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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

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)

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 x

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 x

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 x 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 x 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	x	Smaller reporting company	x
Emerging growth company	x		

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. x

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

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $42,898,789 as of June 30, 2019, 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, 2020, was 49,594,477.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the information required by Part III of Form 10-K will appear in the registrant's definitive proxy statement on Schedule 14A for the 2020 annual meeting of stockholders and are hereby incorporated by reference into this report.

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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.

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

- our projected financial position;
- our estimates regarding expenses, future revenues and capital requirements;
- our ability to continue as a going concern;
- our ability to raise additional capital to fund our operations;
- our ability to obtain the necessary regulatory approvals to market and commercialize our lead Multipurpose Vaginal pH Regulator (MVP-R™) product candidate for prevention of pregnancy, Phexxi™ (formerly known as Amphora) (the U.S. Food and Drug Administration (FDA) has conditionally accepted Phexxi as the trade name for L-lactic acid, citric acid, and potassium bitartrate and its safety and efficacy have not been fully evaluated by any regulatory authority), prevention of urogenital transmission of chlamydia in women and prevention of urogenital transmission of gonorrhea in women, and any other product candidate we may seek to develop;
- the success, cost and timing of our clinical trials;
- our ability to obtain additional patent protection for our product candidates;
- our dependence on third parties in the conduct of our clinical trials;
- our ability to establish and develop sales, manufacturing and marketing capabilities or our ability to enter into agreements with third parties to manufacture or to market and sell any approved product candidates we may have;
- the potential for changes to current regulatory mandates requiring health insurance plans to cover FDA-cleared or approved contraceptive products without cost sharing, our ability to obtain third-party payer coverage and adequate reimbursement, and our reliance on the willingness of patients to pay out-of-pocket absent full or partial third-party payer reimbursement;
- top-line or initial data figures;
- our ability to expand our organization to accommodate potential growth; and
- our ability to retain and attract key personnel.

Our current product candidates have not been approved by the United States Food and Drug Administration (FDA), the European Commission or any other regulatory commission. Our product candidates have not been, nor may they ever be, approved by any regulatory agency or competent authority nor marketed anywhere in the world.

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 document, particularly in the section entitled "*Risk Factors*" of this Annual Report that 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. 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.

Unless the context requires otherwise, (i) references in this Annual Report to "Evofem," "Company," "we," "us" and "our" refer to Evofem Biosciences, Inc. and our subsidiaries, and (ii) references to "Private Evofem" refer to Evofem Biosciences Operations, Inc. and its subsidiaries prior to the closing the Merger as described in the section entitled "Corporate Background" in Part I, Item 1 of this Annual Report.

PART I

Item 1. Business.

Overview

We are a San Diego-based clinical-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health. We exist to advance the lives of women by developing innovative solutions, such as woman-controlled contraception and potential protection from certain sexually transmitted infections (STIs). We are leveraging our proprietary Multipurpose Vaginal pH Regulator (MVP-R™) platform to develop product candidates for several potential indications, including prevention of pregnancy and prevention of certain STIs. In the future, we may also decide to pursue further development of our other MVP-R gel candidate for the reduction of recurrent bacterial vaginosis (BV).

Our MVP-Rs are non-hormonal, acid-buffering bioadhesive vaginal gels designed to regulate vaginal pH within the normal range of 3.5 to 4.5. This vaginal pH range is inhospitable to spermatozoa as well as certain viral and bacterial pathogens associated with certain STIs like chlamydia and gonorrhea, but is integral to the survival of healthy bacteria in the vagina. Our MVP-R's strong bioadhesive properties further inhibit the motility of spermatozoa while also acting as a barrier to spermatozoa penetrating the cervix for an additional level of pregnancy protection.

We are developing our lead MVP-R product candidate, Phexxi™ (formerly known as Amphora) (L-lactic acid, citric acid, and potassium bitartrate), a non-hormonal, on demand, woman-controlled vaginal gel, for three potential indications: prevention of pregnancy, prevention of urogenital *Chlamydia trachomatis* infection (chlamydia) in women and prevention of urogenital *Neisseria gonorrhoeae* infection (gonorrhea) in women.

The U.S. Food and Drug Administration (FDA) has conditionally accepted Phexxi as the trade name for L-lactic acid, citric acid, and potassium bitartrate and its safety and efficacy have not been fully evaluated by any regulatory authority.

In 2014, we completed a randomized, Phase 3 non-inferiority trial for Phexxi as a contraceptive in 3,389 women (AMP001). Phexxi was shown to be non-inferior to the comparator when the complete data set was analyzed in accordance with the pre-specified statistical analysis plan, with a six-month cumulative pregnancy rate of 10.5% with typical use and 4.1% with perfect use. It was well-tolerated with less than 2% of patients experiencing possible treatment-related adverse events (AEs) and no treatment-related serious adverse events (SAEs). On July 2, 2015, pursuant to section 505(b)(2) of the Federal Food, Drug and Cosmetic Act we submitted an NDA for Phexxi to the FDA for the proposed indication of prevention of pregnancy. The submission included, among other things, data from our AMP001 trial as well as other safety and efficacy information. A Complete Response Letter (CRL) was issued by the FDA on April 28, 2016. The primary approvability issue was the difference in results between the United States and Russian cohorts. A Type A meeting was held on October 31, 2016 with the FDA, during which the FDA indicated a confirmatory efficacy trial focused on participants in North America would be required. After further consultation with the FDA, the FDA confirmed a single-arm trial (non-comparative) would be sufficient to address the CRL clinical deficiency. All feedback received from the FDA was incorporated into a protocol for a single-arm trial which was submitted to the FDA on June 30, 2017 (AMPOWER).

In 2018, we completed a second, single-arm Phase 3 trial for Phexxi for the prevention of pregnancy in approximately 1,400 healthy women in the United States (AMPOWER). We have reported top-line data from AMPOWER, which demonstrated a cumulative pregnancy rate of 13.7% over seven cycles of use (95% CI 9.9, 17.4) in the modified intention-to-treat population (referred to as "typical use") which met the pre-determined endpoint of the clinical trial. This corresponds to an 86.3% typical use efficacy rate. We resubmitted the New Drug Application (NDA) to the United States Food and Drug Administration (FDA) in November 2019. The FDA has assigned a six-month review period and a Prescription Drug User Fee Act (PDUFA) goal date of May 25, 2020. Subject to acceptance and timely approval of the NDA by the FDA, we plan to commercialize Phexxi in June 2020.

We believe Phexxi is highly differentiated from other birth control methods currently available or in development. Phexxi is hormone-free and, based on clinical data collected to date, does not exhibit known side effects of traditional hormone-based contraceptives, such as weight gain, headaches, sore breasts, irregular periods, mood changes, decreased sexual desire and nausea. Phexxi is self-administered and we intend to seek regulatory approval for product labeling stating Phexxi can be used on-demand, immediately before or up to one hour before intercourse. In addition, we anticipate Phexxi may provide additional benefits beyond its primary use for prevention of pregnancy, including its lubricant effect for enhanced sexual satisfaction.

We recently concluded a Phase 2b clinical trial of Phexxi for prevention of urogenital transmission of chlamydia and gonorrhea (primary and secondary endpoint, respectively) in women. We refer to this trial as AMPREVENCE. The primary

endpoint of AMPREVENCE is incidence of chlamydia in women treated with Phexxi versus placebo. AMPREVENCE was 100% enrolled at approximately 50 study centers in the United States at the end of March 2019. We reported positive top-line data in December 2019, which 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. We envision our STI program as developing label expansion opportunities to further differentiate Phexxi from other contraceptive products in the market.

Phexxi has been granted Qualified Infectious Disease Product (QIDP) designation by the FDA for the prevention of gonorrhea in women. QIDP designation provides several key potential advantages, including qualification for the FDA Fast Track program and longer market exclusivity, among others. We also received Fast Track designation from the FDA for the development of Phexxi for the prevention of chlamydia.

