-time employees, and we 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 us. These are not the only risks we face. You should carefully consider these risk factors, together with the risk factors set forth in Item 1A. of this Annual Report and the other reports and documents filed by us with the SEC.

Risks Related to Our Financial Condition and Capital Requirements

- 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 generated nominal revenue from product sales and may never be profitable.
- 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.

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 prevention of pregnancy would likely cause our business to fail.
- Our commercialization strategy in light of the COVID-19 pandemic is unproven and if it is not successful, will harm our business and limit our ability to sell our product.
- If we are unable to establish effective internal sales and marketing capabilities or enter into agreements with third parties to market and sell any of our approved products, our ability to generate revenue would be adversely affected.
- Our use of social media platforms to market and promote prescription products, such as Phexxi, presents risks and operational challenges.
- 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 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.
- 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 is difficult to engage sufficient numbers of providers, or if limitations on reimbursement or new state law regulatory requirements impede our ability to implement our telehealth solution, the growth of our business will be harmed.
- The success of Phexxi will depend on the availability of contraceptive alternatives and women’s preferences, in addition to the market’s acceptance of our new form of prevention of pregnancy.
- 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.
- 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.
- Our business has been adversely affected and could be materially and adversely affected in the future by the ongoing COVID-19 pandemic.

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 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. Failure to identify additional product candidates would have a negative impact on our business and operations.
- 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.

- 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.

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.
- 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.

Risks Related to Our Post-Marketing Legal and Regulatory Compliance

- Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of Phexxi or development of potential new indications for 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.

Risks Related to Our Intellectual Property

- Our rights to develop and commercialize Phexxi for current and potential new indications 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 for current and potential new indications, 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.
- If we do not obtain PTE for our products or product candidates, our business may be materially harmed.

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 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.

Risks Related to Our Commercialization of Health Care Products

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

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, and we may experience difficulties in managing this growth or be unable to successfully commercialize our products, develop any product candidates or otherwise implement our business plan.

Risks Related to Our Financial Condition and Capital Requirements

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 $206.2 million and $142.3 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $860.7 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 commercialization and development of Phexxi and to the development of Phexxi 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. We plan to spend significant capital to fund our continued commercialization efforts. Our cash expenses will also continue to be highly dependent on the product development programs we choose to pursue, including Phexxi for the prevention of chlamydia and gonorrhea, the progress of these product development programs, the results of our preclinical and clinical trials, the cost, timing and outcomes of regulatory decisions regarding potential approval for our product candidates or any future product candidates we may choose to develop, and 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 in future quarters and to continue to incur significant losses for the foreseeable future as we:

- incur sales, marketing, and distribution costs to commercialize Phexxi and any other product candidates for which we may obtain marketing approval, including television, media and digital promotional campaigns;
- incur costs associated with the commercial manufacturing of Phexxi and manufacturing of our product candidates;
- implement post-approval changes and process improvements to manufacturing;
- continue the clinical development of Phexxi for the prevention of chlamydia and gonorrhea and our other product candidates;
- initiate clinical trials for any product candidates we may choose to develop in the future;
- seek regulatory and marketing approvals and reimbursement for Phexxi, our product candidates 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 of 2020. The COVID-19 pandemic also led to a slower than forecasted update of Phexxi due to reduced access to medical offices and HCPs, and has also affected our ability to timely screen and enroll participants in our Phase 3 *EVOGUARD* trial. Should we experience any further delays or encounter issues with the commercialization, development and regulatory approval of our product candidates such as safety issues, clinical trial accrual delays and longer follow-up for planned trials, 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, 2021, the report

of our independent registered public accountant on our financial statements as of and for the years ended December 31, 2021 and 2020 filed with this Annual Report for the year ended December 31, 2021 includes explanatory language describing the existence of substantial doubt about our ability to continue as a going concern.

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, to complete the development of, and to obtain necessary regulatory and marketing approvals to commercialize, Phexxi for the prevention of chlamydia and gonorrhea and our other current or future product candidates. 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 alternative contraceptive products;
- manufacturing Phexxi and our other product candidates 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 and the needs of our clinical trials;
- our ability to adapt in a dynamic and challenging pandemic environment;
- obtaining regulatory approval of Phexxi in territories outside of the United States and completing clinical development and obtaining regulatory approval for our other product candidates, including Phexxi for the prevention of chlamydia and gonorrhea;
- 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 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 guidance we may announce, and any information or metrics we may provide may be not be indicative of future results. In addition, we implemented a Phexxi co-pay program and sample program to promote demand for Phexxi. However, the co-pay program significantly reduces the amount of profit we realize per unit sold. As a result, we may curtail the co-pay program in the future. 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 our development of Phexxi for the prevention of chlamydia and gonorrhea, 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 February 28, 2022, will be sufficient to sustain our planned operations into the second quarter of 2022. Our ability to raise additional funds will depend, in part, on our ability to successfully commercialize Phexxi in the United States and to successfully develop Phexxi for the prevention of chlamydia and gonorrhea in a timely manner. 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 or develop our product candidates. In addition, we cannot guarantee

that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. In certain situations, we are also currently prohibited from raising additional debt financing without the consent of the holders of our outstanding convertible notes and promissory notes and the holders of shares of our issued and outstanding Series B-2 Convertible Preferred Stock. 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 commercialize Phexxi as a contraceptive or to continue the development of Phexxi for the prevention of chlamydia and gonorrhea. In addition, we may be required to delay, scale back or eliminate some or all of our other development programs and 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 liquidation preference owed to holders of our Series B-2 Convertible Preferred Stock and 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 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. 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, effective when we achieve one or more equity financings resulting in aggregate gross proceeds to the Company of at least $50.0 million. We plan to seek a similar amendment to the Adjuvant Notes, but there can be no assurance that this will occur. There can also be no assurance that we will be able to complete the financing or financings required to amend the net sales covenants in the Adjuvant Notes or the Baker Notes. 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. 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 Nasdaq Capital Market and, assuming no further amendment of current Note terms, to achieve cumulative net sales of Phexxi of at least $100.0 million by June 30, 2022. 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.

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 million shares of common stock under our amended and restated certificate of incorporation. As of March 2, 2022, we have issued 168,783,009 shares of common stock and approximately 197,117,733 shares of common stock were committed for issuance giving effect to the assumed exercise of all outstanding warrants and options and the assumed conversion of all issued and outstanding convertible notes and outstanding shares of Series B-2 Preferred Stock as of this date. Until late April 2022, the number of shares of common stock we are required to reserve for issuance upon conversion of shares of our Series B-2 Convertible Preferred Stock is subject to full ratchet adjustment for certain dilutive issuances. The conversion prices of the Adjuvant Convertible Notes (if 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. If we make additional draws from the Equity Line of Credit this would further limit the number of shares available for issuance. 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 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 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 effective internal sales and marketing capabilities, or enter into agreements with third parties to market and sell any of our approved products, our ability to generate revenue would be adversely affected.

Although some of 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 representatives and otherwise obtaining these marketing capabilities as a result of the COVID-19 pandemic where, among other restrictions, nonessential business travel and in-person interviews have been eliminated or significantly curtailed by the implementation of social distancing guidelines and a general reluctance of some to engage in these activities. At this time, we are unable to predict how long these effects of the COVID-19 pandemic will

last. Any failure or delay in the timely development of our internal commercialization capabilities could adversely impact the potential for commercial success of Phexxi. While we plan to utilize our sales and marketing infrastructure for Phexxi to successfully commercialize any additional products that may result from our development programs, we may still need to find one or more collaborators to commercialize these products or further invest in and develop these capabilities, either on our own or with others, which would be expensive, difficult and time consuming.

If commercialization collaborators do not commit sufficient resources to commercialize our future products and we are unable to develop the necessary marketing and sales capabilities on our own, we will be unable to generate sufficient product revenue to sustain or grow our business.

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 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. Our efforts to train our sales force may be negatively impacted by the COVID-19 pandemic, particularly due to the fact that we may be unable to conduct in-person meetings and training sessions. 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 prescription products, such as 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 marketed 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 marketing partners 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 will need to 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 offer an alternative form of non-hormonal contraceptive 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, which could negatively affect our level of expertise and our ability to execute our business plan. We also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in connection with identifying and engaging in strategic transactions. 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 vaginal gel 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 our products and the willingness of the target patient population to try new products and of physicians to prescribe them;
- relative convenience and ease of administration compared to alternative treatments;
- the regulatory label requirements for the product, including any potential restrictions on use or precautionary statements;
- sufficient third-party insurance coverage and adequate reimbursement;
- effectiveness of our or our collaborators' sales and marketing strategy;
- the willingness of wholesalers and pharmacies to stock the products;
- the prevalence and severity of any adverse side effects;
- our ability to sufficiently educate physicians with respect to the efficacy and safety of Phexxi; 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.

Further, due in part to circumstances surrounding the COVID-19 pandemic, we observed a reduced acceptance rate for Phexxi as women were reluctant to switch birth control or physically visit a doctor in person to obtain a birth control prescription. We aim to increase acceptance through the Phexxi telehealth platform and by encouraging telehealth appointments, but there can be no assurance this effort will be successful or that acceptance will be what it might have otherwise been without the COVID-19 pandemic. As a result of the COVID-19 pandemic, we may have a reduced ability for our distribution or sales representatives to visit physician offices to provide in-person education regarding the benefits of Phexxi for the prevention of pregnancy. To the extent our marketing and education efforts are restricted by COVID-19, our business may be adversely affected.

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 is difficult 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 solution. 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 are loosening 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 solution. If any of these events occurs, it could have a material adverse effect on our business, financial

condition or results of operations, especially given the ongoing COVID-19 pandemic and patients' reduced access to physician offices to obtain new birth control prescriptions or otherwise consider switching their primary method of contraception.

The success of Phexxi will depend on the availability of contraceptive alternatives and women's preferences, in addition to the market's acceptance of our new form of prevention of pregnancy.

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. 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 ACA's effect 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 as a contraceptive.

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 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 any future approved products 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 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 our product candidates.

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 current and potential new indications, 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, prevention of chlamydia, prevention of gonorrhea, or 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 that are unwilling to use hormone-based contraceptives and are unsatisfied with existing 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 in this Annual Report 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. As part of our launch strategy, we are 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 $30 co-pay for these women if their co-pay is above that amount. 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 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 continues to evolve, and has 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. With respect to our clinical development efforts, the completion of enrollment from our *EVOGUARD* clinical trial was delayed due in part due to challenges related to COVID-19 and the Omicron variant. 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 a Phase 2B/3 clinical trial designed to assess Phexxi for the prevention of urogenital chlamydia in women and for the prevention of gonorrhea in women. Results from this clinical trial demonstrated that the trial met both its primary and secondary endpoints, with women receiving Phexxi experiencing a relative risk reduction for chlamydia and gonorrhea infection of 50% and 78%, respectively, compared to women receiving placebo.

We expect top-line *EVOGUARD* results in the second half of 2022, but we cannot guarantee that the results of this trial will be consistent with the results of the prior Phase 2B/3 clinical trial. Even if we do complete this clinical development, there is no assurance we will obtain regulatory approval of Phexxi for the prevention of either chlamydia or gonorrhea. Such a failure could also impede our ability to market Phexxi for the prevention of pregnancy. Also, any failure to obtain regulatory approvals for additional indications will likely have 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 and development of Phexxi for the prevention of chlamydia and gonorrhea, 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 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 do so;
- 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 we 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 are targeted toward the prevention of STIs. Therefore, it may be especially difficult to recruit patients to participate in our clinical trials when doing so will require patients to refrain from other methods of disease 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 current COVID-19 pandemic delayed enrollment in our Phase 3 *EVOGUARD* trial and may 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. 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. 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, 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.

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, we may fail to receive similar approval 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.

Our development and regulatory approval strategy for Phexxi for the prevention of chlamydia and gonorrhea depends, in part, on published scientific literature and the FDA's prior findings regarding the safety and efficacy of approved products.

The Hatch-Waxman Amendments added section 505(b)(2) to the FDCA, as well as several other provisions. Section 505(b)(2) of the FDCA permits the filing of an NDA where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The FDA interprets section 505(b)(2) of the FDCA, for the purposes of approving an NDA, to permit the applicant to rely, in part, upon published literature or the FDA's previous findings of safety and efficacy for an approved product. The FDA may also require the applicant to perform additional clinical trials or measurements to support any deviation from the previously approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the section 505(b)(2) applicant. The FDA may require an applicant's product label to have all or some of the limitations, contraindications, warnings or precautions included in the reference product's label, including a black box warning, or may require the label to have additional limitations, contraindications, warnings or precautions. We plan to use the 505(b)(2) NDA pathway for our future marketing application for Phexxi for the prevention of chlamydia and gonorrhea, if the *EVOGUARD* is successful and the totality of the data collected on Phexxi are sufficient to support regulatory approval.

Notwithstanding the approval of many products by the FDA pursuant to section 505(b)(2) of the FDCA, over the last few years some pharmaceutical companies and others have objected to the FDA's interpretation of section 505(b)(2) of the FDCA. If the FDA changes its interpretation of section 505(b)(2) of the FDCA, or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any section 505(b)(2) NDAs we submit in the future. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and commercialization of our product candidates.

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 has been designated by the FDA as a QIDP for the prevention of both chlamydia and gonorrhea in women. Phexxi also received a Fast Track designation from the FDA for the prevention of chlamydia and gonorrhea in women. 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.

Risks Related to Our Post-Marketing Legal and Regulatory Compliance

Even though we have obtained FDA approval for Phexxi for prevention of pregnancy and even if we obtain regulatory approval for Phexxi for the prevention of chlamydia and gonorrhea or any other product candidates we may seek to develop, we will remain subject to ongoing regulatory requirements.

Even though Phexxi vaginal gel has been approved by the FDA for the prevention of pregnancy and even if Phexxi is approved for the prevention of chlamydia and gonorrhea or any other product candidate we may seek to develop are approved, 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. For example, the FDA has asked us to conduct, and we have agreed to conduct, a post-approval safety study in female adolescents for the use of Phexxi to prevent the acquisition of chlamydia. 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 or development of Phexxi for the prevention of chlamydia and gonorrhea. 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 in conducting clinical trials of Phexxi for the prevention of chlamydia and gonorrhea 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 Phexxi is approved for the prevention of chlamydia and gonorrhea or 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 and for the development of EVO100. For example, the Rush License Agreement includes intellectual property rights to Phexxi and EVO100. 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 March 10, 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 and EVO100, 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 and EVO100. 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 and EVO100. 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, for the prevention of chlamydia and gonorrhea, 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 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 covering Phexxi for the prevention of pregnancy, and depending upon the timing, duration and specifics of any FDA marketing approval of Phexxi for the prevention of chlamydia and gonorrhea and any other product candidate we may develop, may be eligible for limited PTE under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a PTE of up to five 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).

An important part of our patent strategy is reliant on our or Rush University's ability to obtain PTE on the U.S. patent licensed from Rush University, which currently expires in March 2023. Rush University submitted a PTE application for the U.S. patent in 2020 requesting a five-year PTE to 2026. Two OGIEs were received from the USPTO, extending the expiration of the U.S. patent to 2023. However, we may not be granted a full five-year PTE for the U.S. patent or 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 and Phexxi for the prevention of chlamydia and gonorrhea, if approved 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 occurs under our issued and outstanding secured convertible notes issued pursuant to the Baker Bros. Purchase Agreement, the noteholders could take possession of all assets owned by us, including any directly owned intellectual property.

In connection with the Baker Bros. Purchase Agreement, we executed a Security Agreement in favor of the designated agent of the noteholders granting a security interest in all of our owned assets, whether currently owned or later acquired. If an event of default, including a default arising from our inability to pay any amounts due, occurs under the Baker Bros. Purchase Agreement or under the convertible notes, the designated agent of these noteholders has the right to take possession of all of our assets.

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 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 and/or STI prevention 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. For example, we are party to TherapeuticsMD, Inc. v. Evofem Biosciences, Inc. (filed in the United States District Court for the Southern District of Florida-West Palm Beach Division). While we do not believe the claims in this trademark dispute have merit or are material, there can be no assurance that we will prevail and the dispute has caused management to expend significant time and human resources in managing it. These trademarks and tradenames 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. While, as of December 31, 2021, we estimated that we would have sufficient manufactured Phexxi inventory on hand to support approximately fifteen months of expected demand for Phexxi, this estimate could ultimately be incorrect and our inventory needs may increase more than we currently expect thus increasing our expected reliance on our third-party suppliers. We currently have only one contract manufacturer for drug product, DPT Laboratories, Ltd. (DPT), who we entered into a supply and manufacturing agreement with 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 delay our clinical trials, the approval of our product candidates by the FDA or the commercialization of our product candidates or the continued availability of Phexxi or could result in higher costs or deprive us of potential product revenue. 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 FCPA and the 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 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 ANDAs. An ANDA relies on the preclinical and clinical testing conducted for a previously approved 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 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 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 rule making 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;
- 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 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 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 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 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 the Company's 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.

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 February 28, 2022, we had a total of 119 employees, all of which are full-time employees. In addition, we used third-party consultants to assist with research and development activities, including regulatory filings and clinical trial operations and support, sales and marketing 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 Nasdaq Stock Market (Nasdaq) 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. If we identify 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.

Any 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; Justin J. File, our Chief Financial Officer; and Alex Fitzpatrick, our General Counsel who are all employed at will and for whom we do not have "key man" insurance coverage. The loss of one or more members of our management team or other key employees or advisors could delay our commercialization efforts and research and development programs 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.

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 manmade 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 could be delisted from the Nasdaq Capital Market which 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 is listed on the Nasdaq Capital Market, which imposes, among other requirements, a minimum $1.00 per share bid price requirement for continued inclusion on the Nasdaq Capital Market pursuant to the Bid Price Requirement. The closing bid price for our common stock must remain at or above $1.00 per share to comply with the Bid Price Requirement for continued listing. 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 have been 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. We timely requested a hearing, but there can be no assurance that our appeal to the Nasdaq Hearing Panel will be successful or that we will otherwise maintain compliance with any of the other Nasdaq listing requirements.

Delisting from the Nasdaq Capital Market could make trading our common stock more difficult for investors, potentially leading to declines in our share price and liquidity. If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on an over-the-counter quotation system, where an investor may find it more difficult to sell our stock or obtain accurate quotations as to the market value of our common stock. We cannot ensure that our common stock, if delisted from the Nasdaq Capital Market, will be listed on another national securities exchange or quoted on an over-the counter quotation system. Other 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.

The market price for our common stock is volatile and may 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 results of our efforts to commercialize Phexxi or any other approved products;
- failure or discontinuation of any of our research programs, including Phexxi for the prevention of chlamydia and gonorrhea;
- 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. 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.

The Series B-2 Convertible Preferred Stock has rights, preferences and privileges that are not held by, and are preferential to, the rights of holders of our common stock, which could adversely affect the liquidity and financial condition of the Company, and may result in the interests of the holders of Series B-2 Convertible Preferred Stock differing from those of the holders of our common stock. Any issuance of our common stock upon conversion of the Series B-2 Convertible Preferred Stock will cause dilution to holders of our common stock and may depress the market price of our common stock.

The Series B-2 Convertible Preferred Stock ranks senior to the holders of shares of our common stock with respect to liquidation preferences. Upon any dissolution, liquidation or winding up, whether voluntary or involuntary, holders of Series B-2 Convertible Preferred Stock will be entitled to receive distributions out of our assets in an amount per share equal to $1,000 per share (or approximately $5 million as of October 31, 2021), before any distributions may be made on any shares of our common stock. In addition and following October 26, 2025, holders of Series B-2 Convertible Preferred Stock are entitled to request redemption of their shares of Series B-2 Preferred Stock at the price of $1,000 per share. These preferential rights could result in divergent interests between the holders of shares of Series B-2 Convertible Preferred Stock and the holders of our common stock. Shares of Series B-2 Convertible Preferred Stock are also convertible into shares of our common stock (subject to typical beneficial ownership and Nasdaq 19.99% limitations). Shares of common stock issued upon conversion of the Series B-2 Convertible Preferred Stock will cause dilution to holders of our common stock. The conversion price per share for shares of our Series B-2 Convertible Preferred Stock is the greater of $0.392 or the price computed as the product of 0.85 multiplied by the arithmetic average of the closing sale prices of a per share of our common stock during the five consecutive trading-day period immediately preceding the conversion date. Until late April 2022, this conversion price is subject to full ratchet adjustment for certain dilutive issuances. This conversion price and the shares issuable upon conversion of shares of Series B-2 Convertible Preferred Stock may depress the market price of our common stock.

Sales of shares of our Common Stock pursuant to our Equity Line of Credit, our existing stockholders will experience immediate dilution and, as a result, our stock price may go down.

Pursuant to the February 2022 Purchase Agreement, we may sell up to $50,000,000 of shares of our common stock over a 24-month period at our option and subject to certain limitations. The sale of shares of our common stock pursuant to the February 2022 Purchase Agreement will have a dilutive impact on our existing stockholders. Seven Knots may resell some or all of the shares we issue to it under the February 2022 Purchase Agreement and such sales could cause the market price of our common stock to decline, which decline could be significant.

The terms of the February 2022 Purchase Agreement limit the amount of shares of Common Stock we may issue to Seven Knots, which may have an adverse effect on our liquidity.

The February 2022 Purchase Agreement includes restrictions on our ability to sell shares of our Common Stock to Seven Knots, including, subject to specified limitations, if a sale would cause Seven Knots and its affiliates to beneficially own more than 4.99% (which Seven Knots may increase to up to 9.99% upon 61 days' prior written notice to us) of our issued and outstanding Common Stock. Sales under the February 2022 Purchase Agreement may also be limited by the exchange cap of 32,483,835 shares, which number is equal to 19.99% of the shares of the Common Stock outstanding immediately prior to the execution of the February 2022 Purchase Agreement. Accordingly, we cannot guarantee that we will be able to sell all $50.0 million of shares of Common Stock under the Equity Line of Credit. If we cannot sell the full amount of the shares that Seven Knots has committed to purchase because of these limitations, we may be required to utilize more costly and time-consuming means of accessing the capital markets, which could materially adversely affect our liquidity and cash position.

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 March 2, 2022, there were 13,494,560 shares of our common stock subject to outstanding options which have been registered on registration statements on Form S-8. Furthermore, as of March 2, 2022, there were 98,341,397 shares subject to outstanding warrants to purchase our common stock and 85,281,776 shares reserved for issuance upon conversion of our issued and outstanding convertible notes and convertible preferred stock. 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.

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 indemnitees, 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, our ability to continue to develop Phexxi for the prevention of chlamydia and gonorrhea 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.

Our corporate headquarters are located in San Diego, California, where we lease approximately 33,290 square feet of office space. This existing lease will expire on September 30, 2025.

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 disputes and litigation matters that arise in the ordinary course of business activities. We are currently not a party to any material legal proceedings.

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 under the ticker symbol EVFM on January 18, 2018.

Holders of Common Stock

As of February 28, 2022, there were 167,783,009 shares of our common stock outstanding and 114 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, 2021, 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 or Quarterly Report on Form 10-Q.

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, 2021, 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, including hormone-free, woman-controlled contraception and protection from certain sexually transmitted infections (STIs).
Our first commercial product, Phexxi, was approved by the FDA on May 22, 2020 and 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 other global markets through partnerships or licensing agreements.

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 57 regional sales representatives and eight 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 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 House Rules campaign featuring Emmy Award-winning celebrity Annie Murphy, designed to broaden awareness and drive uptake of Phexxi. The House Rules campaign has significantly raised our target audience awareness of Phexxi, while also driving women to their HCP to request a trial. More importantly, it has also helped drive significant increases in new HCPs recommending and prescribing Phexxi. Through December 31, 2021, the House Rules DTC campaign has impacted key metrics. Total ex-factory units sent to distributors in 2021 was 89,163. Over the course of 2021, ex-factory units grew quarter over quarter with the largest growth in the fourth quarter of 73% in Phexxi units shipped. This growth in the fourth quarter was propelled by over 22,600 new patients starting Phexxi, a 56% increase as compared to the prior quarter. Ex-factory growth was further driven by a significant growth in refills (over 9,700 refill prescriptions, a 111% increase).

We continue working to increase the number of lives covered and to gain a preferred formulary position for Phexxi. As of December 2021, approximately 80% of Phexxi prescriptions are being approved either by payers or through Evofem's patient support programs. We have coverage for approximately 55% of U.S. commercial lives, including approximately 9 million lives covered at no out-of-pocket cost and approximately 13.7 million lives covered under our December 2020 contract award from the U.S. Department of Veterans Affairs. On January 1, 2021, the U.S. Medicaid population gained access to Phexxi through our participation in the Medicaid National Drug Rebate Program. Medicaid provides health coverage to approximately 68 million members, including approximately 16.8 million women 19-49 years of age.

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."

We continue to work with the FDA's Office of Women's Health to update its Birth Control Guide to include a new category for vaginal pH modulators, as the current guide does not have a place for Phexxi due to its unique mechanism of action. While the HRSA and Department of Labor guidance are clear that plans are required to cover FDA- approved contraception at $0 cost share, whether or not it is specifically identified in the FDA Birth Control Guide, we believe there is still merit to the Guide being current and accurate. The Guide is used as an educational tool by obstetrician/gynecologists and we therefore believe it should include all FDA-approved methods of birth control. To support this initiative, we have launched a grassroots coalition that shows the public's support of the need for updating the chart.

Phexxi for the Prevention of Chlamydia and Gonorrhea

Our lead clinical program is evaluating Phexxi for the prevention of urogenital infection in women with both chlamydia and gonorrhea - two of the most pervasive sexually transmitted infections (STIs) in the United States. Currently, there are no FDA-approved prescription products for the prevention of either of these common STIs.

According to the Centers for Disease Control and Prevention (CDC), any sexually active person can be infected with chlamydia or gonorrhea. Despite the CDC recommendation for condom use to prevent STIs, U.S. rates of infection with chlamydia and gonorrhea climbed in 2019 for the sixth consecutive year. The CDC reported 1.8 million new cases of chlamydia in 2021, the most ever reported, and over 600,000 new cases of gonorrhea, also the highest reported. Based on these reports, an estimated 78 million women 18-65 years of age who are sexually active in the United States could be at risk to contract these STIs. Although common, many cases are not reported because most people with chlamydia and many women with gonorrhea are asymptomatic and do not seek testing. We believe this represents a significant unmet medical need, as well as a commercial opportunity.

In October 2020, based on positive and statistically significant top-line results of our Phase 2B/3 AMPREVENCE trial, we initiated our Phase 3 *EVOGUARD* clinical trial. This randomized, placebo-controlled confirmatory trial is designed to enroll 1,730 women with a prior chlamydia or gonorrhea infection and who are at risk for future infection. Participants are enrolled for a 16-week interventional phase followed by a one-month follow-up period. We completed enrollment in March 2022 and expect to report top-line *EVOGUARD* results in the second half of 2022. Assuming positive results from the trial, we expect to submit a marketing application for Phexxi in the first half of 2023 with an anticipated FDA action date under the Prescription Drug User Fee Act in the second half of 2023. This acceleration is due to the expedited review afforded by the Fast Track designations that were granted for the prevention of chlamydia and gonorrhea in women.