In the future, we may also decide to pursue development of another MVP-R gel candidate for the reduction of recurrent BV, a potential indication that has been granted QIDP designation by the FDA. In a Phase I 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 have assembled a management team with significant operational experience in the biopharmaceutical market. Specifically, our senior executives have a successful track record of developing and commercializing women's health products including Mirena, Plan B One-Step, Yasmin, YAZ, NuvaRing, Paragard and Seasonique, among others.

Our Strategy

We are committed to providing women with direct control and management of their sexual and reproductive health. Key elements of our strategy include:

- ***Gain regulatory approval of and subsequently commercialize Phexxi***. Our initial focus is the development and successful commercialization of Phexxi as the first hormone-free, on-demand, woman-controlled contraceptive drug product. We intend to build an internal sales force to commercialize Phexxi in the United States, if approved by the FDA. Outside the United States, we intend to evaluate collaborations for commercialization. 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 MVP-R gel technology to develop and commercialize novel, first-in-class products for women***. In addition to pursuing an initial indication for prevention of pregnancy, we plan to pursue an additional indication for the prevention of certain STIs.
- ***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 will continue seeking domestic and international patent protection and endeavor to proactively file patent applications for new commercially valuable inventions.
- ***Build our product portfolio through business development***. We intend to opportunistically acquire additional products or product candidates to enhance our offerings and complement our core competencies in women's health. We will focus on business development in the near to intermediate term to identify compelling acquisition and licensing candidates.
- ***Establish a world-class organization committed to the discovery, development and commercialization of products addressing unmet needs in women's sexual and reproductive health***. We have assembled a world-class team with industry-recognized expertise in the development and commercialization of products in women's health. We intend to continue to build on our leadership position and grow a culture dedicated to the development and commercialization of medicines addressing the unmet needs of women.

Contraceptive Market Overview

In 2018, the global revenue for contraceptive products was approximately $24 billion and projected to grow at 6.8% per annum to exceed $35 billion by 2024, making contraception a substantial and growing subset of the overall healthcare market. This growth is expected to continue to be driven by the United States, where favorable government policies aimed at preventing unwanted pregnancies are in place.

Current contraceptive options include devices designed to prevent pregnancy through physical means such as condoms, diaphragms and intrauterine devices (IUDs), and hormone-based pharmaceutical products, including oral contraceptives, vaginal rings, intramuscular injections, subcutaneous implants and transdermal patches.

Existing contraceptive options can have significant side effects or other limitations. Long-acting options such as IUDs, injections and implants require medical procedures and are not quickly or easily reversible. Hormonal approaches can be

associated with undesirable side effects such as weight gain, loss of libido and mood changes, which may lead women to seek alternative contraceptive technologies or decide not to use any form of contraceptive options currently available. Besides condoms, the only currently available over-the-counter (OTC) products are spermicides. These products are based on surfactants, which can cause genital irritation and inflammation that may increase the risk of contracting human immunodeficiency virus (HIV) or other STIs from an infected partner. As such, spermicides were pulled from most of the European market and are rarely used in the United States. In contrast to most existing contraceptive methods, Phexxi is hormone-free; its primary mechanism of action is to regulate the vaginal pH at the normal healthy level, even in the presence of semen and bacterial pathogens. It can be easily self-administered as needed, non-invasive, and has lubricating properties that may potentially enhance sexual satisfaction. Unlike other vaginal gel contraceptives currently on the market, Phexxi is manufactured with ingredients that are generally recognized as safe, and it is free of surfactants such as nonoxynol-9. We believe these combined attributes may make Phexxi a more desirable option than currently marketed products.

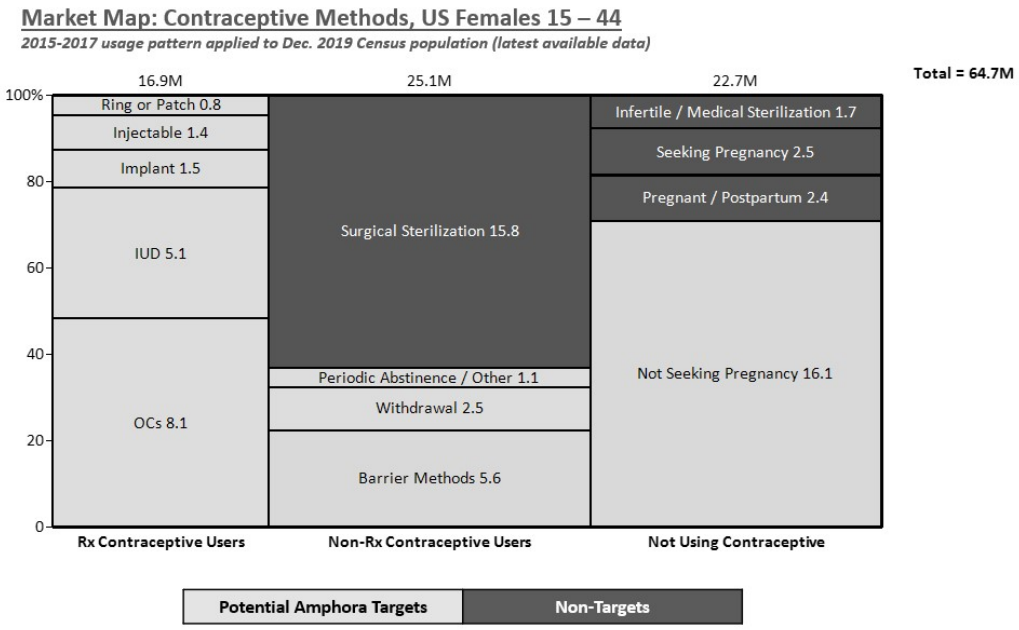
The unmet needs in the contraceptive market and the shift away from traditional methods, such as oral contraceptives, make the entry of a non-hormonal birth control option like Phexxi timely and desirable. Currently, the only non-hormonal prescription contraceptive methods approved in the United States market are a copper IUD and a diaphragm. A copper IUD is a device which requires an invasive, sometimes painful, medical procedure for insertion and may cause heavy menstrual bleeding. In addition, a copper IUD could remain in the user's body for up to 10 years. A diaphragm is a device which can be difficult to insert and must be used with contraceptive gel.

We believe the growing concern associated with the increasing prevalence of sexually transmitted infections along with the recognized need for MVP-Rs and the growing demand for new innovative contraception options that offer additional protective benefits will drive further growth in the global contraceptive market.

United States Contraceptive Market

The total United States contraceptive market was valued at $6.97 billion in 2019 and is expected to grow at a compound annual growth rate of 4.2% from 2020 to 2027 reaching approximately $9.7 billion in 2027. The United States continues to represent the largest segment of the global contraceptive market and is currently dominated by four hormonal methods including birth control pills, IUDs, vaginal rings and subdermal implants representing four of the five top sales generating segments. The only non-hormonal option within the top five is condoms, which ranks #3 in 2019 sales.

As shown in the chart below, 16.1 million US women use no method of birth control, putting them at risk of pregnancy and an additional 9.8 million women in the United States rely on condoms or some other form of non-hormonal contraception (e.g., copper IUD, diaphragm, rhythm, withdrawal). Another 16.4 million women in the United States use hormone-based prescription birth control methods.



European Contraceptive Market

The European contraceptive market was valued at approximately $6.4 billion in 2019 and is estimated to reach $8.7 billion by 2027. Approximately 25% of women in Europe use no contraception and 16.7% use condoms. Among newer products, only IUDs have a double-digit market share in Europe.

The greater European market (inclusive of the European Union (EU)), eastern Europe, and the Commonwealth of Independent States (CIS) has approximately 110 million women of reproductive age eligible for contraceptive use when accounting for factors including sterilization, sexuality, and sexual activity. An analysis of secondary market research from 2017 suggests that approximately 60 million of these women were found to showcase the characteristic of hormone avoidance or were hormone indifferent. Thus, we believe that Phexxi will have the ability to significantly grow the European birth control market through the conversion of non-users, hormonal contraceptive users, and those who will supplement their current methods.

Asia Pacific (APAC) Contraceptive Market

The Asia Pacific region consists of China, Japan, Korea, India, Indonesia, Australia, Vietnam, Thailand, and the Philippines. The total addressable market for hormone avoidance segment in the region is 285 million women with a majority of those women residing in the China, India, and Indonesia. The overall ease of entry across the APAC market varies significantly by country primarily due to their regulatory environment, as well as, strategic implications like pricing, competition, and the diversity of the consumer profile and her behaviors when purchasing or switching contraceptives.

Market Opportunity

Innovation and new product introduction in the women's reproductive healthcare arena have been limited when compared to other therapeutic categories. There have been no innovative contraceptive methods introduced in the United States since NuvaRing was approved in 2001. There are currently no FDA-approved contraceptive products that are indicated for the prevention of chlamydia or gonorrhea.

According to the Centers for Disease Control and Prevention (CDC), reducing the percentage of all unintended pregnancies has been one of the National Health Promotion Objectives since their 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 in the period from 2008 to 2011. Despite this decrease, 45% of pregnancies in the United States are still unintended. Nearly all women with sexual experience in the United States have used some form of contraception in their lives. However, many women may not use contraception consistently or correctly, which may result in an unintended pregnancy. According to research conducted by the CDC, approximately 40% of women surveyed after giving birth to a child resulting from an unintended pregnancy who were not using contraception noted one of the following three reasons for nonuse: did not expect to have sex, worried about side effects of birth control, or male partner did not want to use birth control.

Hundreds of millions of women worldwide seek contraceptive products during their, on average, 30 plus years of fertility. As such, women utilizing contraception consider the most appropriate methods for their purposes and intended use. According to the United Nations, in 2017, model-based estimates indicate approximately 75% of women of reproductive age (18 to 49), worldwide, required some form of family planning. According to the Guttmacher Institute, there are approximately 65 million women of reproductive age in the United States. There are approximately 173 million women of reproductive age located in the greater European market. Additional attractive markets for global expansion include the APAC, where an addressable population of 829 million exist. Brazil and the Russian Federation represent an additional 78 million women of reproductive age in aggregate.

Our Product Candidates

Phexxi as a Contraceptive

We believe Phexxi, our lead MVP-R product candidate, addresses significant gaps in the contraceptive market. If approved by the FDA, Phexxi will be the only hormone-free, on-demand, woman-controlled contraceptive drug product available by prescription in the United States.

We believe Phexxi has significant attributes that will make it an attractive contraceptive choice for women:

Key Attributes	Potential Benefits
Hormone-free	Phexxi is hormone-free and designed to avoid known side effects of hormone-based contraceptives, including weight gain, headaches, sore breasts, irregular periods, mood changes, decreased sexual desire, acne and nausea. These side effects have been shown to discourage women from continuing to use hormonal contraception on a long-term basis, leading them to seek alternative methods or decide to use nothing at all.
On-Demand/Woman-controlled	Phexxi is designed to be used as needed – no need for consistent daily, weekly, or monthly routine – immediately before or up to one hour before intercourse at a woman's discretion.
Bio-adhesive Properties	Phexxi has bio-adhesive and viscosity-retaining properties to form a long-lasting layer of gel over the vaginal and cervical surfaces, which may reduce leakage from the vagina.
Non-invasive	Unlike methods that require a physician to insert the device (i.e. IUD, Implant), Phexxi is free from requiring the invasive procedure at the healthcare providers office.
Personal Lubricant Properties	Phexxi has benefits for use as a personal vaginal lubricant, beyond the primary contraceptive function. We believe Phexxi's personal lubricant properties can reduce friction and ease penetration, enhancing sexual satisfaction.
Ease of Use	The pre-filled Phexxi applicator is designed for convenience and to be stored at room temperature for ease of handling and use.
No Weight Restrictions	Phexxi is designed to be used by women of any Body Mass Index with no weight restrictions, unlike many traditional hormonal birth control options.
No Surgical Procedures	No physician insertion or removal required. The use of Phexxi is private and discrete, requiring no need for recurring doctor appointments, or clinical or surgical procedures.
Cost Effective	We anticipate mandated coverage in the United States under the Affordable Care Act (the ACA). Phexxi is only used when needed, thereby eliminating cost for daily use methods.

The CDC's recommendations for use of combined hormonal birth control options, as shown below, define numerous conditions that create unacceptable health risks if hormonal contraception is used (known as Category 4). The number of women impacted by these conditions is significant. We believe Phexxi, if approved by the FDA, will provide women an attractive solution to avoid hormones and certain other negative side effects from current prescription contraceptives.

Category 4 (a condition that represents an unacceptable health risk if hormonal contraception is used)

- Postpartum < 21 days
- Deep venous thrombosis (current or history with higher risk of recurrence)
- Pulmonary embolism (current or history with higher risk of recurrence)
- Cardiovascular disease or multiple cardiovascular risk factors (preexisting)
- Uncontrolled hypertension
- Major surgery with prolonged immobilization
- Known thrombogenic mutations
- Migraine headaches with aura or without aura in women >/= 35
- Viral Hepatitis (acute or flare)
- Cirrhosis (decompensated)
- Age > 35 years and smoke 15 cigarettes or more per day
- Valvular heart disease (complicated)
- Impaired cardiac function (moderate or severe)
- Systemic lupus erythematosus with positive or unknown antiphospholipid antibodies
- Ischemic heart disease (current or history)

- Stroke (history)
- Diabetes (complicated)
- Breast cancer (current)
- Certain liver tumors
- Solid organ transplantation (complicated)

If approved by the FDA, we believe Phexxi is potentially disruptive to the existing contraceptive landscape and is designed to address underserved and unmet needs in the birth control market, as seen in the table below. We expect to appeal to the 25.9 million women who are currently using no method of birth control or using some other form of non-hormonal contraception methods, as well as, benefit from a favorable shift away from the daily use of oral forms of hormonal birth control options to more innovative technologies that underpin the large and growing global contraceptive market. The table below shows the contraceptive product market and the associated benefits with such products.

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

* Investigational product

We conducted initial market research studies with 152 healthcare providers and 100 obstetrician/gynecologists (OB/GYNs). On a scale of 1-10, approximately 40% of healthcare providers rated their likelihood to prescribe a contraceptive-only version of Phexxi as an 8, 9 or 10. With the added ability to prevent an STI, over 50% of OB/GYNs rated their likelihood to prescribe Phexxi as an 8, 9 or 10 on a 10-point scale.

We conducted additional market research studies with 1024 healthcare providers (476 OB/GYNs, 222 Clinical Staff, and 326 Primary Care Physicians) where we were able to identify those providers whose attitudes indicate they are the most likely to adopt Phexxi early in the launch process. When asked about the likelihood to prescribe once launched, respondents indicated their patients would use Phexxi as their primary form of birth control 15% of the time, which ranks second behind the use of birth control pills.

Similar to our healthcare provider and OB/GYN research, we conducted two separate market research studies with women of reproductive age and healthcare providers in the United States to evaluate potential interest in Phexxi. This market research provided insight on the reasons why Phexxi is appealing, which included the attributes of being non-hormonal and woman-controlled. In one of our market research studies, 71% of the women expressed concerns about hormonal exposure and 58% were not currently satisfied with their contraceptive choice. Our research confirmed there are multiple consumer segments of interest including women seeking prevention of pregnancy and STIs, or older, monogamous women seeking an alternative to hormones and condoms. Overall, approximately 40% of women in two different samples of 287 and 206 consumers rated their likelihood to use Phexxi as an 8, 9, or 10 on a 10-point scale.