Additionally, the FDA has designated EVO100 (Phexxi) as a Qualified Infectious Disease Product for the prevention of gonorrhea in women, which provides several important potential advantages, including, but not limited to, longer market exclusivity.

Multipurpose Prevention Technology Vaginal Gel for HIV Prevention

In December 2021, we launched a collaboration with 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. This collaboration will focus on determining compatibility and stability of OB-002 in Phexxi and is expected to yield results in the third quarter of 2022. Assuming positive results, Evofem and Orion will seek government and philanthropic funding for subsequent clinical trials of the 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, 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 with the quarter ended December 31, 2021 being our fifth full quarter of commercialization and first full fiscal year of product sales.

For the quarter ended December 31, 2021, there was an approximate 73% increase in shipments to wholesale distributors and pharmacies compared to the quarter ended September 30, 2021, driving an increase in net product sales of approximately 109%. Phexxi outperformed the newer branded contraceptive market and the launch of our House Rules campaign on September 9, 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 (COFEPRIS). This is the first of several strategic regulatory submissions planned under Evofem's 2020 Global Health Agreement with Adjuvant Capital.

Cost of Goods Sold

The Company began to capitalize the inventory costs associated with Phexxi in April 2020 when it was determined that the inventory had a probable future economic benefit. These inventory costs include all purchased materials, direct labor and manufacturing overhead. Prior to April 2020, costs incurred for the manufacture of Phexxi were recorded as research and development expenses.

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 $0.2 million and an immaterial amount for the years ended December 31, 2021 and 2020, 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 clinical development of Phexxi for the prevention of chlamydia and gonorrhea and costs associated with the continuous improvements related to Phexxi commercialization efforts. These expenses include:

- 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;
- continuous improvements of manufacturing and analytical efficiency;
- on-going product characterization and process optimization;
- back-up contract manufacturing organization’s evaluation to support future commercial forecast and reduce cost of goods sold;
- 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.

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,	
	2021	**2020**
Allocated third-party development expenses:		
Phexxi for prevention of chlamydia/gonorrhea- Phase 3 *(EVOGUARD)*	$ 23,779	$ 4,757
Phexxi for prevention of chlamydia/gonorrhea- Phase 2B/3 (AMPREVENCE)	—	(27)
Phexxi for the prevention of pregnancy (AMPOWER)	—	(16)
Total allocated third-party development expenses	23,779	4,714
Unallocated internal research and development expenses:		
Noncash stock-based compensation expenses	1,357	1,922
Payroll and related expenses	4,967	5,005
Outside services costs	1,696	4,062
Other	1,330	1,347
Total unallocated internal research and development expenses	9,350	12,336
Total research and development expenses	**$ 33,129**	**$ 17,050**

Completion dates and costs for our clinical development programs are very difficult to predict and may vary significantly for Phexxi for the prevention of chlamydia and gonorrhea and any future product candidate we may seek to develop. We anticipate that we will determine which programs and product candidates to pursue, as well as the most appropriate funding allocations for each program and product candidate on an ongoing basis in response to the results of ongoing and future clinical trials, regulatory developments, and our ongoing assessments of the commercial potential of each current or future product candidate. We expect research and development expenses to decrease slightly primarily due to *EVOGUARD*, which we expect to report top-line results for in the second half of 2022. We will need to raise significant additional capital in the future to complete clinical development of Phexxi for the prevention of chlamydia and gonorrhea and any future product candidates.

The costs of clinical trials may vary significantly over the life of a program owing to the following:

- per patient trial costs;
- the number of sites included in the trials;
- the length of time and level of marketing required to enroll eligible patients;
- the number of patients participating in the trials;
- the number of doses patients receive;
- potential additional safety monitoring or other trials requested by regulatory agencies;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

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.

We expect our selling and marketing expenses to decrease significantly 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.

We expect our general and administrative expenses to increase slightly primarily due to increased corporate insurance and general legal expenses.

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

The Company recognizes 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, the Company recognizes revenue when its performance obligation is satisfied by transferring control of the product to a customer. Per 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 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 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, 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. However, the Company records 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 $2.3 million and $1.0 million, as of December 31, 2021 and 2020, 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, 2021 and 2020 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. 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. The fair value of the Baker Notes was $81.7 million and $50.8 million, as of December 31, 2021 and 2020, respectively.

Fair Value of Stock Options and Warrants

The fair value of stock options and warrants issued in various financing transactions, the change in fair value of options and warrants as a result of any modification to these instruments, and mark-to-market adjustments for liability classified warrants were determined using the Black-Scholes Merton option-pricing model based on the applicable assumptions, which include the exercise price of these options and warrants, time to expiration, expected volatility of our peer group of companies, risk-free interest rate and expected dividends.

Fair Value of Purchase Rights

The fair value of the rights granted to the Baker Purchasers to optionally purchase from the Company up to $10.0 million of Baker Notes, as described in Note 5- Convertible Notes, 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 issued in connection with the Baker Bros. Purchase Agreement, as described in Note 5- Convertible Notes, and the change in fair value

of the Baker Purchasers' option to purchase from the Company 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. The fair value of rights to purchase the accompanying 2,049,180 warrants 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 the Company's peer group, risk-free interest rate and expected dividends.

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, 2021 Compared to Year Ended December 31, 2020 (in thousands):

Net Product Sales

	Year Ended December 31,		2021 vs. 2020	
	2021	2020	$ Change	% Change
Product sales, net	$ 8,244	$ 446	$ 7,798	1,748 %

Phexxi was commercially launched in September 2020. The increase in product sales, net was primarily due to a full year of sales in 2021 versus four months of sales in 2020, continued growth in ex-factory unit sales since commercial launch, and an increase in both gross and net sales from the impact of Phexxi promotional strategies and gross-to-net initiatives implemented since the commercial launch.

Cost of Goods Sold

	Year Ended December 31,		2021 vs. 2020	
	2021	2020	$ Change	% Change
Cost of goods sold	$ 4,055	$ 468	$ 3,587	766 %

The increase in cost of goods sold was primarily due to a full year of sales of Phexxi in 2021 versus four months of sales in 2020.

Research and Development Expenses

	Year Ended December 31,		2021 vs. 2020	
	2021	2020	$ Change	% Change
Research and development	$ 33,129	$ 17,050	$ 16,079	94 %

The increase in research and development expenses was primarily due to an $18.8 million increase in clinical trial costs associated with *EVOGUARD*. This increase was partially offset by a $2.1 million decrease in outside services associated with manufacturing and regulatory related activities and a $0.6 million decrease in noncash stock-based compensation.

Selling and Marketing Expenses

	Year Ended December 31,		2021 vs. 2020	
	2021	2020	$ Change	% Change
Selling and marketing	$ 113,152	$ 56,467	$ 56,685	100 %

The increase in selling and marketing expenses was primarily due to a $46.4 million increase in media and marketing costs related to ongoing promotional strategies, especially those focused on DTC campaigns that commenced in 2021, a $9.1 million increase in payroll and related expenses due to increased headcount and sales activities, $2.2 million in the Phexxi sample program, and a $1.7 million increase in facilities costs. These aggregated increases were partially offset by a $2.6 million decrease in costs for outside services associated with marketing, market access and medical affairs activities, and a $0.5 million decrease in noncash stock-based compensation.

General and Administrative Expenses

	Year Ended December 31,		2021 vs. 2020	
	2021	2020	$ Change	% Change
General and administrative	$ 24,709	$ 30,085	$ (5,376)	(18)%

The decrease in general and administrative expenses was primarily due to a $2.7 million decrease in noncash stock-based compensation, a $2.1 million decrease in financing and recruiting related outside services, a $1.2 million decrease in financing advisory fees and legal fees, and a $0.9 million decrease in payroll and related expenses due to lower headcount. These aggregated decreases were partially offset by a $1.4 million increase in facilities costs.

Total Other Expense, Net

	Year Ended December 31,		2021 vs. 2020	
	2021	2020	$ Change	% Change
Total other expense, net	$ (38,374)	$ (38,681)	$ 307	(1)%

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- Convertible Notes 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.

Total other expense, net, for the year ended December 31, 2020 primarily included a $64.0 million recorded loss on issuance of convertible notes, warrants and purchase rights issued in connection with the Baker Bros. Purchase Agreement as described in Note 5- Convertible Notes and $2.1 million in interest expense related to convertible notes. This loss was offset by a $27.3 million recorded gain from the change in fair value of these financial instruments as a result of mark-to-mark adjustments.

Liquidity and Capital Resources

Overview

As of December 31, 2021, we had a working capital deficit of $107.5 million and an accumulated deficit of $860.7 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, 2021, we had approximately $7.7 million in cash and cash equivalents, and $4.7 million in restricted cash available for use from the Adjuvant Notes (as defined in Note 5- Convertible Notes). Our cash and cash equivalents include amounts held in checking accounts, money market funds, and investments in fixed income debt securities with original maturities of less than three months. We invest cash in excess of immediate requirements in accordance with our investment policy, which limits the amounts we may invest in any one type of investment and requires all investments held by us to maintain minimum ratings from nationally recognized statistical rating organizations so as to primarily achieve liquidity and capital preservation.

We have incurred losses and negative cash flows from operating activities since inception. During the year ended December 31, 2021, we received net proceeds of approximately $81.5 million upon the sale and issuance of common stock and warrants to purchase common stock from two underwritten public offerings that occurred in March and May of 2021. In

October 2021, we received net proceeds of approximately $9.6 million from the issuance of convertible preferred stock in a registered direct offering.

We anticipate that we will continue to incur net losses for the foreseeable future. We expect research and development expenses to decrease slightly primarily due to *EVOGUARD*, which we expect to report top-line results for in the second half of 2022. We expect selling and marketing expenses to decrease significantly due to reductions in media and marketing activities related to ongoing Phexxi promotional strategies. Lastly, we expect general and administrative expenses to increase slightly due to increased general legal expenses.

We currently expect our liquidity resources as of December 31, 2021, together with the net proceeds from the registered direct offerings completed in January 2022 and March 2022, to be sufficient to fund our planned operations into the second quarter of 2022. As of December 31, 2021, our significant commitments for capital expenditures include the Baker Notes, as described in Note 5- Convertible Notes, our office lease, fleet lease, and supply and manufacturing agreement with our Phexxi manufacturer, as described in Note 8- Commitments and Contingencies, and our agreement with our clinical research organization that manages *EVOGUARD*. The purpose of these commitments is to further the commercialization of Phexxi and other future products. We expect to fund these commitments through debt and equity issuances and, to a lesser extent, product sales.

The uncertainties associated with our ability to obtain additional equity financing on terms that are favorable to us or at all, enter into collaborative agreements with strategic partners, and succeed in our future operations raise substantial doubt about our ability to continue as a going concern. In addition, the COVID-19 pandemic caused us to delay the commercial launch of Phexxi until September 2020. Also, due in part to the impact of the COVID-19 pandemic, we completed enrollment in the Phase 3 *EVOGUARD* study in March 2022 and we expect to report top-line *EVOGUARD* results in the second half of 2022. 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, whether we are able to gain revenue traction prior to raising such additional funds, and the success of our research and development efforts, including our ability to develop Phexxi for the prevention of chlamydia and gonorrhea. If the COVID-19 pandemic continues to disrupt and negatively impact the commercialization of Phexxi or our research and development efforts, our ability to raise additional funds may be negatively impacted, or we may not be able to obtain funding on terms favorable to us or at all.

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 strategic plan, we may be forced to make reductions in spending, suspend or terminate development programs, extend payment terms with suppliers, liquidate assets where possible, suspend or curtail planned programs, and/or cease operations. 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 your investment.

The opinion of our independent registered public accounting firm on our audited financial statements as of and for the years ended December 31, 2021 and 2020 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, 2021 and 2020 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.

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 17,142,857 shares of our common stock, and approximately $4.2 million, net of underwriting discounts, from the issuance of 2,571,428 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 50,000,000 shares of common stock and common warrants to purchase 50,000,000 shares of common stock. We received approximately $2.4 million and $0.1 million, both net of underwriting discounts, from the issuance of 2,547,794 shares of common stock and 7,500,000 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.

2020 Debt and Equity Financing

As described in Note 5- Convertible Notes, we received aggregate gross proceeds of $25.0 million upon the first and second closings of convertible senior secured promissory notes pursuant to the Baker Bros. Purchase Agreement during the second quarter of 2020. We also received gross proceeds of $25.0 million from the closing of convertible unsecured promissory notes pursuant to the Adjuvant Purchase Agreement during the fourth quarter of 2020.

As described in Note 10- Stockholders' Equity (Deficit), we received net aggregate proceeds of $103.7 million in June 2020 upon the issuance and sale of 31,700,000 shares of our common stock from our 2020 Public Offering and net aggregate proceeds of $3.8 million during the first half of 2020 upon the issuance and sale of 676,656 shares of our common stock pursuant to the "at the market" (ATM) program. The ATM program was terminated in June 2020.

Summary Statements of Cash Flows

The following table sets forth a summary of the net cash flow activity for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,		2021 vs. 2020	
	2021	2020	$ Change	% Change
Net cash, cash equivalents and restricted cash used in operating activities	$ (146,667)	$ (104,829)	$ (41,838)	40 %
Net cash, cash equivalents and restricted cash (used in) provided by investing activities	(2,689)	6,229	(8,918)	(143) %
Net cash, cash equivalents and restricted cash provided by financing activities	90,693	154,226	(63,533)	(41) %
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (58,663)	$ 55,626	$ (114,289)	(205) %

Cash Flows from Operating Activities. During the years ended December 31, 2021 and 2020, 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 our Phexxi 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, 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. During the year ended December 31, 2020, the change in net cash, cash equivalents and restricted cash provided by investing activities was primarily due to an $8.2 million cash inflow from maturities of short-term investments offset by $2.3 million in purchases of property and equipment.

Cash Flows from Financing Activities. During the year ended December 31, 2021, the primary source of cash, cash equivalents and restricted cash was provided from the issuance of 72,262,079 shares of common stock and 7,500,000 shares of common warrants for proceeds of approximately $81.5 million, net of underwriting discounts, the issuance of 460,636 shares of our common stock under the 2019 Employee Stock Purchase Plan (ESPP) with proceeds of approximately $0.3 million, the issuance of 159,000 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.

During the year ended December 31, 2020, the primary source of cash, cash equivalents and restricted cash was provided from the sale of an aggregate of 31,700,000 shares of common stock for net proceeds of approximately $103.7

million, net of underwriting commissions, gross proceeds of $50.0 million from issuance of convertible notes and warrants, the sale of 676,656 shares of common stock under the at-the-market program for net proceeds of approximately $3.8 million in cash and cash equivalents (including $0.3 million that was included in other receivables in the consolidated balance sheet at December 31, 2019), net of commissions, and the issuance of 150,353 shares of our common stock under the 2019 ESPP and exercise of stock options with aggregate proceeds of $0.4 million. These cash inflows were offset by $2.9 million in payments of tax withholdings related to vesting of restricted stock awards and $1.1 million payments for financing and debt 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 2022 as follows: we expect research and development expenses to decrease slightly, 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

Operating lease ROU assets and lease liabilities were $5.4 and $6.8 million on December 31, 2021, respectively, and were $6.9 and $8.3 million on December 31, 2020, respectively. See Note 8- Commitments and Contingencies for more detailed discussions on leases and financial statements information under ASC 842, *Leases*. *Fleet Lease.*

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.

Intellectual Property Rights

As described in Note 8- Commitments and Contingencies, royalty costs owed to Rush University pursuant to the Rush License Agreement were $0.2 million and immaterial for the years ended December 31, 2021 and 2020, respectively.

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

Disclosure controls and procedures are controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. As of the end of the period covered by this Annual Report, or December 31, 2021, 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, 2021. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures were effective.

Management’s Annual Report on Internal Control over Financial Reporting

The Company's 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). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Management conducted an assessment of the effectiveness of the Company's internal control over financial reporting based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework. Based on this assessment, our management concluded that, as of December 31, 2021, our internal control over financial reporting was effective based on those criteria.

Attestation Report on Internal Control over Financial Reporting

As a “smaller reporting company” as defined in Rule 12(b) of the Exchange Act, we are not required to provide an attestation report.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our latest fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Internal Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company 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 also 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 the 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 Board of Directors

Our Board of Directors (referred to herein as our Board or our Board of Directors), currently consists of eight seats with two vacancies (one for Class II and one for Class III). Vacancies on the Board may be filled by potential candidates nominated by the Nominating and Corporate Governance Committee of the Board, who may seek out potential candidates that meet the criteria for selection as a Board nominee and have the specific qualities or skills being sought, and one or more of such candidates may be appointed as directors as appropriate and in accordance with the Company's organizational documents. The vacancies, if filled, will be filled until the end of the class term. Our Board is divided into three classes as set forth below each serving staggered three-year terms until their respective successors are duly elected and qualified:

- Our Class I directors are Kim P. Kamdar, Ph.D., Colin Rutherford, and Lisa Rarick, M.D. and their terms expire at the annual meeting of stockholders in 2024;
- Our Class II directors are Gillian Greer, Ph.D. and Tony O'Brien and their terms expire at the annual meeting of stockholders in 2022; and
- Our Class III director is Saundra Pelletier and her term expires at the annual meeting of stockholders in 2023.

There are no familiar relationships among our current directors and executive officers.

The following table lists the names, ages as of February 28, 2022 and positions of the individuals who serve as our directors:

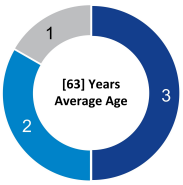
	Name and Principal Occupation	Age	Director Since	Board Committees	Other Current Public Directorships
Class II Directors					
	**Gillian Greer, Ph.D. | Independent** Former Chief Executive Officer of the National Council of Women of New Zealand	77	2018	C, N	
	**Tony O'Brien | Independent** Former Director General of Ireland's Health Service Executive	59	2018	A, C★	Global Leadership And Governance Solutions Limited
Class III Directors					
	**Saundra Pelletier | Interim Chair of the Board of Directors** President and Chief Executive Officer, Evofem Biosciences, Inc.	52	2013		
Class I Continuing Director					
	**Colin Rutherford | Independent** Current member of the board of Spanish based Biopharma Hifas da Terra SA	63	2018	A★	Mitchells & Butlers Plc Renaissance Services SAOG Brookgate Limited
	**Kim P. Kamdar, Ph.D. | Independent** Managing Partner, Domain Associates, LLC	54	2018	A, C, N★	Seraphina Therapeutics, Inc. Truvian Sciences
	**Lisa Rarick, M.D. | Independent** Board-certified Obstetrician/ Gynecologist and Regulatory Affairs Expert	62	2020	N	

A Audit Committee
C Compensation Committee
N Nominating and Corporate Governance Committee
★ Committee Chair

Board Demographics

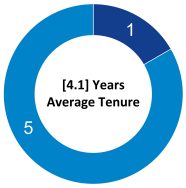
The charts below represent certain demographics of the current composition of our directors.

Age



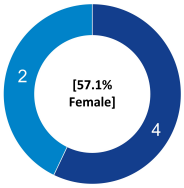
50s
60s
70s

Tenure



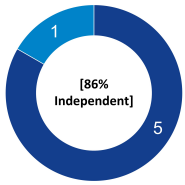
0-3 years
4-7 years

Gender Diversity



Female
Male

Independence



Independent
Non-Independent

We discuss in the Non-employee Directors section below the qualifications, attributes and skills that led our Board to conclude that each of our directors should serve as a director.

Executive Officers

The following table sets forth certain information regarding our executive officers and their respective ages as of February 28, 2022. All executive officers are at-will employees**.**

Saundra Pelletier

Chief Executive Officer
Age: **52**

KEY EXPERIENCE AND QUALIFICATIONS

Ms. Pelletier has been responsible for the company's growth and evolution. Ms. Pelletier brings more than twenty-five years of broad executive leadership experience to Evofem, including a strong track record driving multiple billion-dollar product launches, expanding commercial capabilities in ex-U.S. markets and advocating for women's health. She has assembled an impressive team of seasoned pharmaceutical professionals that have a deep understanding of the women's health care market and what women want. She has also attracted new investor capital, leading multiple equity financing rounds which have raised in excess of $400 million. Throughout her career, she has had oversight and accountability for sales, marketing, operations, medical affairs, regulatory affairs, manufacturing, customer service, business development, and strategic partnerships. Under her leadership in WomanCare Global, WCG secured approximately $68M in committed funding from major foundations and organizations and launched an innovative United States educational campaign with American actress/activist Jessica Biel. We believe Ms. Pelletier's service as our CEO and extensive professional experience in women's health care qualifies her to serve as a member of our Board of Directors.

Background

Ms. Pelletier served as Private Evofem's president and Chief Executive Officer from 2013 to January 2018 and has served as our president and Chief Executive Officer of Evofem Biosciences, Inc. since January 2018

- Member of the board of directors of Evofem Biosciences, Inc. (2017 to Present)
- Founding CEO of WomanCare Global (WCG), an international nonprofit organization focused on creating sustainable supply chains that delivered products to women in more than 100 developing countries. (2009 to 2016)
- Vice President of Pharmaceuticals of Women First Health care, where she raised $40 million in capital (2000 to 2004)
- Corporate Vice President and Global Franchise Leader for G.D. Searle, where she managed a $250 million business unit focused on women's health care (1992 to 2000)
- As a published author, her book, "Saddle Up Your Own White Horse," was published in 2016
- As a skilled moderator and coveted keynote speaker, she has appeared at the Harvard T. H. Chan School of Public Health, the Davos World Economic Forum, the Clinton Global Initiative, the International Conference on Climate Change, the MAKERS Conference, Women Deliver, the International Conference on Family Planning, Reproductive Health Supplies Coalition, the University of Virginia's Darden School of Business, the University of Oregon's Lundquist School of Business and the University of California, San Diego
- Awarded the Athena San Diego Pinnacle Award for Life Sciences in 2014, profiled as a "New Champion for Reproductive Health" by the United Nations Foundation in 2015, and named the San Diego Business Journal's 2019 Business Woman of the Year
- Named to Inc. Magazine's Female Founders 100 List (2020)
- Member of the board of directors of TRACON Pharmaceuticals, Inc., a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, where she serves as the chair of the Governance/Nomination Committee and is a member of the Audit Committee (since March 2020)
- Ms. Pelletier graduated from New England School of Communications, Maine with a Bachelor of Science in Communications and from Husson University, Maine with a Bachelor of Science in Business Administration.

Justin J. File

Chief Financial Officer
Age: **51**

Background

- Justin J. File served as Private Evofem's Chief Financial Officer from April 2015 until January 2018 and has served as our Chief Financial Officer since January 2018.
- Mr. File has also served as the Chief Financial Officer of the women's health nonprofit organization WCG Cares from November 2017 to May 2018.
- Mr. File has approximately 28 years of diverse accounting and finance experience within a variety of both public and private biotechnology and biopharmaceutical companies.
- Most recently, Mr. File provided executive financial and accounting oversight services to various biotechnology companies in San Diego, California, assisting in their initial public offering process and helping to establish and improve their accounting and finance operations as publicly traded entities. Prior to this, Mr. File was Senior Director and Controller of Sequenom, Inc., a diagnostic company that developed and commercialized molecular diagnostics testing services for the women's health market. During that time, Mr. File served as Treasurer of Sequenom's diagnostic subsidiary and provided assistance in the raising of over $400 million in combined equity and convertible note offerings.
- Mr. File also assisted in the commercialization of four diagnostic tests in a two-year period, which included Sequenom's revolutionary noninvasive prenatal test for Down syndrome.
- Earlier in his career Mr. File worked for approximately ten years in public accounting, primarily with Arthur Andersen LLP, where he worked with a variety of clients assisting with attestation and periodic reporting requirements, public offerings and acquisitions.
- Mr. File graduated from Central Washington University with a Bachelor of Science in Accounting and Business Administration. He is a Certified Public Accountant (inactive).

Alexander A. Fitzpatrick, Esq.

General Counsel and Secretary
Age: **55**

Background

- Alexander A. Fitzpatrick, Esq. served as the Executive Vice President, General Counsel and Secretary of Private Evofem from October 2017 until January 2018 and has served as our Executive Vice President, General Counsel and Secretary since January 2018.
- Mr. Fitzpatrick is responsible for our corporate governance, legal, corporate development, intellectual property and risk management functions.
- Prior to joining Evofem, Mr. Fitzpatrick served as Chief Legal Officer of Kyriba Corporation from 2014 to 2015 and Senior Vice President, General Counsel, Compliance Officer and Secretary of Verenium Corporation, a publicly traded biotechnology company from 2010 to 2014. Prior to that, Mr. Fitzpatrick served as Senior Vice President, General Counsel and Secretary of Kintera, Inc., a publicly traded technology company. Following the sale of Kintera, Mr. Fitzpatrick continued to serve in a similar position for a major division of Blackbaud, Inc.
- Prior to moving in-house, Mr. Fitzpatrick was a member of the business, corporate and technology departments with the law firms Cooley LLP and Latham & Watkins LLP in San Diego, and Rogers & Wells LLP (now Clifford Chance) in London. Mr. Fitzpatrick represented pharmaceutical and other technology companies, investment banks and venture capitalists in a variety of transactions including numerous collaborations, mergers and acquisitions, intellectual property matters, licensing and financing activity.
- Mr. Fitzpatrick received a B.S. in mathematics from Georgetown University and a J.D. from the University of California, Berkeley.

Gillian Greer, Ph.D., 77

Independent

Director Since: January 2018

Committees:

- Nominating and Corporate Governance
- Compensation

KEY EXPERIENCE AND QUALIFICATIONS

Throughout her career, Dr. Greer has demonstrated an ongoing commitment to health, education, sustainable development, women's empowerment, and human rights. Dr. Greer is passionate about strengthening civil society and building high performing organizations that are effective, ethical, and accountable and can clearly demonstrate their impact. We believe Dr. Greer's long experience as an executive officer and board member of organizations dedicated to women's sexual health qualifies her to serve as a member of our Board of Directors.

CAREER HIGHLIGHTS

- Chief Executive Officer of Volunteer Service Abroad, a New Zealand non-profit organization that sends volunteers to work with partner organizations in the Pacific and Asia region (2012 to 2017)
- Chief Executive Officer of the National Council of Women of New Zealand (2017 to 2018)
- Trustee for WomanCare Global International (2012 to 2017)
- Director General of the International Planned Parenthood Federation (IPPF), the world's largest international sexual and reproductive health non-profit organization, working in 172 countries providing advocacy, education, and sexual and reproductive health services, including maternal health, HIV/AIDS, family planning and adolescent health (2006 to 2011)
- Worked closely with UN agencies and governments to advocate for investment in health and human rights and served on the board of directors of ICON PLC (2006 to 2011)
- Executive Director of the Family Planning Association of New Zealand, involved in international and regional advocacy training and initiatives, including chairing the Asia Pacific Alliance, and was made a Member of the New Zealand Order of Merit for services to family planning (2005)
- Assistant Vice Chancellor Equity and Human Resources, Victoria University of Wellington, New Zealand (1996 to 1998)
- Early career was in education at secondary and tertiary levels
- Served in a governance capacity for a number of charities and a university Council
- Served in advisory panels to New Zealand Ministers of Foreign Affairs and Trade
- Made a Commander of the British Empire for services to international health and women's rights (2011)

EDUCATION

- B.A. in English from the University of Auckland
- Ph.D. in New Zealand Literature from the Victoria University of Wellington

Tony O’Brien, 59

Independent

Director Since: January 2018

Committees:

- Compensation (Chair)
- Audit

KEY EXPERIENCE AND QUALIFICATIONS

We believe Mr. O’Brien’s extensive experience as an executive and member of the boards of directors for health care and life sciences companies qualifies him to be a member of our Board of Directors.

CAREER HIGHLIGHTS

- Director General of Ireland’s Health Service Executive (HSE), an organization responsible for the provision of health and personal social services for the residents of Ireland (2012 to 2018)
- Chief Operating Officer of the Department of Health’s Special Delivery Unit and a member of the Department’s Management Board (2011 to 2014)
- Director of Clinical Strategy and Programs in the HSE (2011 to 2012)
- Chief Executive Officer of the National Treatment Purchase Fund (2011 to 2013)
- Chief Advisor to the HSE on the implementation of the National Cancer Control Strategy (2006 to 2010)
- Project Director for the National Plan for Radiation Oncology (2005 to 2008)
- Chairman of the National Cancer Registry Board (2009 to 2012)
- Founding Chief Executive Officer of the National Cancer Screening Service (2007 to 2011)
- Director of BreastCheck, CervicalCheck (2002 to 2010)
- Associate and Interim Director of the National Cancer Control Programme (2007 to 2011)
- Chief Executive of the Irish Family Planning Association (1991 to 2002)
- Chief Executive of the UK Family Planning Association (1995 to 1996)
- Chartered Director of the Institute of Directors in Ireland
- Adjunct Assistant Professor in Health Strategy and Management at Trinity College Dublin

OTHER PROFESSIONAL EXPERIENCE AND COMMUNITY INVOLVEMENT

- Director and owner of Global Leadership And Governance Solutions Limited, a private limited company organized in the Republic of Ireland

EDUCATION

- M.Sc. in Management Practice from Trinity College, University of Dublin

Continuing directors:

Kim P. Kamdar, Ph.D., 54

Independent

Director Since: April 2011 (Private Evofem); January 2018 (Evofem Biosciences)

Committees:

- Audit
- Compensation Committee
- Nominating and Corporate Governance (Chair)

KEY EXPERIENCE AND QUALIFICATIONS

We believe Dr. Kamdar is qualified to serve on our Board of Directors based on her extensive experience working and serving on the boards of directors of life sciences companies and her experience working in the venture capital industry.

CAREER HIGHLIGHTS

- Managing Partner of Domain Associates, LLC, a life sciences venture capital firm (since 2005)
- Chair of the board of directors of Seraphina Therapeutics, Inc. and Truvian Sciences
- Member of the board of directors of several private companies including Alume, Epic Sciences, Epitel and Pleno Inc.
- Member of the board of directors of several public companies including NASDAQ: SERA and NASDAQ: OMIC.
- Past investments include Ariosa (acquired by Roche), Corthera (acquired by Novartis), BiPar Sciences (acquired by Sanofi-Aventis) and Omniome (acquired by NASDAQ: PACB)
- Kauffman Fellow with MPM Capital (MPM) (2003 through 2004)
- Research director at Novartis, where she built and led a research team that focused on the biology, genetics and genomics of model organisms (1995 to 2003)
- Author of ten papers as well as the inventor on seven patents
- Advisory board member of Dr. Eric Topol’s NIH supported Clinical and Translational Science Award for Scripps Medicine

EDUCATION

- B.A. from Northwestern University
- Ph.D. in Biochemistry and Genetics from Emory University

Colin Rutherford, 63

Independent

Director Since: November 2015 (Private Evofem); January 2018 (Evofem Biosciences)

Committees:

- Audit (Chair)

KEY EXPERIENCE AND QUALIFICATIONS

We believe that Mr. Rutherford is qualified to serve as a member of our Board of Directors because of his prior experience as a member of Private Evofem's board of directors and his many years of finance and operations leadership experience in the health care and life sciences industries.

CAREER HIGHLIGHTS

- Former Chairman and CEO of LSE quoted European finance specialist Euro-Sales Plc (with 18 offices across Europe), sold to Royal Bank of Scotland Plc, (2000 to 2002)
- Former Chairman of SGI Funds, a Guernsey-, Cayman- and Hong Kong-based diversified fund management group (2004 to 2009)
- Former Chairman and CEO of the LSE quoted UK fund management group, MAM Funds Plc (2008 to 2011)
- Former Member of the board and Audit Committee Chairman of Mitchells & Butlers Plc, the LSE's largest quoted hospitality group (2013 to 2021)
- Former Member of the board and Audit Committee Chairman of the MSE quoted Oil & Gas shipping logistics business, Renaissance Services SAOG, based in Muscat and Dubai (2007 to 2019)
- Former Chairman of European Health Care Group before its acquisition by two U.S.-based hedge funds (2012 to 2014)
- Current Member of the Board of Meallmore Health Care Group (2014 to Present)
- Current Member of the Board of Spanish based Biopharma Hifas da Terra SA, a leader in the field of mycotherapy-related oncology products (2018 to Present)
- Current Chairman of Brookgate Limited, a UK property development business backed by Goldman Sachs and Sixth Street (2010 to Present)
- Former visiting Professor at Edinburgh University's Business School

EDUCATION

- A member of the Scottish Institute of Chartered Accountants, he graduated in Accountancy and Finance from Heriot Watt University in 1980 and qualified with Deloitte (formerly Touche Ross) in 1984.
- Harvard Business School Alumni, having attended over a 10 year period and subsequently Chairing the HBS/YPO Presidents leadership seminar for 5 years.

Lisa Rarick, M.D.F.A.C.O.G., 62

Independent

Director Since: 2020

Committees:

- Nominating and Corporate Governance

KEY EXPERIENCE AND QUALIFICATIONS

We believe that Dr. Rarick is qualified to serve as a member of our Board of Directors because of her extensive experience in health care/women's health matters as well as her vast prior experience with regulatory matters and the life sciences industry.

CAREER HIGHLIGHTS

- Board-certified obstetrician/gynecologist and regulatory affairs expert with 35 years' experience in women's health and 15 years' experience leading several offices within the U.S. Food and Drug Administration (FDA)
- Began her career at the FDA as a Medical Officer, responsible for the management of products indicated for a variety of reproductive health conditions, including oral, transdermal and vaginal contraceptives (1988)
- Director for the Division of Reproductive and Urologic Products (DRUP) at the FDA (1996)
- Held several management roles in the Center for Drug Evaluation and Research (CDER), including Deputy Director of the Office of Drug Evaluation 2 and Associate Director in the Office of the Center Director
- Focused on HIV prevention, pregnancy prevention, pre- and post-pregnancy care and menopausal therapy in her final year at the FDA in the Office of Women's Health
- Reproductive health and regulatory affairs consultant, helping numerous companies navigate the development of their products from early-stage development through FDA approval
- Member of the Scientific Advisory Committee for the National Institute of Child Health and Human Development (since 2004)
- Member of the board of directors for Alliance Partners 360 from (2017 to 2019)
- Family Planning clinical care provider (2020 to present)

EDUCATION

- B.S. and M.D. from the Loma Linda University School of Medicine
- Completed residency training in Obstetrics and Gynecology at Georgetown University

Audit Committee and Financial Expert

Audit Committee

Chair:

Colin Rutherford

Members:

Kim P. Kamdar, Ph.D.
Tony O'Brien

Meetings in 2021: 4

Our Audit Committee's role and responsibilities are set forth in the Audit Committee's written charter.

Principal Responsibilities:

- Reviews annual financial statements;
- Considers matters relating to accounting policy and internal controls;
- Reviews the scope of annual audits;
- Assists the Board of Directors in its oversight of Evofem's financial statements, including internal control over financial reporting;
- Reviews and discusses with senior management the guidelines and policies by which Evofem assesses and manages risk;
- Assists the Board of Directors in its oversight of the qualifications, independence, and performance of Evofem's independent registered public accounting firm, including responsibility for the appointment, compensation, retention, and oversight of the work of the firm;
- Assists the Board of Directors in its oversight of the performance of Evofem's internal audit function, including responsibility for the appointment, replacement, reassignment, or dismissal of, and being involved in the performance reviews of, Evofem's internal auditor; and
- Assists the Board of Directors in its oversight of Evofem's compliance with legal and regulatory requirements, including reviewing periodically with management any significant legal, compliance, and regulatory matters that have arisen or that may have a material impact on Evofem's business, financial statements, or compliance policies, Evofem's relations with regulators and governmental agencies, and any material reports or inquiries from regulators and government agencies.

All members of the Audit Committee satisfy the current independence standards promulgated by the SEC and by The Nasdaq Stock Market (Nasdaq), as such standards apply specifically to members of audit committees. The Board has determined that Mr. Rutherford is an "audit committee financial expert," as the SEC has defined that term in Item 407 of Regulation S-K. Please also see the report of the Audit Committee set forth elsewhere in this Annual Report.

A copy of the Audit Committee's written charter is publicly available on our website at www.evofem.com.

Code of Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees, which is available on our website at www.evofem.com and will be made available to stockholders without charge, upon request, in writing to our Corporate Secretary, Evofem Biosciences, Inc., 12400 High Bluff Drive, Suite 600, San Diego, CA 92130. The Code of Business Conduct and Ethics contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics and is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, disclosure regarding any amendments to, or waivers from, provisions of our Code of Business Conduct and Ethics that apply specifically to our directors, principal executive officer and principal financial officer will be included in a Current Report on Form 8-K within four business days following the date of

the amendment or waiver, unless website posting or the issuance of a press release of such amendments or waivers is then permitted by the rules of the Nasdaq Capital Market.

Item 11. Executive Compensation.

Summary Compensation Table

The following table summarizes information concerning the compensation awarded to, earned by, or paid for services rendered in all capacities by our named executive officers during the years ended December 31, 2021 and 2020:

Name and Principal Position	Year Ended December 31,	Salary ($)	Bonus[1] ($)	Restricted Stock Awards[2] ($)	Option Awards[2] ($)	All Other Compensation[3] ($)	Total ($)
Saundra Pelletier *Chief Executive Officer*	2021	812,083	401,981	171,400 [4]	1,787,940 [5]	20,521 [6]	3,193,925
	2020	780,850	1,045,850 [7]	1,302,900 [8]	1,044,000 [9]	14,744	4,188,344
Justin J. File *Chief Financial Officer*	2021	589,240	218,755	68,560 [10]	383,130 [11]	1,242	1,260,927
	2020	566,577	444,932 [12]	651,450 [13]	348,000 [14]	3,076	2,014,035
Russ Barrans[15] *Chief Commercial Officer*	2021	471,960 [16]	110,726	117,330 [17]	383,130 [18]	67,030 [19]	1,150,176
	2020	491,625	265,813 [20]	816,450 [21]	348,000 [22]	5,538	1,927,426
Alexander A. Fitzpatrick[23] *General Counsel*	2021	469,310	116,154	68,560 [24]	383,130 [25]	8,740 [26]	1,045,894
	2020	451,260	225,630 [27]	651,450 [28]	348,000 [29]	1,242	1,677,582

[1] Consists of a bonus as approved by the Compensation Committee in respect of the named executive officer's performance and the Company's performance during 2021.

[2] Amounts listed in this column represent the aggregate fair value on the date of vesting of the Company's equity awards granted to the named executive officers determined in accordance with Financial Accounting Standards Board (FASB) ASC Topic 718, Compensation-Stock Compensation (FASB ASC Topic 718). See Note 11 to our Consolidated Financial Statements included in our Annual Report for details as to the assumptions used to determine the fair value of these awards.

[3] All Other Compensation primarily includes premiums paid for group term life insurance, except for Ms. Pelletier, Mr. Barrans, and Mr. Fitzpatrick as discussed in note (6), (19), and (26), respectively, below.

[4] On February 3, 2021, the Company granted Ms. Pelletier 500,000 shares of common stock issued as Restricted Stock Awards (RSAs), of which 200,000 vested in connection with the Company's achievement of certain performance milestones in 2021. Of these RSAs, the Company withheld 105,300 shares of common stock to satisfy statutory tax withholding requirements upon vesting of such RSAs during 2021.

[5] February 3, 2021, the Company granted Ms. Pelletier 700,000 stock options which vest in a series of forty-eight (48) successive equal monthly installments upon completion of each additional month of service for the Company measured from the vesting commencement date of February 3, 2021.

[6] All Other Compensation for Ms. Pelletier includes (i) a $1,242 premium paid for group term life insurance and (ii) $19,279 in fringe benefits paid on behalf of Ms. Pelletier.

[7] Consists of (i) an executive officer bonus in the amount of $215,000 paid to Ms. Pelletier in her capacity as the Company's Chief Executive Officer, (ii) a bonus in the amount of $50,000 for the achievement of certain performance milestone by Ms. Pelletier and (iii) a bonus in the amount of $780,850 as approved by the Compensation Committee in respect of her performance and the Company's performance during 2020.

[8] On February 25, 2020, the Company granted Ms. Pelletier 300,000 shares of common stock issued as Restricted Stock Awards (RSAs), which fully vested in connection with the Company's achievement of certain performance milestones in 2020. Of these RSAs, the Company withheld 187,050 shares of common stock to satisfy statutory tax withholding requirements upon vesting of such RSAs during 2020.

[9] February 25, 2020, the Company granted Ms. Pelletier 300,000 stock options which vest in a series of thirty-six (36) successive equal monthly installments upon completion of each additional month of service for the Company measured from the vesting commencement date of February 25, 2020.

[10] On February 3, 2021, the Company granted Mr. File 200,000 shares of common stock issued as RSAs, of which 80,000 vested in connection with the Company's achievement of certain performance milestones in 2021. Of these RSAs, the Company withheld 42,280 shares of common stock to satisfy statutory tax withholding requirements upon vesting of such RSAs during 2021.

[11] February 3, 2021, the Company granted Mr. File 150,000 stock options which vest in a series of forty-eight (48) successive equal monthly installments upon completion of each additional month of service for the Company measured from the vesting commencement date of February 3, 2021.

[12] Consists of (i) a bonus in the amount of $20,000 for the achievement of certain performance milestone by Mr. File and (ii) a bonus in the amount of $424,932 as approved by the Compensation Committee in respect of his performance and the Company's performance during 2020.

[13] On February 25, 2020, the Company granted Mr. File 150,000 shares of common stock issued as RSAs, which fully vested in connection with the Company's achievement of certain performance milestones in 2020. Of these RSAs, the Company withheld 93,492 shares of common stock to satisfy statutory tax withholding requirements upon vesting of such RSAs during 2020.

[14] On February 25, 2020, the Company granted Mr. File 100,000 stock options which vest in a series of thirty-six (36) successive equal monthly installments upon completion of each additional month of service for the Company measured from the vesting commencement date of February 25, 2020.

[15] Russ Barrans retired from his position as chief commercial officer in November 2021.

[16] Consists of (i) $447,379 paid to Mr. Barrans pursuant to Mr. Barrans employment agreement with the Company and (ii) $24,581 paid to Mr. Barrans for vacation payout.

[17] On February 3, 2021, the Company granted Mr. Barrans 200,000 shares of common stock issued as RSAs, of which 80,000 vested in connection with the Company's achievement of certain performance milestones in 2021. Of these RSAs, the Company withheld 31,480 shares of common stock to satisfy statutory tax withholding requirements upon vesting of the RSAs during 2021. The Company also withheld 19,998 shares of common stock to satisfy statutory tax withholding requirements upon vesting of the third tranche of RSAs during 2021 that were granted in July 2019.

[18] February 3, 2021, the Company granted Mr. Barrans 150,000 stock options which vest in a series of forty-eight (48) successive equal monthly installments upon completion of each additional month of service for the Company measured from the vesting commencement date of February 3, 2021.

[19] All Other Compensation for Mr. Barrans includes (i) a $3,119 premium paid for group term life insurance and (ii) $63,911 in severance pay.

[20] Consists of (i) a bonus in the amount of $20,000 for the achievement of certain performance milestone by Mr. Barrans and (ii) a bonus in the amount of $245,813 as approved by the Compensation Committee in respect of his performance and the Company's performance during 2020.

[21] On February 25, 2020, the Company granted Mr. Barrans 150,000 shares of common stock issued as RSAs, which fully vested in connection with the Company's achievement of certain performance milestones in 2020. Of these RSAs, the Company withheld 38,731 shares of common stock to satisfy statutory tax withholding requirements upon vesting of the RSAs during 2020. The Company also withheld 20,381 shares of common stock to satisfy statutory tax withholding requirements upon vesting of the second tranche RSAs during 2020 that were granted in July 2019.

[22] On February 25, 2020, the Company granted Mr. Barrans 100,000 stock options which vest in a series of thirty-six (36) successive equal monthly installments upon completion of each additional month of service for the Company measured from the vesting commencement date of February 25, 2020.

[23] Alex Fitzpatrick became a named executive officer as of December 31, 2021 as a result of Mr. Barrans' retirement.

[24] On February 3, 2021, the Company granted Mr. Fitzpatrick 200,000 shares of common stock issued as RSAs, of which 80,000 vested in connection with the Company's achievement of certain performance milestones in 2021. Of these RSAs, the Company withheld 42,120 shares of common stock to satisfy statutory tax withholding requirements upon vesting of such RSAs during 2021.

[25] February 3, 2021, the Company granted Mr. Fitzpatrick 150,000 stock options which vest in a series of forty-eight (48) successive equal monthly installments upon completion of each additional month of service for the Company measured from the vesting commencement date of February 3, 2021.

[26] All Other Compensation for Mr. Fitzpatrick includes (i) a $2,322 premium paid for group term life insurance and (ii) $6,418 in fringe benefits paid on behalf of Mr. Fitzpatrick.

[27] Consists of a bonus in the amount of $225,630 as approved by the Compensation Committee in respect of Mr. Fitzpatrick's performance and the Company's performance during 2020.

[28] On February 25, 2020, the Company granted Mr. Fitzpatrick 150,000 shares of common stock issued as RSAs, which fully vested in connection with the Company's achievement of certain performance milestones in 2020. Of these RSAs, the Company withheld 78,879 shares of common stock to satisfy statutory tax withholding requirements upon vesting of such RSAs during 2020.

[29] On February 25, 2020, the Company granted Mr. Fitzpatrick 100,000 stock options which vest in a series of thirty-six (36) successive equal monthly installments upon completion of each additional month of service for the Company measured from the vesting commencement date of February 25, 2020.

Employment, Severance and Separation Agreements

Current Executive Officers

Our current executive officers, (Ms. Pelletier, Mr. File and Mr. Fitzpatrick) were each appointed to their offices in January 2018 in connection with the Merger (as defined in the "Certain Relationships and Related Persons Transactions" Section below). The amounts reported for each of them in the Summary Compensation Table above, includes compensation paid to or earned by them pursuant to offer letters for their services provided as our executive officers pursuant to their offer letters and subsequent employment agreements described below.

Current Employment Agreements

On July 2, 2018, we entered into employment agreements with each of Ms. Pelletier, Mr. File and Mr. Fitzpatrick. Pursuant to the terms of these agreements, each of Ms. Pelletier, Mr. File and Mr. Fitzpatrick is eligible to receive an annual base salary of $812,083, $589,240 and $488,083, respectively, and target bonuses as a base salary in amounts up to 100%, 75% and 50% respectively, payable in the discretion of our Board.

The employment agreements also entitle these executive officers to (i) participate in benefit/welfare plans and fringe benefits provided generally to our senior executives, (ii) receive reimbursement for ordinary and reasonably incurred business expenses and (iii) receive paid vacation and holiday time in accordance with policies generally applicable to our senior executives. Each executive officer may terminate his or her employment for good reason after giving us thirty days to correct or "cure" the circumstances giving rise to a termination for good reason, and each executive officer may terminate his or her employment upon at least thirty days' prior written notice to us for any reason other than for good reason. We may terminate the employment of each executive officer without prior written notice for cause or in the event of the executive officer's disability. We may also terminate the employment of each executive officer without cause on thirty days' prior written notice. The employment agreements will be automatically terminated upon the death of the applicable executive officer. If an executive officer's employment is terminated by us for cause, by reason of his or her death or disability, as a result of the applicable executive officer without good reason, we agreed to pay the terminated executive officer the amount of our accrued obligations as of the date of such termination. If an executive officer's employment is terminated without cause or the applicable executive officer resigns for good reason, then we have agreed to make the payments set forth below.

Severance Obligations

Saundra Pelletier

If Ms. Pelletier is terminated by us other than for cause or Ms. Pelletier resigns for good reason, then pursuant to her employment agreement, we have agreed to pay and provide to Ms. Pelletier: (i) all accrued obligations as of the date of termination, (ii) any accrued but unpaid bonus for the prior fiscal year, (iii) a pro-rated bonus for the year in which the

termination occurs as of her termination date, (iv) an amount equal to eighteen months of her then-current base salary in a lump sum and (v) eighteen months of continuing health benefits coverage, each subject to the conditions outlined in the agreement. In addition, fifty percent (50%) of any unvested and outstanding equity interests Ms. Pelletier may have shall immediately vest and become exercisable, in each case subject to the conditions outlined in her equity agreements. If Ms. Pelletier's employment is terminated without cause or if Ms. Pelletier resigns for good reason, in each case within three months prior to or twelve months following a change of control, then we have agreed to pay and provide to Ms. Pelletier: (i) all accrued obligations as of the date of termination, (ii) an amount equal to twenty-four months of her then-current base salary in a lump sum, (iii) any accrued but unpaid bonus for the prior fiscal year, (iv) her target annual bonus for the year in which the termination occurs at the rate in effect immediately prior to such termination multiplied by a factor of 2.0 and (v) twenty-four months of continuing health benefits coverage, each subject to the conditions outlined in the agreement. In addition, any unvested and outstanding equity interests Ms. Pelletier may have shall fully vest and become exercisable, in each case subject to the conditions outlined in her equity agreements.

Justin J. File and Alexander Fitzpatrick

If Justin J. File or Alexander Fitzpatrick (each, a Non-CEO Executive) is terminated by us other than for cause or a Non-CEO Executive resigns for good reason, then we have agreed to pay and provide to each Non-CEO Executive: (i) all accrued obligations as of the date of termination, (ii) any accrued but unpaid bonus for the prior fiscal year, (iii) a pro-rated bonus for the year in which the termination occurs as of his termination date, (iv) an amount equal to twelve months of his or her then-current base salary in a lump sum and (v) twelve months of continuing health benefits coverage, each subject to the conditions outlined in their respective agreements. In addition, fifty percent (50%) of any unvested and outstanding equity interests a Non-CEO Executive may have shall immediately vest and become exercisable, in each case subject to the conditions outlined in his or her equity agreements. If a Non-CEO Executive's employment is terminated without cause or if a Non-CEO Executive resigns for good reason, in each case within three months prior to or twelve months following a change of control, then we have agreed to pay and provide to such Non-CEO Executive: (i) all accrued obligations as of the date of termination, (ii) an amount equal to eighteen months of his then-current base salary in a lump sum, (iii) any accrued but unpaid bonus for the prior fiscal year, (iv) his target annual bonus for the year in which the termination occurs at the rate in effect immediately prior to such termination multiplied by a factor of 1.5 and (v) eighteen months of continuing health benefits coverage, each subject to the conditions outlined in the agreement. In addition, any unvested and outstanding equity interests a Non-CEO Executive may have shall fully vest and become exercisable, in each case subject to the conditions outlined in his equity agreements.

Russell Barrans

Russell Barrans retired as the Company's chief commercial officer on November 15, 2021. In connection with Mr. Barrans' retirement, on November 12, 2021, the Company entered into a separation agreement with Mr. Barrans (the Barrans Separation Agreement). The Barrans Separation Agreement includes a customary release of claims against the Company that are or may be held by Mr. Barrans and entitles Mr. Barrans to (i) a severance payment equal to $511,290, which represents twelve months in value of Mr. Barrans' base salary and is payable, at the Company's election, in a lump sum or by normal payroll until April 30, 2022, and (ii) a prorated performance bonus for fiscal year 2021 of $110,726, which is payable no later than March 15, 2022. The foregoing description of the Barrans Separation Agreement does not purport to be complete and is subject to and qualified in its entirety by reference to the Barrans Separation Agreement filed as Exhibit 10.2 to the quarterly report on Form 10-Q for the quarter ended September 30, 2021 and incorporated by reference herein.

Severance Tax Matters

All payments made and benefits available to each executive officer in connection with his or her employment agreement will or were intended to comply with Section 409A of the Internal Revenue Code of 1986, as amended, (the Code) in accordance with the terms of his or her employment agreement. In the event the benefit provided to an employee (i) constitutes "parachute payments" within the meaning of Section 280G of the Code, and (ii) would otherwise be subject to the excise tax imposed by Section 4999 of the Code, then such "Payments" will be reduced. The reduced amount will be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the excise tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount results in the executive officer's receipt, on an after-tax basis, of the greater amount of the Payment notwithstanding that all or some portion of such benefits may be taxable under Section 4999 of the Code. If a reduction in payments or benefits constituting "parachute payments" is necessary to limit or avoid a certain employee's excise tax, the reduction shall occur at the election of such employee (provided, however, that such election shall be subject to our approval if made on or after the effective date of the event that triggers the Payment) and may reduce cash payments, cancel accelerated vesting of stock award, and/or reduce employee benefits in any order or combination that maximizes the amount of such reduced amount. In the event that acceleration of vesting of stock award compensation is to be reduced, such acceleration of vesting shall be cancelled in the reverse order of the date of grant of such executive officer's stock awards unless the executive officer elects a different order for cancellation.

Outstanding Equity Awards at December 31, 2021

The following table shows the outstanding equity awards held by our named executive officers as of December 31, 2021.