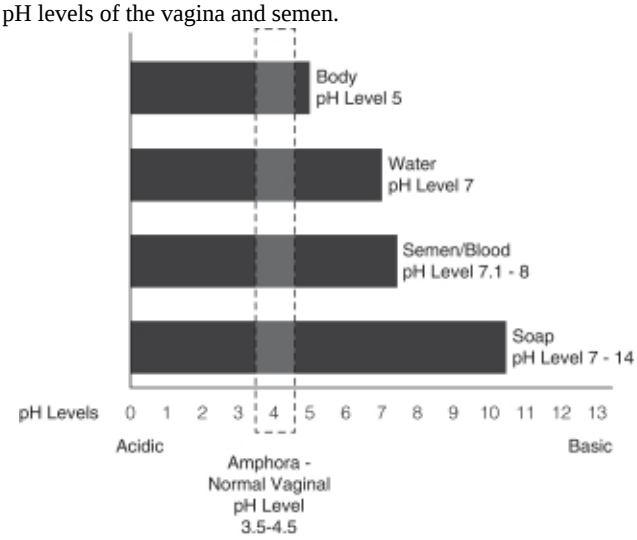
Further, we also performed a consumer segmentation market research project in over 3,000 women to better understand their contraceptive journey; personality traits and life goals in relation to their birth control use/non-use; and their perceptions of hormonal and non-hormonal birth control that shape their attitudes around contraception to identify the ideal “Phexxi woman.” Through this research, we learned that there is a group of 17 million women of reproductive years who clearly fit into the target patient profile because of the importance a healthy lifestyle plays in their lives which includes preference for non-hormonal, on-demand contraception that they control. Additionally, they expressed a high level of interest in new contraceptive options that had fewer side effects, were “natural”, and were not something they had to make part of their daily, weekly, or monthly activities of living.

Multipurpose Vaginal pH Regulator (MVP-R™) Birth Control 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), bio-adhesive, 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. Phexxi prevents pregnancy by maintaining a normal vaginal pH (pH = 3.5-4.5) even in the presence of semen, inhibiting sperm from reaching the ovum to form a zygote. This buffering capacity is due to Phexxi's active pharmaceutical ingredients. Other MVP-R properties contributing to Phexxi's mechanism of action are its capacity to immobilize sperm, maintain sufficient viscosity even upon dilution with the introduction of semen into the vagina and its bio-adhesive strength. Early clinical testing indicated Phexxi may remain active when inserted up to 10 hours prior to intercourse.

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



Phexxi *Clinical Trials*

AMP001 Phase 3 Clinical Trial

A key stage in the development of Phexxi was the completion of a large-scale Phase 3 clinical trial comparing the contraceptive effectiveness, safety and acceptability of Phexxi to Conceptrol, a surfactant-based spermicidal gel containing 4% nonoxynol-9, which is currently available over-the-counter for use as a vaginal contraceptive. The primary endpoint of the trial was the six-month cumulative pregnancy rate. Secondary endpoints included local and systemic signs and symptoms reported by participants or observed upon medical examination, such as itching, burning, irritation, inflammation or lesions to the cervical or vaginal epithelia and vaginal infections.

AMP001 enrolled 3,389 women at 62 research centers in the United States and Russia. This open-label, randomized, non-inferiority trial evaluated the repeated use of Phexxi compared to Conceptrol over seven menstrual cycles. After completing the first seven cycles, some of the women randomized to Phexxi continued for up to a total of 13 cycles (n=341). In a subset of women (75 in each treatment arm) the lower genital tract (cervix, vagina, and vulva) was observed and photographed by colposcopy. The subset was blinded to avoid possible observer bias. A second subset was also examined microbiologically to document any changes in the vaginal flora, particularly the onset of any infection by *Escherichia coli* or yeast.

The trial was fully enrolled in July 2013 and completed during the first half of 2014. In the primary efficacy analysis, the six-month cumulative pregnancy rate for typical use (defined as trial subjects who had at least one episode of coitus without using the product correctly during the study and without any backup or emergency contraception), was approximately 10.5% for Phexxi, as compared to 10.0% for Conceptrol. For those subjects with perfect use (defined as trial subjects who used the product correctly at every episode of coitus within a given cycle), the cumulative pregnancy rate was approximately 4.1% for Phexxi, as compared to 4.2% for Conceptrol. In summary, Phexxi met its primary endpoint of non-inferiority to Conceptrol when the combined United States and Russian data were analyzed in accordance with the pre-specified statistical analysis plan.

Less than 2% of patients using Phexxi experienced an AE that was “definitely” related to treatment. There were no SAEs deemed “definitely” or “probably” related to Phexxi. Of the 30 subjects who experienced at least one SAE, 11 were treated with Phexxi (0.8%) and 19 were treated with Conceptrol (1.3%). There were no SAEs reported in the cycle 8-13 extension phase. Significantly more subjects were highly satisfied Phexxi as compared to Conceptrol and significantly more Phexxi users would use the product again if it were available ($p<0.05$ for both comparisons).

Summary of Initial NDA Submission (Contraceptive Indication)

On July 2, 2015, pursuant to section 505(b)(2) of the Federal Food, Drug and Cosmetic Act we submitted an NDA for Phexxi to the FDA for the proposed indication of prevention of pregnancy. The submission included, among other things, data from the initial Phase 3 clinical trial (AMP001) as well as other safety and efficacy information.

A CRL was issued by the FDA on April 28, 2016. A CRL is issued if the agency determines an application cannot be approved in its present form and will describe all the specific deficiencies identified by the agency. A CRL will also recommend actions the applicant might take to place the application or abbreviated application in condition for approval.

The primary approvability issue was the difference in results between the United States and Russian cohorts. Although the study met its primary endpoint when the combined United States and Russian data were analyzed per the statistical plan, the FDA deemed the data from Russian subjects (approximately 20% of the study population) not generalizable to the United States population. Additionally, the FDA excluded analysis data from certain cycles, specifically data from: cycle 0 (the time from enrollment until the subject's first menstrual cycle); cycles <21 days or >42 days in duration; cycles past 196 days (the aggregate length of seven cycles of 28 days in duration); and cycles in which there was no intercourse.

A Type A meeting was held on October 31, 2016 with the FDA, during which the FDA indicated a confirmatory efficacy trial focused on participants in North America would be required. After further consultation with the FDA, the FDA confirmed a single-arm trial (non-comparative) would be sufficient to address the CRL clinical deficiency. All feedback received from the FDA was incorporated into a protocol for a single-arm trial which was submitted to the FDA on June 30, 2017 (AMPOWER).

Phase 3 Trial (AMPOWER)

We conducted a second, single-arm, Phase 3 trial entitled "A Single-Arm, Phase III, Open Label, Multicenter, Study in Women Aged 18-35 Years of the Contraceptive Efficacy and Safety of Phexxi Contraceptive Vaginal Gel." We refer to this trial as AMPOWER. AMPOWER enrolled approximately 1,400 healthy women aged 18 to 35 at 112 sites in the United States. The first subject enrolled in this trial on July 28, 2017, and enrollment was completed in February 2018. We reported top-line data from AMPOWER in December 2018.

The primary endpoint of the study was the pregnancy rate over seven cycles of use (one cycle 21-35 days) as assessed by the Kaplan-Meier statistical method. Top-line data analysis demonstrates a cumulative pregnancy rate of 13.7% over seven cycles of use (95% CI 9.9, 17.4) in the mITT population (referred to as typical use), which met the pre-determined endpoint of this clinical trial. This corresponds to an 86.3% efficacy rate.