	Option Awards				
Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price ($)	Option Grant Date	Option Expiration Date
Saundra Pelletier	6,719 [1]	—	79.87	6/3/2013	6/3/2023
	42,076 [2]	—	46.36	9/28/2016	9/28/2026
	825,000	—	7.29	3/12/2018	3/12/2028
	313,500	—	2.10	7/31/2018	7/31/2028
	284,625	—	3.45	11/28/2018	11/28/2028
	183,333	116,667	4.87	2/5/2020	2/5/2030
	145,833	554,167	3.25	2/3/2021	2/3/2031
Justin J. File	23,099 [3]	—	46.36	9/28/2016	9/28/2026
	300,000	—	7.29	3/12/2018	3/12/2028
	114,000	—	2.10	7/31/2018	7/31/2028
	103,500	—	3.45	11/28/2018	11/28/2028
	61,111	38,889	4.87	2/5/2020	2/5/2030
	31,250	118,750	3.25	2/3/2021	2/3/2031
Alexander A. Fitzpatrick	275,000	—	7.29	3/12/2018	3/12/2028
	104,500	—	2.10	7/31/2018	7/31/2028
	100,000	—	3.45	11/28/2018	11/28/2028
	61,111	38,889	4.87	2/5/2020	2/5/2030
	31,250	118,750	3.25	2/3/2021	2/3/2031
Russell Barrans[5]	5,133 [4]	—	46.36	9/28/2016	9/28/2026
	260,000	—	7.29	3/12/2018	3/12/2028
	98,800	—	2.10	7/31/2018	7/31/2028
	97,222	—	3.45	11/28/2018	11/28/2028
	58,333	—	4.87	2/5/2020	2/5/2030
	28,125	—	3.25	2/3/2021	2/3/2031

(1) The share numbers and exercise prices reflected are those of options issued to the executive upon completion of the Merger in January 2018. These options were issued upon completion of the Merger in exchange for options to purchase 261,784 shares of Private Evofem common stock, which were fully vested upon grant, at an exercise price of $2.05 per share awarded to the executive by Evofem Operations in 2013 (See more detail described in Note 3 to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2018).

(2) The share numbers and exercise prices reflected are those of options issued to the executive upon completion of the Merger in January 2018. These options were issued upon completion of the Merger in exchange for options to purchase an aggregate of 1,639,404 shares of Private Evofem common stock at an exercise price of $1.19 per share awarded to the executive by Private Evofem in 2016.

(3) The share numbers and exercise prices reflected are those of options issued to the executive upon completion of the Merger in January 2018. These options were issued upon completion of the Merger in exchange for options to purchase an aggregate of 900,000 shares of Private Evofem common stock at an exercise price of $1.19 per share awarded to the executive by Private Evofem in 2016.

(4) The share numbers and exercise prices reflected are those of options issued to the executive upon completion of the Merger in January 2018. These options were issued upon completion of the Merger in exchange for options to purchase 200,000 shares of Private Evofem Common stock at an exercise price of $1.19 per share awarded to the executive by Private Evofem in 2016.

(5) Russell Barrans retired as the Company's chief commercial officer on November 15, 2021.

Employee Benefit and Equity Incentive Plans

Stock Compensation Plans

Summary of the Amended and Restated 2014 Plan

The Company initially adopted the 2007 Stock Plan (the 2007 Plan) in March 2007 under which 211,893 shares of common stock were reserved for issuance to employees, non-employee directors, and consultants of the Company. The Company ceased

granting any additional awards under our 2007 Plan, and presently grants equity awards under the Amended and Restated 2014 Plan.

On September 15, 2014, our board of directors adopted, and our stockholders approved, the 2014 Equity Incentive Plan. The 2014 Equity Incentive Plan, as amended and restated, provides incentives that will assist us to attract, retain, and 27 motivate employees, including officers, consultants, and directors. We may provide these incentives through the grant of stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, and units and other cash-based or share-based awards. In addition, the Amended and Restated 2014 Plan contains a mechanism through which we may adopt a deferred compensation arrangement in the future.

A total of 166,666 shares of our common stock was initially authorized and reserved for issuance under the Amended and Restated 2014 Plan. As of February 15, 2022, a total of 2,921,494 shares of our common stock were reserved and available for issuance under the Amended and Restated 2014 Plan. Per the terms of the Amended and Restated 2014 Plan, this reserve will automatically increase on each January 1 through 2024, by an amount equal to the smaller of:

- 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31; or
- an amount determined by our board of directors.

Appropriate adjustments will be made in the number of authorized shares and other numerical limits in the Amended and Restated 2014 Plan and in outstanding awards to prevent dilution or enlargement of participants' rights in the event of a stock split or other change in our capital structure. Shares subject to awards which expire or are cancelled or forfeited will again become available for issuance under the Amended and Restated 2014 Plan.

The Amended and Restated 2014 Plan is administered by the Compensation Committee of our board of directors. Pursuant to the provisions of the Amended and Restated 2014 Plan, the Compensation Committee determines, in its discretion, the persons to whom and the times at which awards are granted, the sizes of such awards and all of their terms and conditions. The Compensation Committee has the authority to construe and interpret the terms of the Amended and Restated 2014 Plan and awards granted under it. The Amended and Restated 2014 Plan provides, subject to certain limitations, for indemnification by us of any director, officer, or employee against all reasonable expenses, including attorneys' fees, incurred in connection with any legal action arising from such person's action or failure to act in administering the Amended and Restated 2014 Plan.

In the event of a change in control as described in the Amended and Restated 2014 Plan, the acquiring or successor entity may assume or continue all or any awards outstanding under the Amended and Restated 2014 Plan or substitute substantially equivalent awards. The Compensation Committee may provide for the acceleration of vesting of any or all outstanding awards upon such terms and to such extent as it determines, except that the vesting of all awards held by members of the board of directors who are not employees will automatically be accelerated in full upon a change in control. Any award held by a participant whose service has not terminated prior to a change in control that is not assumed, continued, or substituted for in connection with a change in control or are not exercised or settled prior to the change in control will terminate effective as of the time of the change in control. Notwithstanding the foregoing, except as otherwise provided in an award agreement governing any award, in the discretion of the Compensation Committee, any award that is not assumed, continued, or substituted for in connection with a change in control shall, subject to the provisions of applicable law, become fully vested and exercisable and/or settleable as of a date prior to, but conditioned upon, the consummation of the change in control. The Amended and Restated 2014 Plan also authorizes the Compensation Committee, in its discretion and without the consent of any participant, to cancel each or any outstanding award denominated in shares upon a change in control in exchange for a payment to the participant with respect to each vested share subject to the cancelled award (and each unvested share, if so determined by the Compensation Committee) of an amount equal to the excess of the fair market value of the consideration to be paid per share of common stock in the change in control transaction over the exercise price per share, if any, under the award. The vesting schedules of all outstanding options of the Company, excluding any shares issuable pursuant to the assumed equity incentive plan of Private Evofem, were fully accelerated in connection with the Merger and termination of employment or service arrangement with the Company.

The Amended and Restated 2014 Plan will continue in effect until it is terminated, provided, however, that all awards will be granted, if at all, within ten years of its effective date. The Compensation Committee may amend, suspend or terminate the Amended and Restated 2014 Plan at any time, provided that without stockholder approval, the Amended and Restated 2014 Plan cannot be amended by the Compensation Committee without stockholder approval, except as described above, to increase the number of shares authorized, change the class of persons eligible to receive incentive stock options, or effect any other change that would require stockholder approval under any applicable law or listing rule.

Summary of the 2018 Inducement Equity Incentive Plan

On July 24, 2018, upon the recommendation of our Compensation Committee, the board of directors approved our 2018 Inducement Equity Incentive Plan and reserved 250,000 shares of our common stock to be used exclusively for grants of

awards to individuals that were not previously employees or directors of the company, as an inducement to the individual's entry into employment with the company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. On February 25, 2020, the board of directors approved an increase to the number of shares of our common stock reserved and available for issuance under the 2018 Inducement Equity Incentive Plan to 1,250,000. The 2018 Inducement Equity Incentive Plan was adopted without stockholder approval pursuant to Rule 5635(c)(4). The 2018 Inducement Equity Incentive Plan provides for the grant of equity-based awards, including options, restricted and unrestricted stock awards, and other stock- based awards, and its terms are substantially similar to the Amended and Restated 2014 Plan, but with such other terms and conditions intended to comply with the Nasdaq inducement award exception. As of February 15, 2022, there were 392,375 shares of options outstanding and 842,977 shares available for grant under the 2018 Inducement Equity Incentive Plan.

2019 Employee Stock Purchase Plan

On May 7, 2019, the board of directors approved the 2019 ESPP, which was approved by stockholders at the 2019 annual meeting held on June 5, 2019 and which authorizes the issuance of up to 500,000 shares of common stock pursuant to purchase rights granted to employees. This authorized number of shares may be increased annual increase on the first day of each of the Company's fiscal years beginning in 2020 and ending on the first day of 2029, in an amount equal to the lesser of (i) 1,000,000 shares, (ii) two percent (2%) of the shares of common stock outstanding on the last day of the immediately preceding fiscal year, or (iii) such lesser number of shares as is determined by the board of directors. 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 approximately every June 15 and December 15. 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.

As of February 15, 2022, there were 629,672 shares of common stock purchased and 2,083,085 shares of our common stock reserved and available for issuance under the 2019 ESPP.

Private Evofem Equity Incentive Plan

The Private Evofem Equity Incentive Plan was assumed by the Company in connection with the Merger and shares of Private Evofem common stock issuable pursuant to options previously granted under the Private Evofem Equity Incentive Plan became options to purchase our common stock upon completion of the Merger. No new awards may be granted under the Private Evofem Equity Incentive Plan. As of February 15, 2022, a total of 147,930 shares of our common stock were reserved for issuance upon the exercise of outstanding options under the Private Evofem Equity Incentive Plan.

2014 Employee Stock Purchase Plan

In November 2014, the Company adopted the 2014 Employee Stock Purchase Plan (the 2014 ESPP), which enables eligible employees to purchase shares of its common stock using their after-tax payroll deductions of up to 15% of their eligible compensation, subject to certain restrictions. Effective as of May 7, 2019, the 2014 ESPP was terminated by our board of directors and is no longer of any force or effect. There were 1,339 shares of common stock purchased under the 2014 ESPP prior to its termination.

Perquisites, Health, Welfare and Retirement Benefits

Our executive officers are eligible to participate in all of our employee benefit plans, including our medical, dental, vision, group life and disability insurance plans, in each case on the same basis as other employees.

Director Compensation

The following table sets forth the compensation (cash and equity) received by our non-employee directors during the year ended December 31, 2021.

Name	Fees Earned or Paid in Cash ($)	Option Awards[1] ($)	Totals ($)
William Hall, Ph.D., M.D.[2]	88,458	88,227	176,685
Gillian Greer, Ph.D.	62,500	88,227	150,727
Kim Kamdar, Ph.D.	71,250	88,227	159,477
Tony O'Brien	75,000	88,227	163,227
Lisa Rarick, M.D.	52,120	88,227	140,347
Colin Rutherford	70,000	88,227	158,227

(1) Amounts listed in this column represent the aggregate fair value of the option awards computed as of the grant date of each option award in accordance with FASB ASC Topic 718, rather than amounts paid to or realized by the named individual. There can be no assurance that options will be exercised (in which case no value will be realized by the individual) or that the value on exercise will approximate the fair value as computed in accordance with FASB ASC Topic 718. The assumptions used in the valuation of these awards are set forth in Note 11- Stock-based Compensation to our Consolidated Financial Statements on our Annual Report.

(2) Dr. Hall resigned from his positions of director and chairman of the board of directors in November 2021 due to personal health concerns.

The following table shows the outstanding equity awards held by our non-employee directors as of December 31, 2021.

	Option Awards				
Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price ($)	Option Grant Date	Option Expiration Date
William Hall, Ph.D., M.D.[1]	24,691	—	7.29	3/12/2018	3/12/2028
	12,875	—	6.99	5/8/2018	5/8/2028
	50,000	—	6.05	6/5/2019	6/5/2029
	50,000	—	5.06	5/12/2020	5/12/2030
Gillian Greer, Ph.D.	24,691	—	7.29	3/12/2018	3/12/2028
	12,875	—	6.99	5/8/2018	5/8/2028
	50,000	—	6.05	6/5/2019	6/5/2029
	50,000	—	5.06	5/12/2020	5/12/2030
	—	90,000	1.25	5/12/2021	5/12/2031
Kim Kamdar, Ph.D.	6,065	—	37.74	6/16/2015	6/16/2025
	8,905	—	6.78	6/21/2016	6/21/2026
	10,583	—	12.90	5/11/2017	5/11/2027
	2,075	—	13.14	6/20/2017	6/20/2027
	12,875	—	6.99	5/8/2018	5/8/2028
	50,000	—	6.05	6/5/2019	6/5/2029
	50,000	—	5.06	5/12/2020	5/12/2030
	—	90,000	1.25	5/12/2021	5/12/2031
Tony O’Brien	24,691	—	7.29	3/12/2018	3/12/2028
	12,875	—	2.31	7/24/2018	7/24/2028
	50,000	—	6.05	6/5/2019	6/5/2029
	50,000	—	5.06	5/12/2020	5/12/2030
	—	90,000	1.25	5/12/2021	5/12/2031
Lisa Rarick, M.D.	45,833	29,167	5.85	2/25/2020	2/25/2030
	50,000	—	5.06	5/12/2020	5/12/2030
	—	90,000	1.25	5/12/2021	5/12/2031
Colin Rutherford	770	—	43.64	3/8/2017	3/8/2027
	39,691	—	7.29	3/12/2018	3/12/2028
	12,875	—	6.99	5/8/2018	5/8/2028
	5,550	—	2.10	7/31/2018	7/31/2028
	50,000	—	6.05	6/5/2019	6/5/2029
	50,000	—	5.06	5/12/2020	5/12/2030
	—	90,000	1.25	5/12/2021	5/12/2031

[1] Dr. Hall resigned from his positions of director and chairman of the board of directors in November 2021 due to personal health concerns.

Our Non-Employee Director Compensation Policy.

In February 2022, our Compensation Committee amended the Non-Employee Director Compensation Policy as described below which will become effective April 1, 2022.

- Each non-employee director will receive an annual cash retainer in the amount of $40,000 per year.
- The Chair of the Board will receive an additional annual cash retainer in the amount of $30,000 per year.
- The chairperson of the audit committee will receive additional annual cash compensation in the amount of $20,000 per year for such chairperson's service on the audit committee. Each non-chairperson member of the audit committee will receive additional annual cash compensation in the amount of $10,000 per year for such member's service on the audit committee.
- The chairperson of the Compensation Committee will receive additional annual cash compensation in the amount of $15,000 per year for such chairperson's service on the Compensation Committee. Each non-chairperson member of the Compensation Committee will receive additional annual cash compensation in the amount of $7,500 per year for such member's service on the Compensation Committee.
- The chairperson of the nominating and corporate governance committee will receive additional annual cash compensation in the amount of $10,000 per year for such chairperson's service on the nominating and corporate governance committee. Each non-chairperson member of the nominating and corporate governance committee will receive additional annual cash compensation in the amount of $5,000 per year for such member's service on the nominating and corporate governance committee.
- Each non-employee directors will receive a stock option grant with an initial grant equal to 90,000 shares of the Company's common stock upon a director's initial appointment or election to the Board of Directors, vesting quarterly over a 3 year period and an annual stock option grant equal 90,000 shares of the Company's common stock on the date of each annual stockholder's meeting thereafter, fully vesting in one year from the date of grant.

The February 2022 amendment of the Non-Employee Director Compensation Policy reduced, effective as of April 1, 2022, the annual cash retainer for each non-employee director from $50,000 per year to $40,000 per year, the annual cash retainer for the chairperson of the Board from $40,000 to $30,000 and the annual cash compensation for the chairperson of the Nominating and Corporate Governance Committee from $11,250 per year to $10,000 per year.

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

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information concerning the ownership of our common stock as of February 15, 2022, by (i) those persons who are known to us to be the beneficial owner(s) of more than five percent of our common stock, (ii) each of our directors and named executive officers and (iii) all of our directors and named executive officers as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. In the cases of holders who are not directors, director nominees, and named executive officers, Schedules 13G or 13D filed with the SEC (and, consequently, ownership reflected here) often reflect holdings as of a date prior to February 15, 2022. Under such rules, beneficial ownership generally includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days after February 15, 2022, through the exercise of stock options, warrants or other rights. Unless otherwise indicated in the footnotes to this table, we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Unless otherwise noted, the address of the persons in the table below is that of the Company.

Name and Address of Beneficial Owner	Shares Beneficially Owned	Percent of Shares Beneficially Owned
5% Stockholders		
CVI Investments, Inc.[1] Heights Capital Management, Inc., investment manager 101 California Street, Suite 3250 San Francisco, California 94111	10,000,000	6.2%
Directors and Named Executive Officers		
Gillian Greer, Ph.D.[2]	137,566	*
Kim Kamdar, Ph.D.[3]	159,790	*
Tony O'Brien[4]	145,706	*
Lisa Rarick, M.D.[5]	112,333	*
Colin Rutherford[6]	158,886	*
Saundra Pelletier[7]	2,578,589	1.6%
Justin J. File[8]	1,017,553	*
Alex Fitzpatrick[9]	811,894	*
Directors and executive officers as a group (8 Persons)[10]	5,122,317	3.1%

*Includes beneficial ownership of less than 1% of the outstanding shares of Evofem's common stock.

[1] The number of shares reported as beneficially owned consists of shares issuable upon the exercise of warrants to purchase shares of Evofem's common stock.

[2] Consists of 137,566 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of February 15, 2022.

[3] Consists of (i) 19,287 shares of common stock held by Dr. Kamdar and (ii) 140,503 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of February 15, 2022.

[4] Consists of (i) 8,140 shares of common stock held by Mr. O'Brien and (ii) 137,566 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of February 15, 2022.

[5] Consists of (i) 10,250 shares of common stock held by Dr. Rarick and (ii) 102,083 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of February 15, 2022.

[6] Consists of 158,886 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of February 15, 2022.

[7] Consists of (i) 685,837 shares of common stock held by Ms. Pelletier and (ii) 1,892,752 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of February 15, 2022.

[8] Consists of (i) 360,982 shares of common stock held by Mr. File and (ii) 656,571 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of February 15, 2022.

[9] Consists of (i) 216,422 shares of common stock held by Mr. Fitzpatrick and (ii) 595,472 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of February 15, 2022.

[10] Consists of 1,300,918 shares of common stock held by our current executive officers and directors and (ii) 3,821,399 shares of common stock that may be acquired by our current executive officers and directors pursuant to the exercise of stock options within 60 days after February 15, 2022.

Equity Compensation Plan Information

The following table provides certain aggregate information with respect to all of our equity compensation plans in effect as of December 31, 2021:

Plan Category	Number of Securities to be Issued Upon Exercise of Awards (a)		Weighted Average Exercise Price of Outstanding Awards (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
Equity compensation plans approved by Stockholders[1]	10,545,173	$	4.41	4,534,842
Equity compensation plans not approved by Stockholders[3]	440,615	$	4.16	794,737
Total	10,985,788			5,329,579

[1] Includes our 2007 Plan and the Amended and Restated 2014 Plan. This table does not include the number of shares issuable upon exercise of issued and outstanding awards under the Private Evofem Equity Incentive Plan. No new awards may be issued under the Private Evofem Equity

Incentive Plan. As of December 31, 2021, a total of 147,930 shares of our common stock were reserved for issuance upon the exercise of outstanding options under the Private Evofem Equity Incentive Plan with a weighted average exercise price of $57.59 per share.

(2) As of December 31, 2021, an aggregate of 2,701,757 shares of common stock were available for grant under the Amended and Restated 2014 Plan and an aggregate of 1,833,085 shares were available for issuance under the 2019 ESPP. The Amended and Restated 2014 Plan contains a provision for an automatic increase to the number of shares available for grant each January 1st until and including January 1, 2024, subject to certain limitations, by a number of shares equal to the lesser of 4% of the number of shares of our common stock issued and outstanding on the immediately preceding December 31 or a number of shares set by our Board of Directors. The 2019 ESPP contains a provision for an automatic increase to the number of shares available for issuance under the 2019 ESPP each January 1st and including January 1, 2024, subject to certain limitations, by a number of shares equal to the lesser of 1,000,000 shares or 2% of our common stock issued and outstanding on the immediately preceding December 31 or a number of shares set by our Board of Directors.

(3) Includes the 2018 Inducement Equity Incentive Plan. See Item 10, “Directors, Executive Officers, and Corporate Governance” of our Annual Report for a narrative description of the 2018 Inducement Equity Incentive Plan.

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

Related Person Transactions

Company Policy Regarding Related Party Transactions

Our Audit Committee is responsible for reviewing and approving all transactions in which we are a participant and in which any parties related to us, including our executive officers, directors, beneficial owners of more than 5% of our securities, immediate family members of the foregoing persons, and any other persons whom our Board of Directors determines may be considered related parties, has or will have a direct or indirect material interest. If advanced approval is not feasible, the Audit Committee has the authority to ratify a related party transaction at the next Audit Committee meeting. For purposes of our Audit Committee charter, a material interest is deemed to be any consideration received by such a party in excess of the lesser of $120,000 per year or 1% of the average of our total assets for the last two completed fiscal years.

In reviewing and approving such transactions, the Audit Committee shall obtain, or shall direct our management to obtain on its behalf, all information that our committee believes to be relevant and important to a review of the transaction prior to its approval. Following receipt of the necessary information, a discussion shall be held of the relevant factors if deemed to be necessary by our committee prior to approval. If a discussion is not deemed to be necessary, approval may be given by written consent of our committee. This approval authority may also be delegated to the Chairperson of the Audit Committee in respect of any transaction in which the expected amount is less than $500,000.

The Audit Committee or its chairperson, as the case may be, shall approve only those related party transactions that are determined to be in, or not inconsistent with, the best interests of us and our stockholders, taking into account all available facts and circumstances as our committee or the Chairperson determines in good faith to be necessary. These facts and circumstances will typically include, but not be limited to, the material terms of the transaction, the nature of the related party’s interest in the transaction, the significance of the transaction to the related party and the nature of our relationship with the related party, the significance of the transaction to us, and whether the transaction would be likely to impair (or create an appearance of impairing) the judgment of a director or executive officer to act in our best interest. No member of the Audit Committee may participate in any review, consideration, or approval of any related party transaction with respect to which the member or any of his or her immediate family members is the related party, except that such member of the Audit Committee will be required to provide all material information concerning the related party transaction to the Audit Committee.

Except as otherwise set forth below, during the years ended December 31, 2021, 2020 and 2019 and to date there were no transactions to which we will be a party, nor are there any currently proposed transactions to which we will be a party, in which:

- the amounts involved exceeded or will exceed the lesser of $120,000 per year or 1% of the average of our total assets for the last two completed fiscal years; and
- any of our directors, nominees for director, executive officers or holders of more than 5% of our outstanding capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities, had or will have a direct or indirect material interest.

Merger and Concurrent Financing

On January 17, 2018, we completed a business combination (the Merger) in accordance with the terms of an Agreement and Plan of Merger and Reorganization, dated as of October 17, 2017, by and among the Company, Nobelli Merger Sub, Inc., our wholly owned subsidiary (Merger Sub), and Private Evofem, pursuant to which the Merger Sub merged with and into Private Evofem, with Private Evofem surviving as our wholly owned subsidiary.

In connection with the Merger, we issued shares of our common stock to certain investors in Private Evofem, including funds affiliated with Invesco Ltd., at a purchase price of $12.389355 per share in the financing. In addition, we issued shares of our common stock and, with respect to discretionary investment funds, managed by Woodford Investment Management (WIM) as discretionary investment manager, the Post-Merger Warrants. Upon the closing of the Merger, the funds affiliated with Invesco Ltd. and the discretionary investment funds, managed by WIM as discretionary investment manager each beneficially owned more than 10% of our issued and outstanding capital stock. The issuances to funds affiliated with Invesco Ltd. and to discretionary investment funds managed by WIM as discretionary investment manager in connection with the Merger and Financing are reflected below:

Name	Shares of Common Stock Issued in the Financing	Shares of Common Stock Issued in Connection with the Merger	Warrants to Purchase Shares of Common Stock Issued in Connection with the Merger [1]
Omnis Income & Growth Fund a sub-fund of Omnis Portfolio Investments ICVC	None.	171,975	50,000
Woodford Patient Capital Trust Plc	None.	1,672,611	475,000
LF Woodford Equity Income Fund, a sub fund of LF Woodford Investment Fund	None.	5,620,952	1,475,000
Invesco Perp High Income	375,000	3,144,366	None.
Invesco Perp Income	1,239,289	2,278,843	None.

[1] With the exception of the warrant issued to Woodford Patient Capital Trust Plc, the warrants listed in this column were fully exercised as of February 8, 2019 as described in the "Reload Warrant Transaction" Section below.

2019 Private Placement

During the second quarter of 2019, we issued an aggregate of 17,777,779 shares of common stock in connection with a private placement at the offering price of $4.50 per share and common warrants to purchase 4,444,446 shares of common stock at an exercise price of $6.38 per shares (the Private Placement).

Certain of our existing stockholders purchased an aggregate of 4,444,445 shares of our common stock in the Private Placement (including one unit share associated with the common warrants issued to Woodford Patient Capital Trust Plc). The table below sets forth the aggregate number of common shares and common warrants issued to our holders of more than 10% of our capital stock, or an affiliate or immediate family member thereof, at the time of the transaction:

Name	Shares of Common Stock Issued in the Private Placement	Common Warrants to Purchase Shares of Common Stock Issued in The Private Placement
PDL BioPharma, Inc.	13,333,334	3,333,334
Woodford Patient Capital Trust Plc	2,222,223	555,556
Invesco Perpetual High Income Fund	2,222,222	555,556
Total	17,777,779	4,444,446

Consulting Agreements

Effective April 1, 2019, the Company entered into a two-year consulting agreement (the 2019 Consulting Agreement) with Thomas Lynch, the former chair of the Company's Board of Directors. The 2019 Consulting Agreement provided for (i) annual compensation of $0.4 million, including $0.1 million related to Mr. Lynch's board services, (ii) an annual grant of 150,000 RSUs, which will vest quarterly over one year from April 1, 2019 and (iii) an annual bonus of up to 100% of Mr. Lynch's annual consulting fees based upon the achievement of the Company's corporate goals and objectives as determined by and subject to approval of the Board of Directors. The 2019 Consulting Agreement terminated on April 1, 2020 upon the death of Mr. Lynch.

There were no consulting fees incurred under the 2019 Consulting Agreement for the year ended December 31, 2021, and the consulting fees were approximately $0.1 million and $0.6 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2021, there was no additional accrued compensation owed to Mr. Lynch or his estate.

Transactions with WCGI and Related Entities

From 2009 to 2016, Ms. Saundra Pelletier was the founding CEO of WomanCare Global International (WCGI). In February 2013, Private Evofem and WCGI formed an alliance (the WCGI Alliance) and Ms. Pelletier also became Private Evofem's CEO. Concurrent with the forming of the WCGI Alliance, Private Evofem and WCGI entered into (i) a service agreement to which the companies shared resources and employees and (ii) a three-year grant agreement under which the Private Evofem provided funding to WCGI.

From 2011 to 2017, Ms. Pelletier served as a director of the board of WomanCare Global Trading (WCGT), a WCGI subsidiary. Effective February 2015, Private Evofem and WCGT entered into a sublease for office space, which was terminated and reassigned to WCG Cares effective April 1, 2018, and (ii) in October 2015, (a) Private Evofem, through its wholly-owned subsidiaries, entered into two sublicense agreements whereby Private Evofem was responsible for paying $5.0 million in annual sublicense fees, net of amounts paid under the grant agreement during 2015, to WomanCare Global Trading CIC (WCGCIC), also a WCGI affiliate, and (b) the service and grant agreements were cancelled.

Effective January 2016, Private Evofem and WCGI entered into a shared-services agreement (SSA), which replaced the prior service agreement. Under the terms of the SSA, Private Evofem and WCGI cross charged the other company's services provided by each entity on behalf of the other. The SSA also allowed for netting of due to and due from shared-services fees. In July 2019, the SSA was terminated. For the years ended December 31, 2021 and 2020, there were no services provided under the SSA on behalf of WCGI. For the year ended December 31, 2019, services provided were immaterial. As of December 31, 2021 and 2020, there were no net shared-services due to the Company. As of December 31, 2019, net shared-services due to the Company was minimal. As of and for the years ended December 31, 2021, 2020 and 2019, there were no receivables, payables, payments or expenses related to the Company's transactions with WCGI related entities.

Transactions with WCG Cares

In 2013, WCG Cares, a 501(c)(3) nonprofit organization, was incorporated under the laws of the State of California. Its primary purpose is to directly engage in and/or fund the development and implementation of programs that promote reproductive health, education, research and increased access to high-quality, innovative and affordable reproductive health care and health care products around the world. Ms. Pelletier served as the CEO and President of WCG Cares from 2013 to November 2017. She became a member of its board of directors from November 2017 to March 1, 2020, and served as chair of its board of directors from November 2017 to May 2018. Additionally, Mr. Justin J. File served as WCG Cares' Chief Financial Officer from November 2017 to May 2018. See shared-services agreement discussion below.

In March 2018, the Company and WCG Cares entered into a shared-services agreement (the Cares Shared Services Agreement). Under the terms of the Cares Shared Services Agreement, the Company and WCG Cares cross charged services provided by each entity (or its subsidiaries) on behalf of the other. The Cares Shared Services Agreement also allowed for netting of due to and due from shared-services fees In July 2019, the Company provided a notice of termination to WCG Cares to terminate the Cares Shared Services Agreement effective September 2019. For the years ended December 31, 2021 and 2020, there were no services provided under the Cares Shared Services on behalf of WCG Cares. For the year ended December 31, 2019, services provided under the Cares Shared Services on behalf of WCG Cares were immaterial. As of December 31, 2021 and 2020, there were no net shared-services due to the Company. As of December 31, 2019, net shared- services due to the Company was minimal.

The following table summarizes payments and expenses related to the Company's transactions with WCG Cares as of and for the years ended December 31, 2021, 2020 and 2019 (in thousands).

	2021	2020	2019
Receivables	$ —	$ —	$ —
Payables	$ —	$ —	$ —
Payments	$ —	$ —	$ 1,000
Expenses	$ —	$ —	$ —

Transactions with Women Deliver

Women Deliver is a tax-exempt charitable organization under Section 501(c)(3) of the Internal Revenue Code. Its mission is to drive progress for gender equality, particularly in maternal, sexual, and reproductive health and rights globally through advocacy and Women Deliver programs. Ms. Pelletier became a director of the board in January 2013 and served as chair of the board of directors from May 2017 to July 2018. In July 2018, the Company and Women Deliver entered into a Corporate Sponsorship Agreement, under which the Company desired to become a corporate sponsor of the Women Deliver 2019

Conference and to provide financial support for Women Deliver programs. The Company agreed to pay $0.2 million to Women Deliver no later than January 31, 2019. In February 2019, the Company received a letter from Women Deliver, under which both parties mutually agreed to release the Company's sponsorship on this outstanding payment and to terminate the Corporate Sponsor Agreement. Following this release, there have been no further obligations between the parties.

Private Evofem Series D Preferred Stock Financings

Upon completion of the Merger, Private Evofem's Series D warrant rights issued in connection with the issuance of shares of Private Evofem Series D Preferred Stock in July 2016 were assumed by Neothetics, and exchanged for an aggregate of three shares of the Company's common stock and warrants to purchase up to 2,000,000 shares of the Company's common stock (WIM Warrants). The three shares issued in connection with the WIM Warrants were not, by their terms, able to be separately transferred from the WIM Warrants. The WIM Warrants became exercisable on January 17, 2019 and shall remain exercisable until the earlier of January 17, 2022 or immediately prior to the completion of an acceleration event, as defined, and had an exercise price of $8.35 per share. On February 5, 2019, the Company entered into a repricing letter agreement with WIM. Upon execution of the repricing letter, investment funds managed by WIM exercised their WIM Warrants to purchase an aggregate 1,525,000 shares of common stock at a reduced exercise price of $2.64 per share. On June 10, 2019, upon the Second Closing of the Private Placement as discussed at Note 10- 2019 Private Placement to our Consolidated Financial Statements included in our Annual Report for the fiscal year ended December 31, 2020, the remaining WIM Warrants to purchase up to 475,000 shares of common stock were cancelled.

Reload Warrant Transaction

On February 5, 2019, we entered into letter agreements (the Letter Agreements) with holders of issued and outstanding warrants. These holders consisted of funds, managed by WIM as discretionary investment manager and entities affiliated with Invesco Ltd. (collectively, the Warrant Holders), pursuant to which we offered the Warrant Holders the opportunity to exercise previously issued and outstanding warrants to purchase common stock for cash at a reduced exercise price of $2.64 per share. In addition, on February 8, 2019, we issued common stock warrants (the Reload Warrants) to the Warrant Holders which are exercisable for the number of shares of common stock equal to fifty percent of the shares of common stock issued upon exercise of the previously issued and outstanding warrants in the Letter Agreements which equals an aggregate total of 1,188,029 shares of common stock. The Reload Warrants had an exercise price of $5.20 per share, subject to adjustment for splits and recapitalization as set forth in the Reload Warrants. The Reload Warrants were exercisable at all times beginning on the earlier of the six-month anniversary of their respective issuance dates or the date of approval of the issuance of the Reload Warrants and the shares of common stock issuable upon exercise of the Reload Warrants by our stockholders. The terms of the Reload Warrants also provided for customary resale registration rights (see our registration statement on Form S-3, filed with the SEC on March 11, 2019).

On June 10, 2019, upon the Second Closing of the Private Placement, all the Reload Warrants were cancelled.

Securities Purchase Agreement and Private Placement

2019 Private Placement

On April 10, 2019, we entered into a Securities Purchase Agreement (the Securities Purchase Agreement) with PDL BioPharma, Inc. (PDL), funds discretionally managed by Invesco Ltd. (Invesco) and funds managed by WIM (WIM; collectively with Invesco and PDL, the Purchasers), pursuant to which the Company will issue and sell an aggregate of up to $80.0 million of the Company's common stock and warrants to purchase shares of common stock (collectively, the Securities) in the Private Placement. The Private Placement occurred in two closings.

The first closing was completed on April 11, 2019 (the First Closing), pursuant to which we issued and sold to PDL 6,666,667 shares of our common stock and warrants to purchase up to 1,666,667 shares of common stock for an aggregate purchase price of $30 million, representing a purchase price of $4.50 per share of common stock. The warrants have an exercise price of $6.38 per share.

The second closing was completed on June 10, 2019 (the Second Closing), pursuant to which we issued and sold to the Purchasers 11,111,111 additional shares of common stock and warrants to purchase up to an additional 2,777,779 shares of common stock for an aggregate purchase price of $50 million. The purchase price per share and warrant exercise price per share for securities sold in the Second Closing were the same as those sold in the First Closing.

Upon completion of the First Closing and the Second Closing, we received net proceeds of approximately $28.2 million and $47.2 million, net of $1.8 million and $2.8 million advisory fees, respectively. We used these net proceeds for clinical research and development purposes, including resubmission of our Phexxi New Drug Application to the FDA and pre-commercialization activities, and for general corporate purposes.

Baker Bros. Notes

On April 23, 2020, the Company entered into 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 and Baker Warrants exercisable for 3,073,770 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 Purchasers acquired the remaining Baker Notes with an aggregate principal amount of $10.0 million and Baker Warrants exercisable for 2,049,180 shares of common stock. With the completion of the underwritten public offering in June 2020 as further discussed in Note 10- Stockholders' Equity (Deficit), the exercise price of the Baker Warrants is $2.44. 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.

On November 20, 2021, the Company entered into the first amendment to the Baker Bros. Purchase Agreement (the 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) $2.44 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 security financing until the Company has met the qualified financing threshold (Financing Threshold) defined as one or more equity financings resulting in aggregate gross proceeds to the Company of at least $50 million.

The Baker Amendment also extends the affirmative covenant to achieve $100.0 million in cumulative net sales of Phexxi by June 30, 2022 to June 30, 2023, which will be effective upon the Company's achievement of the Financing Threshold. Additionally per the Baker Amendment, if in any financing closing on or prior to the date the Company has met the Financing Threshold, the Company shall issue warrants to purchase capital stock of the Company (or other similar consideration), to the Baker Purchasers of 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 Baker Notes held by the Baker Purchasers.

Adjuvant Notes

On October 14, 2020, the Company entered into the Adjuvant Purchase Agreement with Adjuvant Global Health Technology Fund, L.P., pursuant to which the Company sold unsecured convertible promissory notes in aggregate principal amount of $25.0 million.

Indemnification Arrangements

We entered into indemnification agreements with each of our officers and directors and purchased directors' and officers' liability insurance. Our indemnification agreements and amended and restated bylaws require us to indemnify our directors and officers to the fullest extent permitted under Delaware law.

Employment Arrangements

We entered into employment arrangements with our named executive officers as is further described under "Current Employment Agreements" above.

Item 14. Principal Accounting Fees and Services.

The following table shows the fees billed by Deloitte & Touche LLP for the audit of our annual financial statements for the last two fiscal years and for other services rendered by Deloitte & Touche LLP to the Company during our last two fiscal years.

	Fiscal Year 2021	Fiscal Year 2020
Audit Fees[1]	$ 857,675	$ 841,453
Audit-Related Fees	—	—
Tax Fees[2]	76,602	157,785
All Other Fees[3]	1,895	1,895
Total	$ 936,172	$ 1,001,133

(1) Audit Fees represent fees and out-of-pocket expenses whether or not yet invoiced for professional services provided in connection with the audit of the Company's financial statements, the review of the Company's quarterly financial statements, professional services in connection with the Company's registration statements on Form S-3 and S-8 and comfort letters, and audit services provided in connection with other regulatory filings.
(2) Tax fees represent fees and out-of-pocket expenses for professional services for tax compliance, tax advice or tax return preparations.
(3) All Other Fees represent annual licensing fees for an accounting database subscription.

Pre-Approval Policies and Procedures

The Audit Committee annually reviews and pre-approves certain audit and non-audit services that may be provided by our independent registered public accounting firm and establishes and pre-approves the aggregate fee level for these services. Any proposed services that would cause us to exceed the pre-approved aggregate fee amount must be pre-approved by the Audit Committee. All audit services for 2021 were pre-approved by the Audit Committee.

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
2.1^	Agreement and Plan of Merger and Reorganization, dated as of October 17, 2017, by and among the Registrant, Evofem Biosciences Operations, Inc. and Nobelli Merger Sub, Inc.		8-K	001-36754	10/17/2017
2.2	Form of Support Agreement, by and between Evofem Biosciences Operations, Inc. and certain of its stockholders.		8-K	001-36754	10/17/2017
3.1	Amended and Restated Certificate of Incorporation.	X			
3.2	Amended and Restated Bylaws of the Registrant.		8-K	001-36754	1/17/2018
3.3	Certificate of Designation of the Series A Preferred Stock of the Company.		8-K	001-36754	3/25/2020
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock.		8-K	001-36754	10/12/2021
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series B-2 Convertible Preferred Stock.		8-K	001-36754	10/12/2021
4.1	Form of Stock Certificate.		10-K	001-36754	2/26/2018
4.2	Warrant to Purchase Stock, dated as of February 23, 2010, issued to Silicon Valley Bank.		S-1	333-199449	10/17/2014
4.3	Warrant to Purchase Stock, dated as of March 30, 2012, issued to Silicon Valley Bank.		S-1	333-199449	10/17/2014
4.4	Warrant to Purchase Stock, dated as of August 17, 2012, issued to Silicon Valley Bank.		S-1	333-199449	10/17/2014
4.5	Warrant Agreement, dated as of June 11, 2014, by and between the Registrant and Hercules Technology III, L.P.		S-1	333-199449	10/17/2014
4.6	Letter Terminating Registrant's Fourth Amended and Restated Investors' Rights Agreement, dated as of January 17, 2018, by and among the Registrant and the investors listed therein.		10-K	001-36754	2/26/2018
4.7	Form of Amended and Restated Warrant to Purchase Common Stock of the Registrant.		S-4	333-221592	11/15/2017
4.8	Rights Agreement, dated as of March 24, 2020, by and between the Company and Philadelphia Stock Transfer, Inc., as rights agent.		8-K	001-36754	3/25/2020
4.9	Form of Voting Agreement.		S-4	333-221592	11/15/2017
4.10	Form of Common Warrant.		S-1	333-224958	5/16/2018
4.11	Form of Pre-Funded Warrant.		S-1	333-224958	5/16/2018
4.12	Form of Reload Warrant.		8-K	001-36754	2/11/2019
4.13	Form of Reload Warrant.		8-K	001-36754	2/11/2019
4.14	Form of Warrant.		8-K	001-36754	4/11/2019
4.15	Form of Warrant for Woodford.		8-K	001-36754	4/11/2019
4.16	Form of Warrant.		8-K	001-36754	4/27/2020
4.17	Form of Warrant to Purchase Common Stock.		8-K	001-36754	5/19/2021
4.18	Form of Warrant.		8-K	001-36754	1/13/2022
4.19^^	Form of Senior Subordinated Note.		8-K	001-36754	1/13/2022
4.20^^	Form of Warrant.		8-K	001-36754	3/1/2022
4.21	Form of Senior Subordinated Note.		8-K	001-36754	3/1/2022
4.22	Description of Evofem's securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934.	X			
9.1	Form of Voting and Support Agreement.		8-K	001-36754	4/11/2019
10.1	Securities Purchase Agreement, dated as of October 17, 2017, by and among the Registrant, Evofem Biosciences Operations, Inc. and the investors listed therein.		8-K	001-36754	10/17/2017

10.2	Form of Repricing Letter Agreement.	8-K	001-36754	2/11/2019
10.3	Form of Repricing Letter Agreement.	8-K	001-36754	2/11/2019
10.4	Securities Purchase Agreement.	8-K	001-36754	4/11/2019
10.5	Registration Rights Agreement.	8-K	001-36754	4/11/2019
10.6	Securities Purchase and Security Agreement, dated as of April 23, 2020, by and among Evofem Biosciences, Inc., its wholly-owned domestic subsidiaries as guarantors, certain affiliates of Baker Bros. Advisors LP, as purchasers, and Baker Bros. Advisors LP, as designated agent.	8-K	001-36754	4/27/2020
10.7	First Amendment to Securities Purchase and Security Agreement, dated as of November 20, 2021, by and among Evofem Biosciences, Inc., certain affiliates of Baker Bros. Advisors LP, as purchasers, and Baker Bros. Advisors LP, as designated agent.	8-K	001-36754	11/22/2021
10.8^^	Securities Purchase Agreement, dated as of January 13, 2022, by and among Evofem Biosciences, Inc. and each investor listed therein.	8-K	001-36754	1/13/2022
10.9	Intellectual Property Security Agreement, dated as of April 23, 2020, by and among Evofem Biosciences, Inc., Evofem, Inc. and Baker Bros. Advisors LP, as collateral agent.	8-K	001-36754	4/27/2020
10.10	Form of Note.	8-K	001-36754	4/27/2020
10.11	Form of Registration Rights Agreement.	8-K	001-36754	4/27/2020
10.12^^	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, L.P., as purchasers.	8-K	001-36754	10/15/2020
10.13	Form of Convertible Promissory Note.	8-K	001-36754	10/15/2020
10.14^^	Registration Rights 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, L.P., as investors.	8-K	001-36754	10/15/2020
10.15	Letter 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, L.P.	8-K	001-36754	10/15/2020
10.16^^	Securities Purchase Agreement, dated as of October 11, 2021, by and between Evofem Biosciences, Inc. and Keystone Capital Partners, LLC.	8-K	001-36754	10/12/2021
10.17^^	Common Stock Purchase Agreement, dated as of February 15, 2022, by and between Evofem Biosciences, Inc. and Seven Knots, LLC	8-K	001-36754	2/16/2022
10.18^^	Securities Purchase Agreement, dated as of March 1, 2022, by and among Evofem Biosciences, Inc. and each investor listed therein.	8-K	001-36754	3/1/2022
10.19Δ	Amended and Restated 2007 Stock Plan, as amended.	S-1/A	333-199449	11/10/2014
10.20Δ	Form of Stock Option Agreement under 2007 Stock Plan.	S-1	333-199449	10/17/2014
10.21Δ	Evofem Biosciences, Inc. Amended and Restated 2014 Equity Incentive Plan.	10-K	001-36754	3/4/2021
10.22Δ	Form of Stock Option Agreement under Amended and Restated 2014 Equity Incentive Plan.	S-1/A	333-199449	11/10/2014
10.23Δ	Form of Restricted Stock Units Agreement under the Amended and Restated 2014 Equity Incentive Plan.	S-1/A	333-199449	11/10/2014
10.24Δ	Form of Restricted Stock Agreement under the Amended and Restated 2014 Equity Incentive Plan.	S-1/A	333-199449	11/10/2014
10.25Δ	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
10.26Δ	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

10.27Δ	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
10.28Δ	2014 Employee Stock Purchase Plan.		S-1/A	333-199449	11/10/2014
10.29Δ	Evofem Biosciences Operations, Inc. Amended and Restated 2012 Equity Incentive Plan.		S-4	333-221592	11/15/2017
10.30Δ	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
10.31Δ	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
10.32Δ	Evofem Biosciences, Inc. Amended and Restated 2018 Inducement Equity Incentive Plan.		10-K	001-36754	3/4/2021
10.33Δ	Form of Notice of Grant of Stock Option under the 2018 Inducement Equity Incentive Plan.		10-Q	001-36754	8/2/2018
10.34	Evofem Biosciences, Inc. 2019 Employee Stock Purchase Plan.		8-K	001-36754	6/5/2019
10.35Δ	Evofem Biosciences, Inc. Incentive Recoupment Policy		10-K	001-36754	3/4/2021
10.36Δ	Amended and Restated Non-Employee Director Compensation Policy (to be effective April 1, 2022).	X			
10.37Δ	Severance Agreement, dated as of November 16, 2015, by and between Evofem Biosciences Operations, Inc. and Justin J. File.		S-4	333-221592	11/15/2017
10.38Δ	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
10.39Δ	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
10.40Δ	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
10.41Δ	Offer Letter, dated as of March 8, 2015, as amended, by and between Evofem Biosciences Operations, Inc. and Justin J. File.		S-4	333-221592	11/15/2017
10.42Δ	Amended Offer Letter, dated as of November 16, 2015, by and between Evofem Biosciences Operations, Inc. and Justin J. File.		S-4	333-221592	11/15/2017
10.43Δ	Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers.		S-1	333-199449	10/17/2017
10.44Δ	Executive Employment Agreement, dated as of July 2, 2018, by and between the Registrant and Saundra Pelletier.		8-K	001-36754	7/3/2018
10.45Δ	Executive Employment Agreement, dated as of July 2, 2018, by and between the Registrant and Justin J. File.		8-K	001-36754	7/3/2018
10.46Δ	Executive Employment Agreement, dated as of July 2, 2018, by and between the Registrant and Kelly Culwell, M.D.		8-K	001-36754	7/3/2018
10.47Δ	Executive Employment Agreement, dated as of July 2, 2018, by and between the Registrant and Russell Barrans.		8-K	001-36754	7/3/2018
10.48Δ	Executive Employment Agreement, dated as of July 2, 2018, by and between the Registrant and Alexander A. Fitzpatrick.		8-K	001-36754	7/3/2018
10.49Δ	Separation and Release Agreement, dated as of January 17, 2018, by and between the Registrant and Susan Knudson.		8-K	001-36754	1/17/2018
10.50Δ	Separation and Release Agreement, dated as of February 6, 2018, by and between the Registrant and Maria Feldman.		10-K	001-36754	2/26/2018

10.51Δ	Confidential Employment Transition Plan and General Release Agreement, dated November 12, 2021.		10-Q	001-36754	11/15/2021
10.52†	Amended and Restated License Agreement, by and between Rush University Medical Center and Evofem, Inc. dated as of March 27, 2014.		S-4	333-221592	11/15/2017
10.53††	Amendment No. 1 to Amended and Restated License Agreement, by and between Rush University Medical Center and Evofem, Inc., dated September 29, 2020		10-Q	001-36754	11/9/2020
10.54	Form of Registration Rights Agreement.		8-K	001-36754	10/17/2017
10.55	Consent to Sub-Sublease, dated as of January 30, 2015, by and among Evofem, Inc., Kilroy Realty, L.P., Relational Investors LLC and WomanCare Global Trading, Inc.		S-4	333-221592	11/15/2017
10.56	Sublease Guaranty, dated as of January 30, 2015, by and between Evofem Biosciences Operations, Inc. and Relational Investors LLC.		S-4	333-221592	11/15/2017
10.57	Office Sublease, dated as of January 30, 2015, by and between Evofem, Inc. and Relational Investors LLC.		S-4	333-221592	11/15/2017
10.58	First Amendment to Sublease, dated as of February 22, 2017, by and between Evofem, Inc. and WomanCare Global Trading Inc.		S-4	333-221592	11/15/2017
10.59	Sublease, dated as of January 30, 2015, by and between Evofem, Inc. and WomanCare Global Trading, Inc.		S-4	333-221592	11/15/2017
10.60	Lease, entered into October 3, 2019, by and between the Registrant and Kilroy Realty, L.P.		10-Q	001-36754	11/7/2019
10.61††	First Amendment to Office Lease, dated as of April 14, 2020, by and between the Registrant and Kilroy Realty, L.P.		10-Q	001-36754	5/6/2020
10.62††	Supply and Manufacturing Agreement, dated November 4, 2019, by and between the Registrant and DPT Laboratories, Ltd.		10-K	001-36754	3/12/2020
10.63Δ	Amended and Restated Non-Employee Director Compensation Policy (currently in effect).	X			
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			

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.
††	Pursuant to Item (6)(10) of Regulation S-K, certain confidential portions of this exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.
^	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, 2021 filed on March 10, 2022 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.

Date: March 10, 2022

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*)	March 10, 2022
/s/ Justin J. File Justin J. File	Chief Financial Officer (*Principal Financial Officer and Principal Accounting Officer*)	March 10, 2022
/s/ Gillian Greer, Ph.D. Gillian Greer, Ph.D.	Director	March 10, 2022
/s/ Kim P. Kamdar, Ph.D. Kim P. Kamdar, Ph.D.	Director	March 10, 2022
/s/ Tony O'Brien Tony O'Brien	Director	March 10, 2022
/s/ Colin Rutherford Colin Rutherford	Director	March 10, 2022
/s/ Lisa Rarick, M.D. Lisa Rarick, M.D.	Director	March 10, 2022

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, 2021 and 2020, the related consolidated statements of operations, comprehensive operations, convertible and redeemable preferred stock and stockholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, 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, has a working capital deficit and negative cash flows from operations since inception that 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.

Convertible Notes 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 (the “Baker Bros. Purchase Agreement”) with certain affiliates of Baker Bros. Advisors LP, as purchasers (the “Baker Purchasers”), pursuant to which the Company agreed to issue and sell to the Baker Purchasers convertible 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, 2021. The Company elected the fair value option (FVO) under ASC 825, Financial Instruments ("ASC 825") and recognized the hybrid debt instrument at fair value inclusive of the Embedded Features. As of December 31, 2021, the Company recorded the fair value of the Baker Notes at $81.7 million.

We identified the Company's determination of the fair value for the Baker Notes as a critical audit matter due to the complexity of the valuation model and the assumptions used to simulate the various scenarios associated with the Embedded Features.

These matters required a high degree of auditor judgement and increased extent of effort, including the need to involve fair value specialists who possess significant quantitative and modeling expertise.

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 tested the accuracy and completeness of the Embedded Features and their impact to assumptions used in the valuation model by agreeing the terms to the Baker Bros. Purchase Agreement and subsequent amendment.

- We evaluated the assumptions used to simulate the various scenarios associated with the Embedded Features by comparing them to management's internal plans, forecasts and board presentations, as well as to those used in the Company's other estimates.

- With the assistance of fair value specialists, we evaluated the acceptability of the valuation model and developed an independent fair value estimate which we then compared to the Company's fair value estimate.