In women who correctly used Phexxi following the study protocol, the cumulative pregnancy rate was 6.7% over seven cycles of use (95% CI 4.6, 8.7), which corresponds to a 93.3% efficacy rate. The "perfect use" or "per protocol" population is a subset of the overall use or "typical" use population that includes all cycles in which the product was used. For a subject to qualify for the perfect use population, she had to indicate via her E-diary that she used the product correctly and without use of another contraceptive method for every act of intercourse for at least one cycle. The results demonstrate that when Phexxi is used as directed, the efficacy is similar to other frequently used contraceptive methods.

Overall in the AMPOWER study there were more than 32,000 acts of intercourse in which Phexxi use was reported and of these, Phexxi was used as directed 88.9% of the time. Less than 2% of women in AMPOWER discontinued due to an adverse event and there were no treatments related serious adverse events. There were minimal side effects reported by AMPOWER study participants.

Adverse events in greater than 2% of Phexxi treated subjects in AMPOWER (safety population):

	Phexxi
	(N=1329)
Preferred term	**n (%)**
Total number (%) of subjects with at least one AE	589 (44.3%)
Bacterial vaginosis/vulvovaginitis	34 (2.6%)
Nasopharyngitis (common cold)	34 (2.6%)
Urinary tract infection	72 (5.4%)
Vulvovaginal mycotic infection/candidiasis	48 (3.7%)
Vulvovaginal burning sensation	263 (19.8%)
Vulvovaginal pruritis (itching)	149 (11.2%)

Demographics of subjects in AMPOWER (intention-to-treat population):

	Phexxi
	(n= 1384)
Age at Enrollment (years)	
Mean	27.7
Median	28
Ethnicity, n (%)	
Hispanic or Latino origin	571 (41.3%)
Not Hispanic or Latino origin	805 (58.2%)
Not reported	8 (0.5%)
Race, n (%)	
Asian	35 (2.5%)
Black or African American	348 (25.1%)
American Indian or Alaska Native	6 (0.4%)
Native Hawaiian or Pacific Islander	2 (0.1%)
White	955 (69.0%)
Other	38 (2.7%)
BMI (kg/m2) at screening	
Mean	28.8
Median	27.0
Min, Max	13.2, 110.5

In addition to the prevention of pregnancy outcome and secondary safety outcomes, this trial also included an exploratory endpoint of sexual satisfaction, which could be further explored in future trials and potentially utilized in labeling and marketing materials for Phexxi. We believe this is the first contraceptive registration trial to include sexual satisfaction as an outcome.

Summary of NDA Resubmission (Contraceptive Indication)

On November 25, 2019, we resubmitted the NDA for our contraceptive product candidate currently known as Phexxi which includes full results from the Phase 3 AMPOWER study, a confirmatory single-arm, open-label Phase 3 trial evaluating the efficacy and safety of Phexxi in approximately 1,400 healthy women aged 18-35 years. The trial was designed with guidance and input from the FDA to address questions raised in the Complete Response Letter received by Evofem in April 2016. Also included in the resubmission was 3-month stability data from our commercial manufacturer, DPT Laboratories Ltd (DPT). According to the FDA's classification, this application will be considered a Class 2 resubmission. The FDA has assigned a six-month review period and a Prescription Drug User Fee Act (PDUFA) goal date of May 25, 2020.

Scientific Advice Process in the EU

We previously conducted a regulatory gap analysis with Pharmalex GmbH to determine how the EU regulatory bodies were likely to view a marketing authorization application (MAA) upon submission to the EU. Scientific advice was previously sought in April 2016 from the Medical Products Agency of Sweden and the Agency of Medicine and Sanitary Products of Spain, but an MAA was not pursued due to a lack of resources to support a filing at that time. We have reinitiated discussions on EU regulatory strategy and plan to seek marketing authorization for Phexxi in the EU through a collaboration with a licensing partner.

Phexxi for STI Prevention

In the United States, the CDC reported there were 1.8 million new cases of chlamydia, the most ever reported, and approximately 583,000 new cases of gonorrhea, also the highest reported, in 2018. We believe this represents a significant commercial opportunity for Phexxi.

Preclinical tests conducted in the early developmental stages by Rush University and later by us, suggest Phexxi has the potential to suppress many of the pathogens responsible for sexually transmitted and commonly occurring bacterial infections while not affecting lactobacilli, a normal and beneficial bacterium found in a healthy vagina.

Researchers at Rush University conducted preclinical studies to assess the ability of Phexxi to prevent transmission of chlamydia in mice. Data from these studies showed Phexxi was highly effective at preventing upper and lower genital tract infection when compared to various vaginally-administered controls containing nonoxynol-9. The following table summarizes the results from the mouse study showing the protective effect of Phexxi compared to several other vaginal gels or no treatment

in the upper and lower genital tract.

Treatment	Lower Genital Tract Protected/inoculated[1]	Upper Genital Tract Protected/Inoculated
No Treatment	2/29 (7%)	4/29 (14%)
Gynol II	6/16 (38%)[2]	6/16 (38%)
K-Y Plus	0/16 (0%)	1/16 (6%)
Advantage-S	3/16 (19%)	3/16 (19%)
Conceptrol	0/16 (0%)	0/16 (0%)
Phexxi	13/16 (81%)[3]	8/8 (100%)[4]

1 Animals defined as infected if *C. trachomatis* was isolated by culture from samples collected on day 3 or 6 post challenge

2 $p < 0.05$ vs. No Treatment

3 $p < 0.001$ vs. No Treatment

4 $p < 0.01$ vs. No Treatment

In another study, Phexxi (at the time called ACIDFORM) was tested for its ability to prevent transmission of gonorrhea in the genital tract compared to other vaginal microbicides in mice. Phexxi displayed significant protection against transmission of gonorrhea, with only 1 of 17 Phexxi-treated mice having positive gonorrhea culture results, compared with 13 of 15 untreated control mice. The following table represents recovery rates from gonorrhea in mice receiving pretreatment or no treatment before intravaginal challenge with gonorrhea strain FA1090:

	Number of mice culture positive for gonorrhea/ total number of mice	
Test Agent	Test Agent	No. Treatment
PRO2000 (0.5%)	0/17	11/12 (91.7%)
CAP gel	0/7	13/15 (86.7%)
Cellulose sulfate	2/11	8/10 (80%)
BufferGel	10/23	14/14 (100%)
CarraGuard	3/20	13/17 (76.5%)
T-PSS (5%)	0/17	11/12 (91.7%)
Carbopol 1382	10/23	14/14 (100%)
Methylcellulose	16/20	13/17 (76.5%)
Phexxi	1/17	13/15 (86.7%)

Of all agents tested, Phexxi was the most highly active against gonorrhea *in vitro*. The following table represents *in vitro* activity of test articles and control agents against seven strains of gonorrhea:

Test Agent	Number of gonorrhea strains inhibited/total number of strains tested				
	Dilution of formulated agent				
	10%	5%	2.5%	1.25%	0.625%
PRO2000	6/7	4/7	2/7	0/7	0/7
CAP gel	6/7	0/7	0/7	0/7	0/7
Cellulose sulfate	1/7	1/7	1/7	0/7	0/7
BufferGel	7/7	3/7	0/7	0/7	0/7
CarraGuard	0/7	0/7	0/7	0/7	0/7
T-PSS[1] (5%)	6/7	5/7	3/7	2/7	1/7
Carbopol 1382	0/7	0/7	0/7	0/7	0/7
Methylcellulose	0/7	0/7	0/7	0/7	0/7
Phexxi	7/7	7/7	7/7	6/7	6/7

[1] T-PSS =polysodium 4-styrene sulfonate

Phase 2 Trial for STI Prevention (AMPREVENCE)

Building on the microbicide potential of Phexxi demonstrated in preclinical trials, we recently completed AMPREVENCE: a double-blinded, placebo-controlled pivotal Phase 2b trial to evaluate the efficacy of Phexxi for the prevention of sexual transmission of two common STIs, 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, consistent with previous trial results for use of this investigational drug for pregnancy prevention. The number of adverse events was similar across both arms (7.2% for Phexxi and 7.5% for placebo), and no serious treatment-related adverse events were reported.