/s/ Deloitte & Touche LLP

San Diego, CA
March 10, 2022

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, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 7,732	$ 48,892
Restricted cash	5,056	22,559
Trade accounts receivable, net	6,449	1,067
Inventories	7,674	7,162
Prepaid and other current assets	3,229	18,050
Total current assets	30,140	97,730
Property and equipment, net	5,774	4,334
Operating lease right-of-use assets	5,395	6,856
Other noncurrent assets	1,203	1,048
Total assets	$ 42,512	$ 109,968
Liabilities, convertible and redeemable preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 10,316	$ 10,641
Convertible notes payable - Baker Bros. (Note 5)	81,717	52,409
Convertible notes payable - Adjuvant (Note 5)	27,209	—
Accrued expenses	8,370	4,476
Accrued compensation	4,653	6,514
Operating lease liabilities – current	2,332	2,290
Derivative liabilities	202	—
Other current liabilities	2,864	953
Total current liabilities	137,663	77,283
Operating lease liabilities – noncurrent	4,424	6,030
Long-term convertible notes payable (Note 5)	—	25,211
Other noncurrent liabilities	—	97
Total liabilities	142,087	108,621
Commitments and contingencies (Note 8)		
Convertible and redeemable preferred stock, $.0001 par value		
Series B-1 convertible preferred stock, 5,000 shares issued and no shares outstanding as of December 31, 2021; no shares issued and outstanding at December 31, 2020	—	—
Series B-2 convertible preferred stock, 5,000 shares and no shares issued and outstanding at December 31, 2021 and 2020, respectively	4,740	—
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized; no equity-classified preferred stock issued and outstanding at December 31, 2021; no shares issued and outstanding at December 31, 2020	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized; 162,500,425 and 81,351,533 shares issued and outstanding at December 31, 2021 and 2020, respectively	16	8
Additional paid-in capital	751,260	656,827
Accumulated other comprehensive income	5,089	—
Accumulated deficit	(860,680)	(655,488)
Total stockholders' equity (deficit)	(104,315)	1,347
Total liabilities, convertible and redeemable preferred stock and stockholders' equity (deficit)	$ 42,512	$ 109,968

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,	
	2021	**2020**
Product sales, net	$ 8,244	$ 446
Operating expenses:		
Cost of goods sold	4,055	468
Research and development	33,129	17,050
Selling and marketing	113,152	56,467
General and administrative	24,709	30,085
Total operating expenses	175,045	104,070
Loss from operations	(166,801)	(103,624)
Other income (expense):		
Interest income	15	169
Other expense	(4,732)	(2,082)
Loss on issuance of financial instruments	—	(64,049)
Change in fair value of financial instruments	(33,657)	27,281
Total other expense, net	(38,374)	(38,681)
Loss before income tax	(205,175)	(142,305)
Income tax expense	(17)	(4)
Net loss	(205,192)	(142,309)
Series B-1 and B-2 convertible preferred stock deemed dividends	(1,047)	—
Net loss attributable to common stockholders	$ (206,239)	$ (142,309)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.58)	$ (2.12)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	130,908,794	67,157,278

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,	
	2021	**2020**
Net loss	$ (205,192)	$ (142,309)
Other comprehensive income:		
Change in fair value of financial instruments attributed to credit risk change	5,089	—
Comprehensive loss	$ (200,103)	$ (142,309)

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)

	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				
Balance at January 1, 2020	—	$ —	48,137,880	$ 5	$ 528,810	$ —	$ (513,179)	$ 15,636
Issuance of common stock in connection with the 2020 Public Offering (see Note 10)	—	—	31,700,000	3	103,263	—	—	103,266
Issuance of common stock in connection with ATM (see Note 10)	—	—	676,656	—	3,362	—	—	3,362
Issuance of common stock - ESPP and exercise of stock options	—	—	150,353	—	360	—	—	360
Issuance of common stock upon cash exercise of warrants and issuance of Reload Warrants	—	—	200	—	2	—	—	2
Restricted stock awards issued/restricted stock units released	—	—	1,356,667	—	—	—	—	—
Shares withheld to cover taxes related to vesting of restricted stock awards	—	—	(670,223)	—	(2,869)	—	—	(2,869)
Short-swing profit disgorgement	—	—	—	—	187	—	—	187
Reclassification from financial instruments liability to equity	—	—	—	—	11,015	—	—	11,015
Stock-based compensation	—	—	—	—	12,697	—	—	12,697
Net loss	—	—	—	—	—	—	(142,309)	(142,309)
Balance at December 31, 2020	—	$ —	81,351,533	$ 8	$ 656,827	$ —	$ (655,488)	$ 1,347
Issuance of common stock in connection with the March 2021 and May 2021 Public Offerings (see Note 10)	—	$ —	72,262,079	$ 8	$ 80,791	$ —	$ —	$ 80,799
Issuance of common stock - ESPP	—	—	460,636	—	297	—	—	297
Issuance of common stock upon cash exercise of warrants	—	—	159,000	—	159	—	—	159
Issuance of series B-1 and B-2 convertible preferred stock in a registered direct offering (see Note 10)	10,000	9,081	—	—	—	—	—	—
Conversion of series B-1 convertible preferred stock	(5,000)	(4,631)	7,936,508	—	5,662	—	—	5,662
Series B-1 and B-2 convertible preferred stock deemed dividends	—	290	—	—	(1,047)	—	—	(1,047)
Restricted stock awards issued	—	—	1,777,500	—	—	—	—	—
Restricted stock awards cancelled	—	—	(1,073,833)	—	—	—	—	—
Shares withheld to cover taxes related to vesting of restricted stock awards	—	—	(372,998)	—	(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	162,500,425	$ 16	$ 751,260	$ 5,089	$ (860,680)	$ (104,315)

See accompanying notes to the consolidated financial statements.

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended December 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (205,192)	$ (142,309)
Adjustments to reconcile net loss to net cash, cash equivalents and restricted cash used in operating activities:		
Loss on issuance of financial instruments	—	64,049
Change in fair value of financial instruments	33,657	(27,281)
Stock-based compensation	8,898	12,697
Depreciation	1,023	302
Noncash lease expenses	1,404	879
Noncash interest expenses	2,665	2,061
Noncash inventory reserve	300	—
Changes in operating assets and liabilities:		
Accounts receivable	(5,382)	(1,067)
Inventories	(21)	(6,010)
Prepaid and other assets	13,882	(17,356)
Accounts payable	(4)	4,126
Accrued expenses and other liabilities	5,471	2,729
Accrued compensation	(1,861)	2,844
Operating lease liabilities	(1,507)	(493)
Net cash, cash equivalents and restricted cash used in operating activities	(146,667)	(104,829)
Cash flows from investing activities:		
Proceeds from sale of Softcup line of business	250	250
Purchases of property and equipment	(2,939)	(2,254)
Maturities of short-term investments	—	8,233
Net cash, cash equivalents and restricted cash (used in) provided by investing activities	(2,689)	6,229
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants, net of discounts and commissions - public offerings	81,534	103,738
Proceeds from issuance of common stock - exercise of warrants	159	2
Proceeds from issuance of common stock, net of commissions - ATM transactions	—	3,781
Proceeds from issuance of common stock - ESPP and exercise of stock options	297	447
Proceeds from issuance of preferred stock - registered direct offering	10,000	—
Borrowings under convertible notes	—	50,000
Short-swing profit disgorgement	—	187
Cash paid for financing costs	(970)	(1,060)
Payments of tax withholdings related to vesting of restricted stock awards	(327)	(2,869)
Net cash, cash equivalents and restricted cash provided by financing activities	90,693	154,226
Net change in cash, cash equivalents and restricted cash	(58,663)	55,626
Cash, cash equivalents and restricted cash, beginning of period	72,251	16,625
Cash, cash equivalents and restricted cash, end of period	$ 13,588	$ 72,251
Supplemental cash flow information:		
Cash paid for interest	$ 1,389	$ —
Cash paid for taxes	$ 11	$ 2
Supplemental disclosure of noncash investing and financing activities:		
Right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ 7,618
Purchases of property and equipment included in accounts payable and accrued expenses	$ 476	$ 823
Reclassification of financial instruments liability to equity	$ —	$ 11,015
Conversion of series B-1 convertible preferred stock to common stock	$ 1,032	$ —

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, including hormone-free, woman-controlled contraception and protection from certain sexually transmitted infections (STIs).

The Company's first commercial product, Phexxi® (lactic acid, citric acid, and potassium bitartrate) 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.

Phexxi is currently being evaluated for two potential new indications, the prevention of chlamydia and gonorrhea in women – two of the most pervasive STIs in the United States. Currently, there are no FDA-approved prescription products for the prevention of either of these dangerous infections.

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 vaginal gel (Phexxi) and/or the completion of the Company's clinical trials, data analysis or readouts and/or any disruption in its supply chain could have a material adverse effect on its business, results of operations and financial condition. The full extent to which the 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, and the 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 has led to a slower than forecasted uptake of Phexxi due to reduced access to medical offices and health care providers (HCPs), and has affected the Company's ability to timely screen and enroll participants in its confirmatory Phase 3 clinical trial of Phexxi to prevent certain STIs *(EVOGUARD)*.

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 described in Note 5- Convertible Notes and Note 10- Stockholders' Equity (Deficit), the Company received net proceeds of approximately $9.6 million upon the sale and issuance of convertible preferred stock from a registered direct offering in October 2021, and net proceeds of approximately $81.5 million upon the sale and issuance of common stock and warrants to purchase common stock from two underwritten public offerings that occurred in the first half of 2021. As of December 31, 2021, the Company had cash

and cash equivalents of $7.7 million, $4.7 million in restricted cash from the Adjuvant Notes (as defined in Note 5- Convertible Notes) that is available for use, a working capital deficit of $107.5 million and an accumulated deficit of $860.7 million.

The Company is subject to risks common to other life science companies in the development and early commercial stage including, but not limited to, uncertainty regarding the commercial success of Phexxi and the development of its pipeline program evaluating Phexxi for the prevention of chlamydia and gonorrhea; potential disruption of its research and development and commercialization activities as a result of the COVID-19 pandemic; lack of marketing and sales history; potential development by its competitors of new and competitive technological innovations; dependence on key personnel; market acceptance of Phexxi or any other future approved products, if any; product liability; protection of proprietary technology; ability to raise additional funds through financings; ability to comply with debt covenants; and compliance with FDA and other government regulations, including post marketing regulations. Management's plans to meet its cash flow needs in the next 12 months include generating recurring product revenue and obtaining additional funding, such as through the issuance of its capital stock, non-dilutive financings, or through collaborations or partnerships with other companies and negotiating possible amendments to our current agreements.

The Company's common stock is listed on the Nasdaq Capital Market, which imposes, among other requirements, a minimum $1.00 per share bid price requirement (the Bid Price Requirement) for continued inclusion on The Nasdaq Capital Market pursuant to the Bid Price Requirement. The closing bid price for the Company's common stock must remain at or above $1.00 per share to comply with the Bid Price Requirement for continued listing. Since July 12, 2021, the closing bid price for the Company's common stock has been below $1.00 per share. On August 23, 2021, the Company received a deficiency letter from the Staff of Nasdaq notifying it, that, for the preceding 30 consecutive trading days, the closing bid price for shares of its common stock was below the minimum $1.00 per share requirement and that the Company had failed to comply with the Bid Price Requirement. In accordance with Nasdaq rules, the Company has been provided until the Compliance Date to regain compliance with the Bid Price Requirement. The Company did not evidence compliance with the Bid Price Requirement by the Compliance Date and, as a result, the Staff of Nasdaq notified it on February 22, 2022 that shares of its common stock were subject to delisting unless the Company timely requested a hearing before the Nasdaq Hearings Panel. The Company timely requested a hearing. Delisting of the Company's shares from the Nasdaq Capital Market would likely result in an event of default under the Company's existing debt arrangements, make shares of the Company's common stock less liquid and make it more difficult for the Company to raise funds when and as needed to fund its operations.

While the Company has recognized limited revenues since the launch of Phexxi in September 2020, the Company anticipates it will continue to incur net losses for the foreseeable future. According to management estimates, liquidity resources as of December 31, 2021 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.

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; enter into collaborative agreements with strategic partners; and otherwise succeed in its future operations raise substantial doubt about the Company's ability to continue as a going concern.

If the Company is not able to obtain the required funding in the near term, through equity or debt financings or other means, or is unable to obtain funding on terms favorable to the Company, there will be a material adverse effect on commercialization and development operations and the Company's 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 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.

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; clinical trial accruals; the assumptions used in estimating the fair value of stock-based compensation expense; and in assessing the probability of achieving certain milestones associated with the performance-based restricted stock awards (performance-based RSAs). These assumptions are more fully described in Note 3- Revenue, Note 5- Convertible Notes, 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 (CEO) 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 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, 2021, 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, 2021, and 2020, the Company's three largest customers combined made up approximately 75% and 92% of its gross product sales, respectively. As of December 31, 2021 and 2020, the Company's three largest customers combined made up 75% and 95%, 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, 2021, 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 $4.7 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.

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,	
	2021	2020
Cash and cash equivalents	$ 7,732	$ 48,892
Restricted cash	5,056	22,559
Restricted cash included in other noncurrent assets	800	800
Total cash, cash equivalents and restricted cash presented in the consolidated statements of cash flows	$ 13,588	$ 72,251

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. As of December 31, 2021 and 2020, based on the borrowing rate currently available to the Company for loans with similar terms, which is considered a Level 2 input, the Company believes the fair value of the Flex Note (as defined below) approximates its carrying value.

Inventory

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. While the Company's current and historical operating losses and negative cash flows are possible indicators of impairment, management believes that future cash flows to be generated by these assets support the carrying value of its long-lived assets and, accordingly, did not recognize any impairment losses during the years ended December 31, 2021 and 2020.

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

The fair value of the warrants issued in April and June 2020 in connection with the Baker Notes (as defined below) were determined using the Black Scholes Merton (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.

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. As the Company's leases 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. 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.

Operating lease ROU assets and lease liabilities were $5.4 million and $6.8 million on December 31, 2021, respectively, and were $6.9 and $8.3 million on December 31, 2020, 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, nonemployee 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 nonemployees:

	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,	
	2021	2020
Unvested restricted common stock subject to repurchase	—	80,000
Common stock to be purchased under the 2019 ESPP	508,656	204,664
Options to purchase common stock	10,625,062	8,935,801
Warrants to purchase common stock	67,767,107	10,426,107
Series B-2 convertible preferred stock	8,333,334	—
Convertible debt	17,882,508	—
Total	105,116,667	19,646,572

Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes* (ASU No. 2019-12), modifying and removing certain exceptions of ASC 740, *Income Taxes*. ASU No. 2019-12 was effective for the Company on January 1, 2021. The adoption of this new standard did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements — Not Yet Adopted

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 Company is currently evaluating the expected impact on the Company's consolidated financial statements.

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, 2021. 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.

As of December 31, 2021, the variable considerations discussed above was recorded in the consolidated balance sheet and consisted of $0.1 million in contra trade accounts receivable and $2.2 million in other current liabilities. As of December 31, 2020, the variable considerations consisted of $1.0 million in other current liabilities.

4. Inventories

The inventory costs include all purchased materials, direct labor and manufacturing overhead. Prior to April 2020, costs incurred for the manufacture of Phexxi were recorded as research and development expenses.

Inventories consist of the following (in thousands) for the period indicated:

	December 31, 2021	December 31, 2020
Raw materials	$ 574	$ 332
Work in process[(1)]	1,712	4,162
Finished goods[(2)]	5,629	2,668
Total[(3)]	$ 7,915	$ 7,162

(1) The work in process balance represents all production costs incurred for partially completed goods.
(2) The finished goods balance as of December 31, 2021 includes a $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. 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 3,073,770 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 2,049,180 shares of common stock. With the completion of the underwritten public offering in June 2020, as further discussed in Note 10-Stockholders' Equity (Deficit), the exercise price of the Baker Warrants is $2.44. 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. Interest expense pertaining to the Baker Notes for the years ended December 31, 2021 and 2020 was approximately $2.8 million and 1.7 million respectively. The Baker Purchasers elected to have the accrued interest for first quarter of 2021 paid-in-kind, and the accrued interest going forward to be paid in cash. 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. The Company accounts for the Baker notes under the fair value method as described below and, therefore, the debt issuance costs were expensed. As of December 31, 2021, the Baker Notes could be converted into 11,484,032 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 $4.99 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, these options are the "Embedded Features" of the Baker Notes. The Baker Notes were convertible at any time at the option of the Baker Purchasers at the conversion price of $2.44 per share prior to the Baker Amendment as defined below.

On November 20, 2021, the Company entered into the first amendment to the Baker Bros. Purchase Agreement (the 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) $2.44 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 security financing until the Company has met the qualified financing threshold (Financing Threshold) defined as one or more equity financings resulting in aggregate gross proceeds to the Company of at least $50 million. Pursuant to the terms of the Baker Amendment, the conversion price was reduced to $0.42 as a result of the Seven Knots Purchase Agreement in February 2022, as described in Note 14- Subsequent Events.

The Baker Amendment also extends the affirmative covenant to achieve $100.0 million in cumulative net sales of Phexxi by June 30, 2022 to June 30, 2023, which will be effective upon the Company's achievement of the Financing Threshold. Additionally per the Baker Amendment, if in any financing closing on or prior to the date the Company has met the Financing Threshold, the Company shall issue warrants to purchase capital stock of the Company (or other similar consideration), to the Baker Purchasers of 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 Baker Notes held by the Baker Purchasers. As of December 31, 2021, no terms of the Baker Amendment have become effective, and therefore, there was no impact on the consolidated financial statements.

The Company's stockholders approved the issuance of the shares issuable upon conversion of the Baker Notes and the exercise of the Baker Warrants in order to comply with Nasdaq Listing Rules 5635(b) and 5635(d) at its special meeting of stockholders held on June 18, 2020 (the Approval Date).

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. The Company also determined that the Baker Warrants and the Baker Purchase Rights were free standing financial instruments and were classified as liabilities at the time of issuance in accordance with ASC 480, *Distinguishing Liabilities From Equity* (ASC 480) due to the required stockholders' approval noted above.

Under the valuation methods as described in Note 7- Fair Value Financial Instruments, the Company recorded the following in the consolidated financial statements related to the Baker Notes and Baker Warrants during the quarter ended June 30, 2020: (i) an aggregate of $58.1 million in convertible notes and an aggregate of $46.7 million for warrants and purchase rights liability at the Baker Initial Closing and Exercise Date; (ii) a $64.0 million loss on issuance of financial instruments

recognized at the Baker Initial Closing in the consolidated statement of operations; (iii) an aggregate $34.1 million gain on fair value changes of financial instruments as a result of mark-to-market adjustments on the Baker Notes, Baker Warrants and Baker Purchase Rights recognized respectively at the Exercise Date, Approval Date and the quarter ended June 30, 2020, in the consolidated statement of operations; (iv) a $15.8 million reclassification from purchase rights liability to the convertible notes and warrants liability on the Exercise Date; and (v) an $11.0 million reclassification from warrants liability to additional paid-in capital in the consolidated balance sheet on the Approval Date. During 2021, the Company concluded that there was a change in the underlying instrument-specific credit risk since the issuance dates for the Baker Notes. As a result of this difference in credit risk, the Company recognized a $5.1 million gain in the fair value of the convertible notes that is presented separately as a component of other comprehensive income. 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.

Using the same valuation methods discussed in Note 7- Fair Value Financial Instruments, the Company recorded a $33.7 million loss in fair value of financial instruments in the consolidated financial statements as a result of mark-to-market adjustments recognized on the Baker Notes for the year ended December 31, 2021. The mark-to-market adjustment in 2021 was in consideration of the increased probability of the failure to meet the affirmative covenant to achieve $100.0 million in cumulative net sales of Phexxi by June 30, 2022, resulting in the Company paying a higher repurchase price.

The Baker Notes contain various customary affirmative and negative covenants agreed to by the Company. The Company was in compliance with all applicable covenants at December 31, 2021. The Baker Notes also include customary events of default as set forth in the Baker Bros. Purchase Agreement, such that, in an event of default, the Baker Purchasers will have the right to accelerate repayment of the aggregate loan balance then outstanding.

As of December 31, 2021, the fair value of the Baker Notes are recorded in the consolidated balance sheet as short-term convertible notes payable with a total balance of $81.7 million, and the total outstanding balance including principal and accrued interest is $28.0 million.

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 long-term convertible notes payable on the accompanying consolidated balance sheet as of December 31, 2021 (in thousands):

	Years Ended December 31,	
	2021	**2020**
Coupon interest	$ 1,959	$ 396
Amortization of issuance costs	39	8
Total	$ 1,998	$ 404

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 $3.65 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 $3.65 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 is $10.00 per share, or (ii) Company achieves cumulative net sales from the sales of Phexxi of $100.0 million, provided such net sales are achieved prior to July 1, 2022. As of December 31, 2021, the Adjuvant Notes could be converted into 7,494,456 shares on common stock.

The Adjuvant Notes contain various customary affirmative and negative covenants agreed to by the Company. The Company was in compliance with all applicable covenants at December 31, 2021. The Adjuvant Notes also include customary

events of default as set forth in the Adjuvant Purchase Agreement, such that, in an event of default, the Adjuvant Purchasers will have the right to accelerate repayment of the aggregate loan balance then outstanding. As of December 31, 2021, the Adjuvant Notes were reclassified from noncurrent to current liabilities in the Consolidated Balance Sheets due to the increased probability of an event of default on certain affirmative covenants, which would trigger potential acceleration repayment at the discretion of the Adjuvant Purchasers.

The Adjuvant Notes are accounted for in accordance with authoritative guidance for convertible debt instruments. The $25.0 million in proceeds is considered to be 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. As of December 31, 2021, there is $4.7 million in proceeds remaining that is included in restricted cash on the accompanying consolidated balance sheet.

As of December 31, 2021, the Adjuvant Notes are recorded in the consolidated balance sheet as short-term convertible notes payable with a total balance of $27.2 million. The balance is comprised of $24.8 million in principal, net of unamortized debt issuance costs, and $2.4 million in accrued interest.

6. Balance Sheet Details

Prepaid and Other Current Assets

Prepaid and other current assets consist of the following (in thousands):

	Years Ended December 31,	
	2021	2020
Insurance	$ 1,144	$ 900
Selling and marketing related costs	1,134	15,414
Manufacturing related costs	322	382
Flex note receivable [(1)]	—	250
Other	629	1,104
Total	$ 3,229	$ 18,050

[(1)] In July 2016, the Company entered into an Asset Purchase Agreement with The Flex Company (Flex), whereby Flex would acquire certain assets and assume certain liabilities associated with the Company's Softcup line of business (Softcup). Total consideration for the Softcup sale was $1.9 million, with $0.6 million received in cash at closing and the remaining $1.3 million due and payable under a note in favor of the Company (the Flex Note) through January 1, 2021 (the Maturity Date). The Flex Note bears simple interest at a rate of 5.0% per annum on the remaining principal amount outstanding. An annual principal payment of approximately $0.3 million and the annual accrued and unpaid interest are payable each January 1, beginning in 2017 through the Flex Maturity Date. The Flex Note is secured by the Softcup assets and has been recorded at fair value. The Company's incremental borrowing rate and the stated interest rate of the Flex Note are materially consistent. The note was paid off on January 4, 2021.

Property and Equipment, Net

Property and equipment, net, consists of the following (in thousands):

		Years Ended December 31,	
	Useful Life	2021	2020
Research equipment	5 years	$ 653	$ 623
Computer equipment and software	3 years	619	444
Office furniture	5 years	881	629
Leasehold improvements	5 years or less	3,388	1,540
Construction in-process	—	2,407	2,249
		7,948	5,485
Less: accumulated depreciation		(2,174)	(1,151)
Total, net		$ 5,774	$ 4,334

Depreciation expense was approximately $1.0 million and $0.3 million for the years ended December 31, 2021 and 2020, respectively.

Other Noncurrent Assets

Other noncurrent assets consist of the following (in thousands):

	Years Ended December 31,	
	2021	2020
Restricted cash included in noncurrent assets	$ 800	$ 800
Inventories, long-term	241	
Prepaid directors & officers' insurance	109	214
Other	53	34
Total	$ 1,203	$ 1,048

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	Years Ended December 31,	
	2021	2020
Clinical trial related costs	$ 5,294	$ 1,417
Selling and marketing related costs	1,997	564
Legal and other professional fees	550	1,631
Manufacturing related costs	201	498
Other	328	366
Total	$ 8,370	$ 4,476

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, 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	$ —	$ —

	December 31, 2020	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]	$ 53,485	$ 53,485	$ —	$ —
Fixed income debt securities classified as cash and cash equivalents	16,498	—	16,498	—
Flex note receivable	250	—	250	—
Total assets	$ 70,233	$ 53,485	$ 16,748	$ —

[1] Included as a component of cash and cash equivalents and restricted cash on the accompanying 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, 2021 and 2020, respectively (in thousands).

					Fair Value	
As of December 31, 2021	**Principal Amount**	**Unamortized Issuance Costs**	**Accrued Interest**	**Net Carrying Amount**	**Amount**	**Leveling**
Baker Notes	$ 27,323	$ —	$ 698	$ 28,021	$ 81,717	Level 3
Adjuvant Notes	25,000	(146)	2,355	27,209	27,209	Level 3

					Fair Value	
As of December 31, 2020	**Principal Amount**	**Unamortized Issuance Costs**	**Accrued Interest**	**Net Carrying Amount**	**Amount**	**Leveling**
Baker Notes	$ 25,000	$ —	$ 1,656	$ 26,656	$ 50,752	Level 3
Adjuvant Notes	25,000	(185)	396	25,211	25,211	Level 3

The following table is a summary of the Company's derivative liabilities as of December 31, 2021 embedded in the convertible preferred stock host contract as discussed in Note 10- Stockholders' Equity (Deficit) (in thousands). No such derivative liabilities as of December 31, 2020.

	Fair Value	
As of December 31, 2021	**Amount**	**Leveling**
Derivative Liabilities	$ 202	Level 3

Change in Fair Value of Level 3 Financial Liabilities

The Baker Warrants and the Baker Purchase Rights, as discussed in Note 5- Convertible Notes, 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 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
Change in fair value presented in the Statements of Operations	21,632	14,422	36,054
Change in fair value presented in the Statements of Comprehensive Operations	(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 Baker Notes measured at fair value on a recurring basis for the years ended December 31, 2020 (in thousands).

	Baker First Closing Notes	Baker Second Closing Notes	Total
Balance at December 31, 2019	$ —	$ —	$ —
Initial liability at issuance	37,405	20,715	58,120
Change in fair value	(6,954)	(414)	(7,368)
Balance at December 31, 2020 [1]	$ 30,451	$ 20,301	$ 50,752

[1] The convertible notes payable as of December 31, 2020 on the accompanying consolidated balance sheet also includes approximately $1.7 million in accrued interest on the Baker Notes.

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, 2021 (in thousands).

	Derivative Liabilities	Total
Balance at December 31, 2020	$ —	$ —
Initial liability at issuance	550	550
Conversion of series B-1 convertible preferred stock	(275)	(275)
Change in fair value presented in the Statements of Operations	(73)	(73)
Balance at December 31, 2021	$ 202	$ 202

Valuation Methodology

Baker Notes

The fair value of the Baker Notes issued as described in Note 5- Convertible Notes, and subsequent changes in fair value recorded at each reporting date, were determined using a Monte Carlo simulation-based model. Monte Carlo simulation 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 Baker Notes, 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.

Baker Warrants

The fair value of the Baker Warrants issued during the second quarter of 2020 as described in Note 5- Convertible Notes, and the respective changes in fair value of these warrants as a result of mark-to-market, were determined using the Black-Scholes option pricing model based on the following weighted-average assumptions for the period indicated.

	Year Ended December 31, 2020
Expected volatility	93.7 %
Risk-free interest rate	0.4 %
Expected dividend yield	— %
Expected term (years)	4.9

Baker Purchase Rights

The fair value of the Baker Purchase Rights, and the subsequent change in fair value of these rights upon exercise of such rights, was determined as the maximum of (i) the fair value of rights to purchase the additional $10 million Baker Notes and (ii) the fair value of the shares of on as-if converted basis, which was determined by the lattice model. The fair value of rights to purchase an additional 2,049,180 Baker Warrants 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 Baker Warrants, the term of the Baker Warrants, the term of the rights to purchase the Baker Warrants, the expected volatility of the Company’s peer group, risk-free interest rate and expected dividend.

Derivative Liabilities

The fair value of the derivative liabilities embedded in the convertible preferred stock host contract as described in Note 10- Stockholders' Equity (Deficit), and subsequent changes in fair value recorded at each reporting date, were determined using a Monte Carlo simulation-based model. Monte Carlo simulation was used to take into account several path dependencies including the future value of the Company's common stock, ability to raise additional funds in near term, risk of dissolution, a potential change of control event, and the probability of converting the remaining shares of convertible preferred stock before they become redeemable.

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. There was a total of 72 leased vehicles as of December 31, 2021. 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, 2021 and 2020, this letter of credit was $0.3 million. The Company determined that the leased vehicles are accounted for as operating leases under ASC 842.

2015 Lease

Effective January 30, 2015, the Company entered into a sublease for office space under a noncancelable lease agreement that expired in March 2020 (the 2015 Lease), which is the Company’s primary office space. The 2015 Lease expired on March 31, 2020.

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, 2021 and 2020, restricted cash maintained as collateral for the Company’s security deposit was $0.8 million.

		Year Ended December 31,	
Lease Cost (in thousands)	**Classification**	**2021**	**2020**
Operating lease expense	Research and development	$ 499	$ 413
Operating lease expense	Selling and marketing	1,012	568
Operating lease expense	General and administrative	827	625
Total		$ 2,338	$ 1,606

Lease Term and Discount Rate	**December 31, 2021**	**December 31, 2020**
Weighted Average Remaining Lease Term (in years)	3.58	4.43
Weighted Average Discount Rate	12 %	12 %

Maturity of Operating Lease Liabilities (in thousands)	Year Ended December 31
2022	$ 2,480
2023	2,163
2024	2,192
2025	1,502
Total lease payments	8,337
Less: imputed interest	(1,581)
Total	$ 6,756

Other information (in thousands)	Year Ended December 31, 2021	Year Ended December 31, 2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash outflows in operating leases	$ 2,426	$ 1,185

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 $3.0 million and $3.7 million for the years ended December 31, 2021 and 2020, respectively.

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- West Palm Beach Division against the Company, alleging trademark infringement of certain trademarks owned by TherapeuticsMD under federal and state law (Case No. 9:20-cv-82296). The Company answered the claims and has counterclaimed against TherapeuticsMD on April 5, 2021 and filed motion for summary judgment. The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome. As of December 31, 2021, there were no other other claims or actions pending against the Company, which management believes has a probable, or reasonably possible, probability of an unfavorable outcome.

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 were $0.2 million and immaterial for the years ended December 31, 2021 and 2020, respectively.

9. Related-party Transactions

Consulting Agreements

Effective April 1, 2019, the Company entered into a two-year consulting agreement with Thomas Lynch (the 2019 Consulting Agreement). The 2019 Consulting Agreement provided for (i) annual compensation of $0.4 million, including $0.1 million related to Mr. Lynch's board services, (ii) an annual grant of 150,000 restricted stock units (RSUs), which vested quarterly over one year from the grant date, and (iii) an annual bonus of up to 100% of Mr. Lynch's annual consulting fees based upon the achievement of the Company's corporate goals and objectives, as determined by and subject to approval of the board of directors. The 2019 Consulting Agreement terminated on April 1, 2020 upon the passing of Mr. Lynch.

Consulting fees incurred under the 2019 Consulting Agreement were zero and $0.1 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021 and 2020, excluding board fees, there was no accrued compensation owed to Mr. Lynch.

10. Stockholders' Equity (Deficit)

Warrants

In April and June 2020, pursuant to the Baker Bros. Purchase Agreement, as discussed in Note 5- Convertible Notes, the Company issued warrants to purchase up to 5,122,950 shares of common stock in a private placement at an exercise price of $2.44 per share. In May 2021, pursuant to the May 2021 Public Offering as defined below, the Company issued warrants to purchase up to 57,500,000 shares of common stock at an exercise price of $1.00 per share, of which warrants to purchase 159,000 shares of common stock were exercised in 2021.

As of December 31, 2021, warrants to purchase up to 67,767,107 shares of the Company's common stock remain outstanding at a weighted average exercise price of $1.54 per share. These warrants are summarized below:

Type of Warrants	Underlying Common Stock to be Purchased	Exercise Price	Issue Date	Exercise Period
Common Warrants	878	$ 51.24	March 30, 2012	March 30, 2012 to March 30, 2022
Common Warrants	1,171	$ 51.24	August 17, 2012	August 17, 2012 to July 17, 2022
Common Warrants	7,806	$ 3.69	June 11, 2014	June 11, 2014 to June 11, 2024
Common Warrants	848,674	$ 7.50	May 24, 2018	May 24, 2018 to May 24 2025
Common Warrants	182	$ 7.50	June 26, 2018	June 26, 2018 to June 26, 2025
Common Warrants	1,666,667	$ 6.38	April 11, 2019	October 11, 2019 to April 11, 2026
Common Warrants	2,777,779	$ 6.38	June 10, 2019	December 10, 2019 to June 10, 2026
Common Warrants	3,073,770	$ 2.44	April 24, 2020	April 24, 2020 to April 24, 2025
Common Warrants	2,049,180	$ 2.44	June 9, 2020	June 9, 2020 to June 9, 2025
Common Warrants	57,341,000	$ 1.00	May 20, 2021	May 20, 2021 to May 22, 2023
Total	**67,767,107**			

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 are convertible into shares of common stock at any time at a conversion price per share of the greater of $0.60 (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 $0.63 per share into 7,936,508 shares of the Company's common stock. Effective January 13, 2022, pursuant to the terms of the Series B-2 Convertible Preferred Stock, the Fixed Conversion Price was reduced to $0.392 as a result of the registered direct offering of unsecured notes, as described in Note 14- Subsequent Events. The Fixed Conversion Price of the Convertible Preferred Stock is subject to continued adjustment until April 25, 2022.

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 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 12/31/2021.

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.

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

On June 5, 2020, the Company completed an underwritten public offering (the 2020 Public Offering), whereby the Company issued 28,500,000 shares of common stock at a price to the public of $3.50 per share (the 2020 Public Offering Price). The Company received proceeds from the 2020 Public Offering of $93.2 million, net of underwriting discounts. In addition, the Company granted the underwriters a 30-day option to purchase up to an additional 4,275,000 shares of its common stock at the Public Offering Price, less applicable underwriting discounts. On June 10, 2020, the Company issued an additional 3,200,000 shares of common stock upon exercise of the underwriters' option and received $10.5 million in proceeds from this exercise, net of underwriting discounts. The common stock issued in the 2020 Public Offering were registered pursuant to a shelf registration statement on Form S-3 filed with the SEC on November 18, 2019 and declared effective on December 2, 2019.

On March 29, 2021, the Company completed an underwritten public offering (the March 2021 Public Offering), whereby the Company issued 17,142,857 shares of common stock at a price to the public of $1.75 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 2,571,428 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.

On May 20, 2021, the Company completed an underwritten public offering (the May 2021 Public Offering), whereby the Company issued 50,000,000 shares of common stock at a price to the public of $1.00 per share and accompanying common warrants to purchase 50,000,000 shares of common stock. The common warrants have an exercise price of $1.00 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 7,500,000 shares of its common stock at $0.99 per share, less applicable underwriting discounts, and/or common warrants to purchase 7,500,000 shares of common stock, at $0.01 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 2,547,794 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.

ATM Program

In November 2019, the Company entered into an Equity Distribution Agreement (the Equity Distribution Agreement) with Piper Sandler & Co. (Piper Sandler), which provided the Company the ability to offer and sell, from time to time, shares of its common stock in ATM offerings (as defined in Rule 415 of the Securities Act of 1933, as amended) having an aggregate offering price up to $50 million through Piper Sandler acting as sales agent. On June 2, 2020, in connection with the aforementioned 2020 Public Offering, the Equity Distribution Agreement was terminated. During the year ended December 31, 2020, the Company received proceeds of approximately $3.8 million in cash and cash equivalents, net of commissions, from the sale of 676,656 shares of its common stock.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance is as follows in common equivalent shares as of December 31, 2021:

Common stock issuable upon the exercise of stock options outstanding	10,625,062
Common stock issuable upon the exercise of common stock warrants	67,767,107
Common stock available for future issuance under the 2019 ESPP	1,833,085
Common stock available for future issuance under the Amended and Restated 2014 Plan	2,701,757
Common stock available for future issuance under the Amended Inducement Plan	794,737
Total common stock reserved for future issuance	83,721,748

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,	
	2021	2020
Research and development	$ 1,357	$ 1,922
Selling and marketing	1,870	2,388
General and administrative	5,671	8,387
Total	$ 8,898	$ 12,697

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), which among other things, increased the number of authorized shares under the 2014 Plan from 749,305 to an aggregate of 7,800,000 shares. On February 25, 2020, the Company's board of directors approved, subject to stockholder approval, and recommended its stockholders approve at the 2020 Annual Meeting, an additional 2,000,000 authorized shares reserved for issuance under the Amended and Restated 2014 Plan to an aggregate of 11,725,515 shares, including the Evergreen Shares, as defined and discussed below. Such stockholder approval was obtained on May 12, 2020. 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. This provision resulted in an additional 5,000,000 shares (Evergreen Shares) added to the total number of authorized shares on January 1, 2022.

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), pursuant to which the Company reserved 250,000 shares for the issuance of equity awards under the Inducement Plan. The Inducement Plan was amended effective February 25, 2020 (the Amended Inducement Plan), which increased the number of authorized shares to an aggregate of 1,250,000 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, 2021:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2020	8,935,801	$ 6.08	7.76	$ 338
Granted	3,208,525	$ 2.77		
Exercised	—	$ —		
Cancelled	(1,519,264)	$ 4.30		
Outstanding as of December 31, 2021	10,625,062	$ 5.34	6.80	$ —
Options vested and expected to vest as of December 31, 2021	10,625,062	$ 5.34	6.80	$ —
Options exercisable as of December 31, 2021	7,384,269	$ 6.26	5.93	$ —

The following table summarizes certain information regarding stock options for the years ended December 31, 2021 and 2020 (in thousands, except per share data):

	2021	2020
Weighted average grant date fair value per share of options granted during the period	$ 2.18	$ 3.20
Fair value per share of options vested during the period	$ 3.15	$ 3.51
Cash received from options exercised during the period	$ —	$ 83
Intrinsic value of options exercised during the period	$ —	$ 47

The Company recognized $6.1 million and $6.0 million in stock-based compensation expense related to stock options for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, unrecognized stock-based compensation expense for employee stock options was approximately $7.3 million, which the Company expects to recognize over a weighted-average remaining period of 2.3 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,			
	2021		2020	
Expected volatility	101.1	%	82.7	%
Risk-free interest rate	0.7	%	0.6	%
Expected dividend yield	—	%	—	%
Expected term (years)	5.9		6.0	

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, 2021:

	Shares (RSAs)	Weighted Average Fair Value per Share
Unvested as of December 31, 2020	80,000	$ 4.78
Granted	1,777,500	$ 3.25
Forfeited	(1,073,833)	$ 3.27
Released	(783,667)	$ 3.36
Unvested as of December 31, 2021	—	$ —

There were 1,777,500 shares and 1,275,000 shares of RSAs granted under the Amended and Restated 2014 Plan and the Inducement Plan during the years ended December 31, 2021 and 2020, respectively, to its executive management team, certain non-executive employees and consultants. Of the total RSAs granted during the years ended December 31, 2021 and 2020, 707,000 and 1,245,000 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.

For the year ended December 31, 2021, the Company recognized $2.5 million in noncash stock-based compensation expense related to RSAs. For the year ended December 31, 2020, the Company recognized $6.5 million in noncash stock-based

compensation expense related to RSAs and RSUs. As of December 31, 2021, 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 500,000 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) 1,000,000 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 250,000 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, 2021 and 2020, there were 460,636 and 128,701 shares of common stock purchased under the 2019 ESPP, respectively.

The Company recognized $0.3 million and $0.2 million in noncash stock-based compensation expense related to the 2019 ESPP for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, unrecognized noncash stock-based compensation expense related to the 2019 ESPP was approximately $0.1 million, which the Company expects to recognize over a weighted-average remaining period of 0.5 years, assuming all unvested shares become fully vested.

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.

	Year Ended December 31, 2021	Year Ended December 31, 2020
Expected volatility	83.9 %	94.8 %
Risk-free interest rate	0.1 %	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, 2021 and 2020, the Company made safe-harbor contributions of approximately $0.8 million and $0.4 million, respectively.

13. Income Taxes

The Company is subject to taxation in the United States, United Kingdom 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, 2021 and 2020 were generated by domestic as follows (in thousands). There are no consolidated pretax loss generated by foreign operations for the periods indicated.

	2021	2020
United States	$ (205,175)	$ (142,305)
Total	$ (205,175)	$ (142,305)

Income tax provision for the years ended December 31, 2021 and 2020 consisted of the following (in thousands):

	2021	2020
United States	$ —	$ —
State	(17)	(4)
Total current tax provision	(17)	(4)
Total deferred tax provision	—	—
Total	$ (17)	$ (4)

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, 2021 and 2020 was as follows:

	2021	2020
Statutory rate	21.00 %	21.00 %
State income tax, net of federal benefit	1.17 %	2.26 %
Nondeductible expenses	(0.48)%	(1.59)%
Equity-based expenses	(0.70)%	(0.76)%
Loss on issuance of financial instruments	— %	(9.48)%
Change in fair value of financial instruments	(3.44)%	4.04 %
Section 382 adjustment	— %	(7.49)%
Return to provision	(0.30)%	0.03 %
Tax credits	0.68 %	0.45 %
Uncertain tax positions	(0.50)%	0.68 %
Change in valuation allowance	(17.43)%	(9.14)%
Effective tax rate	— %	— %

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, 2021 and 2020 (in thousands):

	2021	2020
Deferred tax assets:		
Net loss carryforwards	$ 112,891	$ 78,124
Fixed assets and intangibles	423	538
Research and development credits	5,233	4,059
Stock-based compensation	3,513	3,840
Other	2,726	3,230
Total deferred tax assets	124,786	89,791
Deferred tax liabilities		
Lease assets	(1,218)	(1,621)
Fixed assets	(101)	(457)
Less: valuation allowance	(123,467)	(87,713)
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, 2021, the Company had net operating loss (NOL) carryforwards for federal income tax purposes of approximately $492.1 million, which will begin to expire in 2029 if not utilized. As of December 31, 2021, the Company had NOL carryforwards in various states of approximately $188.6 million. The state carryforwards have varying expiration dates beginning in 2029.

As of December 31, 2021, the Company had federal and state research and development (R&D) tax credit carryforwards of approximately $5.1 million and $2.3 million, respectively. As of December 31, 2020, the Company had federal and state R&D tax credit carryforwards of approximately $3.7 million and $2.1 million, respectively. The federal R&D tax credits begin to expire in 2031, unless utilized, and the state credits do not expire.

The following table summarized the activity related to the Company's gross unrecognized tax benefits as of December 31, 2021 and 2020 (in thousands):

	2021	2020
Balance at the beginning of the year	$ 1,465	$ 2,413
Adjustments related to prior year tax positions	813	(1,177)
Increases related to current year tax positions	401	229
Decreases due to statute of limitation expiration	—	—
Balance at end of year	$ 2,679	$ 1,465

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, 2021. 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, March 10, 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 Purchasers) pursuant to which the Company agreed to offer, issue and sell to the January 2022 Purchasers in a registered direct offering (i) unsecured 5.0% Senior Subordinated Notes due 2025 of the Company 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 15,006,003 shares of the Company's common stock, $0.0001 par value per share. The January 2022 Warrants have an exercise price of $0.392 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, the January 2022 Warrants became exercisable on March 1, 2022.

The January 2022 Notes carry an interest rate of 5% per annum (which may increase to 18% upon and during the continuance of an event of default). The January 2022 Notes may 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 2022 Notes

may require the Company to redeem the January 2022 Notes upon the occurrence of and during the continuation of an event of default with a redemption premium of 25%. The holders of the January 2022 Notes may also require the Company to redeem the January 2022 Notes upon the occurrence of certain subsequent transactions.

Pursuant to the terms of the January 2022 Purchase Agreement, the Company has agreed to certain restrictions on effecting variable rate transactions so long as the January 2022 Notes are outstanding. Also, pursuant to the terms of the January 2022 Purchase Agreement, the January 2022 Purchasers have certain rights to participate in subsequent issuances of the Company's securities, subject to certain exceptions.

On March 1, 2022, the Company entered into a Securities Purchase Agreement (the March 2022 Purchase Agreement) with institutional investors (the March 2022 Purchasers) pursuant to which the Company agreed to offer, issue and sell to the March 2022 Purchasers in a registered direct offering (i) unsecured 5.0% Senior Subordinated Notes due 2025 of the Company with an aggregate issue price of $7.45 million (the March 2022 Notes) which included an original issue discount of $2.45 million, and (ii) warrants (the March 2022 Warrants) to purchase up to 15,568,287 shares of the Company's common stock, $0.0001 par value per share. The March 2022 Warrants have an exercise price of $0.4787 per share and are immediately exercisable with a five year term.

The March 2022 Notes carry an interest rate of 5% per annum (which may increase to 18% upon and during the continuance of an event of default). The March 2022 Notes may 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 March 2022 Notes may require the Company to redeem the March 2022 Notes upon the occurrence of and during the continuation of an event of default with a redemption premium of 25%. The holders of the March 2022 Notes may also require the Company to redeem the March 2022 Notes upon the occurrence of certain subsequent transactions.

Pursuant to the terms of the March 2022 Purchase Agreement, the Company has agreed to certain restrictions on effecting variable rate transactions so long as the March 2022 Notes are outstanding. Also, pursuant to the terms of the March 2022 Purchase Agreement, the March 2022 Purchasers have certain rights to participate in subsequent issuances of the Company's securities, subject to certain exceptions.

Common Stock Purchase Agreement

On February 15, 2022, the Company entered into a common stock purchase agreement (the Seven Knots Purchase Agreement) with Seven Knots, LLC (Seven Knots), pursuant to which Seven Knots has agreed to purchase from the Company up to $50,000,000 in shares of the Company's common stock. Sales made to Seven Knots are at the Company's sole discretion and the Company controls the timing and amount of any and all sales. The price per share is based on the market price of the Company's common stock at the time of sale as computed under the Seven Knots Purchase Agreement. As consideration for Seven Knots's commitment to purchase shares of common stock, the Company issued 1,992,584 shares of common stock to Seven Knots as commitment fee shares and has issued 4,000,000 shares of its common stock at a weighted average purchase price of $0.41 per share.

Sales of common stock to Seven Knots are subject to customary 4.99% and 19.99% beneficial ownership limitations. The Seven Knots Purchase Agreement will terminate on the earliest of March 1, 2024, or when Seven Knots has purchased from the Company $50,000,000 in shares of the Company's common stock, or as otherwise determined by the Seven Knots Purchase Agreement.

Stock Options and Restricted Stock Awards

On February 18, 2022, the Company issued an aggregate 2,360,000 shares of performance-based RSAs to its executive management team and an aggregate 3,019,000 shares of stock options to its employees under the Amended and Restated 2014 Plan. The performance-based RSAs will vest in accordance with the Company's achievement of certain performance milestones in 2022.

Exhibit 3.1

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF NEOTHETICS, INC., a Delaware corporation

State of Delaware
Secretary of State
Division of Corporations
Delivered 01:30 PM 11/24/2014
FILED 01:30 PM 11/24/2014
SRV 141448955 - 4055778 FILE

The undersigned, George Mahaffey, hereby certifies that:

1. He is the duly elected and acting President and Chief Executive Officer of Neothetics, Inc., a Delaware corporation.

2. The Certificate of Incorporation of this corporation was originally filed with the Secretary of State of the State of Delaware on February 1, 2007, under the name Lipothera, Inc., as thereafter amended.

3. The Certificate of Incorporation of this corporation shall be amended and restated to read in full as follows:

ARTICLE I.

The name by which the corporation is to be known is Neothetics, Inc. (the "Corporation").

ARTICLE II.

The address of the Corporation's registered office in the State of Delaware and the County of Kent is 615 South DuPont Highway, Dover, Delaware 19901. The name of its registered agent at such address is National Corporate Research, Ltd. The Corporation may have such other offices, either within or without the State of Delaware, as the Board of Directors of the Corporation (the "Board of Directors") may designate or as the business of the Corporation may from time to time require.

ARTICLE III.

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware, as from time to time amended.

ARTICLE IV.

The total number of shares of all classes of stock which the Corporation shall have authority to issue is 305,000,000 shares, consisting of (a) 300,000,000 shares of common stock, par value $0.0001 per share (the "Common Stock"), and (b) 5,000,000 shares of preferred stock, par value $0.0001 per share (the "Preferred Stock").

The designations, preferences, privileges, rights and voting powers and any limitations, restrictions or qualifications thereof, of the shares of each class are as follows:

(a) The holders of outstanding shares of Common Stock shall have the right to vote on all questions to the exclusion of all other stockholders, each holder of record of Common Stock being entitled to one vote for each share of Common Stock standing in the name of the stockholder on the books of the Corporation, except as may be provided in this Amended and Restated Certificate of Incorporation, in a Preferred Stock Designation (as hereinafter defined), or as required by law.

(b) The Preferred Stock may be issued from time to time in one or more series. The Board of Directors (or any committee to which it may duly delegate the authority granted in this Section (b) of Article IV) is hereby empowered to authorize the issuance from time to time of shares of Preferred Stock in one or more series, for such consideration and for such corporate purposes as the Board of Directors may from time to time determine, and by filing a certificate pursuant to applicable law of the State of Delaware (hereinafter referred to as a "Preferred Stock Designation") as it presently exists or may hereafter be amended to establish from time to time for each such series the number of shares to be included in each such series and to fix the designations, powers, rights and preferences of the shares of each such series, and the qualifications, limitations and restrictions thereof to the fullest extent now or hereafter permitted by this Amended and Restated Certificate of Incorporation and the laws of the State of Delaware, including, without limitation, voting rights (if any), dividend rights, dissolution rights, conversion rights, exchange rights and redemption rights thereof, as shall be stated and expressed in a resolution or resolutions adopted by the Board of Directors (or such committee thereof) providing for the issuance of such series of Preferred Stock. Each series of Preferred Stock shall be distinctly designated. The authority of the Board of Directors with respect to each series of Preferred Stock shall include, but not be limited to, determination of the following:

(i) The designation of the series, which may be by distinguishing number, letter or title.

(ii) The number of shares of the series, which number the Board of Directors may thereafter (except where otherwise provided in the Preferred Stock Designation) increase or decrease (but not below the number of shares thereof then outstanding).

(iii) The amounts payable on, and the preferences, if any, of shares of the series in respect of dividends, and whether such dividends, if any, shall be cumulative or noncumulative.

(iv) Dates at which dividends, if any, shall be payable.

(v) The redemption rights and price or prices, if any, for shares of the series.

(vi) The terms and amount of any sinking fund provided for the purchase or redemption of shares of the series.

(vii) The amounts payable on, and the preferences, if any, of shares of the series in the event of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Corporation.

(viii) Whether the shares of the series shall be convertible into or exchangeable for shares of any other class or series, or any other security, of the Corporation or any other corporation, and, if so, the specification of such other class or series or such other security, the conversion or exchange price or prices or rate or rates, any adjustments thereof, the date or dates at which such shares shall be convertible or exchangeable and all other terms and conditions upon which such conversion or exchange may be made.

(ix) Restrictions on the issuance of shares of the same series or of any other class or series.

(x) The voting rights, if any, of the holders of shares of the series.

ARTICLE V.

The term of existence of the Corporation is to be perpetual.

ARTICLE VI.

The number of its directors shall be determined in the manner provided in the Bylaws of the Corporation.

ARTICLE VII.

Subject to the rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, the Board of Directors of the Corporation shall be divided into three classes designated as Class I, Class II and Class III, respectively. Directors shall be assigned to each class in accordance with a resolution or resolutions adopted by the Board of Directors. To the extent practicable, the Board of Directors shall assign an equal number of directors to Class I, Class II and Class III. At the first annual meeting of stockholders after the filing of this Amended and Restated Certificate of Incorporation, the terms of the Class I directors shall expire and Class I directors shall be elected for a full term of office to expire at the third succeeding annual meeting of stockholders after their election. At the second annual meeting of stockholders, the terms of the Class II directors shall expire and Class II directors shall be elected for a full term of office to expire at the third succeeding annual meeting of stockholders after their election. At the third annual meeting of stockholders, the terms of the Class III directors shall expire and Class III directors shall be elected for a full term of office to expire at the third succeeding annual meeting of stockholders after their election. At each succeeding annual meeting of stockholders, directors elected to succeed the directors of the class whose terms expire at such meeting shall be elected for a full term of office to expire at the third succeeding annual meeting of stockholders after their election. If the number of directors is changed, any increase or decrease shall be apportioned among the classes so as to maintain the number of directors in each class as nearly equal as possible, and any additional director of any class elected to fill a vacancy resulting from an increase in such class shall hold office for a term that shall coincide with the remaining term of that class.

Notwithstanding the foregoing provisions of this Article VII, each director shall serve until such director’s successor is duly elected and qualified or until such director’s death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

ARTICLE VIII.

Subject to the rights of the holders of any series of Preferred Stock with respect to such series of Preferred Stock, any action required or permitted to be taken by the stockholders may be taken without a meeting, without prior notice and without a vote, if a consent in writing, setting forth the action so taken, shall be signed by the holders of record of all of the issued and outstanding capital stock of the Corporation authorized by law or by this Amended and Restated Certificate of Incorporation to vote on such action, and such writing or writings are filed with the permanent records of the Corporation.

ARTICLE IX.

Subject to the rights of the holders of any series of Preferred Stock with respect to such series of Preferred Stock, special meetings of stockholders for the transaction of such business as may properly come before the meeting may only be called by order of the Chairman of the Board of Directors, the Board of Directors (pursuant to a resolution adopted by a majority of the total number of directors that the Corporation would have if there were no vacancies) or the Chief Executive Officer of the Corporation, and shall be held at such date and time, within or without the State of Delaware, as may be specified by such order. If such order fails to fix such place, the meeting shall be held at the principal executive offices of the Corporation.

ARTICLE X.

In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, the Board of Directors of the Corporation is expressly authorized to make, alter and repeal the Bylaws of the Corporation, subject to the power of the stockholders of the Corporation to alter or repeal the Bylaws under

applicable law as it presently exists or may hereafter be amended. Stockholders of the Corporation are authorized to make, alter and repeal the Bylaws of the Corporation only pursuant to Article XV of the Bylaws of the Corporation.

ARTICLE XI.