FDA previously indicated that if AMPREVENCE met its primary endpoint, it may be considered as one of two pivotal trials required for approval of Phexxi for the prevention of chlamydia in women, for which it has been granted Fast Track designation by the FDA. The FDA's Fast Track program is intended to expedite or facilitate the process of reviewing new drugs and provides eligibility for priority review, if relevant criteria are met. We plan to request an end of Phase 2 meeting in the first half of 2020 to confirm this as well as obtain agreement on the Phase 3 study design.

As previously noted, Phexxi has been granted QIDP designation by the FDA for the prevention of urogenital gonorrhea infection in women.

Pre-Commercialization and Commercialization Strategy

We plan to implement a global strategy to commercialize Phexxi, if approved by the FDA. In the United States, our plan is to build our own integrated sales and marketing infrastructure. Outside of the United States, we expect to leverage global pharmaceutical companies or other qualified potential partners to license commercialization rights or enter collaborations for the commercialization and distribution of Phexxi.

While awaiting the decision from the FDA as to the approval of Phexxi, our planned pre-commercialization activities will include:

- the selection of commercial suppliers, which includes agency of record for the Phexxi brand, hiring of sales and sales support personnel to support our anticipated commercialization of Phexxi, initiation of payer programs including the addition of medical science liaisons and national/key account managers, and the selection of third-party logistic provider(s); and
- the optimization of manufacturing capabilities to include the installation of new equipment into manufacturers' facilities, planning and preparing for all requisite inspections, planning for process validation and registration batch quantities, and establishing secondary (back-up) manufacturing capability.

United States

We estimate the United States market is the largest commercial opportunity for our product candidates. If Phexxi is approved for commercialization by the FDA, we intend to establish a commercial sales force to market Phexxi directly to obstetricians and OB/GYNs who write the majority of prescriptions for contraceptive products.

The top 10% of prescribers (98% of which are OB/GYNs) account for 46% of the annual contraception prescriptions in the United States. The American Congress of Obstetricians and Gynecologists (ACOG) reports there are approximately 36,000 fellows currently practicing in the United States. We intend to target the top 30% by deploying a sales force of approximately 140 sales representatives and managers. Our healthcare provider segmentation project will aid in our targeting of those high-volume potential providers whose attitudes suggest they will be early adopters based on their beliefs that the best form of birth control for women is one they will use. Evofem's sales team will be complemented by print and digital advertising, social media campaigns, access programs, educational campaigns, and non-personal promotion campaigns targeting both consumers and healthcare providers.

Successful prescription drug market launches require comprehensive and integrated pre-launch activities. We have assembled an experienced team of key account managers and medical science liaisons expected to focus on ensuring key payer accounts, pharmacy benefit managers, key opinion leaders and medical associations who are educated about the need to offer a wider set of options to women seeking non-hormonal, woman-controlled contraceptive methods. We expect these educational activities will be supported by presentation of clinical data at key national congresses (such as the annual meetings of ACOG, 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. Our pre- and post-commercialization activities are expected to include multi-channel marketing campaigns to raise brand awareness, including direct-to-consumer and health care

professional campaigns. These key initiatives will be supported by awareness campaigns in social media, online and print advertisements, paid and earned social media support, and public relations efforts. We expect these campaigns to encourage patients to consult their healthcare providers and ensure payer and healthcare provider strategies are implemented.

Ex-United States Markets

In markets outside of the United States, if our MVP-R product candidate is approved for marketing in an individual market, 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 the applicable product candidate in that market.

Payer and Reimbursement Strategy

United States

We have conducted market research with 45 different healthcare plans covering approximately 80% of covered lives within the United States to better understand viable access and pricing strategies for Phexxi. Overall, a majority of respondents were positive about the introduction of a new contraceptive method. These respondents cited the many unintended pregnancies, high costs associated with unwanted pregnancies, and the underlying limitations in the contraceptive category (i.e. the lack of non-hormonal options) as reasons a new contraceptive option is desirable. We aim to have approximately 60% of all commercial healthcare plans offering full access and complete coverage of Phexxi for all the reproductive aged women's lives they are managing by the end of the first year of commercialization of Phexxi. This coverage is expected to build to approximately 85% to 90% at peak sales.

Pricing Strategy

Overall, healthcare plans appear receptive to the idea of pricing Phexxi like that of branded oral contraceptives. Healthcare plans interviewed during market research expected Phexxi to be priced between $100 and $200 for a monthly supply of a 12-applicator box (comparable to branded contraceptives), believing Phexxi would ultimately offset other costs the payer may incur (i.e. unwanted pregnancies).

Third-party Payers

Market acceptance and sales of Phexxi and our other MVP-R gel product candidate, if approved by the FDA, 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 candidates we develop will be made on a payer-by-payer basis. One payer's determination to provide coverage for a drug does not assure 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. The United States 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. We may incur significant costs to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain FDA 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, healthcare providers may not prescribe them or patients may ask their healthcare providers 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, which might not include all the approved products for a particular indication, to control costs by negotiating discounted prices in exchange for formulary inclusion. We intend to target those healthcare plans managing the largest number of covered lives to achieve optimal access for our product portfolio.

Europe

Our market research found that EU consumers were interested in the unique benefits of Phexxi product profiles, especially since Phexxi is non-hormonal. Contraceptive products are not reimbursed in all the EU member countries. For example, in Italy there is no coverage for contraceptives, in France and Spain, only oral contraceptives are generally covered, and in Germany, individual reimbursement policies apply.

Pricing and reimbursement

In the EU, pricing and reimbursement strategies vary widely from country to country. Some countries mandate that drug products may be marketed only after a reimbursement price has been agreed, while others may require the completion of additional studies that compare the cost-effectiveness of a product candidate to currently available therapies. For example, the EU provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of offering a drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become intense, creating increasingly high barriers for entry of new products. In addition, in some countries, cross-border imports from lower-priced markets exert competitive pressure that may reduce pricing within a country. Therefore, the development of new drug launch strategies has become very challenging to meet both patient need/demand while ensuring products are commercially viable in those markets.

APAC

We believe the APAC region offers a major commercial opportunity across multiple regions in the Asia Pacific with 30% of women indicating they have hormonal avoidance tendencies. China is the largest overall market opportunity in terms of both population size and total birth control market value. Japan is the second largest in terms of total birth control market value. When looking at the opportunity in terms of frequency of birth control usage, China and India are the two largest APAC markets. China is the most significant commercial opportunity for the birth control/STI MVP-R gel followed by India and Indonesia due to their ease of market entry and their sizeable market opportunities.

Pricing and Reimbursement

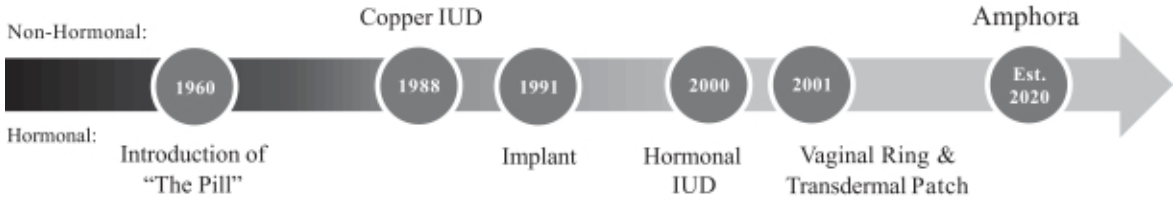
In APAC, the patient journey to birth control, whether it is prescription or over-the-counter, differs based on the level of involvement from healthcare providers. However, since a majority of women access birth control over-the-counter in the APAC region, it will be important to develop a pricing strategy that considers the average price per sexual encounter by the type of birth control method. Further, an inclusive regional strategy will be required to contemplate consumer behaviors and key influencers as a part of go to market strategy in each of these regions to ensure commercial viability.

Phexxi Manufacturing

We plan to outsource the manufacturing of Phexxi (and our other potential product candidates) to third parties. We are currently contracted with DPT, a gel manufacturer located in San Antonio, Texas, to manufacture Phexxi and potential other product candidates 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.

Contraceptive Market Landscape

As shown below, the contraception market was established in 1960 with the introduction of “the pill,” the first oral contraceptive widely available to women in the United States. This high-dose hormonal option remained the primary form of available contraception on the market until 1988 when the copper IUD was introduced, offering the first hormone-free option for birth control. As shown in the time line below, there was no notable innovation providing additional options in women’s reproductive health until 30 years after the introduction of “the pill,” when pharmaceutical companies introduced synthetic hormonal products with different hormonal delivery systems, including the hormonal IUD, implants, the patch, and vaginal ring.



If approved by the FDA, we expect that Phexxi will grow the prescription birth control user market when considering the 25.9 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 four categories: 1) oral contraception, 2) Long-Acting Reversible Contraception

(LARC), comprising implants and IUDs, 3) non-oral hormonal contraceptives, comprising weekly or monthly options including the patch, vaginal ring and injectables, and 4) OTC methods, dominated primarily by the condom.

Oral Contraceptives (the "pill")

The pill is the most commonly used form of birth control in the United States today. Birth control pills are marketed under a variety of brand names, and currently, there are only two promoted branded pills — Lo Loestrin® Fe (Allergan) and Natazia® (Bayer). There are two main kinds of oral contraceptives — combination birth control pills, which contain estrogen and progestin, and the "mini pill," which contains only progestin. Oral contraceptives typically must be taken on a regular or daily basis to be effective.

LARC

Implants

The contraception implant (principally marketed in the United States as Nexplanon® by a subsidiary of Merck & Co.), which must be implanted under the skin and removed by a qualified healthcare provider, requiring a medical procedure, provides contraception by releasing hormones over a three-year period. The implant has realized an increase in market share over the past five years, outpacing the overall contraceptive category year-over-year, with annual sales in the United States of approximately $570 million.

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. IUDs have annual sales in North America of approximately $1.3 billion. All IUDs must be inserted or removed by a physician.

The LARCs are 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 decided to remove their LARC due to the hormonal side effects they experience.

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 healthcare and contraception as a promotional category. In 2019, the patch market was valued at $290 million.

Vaginal Ring

The hormonal vaginal ring by Merck & Co. was introduced to the market in 2001 and had annual sales in the United States of $680 million in 2019. 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 for the vaginal ring is similar to hormonal oral contraception. Users of the vaginal ring report the same incidence of hormonal related side effects as those using oral hormonal contraception.

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 full contraceptive protection. Depo-Provera was introduced to the market in 1992 and has annual sales in the United States of approximately $224 million.

Non-prescription OTC

Condoms are the dominate product offering in OTC sales. They are manufactured primarily by Trojan (Church & Dwight) and Durex (Reckitt Benckiser) brands, with approximately six million women who depend on condom use as their only method of birth control. The market size in the United States for condoms in 2019 was over $1.12 billion. In addition, spermicides are also available in sponges, jelly/creams, and foams and have very limited utilization.

The adoption of Phexxi, if approved by the FDA, is 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.

Rush License Agreement

We amended and restated our license agreement with Rush University (the Rush License Agreement) in March 2014. Pursuant to the Rush License Agreement, Rush University granted us an exclusive, worldwide license of certain patents and know-how (the Rush Licensed IP) related to our MVP-R gel technology 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 contraception.

As further described in the Rush License Agreement, we are under an obligation to make tiered royalty payments in the mid-single digits to Rush University based on net sales of products and/or processes that are claimed in the patents or the know-how licensed to us under the Rush License Agreement. To the extent one of our products is not claimed in a licensed patent but does utilize the licensed know-how, the applicable royalty rate to such product and/or processes would be reduced.

In addition, if during the three years after one of our products or processes has received regulatory approval and is introduced to the market, if the amounts paid to Rush University as royalties or sublicensing fees do not total a minimum royalty amount, then we must pay a minimum annual royalty to Rush University. If we have to pay a royalty or other payment to a third party in order for us to avoid infringement of third-party rights, we may offset up to 50% owed to such third party by up to 50% of the amounts owed to Rush University under the Rush License. The above-described royalty payments expire upon termination of the Rush License Agreement in accordance with its terms.

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, not to be unreasonably delayed or conditioned). 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.

Pursuant to the Rush License Agreement, Rush University, its affiliates and/or its sublicensees have the right in the form of a royalty free, non-exclusive license from us under the applicable patents and know-how to use the technology embodied by such patents and know-how for non-commercial research purposes.

The Rush License Agreement provides that we must use our best efforts to bring one or more products or processes based on the licensed patents to market, and to continue diligent marketing efforts for one or more such products or processes during the term of the agreement. Additionally, within one month of the end of each fiscal quarter until the date of first commercial sale of a product, we must provide Rush University with a written development report summarizing our product development activities since the prior such report, as well as any necessary adjustments to the plan of development.

The Rush License Agreement contains additional customary representations and warranties, insurance and confidentiality provisions and is governed by the laws of the State of Illinois, except that questions affecting the licensed patents will be determined in accordance with the national law of the country in which the applicable patent was granted. We have the first right, but not the obligation, to pursue potential infringers of the licensed patents technology and know-how and the prior written approval of Rush University is required to settle any related claim.

We have agreed to defend, indemnify and hold harmless Rush University, its employees and certain other related parties from and against any and all liabilities, damages, settlements, penalties, fines, costs or expenses arising out of any claim, complaint, suit, proceeding or cause of action brought against the relevant indemnity by a third party alleging damage arising from or occurring as a result of the activities performed by or under the authority of us, our affiliates or sub-licensees in connection with the exercise of our licenses and rights under the Rush License Agreement, except to the extent caused by Rush University’s negligence or willful misconduct.

Unless terminated in accordance with its terms, the term of 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, which includes any patent claiming an improvement made within the term of the Rush License Agreement in the course of research supported or developed by Rush University utilizing the technology.

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 such breach within thirty (30) days after receiving written notice of such breach or default.

If we are in default of our obligations under the Rush License Agreement and such default has not been cured within thirty (30) days, Rush University has the option to: (a) terminate the Rush License Agreement; or (b) convert the exclusive license to a non-exclusive license (subject to the rights of any pre-approved sub-licensee under any pre-approved sub-license). Termination of the Rush License Agreement or conversion to a non-exclusive license shall give Rush University the right to terminate all sub-licenses granted by us that were not approved by Rush University. If Rush University declines to terminate any such sub-license agreement (or such sub-license agreement was approved by Rush University) then: (a) in the case of termination of the Rush License Agreement, the sub-license agreement shall become a direct agreement between Rush

University and the relevant sub-licensee; and (b) in the case of conversion of the Rush License Agreement license to a non-exclusive license, such license shall continue in full force and effect in accordance with its terms.

In addition, Rush University may terminate the agreement: (i) upon thirty (30) days' notice in the event that the aggregate royalties paid under such agreement in any calendar year following March 27, 2017 do not equal a minimum of at least $50,000, except that we may pay to Rush University the difference between the royalties actually paid and $50,000 to prevent Rush University from so terminating the Rush License Agreement, and under such circumstances the Rush License Agreement will continue for an additional two (2) years beyond March 27, 2017, or until March 27, 2019; and (ii) in a given country as regards our rights in such country, upon sixty (60) days' notice if, prior to March 27, 2022, we have not, in such country, engaged in certain specified activities in such country in an effort to exploit the products and processes covered by the licensed patents and technology in such country. To date, we have not paid any royalties pursuant to the Rush License Agreement. However, to the extent an extension of the Rush License Agreement is required, we believe we would be able to obtain such an extension on commercially reasonable terms.