A director of the Corporation shall not be personally liable either to the Corporation or to any of its stockholders for monetary damages for breach of fiduciary duty as a director, except to the extent such exemption from liability or limitation thereof is not permitted under the General Corporation Law of the State of Delaware as the same exists or may hereafter be amended. Any amendment or modification or repeal of the foregoing sentence shall not adversely affect any right or protection of a director of the Corporation hereunder in respect of any act or omission occurring prior to the time of such amendment, modification or repeal.

ARTICLE XII.

(a) Right to Indemnification. The Corporation shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than said law permitted the Corporation to provide prior to such amendment), any person (a "Covered Person") who was or is a party or is threatened to be made a party to, or is otherwise involved in, any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative in nature (a "proceeding"), by reason of the fact that such Covered Person, or a person for whom he or she is the legal representative, is or was, at any time during which this Section (a) of Article XII is in effect (whether or not such Covered Person continues to serve in such capacity at the time any indemnification or payment of expenses pursuant hereto is sought or at the time any proceeding relating thereto exists or is brought), a director or officer of the Corporation, or has or had agreed to become a director of the Corporation, or is or was serving at the request of the Corporation as a director, officer, trustee, employee or agent of another corporation, limited liability company, partnership, joint venture, employee benefit plan, trust, nonprofit entity or other enterprise, whether the basis of such proceeding is alleged action in an official capacity as a director, officer, trustee, employee or agent or in any other capacity while serving as a director, officer, trustee, employee or agent, against all liability and loss suffered (including, without limitation, any judgments, fines, ERISA excise taxes or penalties and amounts paid in settlement) and expenses (including attorneys' fees), actually and reasonably incurred by such Covered Person in connection with such proceeding to the fullest extent permitted by law, and such indemnification shall continue as to a person who has ceased to be a director, officer, trustee, employee or agent and shall inure to the benefit of his or her heirs, executors and administrators; provided however, that, except as provided in Section (b) of this Article XII, the Corporation shall be required to indemnify a person in connection with a proceeding (or part thereof) initiated by such person only if the proceeding (or part thereof) was authorized by the Board of Directors. The right to indemnification conferred in this Section (a) of Article XII and such rights as may be conferred in the Bylaws of the Corporation shall include the right to be paid by the Corporation the expenses (including attorneys' fees) incurred by a Covered Person in defending any such proceeding in advance of its final disposition, in accordance with the Bylaws of the Corporation. The rights conferred upon Covered Persons in this Section (a) of Article XII shall be contract rights that vest at the time of such person's service to or at the request of the Corporation and such rights shall continue as to a Covered Person who has ceased to be a director, officer, trustee, employee or agent and shall inure to the benefit of the indemnitee's heirs, executors and administrators. The Corporation may, by action of the Board of Directors, provide indemnification to employees and agents of the Corporation with the same (or lesser) scope and effect as the foregoing indemnification of directors and officers.

(b) Right of Claimant to Bring Suit. In accordance with the Bylaws of the Corporation, if a claim for indemnification under Section (a) of this Article XII is not paid in full within sixty (60) days after a written claim has been received by the Corporation, the Covered Person making such claim may at any time thereafter file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim.

(c) Non Exclusivity of Rights. In accordance with the Bylaws of the Corporation, the right to indemnification and the payment of expenses incurred in defending a proceeding in advance of its final

disposition conferred any Covered Person by Section (a) of this Article XII (i) shall not be exclusive of any other rights which such Covered Person may have or hereafter acquire under any statute, provision of this Amended and Restated Certificate of Incorporation, the Bylaws, agreement, vote of stockholders or disinterested directors or otherwise and (ii) cannot be terminated by the Corporation, the Board of Directors or the stockholders of the Corporation with respect to a Covered Person's service occurring prior to the date of such termination.

ARTICLE XIII.

The Corporation may purchase and maintain insurance, at its expense, on behalf of any person who is or was a director, officer, employee or agent of the Corporation, or is or was a director, officer, employee or agent of the Corporation serving at the request of the Corporation as a director, officer, employee or agent of another corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise against any liability, expense or loss asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the Corporation would have the power or the obligation to indemnify such person against such liability, expense or loss under the provisions of the Bylaws of the Corporation or the General Corporation Law of the State of Delaware. To the extent that the Corporation maintains any policy or policies providing such insurance, each such person shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage thereunder for any such person.

ARTICLE XIV.

In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware as they presently exist or may hereafter be amended, subject to any limitations contained elsewhere in this Amended and Restated Certificate of Incorporation, the Corporation may adopt, amend or repeal this Amended and Restated Certificate of Incorporation; provided that Articles VI, VII, VIII, IX, X, XII and this Article XIV may only be amended or repealed by the affirmative vote of the holders of record of no less than 80% of the issued and outstanding shares of the capital stock of the Corporation entitled to vote at the meeting, present in person or by proxy.

The foregoing Amended and Restated Certificate of Incorporation has been duly adopted by this Corporation's Board of Directors and stockholders in accordance with the applicable provisions of Sections 228,242 and 245 of the Delaware General Corporation.

IN WITNESS WHEREOF, Neothetics, Inc. has caused this Amended and Restated Certificate of Incorporation to be signed by its President and Chief Executive Officer this 24 th day of November, 2014.

/s/ George Mahaffey
George Mahaffey
President and Chief Executive Officer

CERTIFICATE OF AMENDMENT TO THE AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF NEOTHETICS, INC.

Neothetics, Inc., a corporation organized and existing under the laws of the State of Delaware (the **"Corporation"**), hereby certifies as follows:

1. The Corporation's original Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on February 1, 2007 under the name Lipothera, Inc,.

2. Article I of the Amended and Restated Certificate of Incorporation, as amended, of the Corporation is hereby amended to read in its entirety as follows:

"The name of the Corporation is Evofem Biosciences, Inc. (hereinafter, the "Corporation")."

3. The following paragraph is hereby inserted after the first paragraph in Article IV of the Amended and Restated Certificate of Incorporation:

"Upon the close of trading on the NASDAQ Capital Market on January 17, 2018 (the "Effective Time"), each six (6) shares of the Common Stock, par value $0.0001 per share, of the Corporation issued and outstanding or held in treasury at the Effective Time shall be reclassified as and changed into one (1) share of Common Stock, par value $0.0001 per share, of the Corporation, without any action by the holders thereof. In lieu of any fractional shares to which a holder of shares of Common Stock of the Corporation would be otherwise entitled, the Corporation shall pay in cash, without interest, an amount equal to such fractional interest (after taking into account and aggregating all shares of Common Stock then held by such holder) multiplied by the closing price of the Common Stock as last reported on the NASDAQ Capital Market on the day of the Effective Time (determined on a post-split basis)."

4. The following new paragraph is hereby inserted as Article XV:

"The Corporation shall not be governed by or subject to the provisions of Section 203 of the Delaware General Corporation Law."

5. This Certificate of Amendment has been duly authorized and adopted by the Corporation's Board of Directors in accordance with the provisions of Section 242 of the Delaware General Corporation Law.

(Signature page follows)

State of Delaware
Secretary of State
Division of Corporations
Delivered 11:17 AM 01/17/2018
FILED 11:17 AM 01/17/2018
SR 20180297165 – File Number 4055778

IN WITNESS WHEREOF, Neothetics, Inc. has caused this Certificate of Amendment to be signed by Susan Knudson, a duly authorized officer of the Corporation, on January 17, 2018.

/s/ Susan Knudson
Susan Knudson
Chief Financial Officer

[Signature page to Certificate of Amendment]

CERTIFICATE OF AMENDMENT
OF
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
EVOFEM BIOSCIENCES, INC.

It is hereby certified that:

FIRST: The name of the corporation is **Evofem Biosciences, Inc.** (the "Corporation").

SECOND: The Amended and Restated Certificate of Incorporation of the Corporation, as amended to date, is hereby further amended by striking out the first paragraph of Article IV in its entirety and by substituting in lieu of the following:

"The total number of shares of all classes of stock which the Corporation shall have authority to issue is 505,000,000 shares, consisting of (a) 500,000,000 shares of Common Stock, $0.0001 par value per share (the "Common Stock") and (b) 5,000,000 shares of Preferred Stock, $0.0001 par value per share (the "Preferred Stock")."

THIRD: The amendment of the Amended and Restated Certificate of Incorporation herein certified has been duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

EXECUTED, effective as of this 15th day of December, 2021.

EVOFEM BIOSCIENCES, INC.

By: /s/ Saundra Pelletier
Saundra Pelletier
President and Chief Executive Officer

State of Delaware
Secretary of State
Division of Corporations
Delivered 01:05 PM 12/15/2021
FILED 01:05 PM 12/15/2021
SR 20214102793 - File Number 4055778

Exhibit 4.22

DESCRIPTION OF EVOFEM BIOSCIENCES, INC.'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2021, Evofem Biosciences, Inc. had two classes of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): common stock, $0.0001 par value per share and Series A Preferred Stock Purchase Rights, $0.0001 par value per share.

Unless the context otherwise requires, all references to "we", "us", the "Company", or "Evofem" in this Exhibit 4.22 refer to Evofem Biosciences, Inc.

DESCRIPTION OF CAPITAL STOCK

The following description of our common stock and preferred stock summarizes the material terms and provisions of our common stock and the preferred stock. For the complete terms of our common stock and preferred stock, please refer to our amended and restated certificate of incorporation and our amended and restated bylaws, each as amended to date, that are incorporated by reference into the registration statement of which this prospectus is a part. The terms of our capital stock may also be affected by the Delaware General Corporation Law (the "DGCL"). The summary below is qualified in its entirety by reference to our amended and restated certificate of incorporation and amended and restated bylaws, as in effect at the time of any offering of securities under this prospectus.

General

Our amended and restated certificate of incorporation authorizes us to issue up to 500,000,000 shares of common stock, $0.0001 par value per share, and 5,000,000 shares of preferred stock, $0.0001 par value per share.

Common Stock

Voting

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our amended and restated certificate of incorporation and amended and restated bylaws do not provide for cumulative voting rights. Because of this absence of cumulative voting, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by our board of directors (our "Board of Directors") out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preferences that may be granted to the holders of any then outstanding shares of preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences, and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock, which we may designate and issue in the future.

Fully-paid

All of the outstanding shares of our common stock are, and the shares of common stock issued upon the conversion of any securities convertible into our common stock will be, fully paid and non-assessable. The shares of common stock offered by this prospectus or upon the conversion of any preferred stock or debt securities or exercise of any warrants offered pursuant to this prospectus, when issued and paid for, will also be, fully paid and non-assessable.

Stock Exchange Listing

Our common stock is listed on The Nasdaq Capital Market under the symbol "EVFM."

Preferred Stock

Our Board of Directors has the authority, without further action by the stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and:

1. to establish from time to time the number of shares to be included in each such series;
2. to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon; and
3. to increase or decrease the number of authorized shares of any such series (but not below the number of shares of such series then outstanding).

Our Board of Directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. In connection with the Company's prior entry into a rights agreement (the "Rights Agreement") with Philadelphia Stock Transfer, as rights agent, the Board approved a certificate of designation setting forth the rights, preferences and limitations of 1,000,000 shares of Series A Preferred Stock. This certificate was filed with the Secretary of State of the State of Delaware on March 24, 2020. The Rights Agreement expired in accordance with its terms on March 24, 2021, and no shares of Series A Preferred Stock were ever issued. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, delay, defer or prevent a change of control of the Company and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

If we offer a specific series of preferred stock under this prospectus, we will describe the terms of the preferred stock in the prospectus supplement for such offering and will file a copy of the restated certificate establishing the terms of the preferred stock with the SEC. To the extent required, this description will include:

- the title and stated value;
- the number of shares offered, the liquidation preference, if any, per share and the purchase price;
- the dividend rate(s), period(s) and/or payment date(s), or method(s) of calculation for such dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- the procedures for any auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provisions for redemption, if applicable;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price (or how it will be calculated) and conversion period;

- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price (or how it will be calculated) and exchange period;
- voting rights, if any, of the preferred stock;
- a discussion of any material and/or special United States federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of the affairs of the Company; and
- any material limitations on issuance of any class or series of preferred stock ranking *pari passu* with or senior to the series of preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of the Company.

Series B Preferred Stock

In connection with a registered direct offering completed in October 2021, the Company filed Certificates of Designation of Preferences, Rights and Limitations (the "Certificates of Designation") with the Secretary of State of the State of Delaware to designate 5,000 shares of Series B-1 Convertible Preferred Stock, par value $0.0001 per share (the "Series B-1 Preferred Stock"), and 5,000 shares of Series B-2 Convertible Preferred Stock, par value $0.0001 per share (the "Series B-2 Preferred Stock"; collectively with the Series B-1 Preferred Stock, the "Series B Preferred Stock"). As of December 31, 2021, there were no shares of Series B-1 Preferred Stock issued and outstanding, and 5,000 shares of Series B-2 Convertible Preferred Stock were issued and outstanding.

Each share of Series B-2 Preferred Stock is convertible (subject to a customary 19.99% exchange cap limitation and a customary 4.99%/9.99% beneficial ownership limitation), at the holder's option, into shares of the Company's common stock As of February 28, 2022, the Series B-2 Convertible Preferred Stock may be converted into shares of the Company's common stock at any time at a conversion price per share equal to the greater of $0.392, 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. The $0.392 portion of the Series B-2 Convertible Preferred Stock conversion price is subject to continued adjustment for certain dilutive issuances until late April 2022.

Each holder of shares of Series B-2 Preferred Stock is entitled to receive dividends on a pari passu basis, when and if declared, on an as-converted-basis with the holders of shares of the Company's common stock, and each share of Series B-2 Preferred Stock carries a liquidation preference equal to $1,000.00 per share for any voluntary or involuntary liquidation or winding up of the Company as well as for certain deemed liquidation events described in the Certificates of Designation.

The holders of the Series B-2 Preferred Stock will not have the right to vote on any matter presented to the holders of the Company's common stock but, the Company may not take the following actions without the prior consent of the holders of at least a majority of the shares of Series B-2 Preferred Stock then outstanding: (i) alter or change adversely the powers, preferences or rights given to the Series B-1 Preferred Stock or Series B-2 Preferred Stock or alter or amend the Certificates of Designation, (ii) amend the Company's certificate of incorporation in any manner that adversely affects any rights of the holders of the Series B-1 Preferred Stock or Series B-2 Preferred Stock, (iii) increase the number of authorized shares of Series B-1 Preferred Stock or Series B-2 Preferred Stock, or (iv) enter into any agreement with respect to any of the foregoing.

Commencing in October 2025 and unless prohibited by Delaware law, the Company will be required to redeem the issued and outstanding shares of Series B-2 Preferred Stock within 60 days following the request of the holders of a majority of the then issued and outstanding shares of Series B-2 Preferred Stock at a price of $1,000 per share. If Delaware law then prohibits the Company from completing a redemption of all the then outstanding shares of Series B-2 Preferred Stock, the Company will be required to ratably redeem the maximum number of shares of Series B-2 Preferred Stock on a pro rata basis as permitted by Delaware law.

There is no established trading market for the Series B Preferred Stock, and the Company does not intend to list the Series B Preferred Stock on any securities exchange or nationally recognized trading system. Without a trading market, the liquidity of the Series B Preferred Stock may be extremely limited.

Registration Rights Agreements

On January 17, 2018, in connection with the Merger, we entered into a registration rights agreement with certain of our stockholders, including funds managed by Invesco Ltd., discretionary investment funds managed by Woodford Investment Management as discretionary investment manager, and funds managed by Domain Partners VII, L.P. Pursuant to the registration rights agreement, we were required to file a registration statement with respect to shares of our capital stock, (the "Registrable Securities"), held by the stockholders who are party to this agreement. Subject to limited exceptions, we are required to maintain the effectiveness of this registration statement until the Registrable Securities covered by this registration have been disposed of or are no longer Registrable Securities. In addition, the rights holders have the right to demand we effect the registration of any or all the Registrable Securities and/or effectuate the distribution of any or all their Registrable Securities subject to certain exceptions and limitations. The rights holders also have customary piggyback registration rights, subject to the limitations set forth in the registration rights agreement. In connection with these obligations, we filed a registration statement on Form S-3 (No. 333-223731) on March 16, 2018 and amended on March 27, 2018, which was declared effective on April 3, 2018.

On April 10, 2019, in connection with a securities purchase agreement and private placement (the "2019 Private Placement"), we entered into a registration rights agreement with PDL BioPharma, Inc., a Delaware corporation, funds discretionally managed by Invesco Asset Management Ltd. and funds managed by Woodford Investment Management Limited. Pursuant to the registration rights agreement, we were required to (i) file a registration statement with the SEC within 30 days following the first closing of the 2019 Private Placement (the "First Closing") registering for resale the shares of our common stock issued in the First Closing and the shares of our common stock issuable upon exercise of the warrants issued in the First Closing (the "First Closing Registration Statement"), (ii) use our commercially reasonable efforts to have the First Closing Registration Statement declared effective, (iii) file a registration statement with the SEC within 30 days following the second closing of the 2019 Private Placement (the "Second Closing") registering for resale the shares of our common stock issued in the Second Closing and the shares of our common stock issuable upon exercise of the warrants issued in the Second Closing (the "Second Closing Registration Statement"), (iv) use our commercially reasonable efforts to have the Second Closing Registration Statement declared effective and (v) maintain the effectiveness of the First Closing Registration Statement and Second Closing Registration Statement until all registrable securities have been sold or may be sold without volume or manner-of-sale restrictions pursuant to Rule 144 under the Securities Act.

The registration rights agreement contains customary terms and conditions for transactions of this type, and includes liquidated damages penalties in the event that we fail to satisfy or maintain the specified filing and effectiveness time periods in the registration rights agreement.

In connection with these obligations, we filed a registration statement on Form S-3 (No. 333-231126) on April 30, 2019 which was declared effective on May 7, 2019, and filed a registration statement on Form S-3 (No. 333-232303) on June 24, 2019 which was declared effective on July 2, 2019.

On April 23, 2020, we entered into a securities purchase and security agreement with certain institutional investors and their designated agent pursuant to which issued and sold to these purchasers convertible senior secured promissory notes in an aggregate principal amount of up to $25.0 million and warrants to purchase shares of our common stock. These purchasers may require us to enter into a registration rights agreement pursuant to which we would grant these purchasers certain demand resale registration rights with respect to the common stock issuable upon conversion of their notes and warrants. The rights under the registration rights agreement will terminate upon the earlier of the tenth anniversary of the date of the agreement or automatically once all applicable registrable securities (i) have been sold pursuant to an effective registration statement, (ii) have been sold by these purchasers pursuant to Rule 144 under the Securities Act or (iii) may be resold by these purchasers without limitations as to volume or manner or sale pursuant to Rule 144.

On October 14, 2020, in connection with a securities purchase agreement and private placement of convertible promissory notes, we entered into a registration rights agreement with Adjuvant Global Health Technology Fund, L.P., and Adjuvant Global Health Technology Fund DE, L.P. Pursuant to the registration rights agreement, we are required to file a registration statement with the SEC within 30 days following the conversion of notes purchased in the private placement with an outstanding balance of at least $5 million registering for resale the shares of our common stock issued upon conversion of these notes. Subject to limited exceptions, we are required to use our commercially reasonable efforts to have this registration statement declared effective, and to maintain the effectiveness of this registration statement until all applicable registrable securities have been sold or may be sold without volume or manner-of-sale restrictions pursuant to Rule 144 under the Securities Act.

Possible Anti-Takeover Effects of Delaware Law and Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Provisions of the DGCL and our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult to acquire the Company by means of a tender offer, a proxy contest or otherwise, or to remove incumbent officers and directors. These provisions, summarized below, are expected to discourage certain types of coercive takeover practices and takeover bids that our Board of Directors may consider inadequate and to encourage persons seeking to acquire control of the company to first negotiate with our Board of Directors. We believe that the benefits of increased protection of our ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure the company outweigh the disadvantages of discouraging takeover or acquisition proposals because, among other things, negotiation of these proposals could result in an improvement of their terms.

Classified Board

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that our Board of Directors is divided into three classes. The directors designated as Class I directors have terms that will expire at the annual meeting of stockholders in 2024. The directors designated as Class II directors will have terms expiring at the annual meeting of stockholders in 2022, and the directors designated as Class III directors will have terms expiring at the annual meeting of stockholders in 2023. Directors for each class will be elected at the annual meeting of stockholders held in the year in which the term for that class expires and thereafter will serve for a term of three years. At any meeting of stockholders for the election of directors at which a quorum is present, the election will be determined by a plurality of the votes cast by the stockholders entitled to vote at the election. Under the classified board provisions, it would take at least two elections of directors for any individual or group to gain control of our Board of Directors. Accordingly, these provisions could discourage a third party from initiating a proxy contest, making a tender offer or otherwise attempting to gain control of the Company.

Removal of Directors

Our amended and restated bylaws provide that our stockholders may only remove our directors with cause, as defined in the amended and restated bylaws.

Amendment

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that the affirmative vote of the holders of at least 80% of our voting stock then outstanding is required to amend certain provisions relating to the number, term, election and removal of our directors, stockholder notice procedures, the calling of special meetings of stockholders and the indemnification of directors.

Size of Board and Vacancies

Our amended and restated bylaws provide that the number of directors on our Board of Directors is fixed exclusively by our Board of Directors. Newly created directorships resulting from any increase in our authorized

number of directors will be filled by a majority of the members of our Board of Directors then in office, provided that a majority of the entire Board of Directors, or a quorum, is present and any vacancies in our Board of Directors resulting from death, resignation, retirement, disqualification, removal from office or other cause will be filled generally by the majority vote of our remaining directors in office, even if less than a quorum is present.

Special Stockholder Meetings

Our amended and restated certificate of incorporation provides that only the Chairman of our Board of Directors, our Chief Executive Officer or our Board of Directors pursuant to a resolution adopted by a majority of the total number of directors it would have if there were no vacancies may call special meetings of our stockholders.

Stockholder Action by Unanimous Written Consent

Our amended and restated certificate of incorporation expressly eliminates the right of our stockholders to act by written consent other than by unanimous written consent.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws provide advance notice procedures with respect to stockholder proposals and nomination of candidates for election as directors other than nominations made by or at the direction of our Board of Directors or a committee of our Board of Directors.

No Cumulative Voting

The DGCL provides that stockholders are denied the right to cumulate votes in the election of directors unless our certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation does not provide for cumulative voting.

Undesignated Preferred Stock

The authority that is possessed by our Board of Directors to issue preferred stock could potentially be used to discourage attempts by third parties to obtain control of the company through a merger, tender offer, proxy contest, or otherwise by making it more difficult or more costly to obtain control of the company. Our Board of Directors may issue additional shares of preferred stock with voting rights or conversion rights that, if exercised, could adversely affect the voting power of the holders of common stock.

Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. We may use additional shares for a variety of purposes, including future public offerings to raise additional capital, to fund acquisitions and as employee compensation. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of the Company by means of a proxy contest, tender offer, merger or otherwise.

The above provisions may deter a hostile takeover or delay a change in control or management of the Company.

Transfer Agent and Registrar

The transfer agent and registrar for our capital stock is Philadelphia Stock Transfer, Inc. The transfer agent and the registrar's address is 2320 Haverford Road, Suite 230, Ardmore, Pennsylvania 19003.

Exhibit 10.36

Amended and Restated Non-Employee Director Compensation Policy

The following non-employee director compensation shall apply to all non-employee directors of the Company effective as of April 1, 2022.

- Each non-employee director will receive an annual cash retainer in the amount of $40,000 per year.
- The Chairperson of the Board will receive an additional annual cash retainer in the amount of $30,000 per year.
- The chairperson of the audit committee will receive additional annual cash compensation in the amount of $20,000 per year for such chairperson's service on the audit committee. Each non-chairperson member of the audit committee will receive additional annual cash compensation in the amount of $10,000 per year for such member's service on the audit committee.
- The chairperson of the compensation committee will receive additional annual cash compensation in the amount of $15,000 per year for such chairperson's service on the compensation committee. Each non-chairperson member of the compensation committee will receive additional annual cash compensation in the amount of $7,500 per year for such member's service on the compensation committee.
- The chairperson of the nominating and corporate governance committee will receive additional annual cash compensation in the amount of $10,000 per year for such chairperson's service on the nominating and corporate governance committee. Each non-chairperson member of the nominating and corporate governance committee will receive additional annual cash compensation in the amount of $5,000 per year for such member's service on the nominating and corporate governance committee.

- Each non-employee directors will receive a stock option grant with an initial grant equal 90,000 shares of the Company's common stock upon a director's initial appointment or election to the Board of Directors, vesting quarterly over a 3 year period and an annual stock option grant equal 90,000 shares of the Company's common stock on the date of each annual stockholder's meeting thereafter, fully vesting in one year from the date of grant.

Rev February 18, 2022

Exhibit 10.63

Amended and Restated Non-Employee Director Compensation Policy

The following non-employee director compensation shall apply to all non-employee directors of the Company.

- Each non-employee director will receive an annual cash retainer in the amount of $50,000 per year.
- The Chairperson of the Board will receive an additional annual cash retainer in the amount of $40,000 per year.
- The chairperson of the audit committee will receive additional annual cash compensation in the amount of $20,000 per year for such chairperson's service on the audit committee. Each non-chairperson member of the audit committee will receive additional annual cash compensation in the amount of $10,000 per year for such member's service on the audit committee.
- The chairperson of the compensation committee will receive additional annual cash compensation in the amount of $15,000 per year for such chairperson's service on the compensation committee. Each non-chairperson member of the compensation committee will receive additional annual cash compensation in the amount of $7,500 per year for such member's service on the compensation committee.
- The chairperson of the nominating and corporate governance committee will receive additional annual cash compensation in the amount of $11,250 per year for such chairperson's service on the nominating and corporate governance committee. Each non-chairperson member of the nominating and corporate governance committee will receive additional annual cash compensation in the amount of $5,000 per year for such member's service on the nominating and corporate governance committee.
- Each non-employee directors will receive a stock option grant with an initial grant equal 90,000 shares of the Company's common stock upon a director's initial appointment or election to the Board of Directors, vesting quarterly over a 3 year period and an annual stock option grant equal 90,000 shares of the Company's common stock on the date of each annual stockholder's meeting thereafter, fully vesting in one year from the date of grant.

Rev Feb 25, 2021

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 Nos. 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 and 333-252516 on Form S-8 of our report dated March 10, 2022, relating to the financial statements of Evofem Biosciences, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ DELOITTE & TOUCHE LLP

San Diego, California
March 10, 2022

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: March 10, 2022 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, Justin J. File, 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: March 10, 2022 By: /s/ Justin J. File

Justin J. File

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, 2021, 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: March 10, 2022 By: /s/ Saundra Pelletier

Saundra Pelletier
President, Chief Executive Officer, and Interim Chairperson of the Board
(Principal Executive Officer)

Date: March 10, 2022 By: /s/ Justin J. File

Justin J. File
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.