Intellectual Property

We strive to protect the proprietary MVP-R 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 commercially valuable inventions. 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 to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, and other intellectual property rights, 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, 2020, we owned or had exclusive license to 40 issued patents and allowed applications in the United States and other countries and jurisdictions, and had 29 patent applications pending in the United States and other countries and jurisdictions.

We have an exclusive worldwide license to a portfolio of licensed patents held by Rush University, which provide general protection for our MVP-R gel asset, which expire in 2021 and could be eligible for extensions to at least 2024 in the United States and to 2026 in certain European jurisdictions, if granted by those regulatory bodies. Further, we solely own several patent application families relating to the composition and therapeutic use of our MVP-R 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, we commissioned an expert opinion in 2015 whose view was that bioequivalence for our MVP-R gel would be difficult to show, thus making it potentially more difficult to develop a generic version of our MVP-R gel.

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, by 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 report are the property of Evofem Biosciences, Inc. All other third-party trademarks appearing in this report are the property of their respective holders. Our use or display of other parties' trademarks, trade dress, or products in this 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.

United States

In the United States, the FDA regulates drugs under the 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. Medical products containing a combination of new drugs, biological products or medical devices are regulated as "combination products" in the United States. A combination product generally is defined as a product comprising of components from two or more regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic or device. To facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of the overall product based upon a determination by the FDA of the primary mode of action of the combination product. Phexxi is subject to review by the FDA and is being regulated as a drug/device combination product with a drug primary mode of action, which requires the submission and approval of an NDA by the Center for Drug Evaluation and Research before it maybe marketed in the United States.

Drug Development and FDA Review and Approval Process

Phexxi and our other MVP-R 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:

- completion of preclinical laboratory tests, animal studies, and formulation studies, performed in accordance with the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an Investigational New Durg (IND) application to permit human clinical testing of the therapeutic candidate;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical trial site before each clinical trial may be initiated;
- 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;
- submission to the FDA of an NDA for marketing approval, including payment of application user fees;
- 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;
- 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
- 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 or biological 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. Our first IND submitted in 2011 relates to Phexxi for the prevention of pregnancy (AMP001). Our second IND relates to our BV product candidate (EVO-002). We have also been allowed to conduct a clinical trial relating to prevention of chlamydia and gonorrhea (AMPREVENCE) under this second IND, and the clinical phase of this trial was completed and we reported positive top-line data in December 2019.

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.

- ***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.
- ***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.
- ***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 eventually 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 FY2020 this application fee exceeds $2.9 million), and establishment and product fees are payable annually 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 sixty 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 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 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. Our recently resubmitted NDA seeking approval from the FDA to market Phexxi for the prevention of pregnancy responds to all issues raised in the CRL issued to us in April 2016 and is a Class 2 resubmission with a six-month PDUFA goal date. 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.

Pediatric Information and Pediatric Exclusivity

Under the Pediatric Research Equity Act (the PREA) amendments to the FDCA, an NDA or supplement to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, made permanent PREA to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase II meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase III or Phase II/III study. The FDA has indicated that Phexxi is covered by the PREA, but the FDA may, on its own initiative or at the request of an applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. We requested and were granted a partial waiver for pre-menarcheal females and all pediatric males, as these populations are not

at risk of pregnancy. Extrapolation of efficacy and safety data based on data in adult populations is planned for pediatric post-menarcheal females (≤17 years).

In addition, pediatric exclusivity is a type of non-patent marketing exclusivity available in the United States that, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patents. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a Written Request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. The issuance of a Written Request does not require the sponsor to undertake the described studies.

Post-Approval Requirements

Following approval of a new product, 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 or combination product, 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.

The FDA may also place other conditions on approvals including the requirement for REMS to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these 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 following initial marketing.

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 candidates must meet cGMP requirements and satisfy the FDA or comparable foreign regulatory authorities' satisfaction before any product 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 Molecular's products in accordance with cGMPs. These manufacturers must 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.

Once an approval or clearance of a drug or combination product 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; imposition of post-market or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. 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 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. Most 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 and 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. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations 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, otherwise known as the Hatch-Waxman Amendments to the 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, or 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. Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the Listed Drug 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 Listed Drug 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. When an ANDA applicant submits its application to the FDA, the applicant is required to certify to the FDA concerning any patents listed in the Orange Book for the Listed Drug, except for patents covering methods of use for which the follow-on applicant is not seeking approval. 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 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 Listed Drug'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 Listed Drug 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 Listed Drug 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 a 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.

Designation of and Exclusivity for Qualified Infectious Disease Products

In 2012 as part of FDASIA, Congress passed legislation known as the Generating Antibiotic Incentives Now Act, or 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 Qualified Infectious Disease Product, or 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 10 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. 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 QIDP designation from the FDA for Phexxi for the prevention of urogenital gonorrhea infection in women.

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 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 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.

Patent Term Restoration

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 patent term extension under other provisions of the Hatch-Waxman Amendments. These patent term extensions 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 patent term extension or restoration.

Other U.S. 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 commercial sales and distribution of our products, if approved.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the 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 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, (EU) No 536/2014 (Clinical Trials Regulation) was adopted and it is anticipated to come into application in late 2020 or early 2021. 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 European Union 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 European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the “EU portal”; 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 (Member States concerned). Part II is assessed separately by each 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 a marketing authorization application (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 European Medicines Agency (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 E.U. 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 healthcare 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.

European Union 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 European Union 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 European Union and the United States, such as countries in Eastern Europe, Latin America or Asia, 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.

U.S. Healthcare Laws and Regulations

If our product candidates are approved in the United States, we will have to comply with various U.S. federal and state laws, rules and regulations pertaining to health care fraud and abuse, including anti-kickback laws and physician self-referral laws, rules and regulations. Healthcare providers 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 healthcare professionals, principal investigators, consultants, third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare 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 healthcare 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 healthcare benefit program or making any false statements relating to healthcare 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 healthcare providers, health plans, and healthcare 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.

Physician Self-Referral Law (***Stark Law***) - the federal ban on physician self-referrals prohibits, subject to certain exceptions, physician referrals of Medicare or Medicaid patients to an entity providing certain "designated health services" if the physician or an immediate family member of the physician has any financial relationships, including compensation arrangements or ownership interests, with that entity.

Sunshine Act - the federal transparency or "sunshine" requirements of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, 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.

Federal Food, Drug, and Cosmetic Act - The Federal Food Drug and Cosmetic Act (the FDCA) and the regulations promulgated pursuant to the FDCA by the FDA govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products as well as so-called combination products, such as those consisting of a drug and a delivery device. Failure to comply with applicable FDA pre-market, post-market, or other compliance requirements may subject a company to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending applications, clinical holds, warning letters, recall or seizure of products, partial or total suspension of production, withdrawal of products from the market, injunctions, fines, civil penalties or criminal prosecution.

State Transparency Laws - Some United States 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 healthcare providers and other healthcare providers 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 healthcare providers 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 healthcare 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 while applying simultaneously with HIPAA, thus complicating compliance efforts.

The scope and enforcement of these laws is uncertain and subject to rapid change. 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. 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 healthcare 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.

Healthcare 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 healthcare 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, or 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. 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 healthcare systems with the stated goals of containing healthcare 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 Affordable Care Act 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, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. The current Presidential administration and members of the US Congress have indicated that they may continue to seek to modify, repeal or otherwise invalidate all, or certain provisions of, the ACA. President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017 repealed the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In December 2019, the Fifth Circuit Court of Appeals upheld a district court's finding that the individual mandate in the ACA is unconstitutional following removal of the penalty provision from the law. However, the Fifth Circuit reversed and remanded the case to the district court to determine if other reforms enacted as part of the ACA but not specifically related to the individual mandate or health insurance could be severed from the rest of the ACA so as not to have the law declared invalid in its entirety. It is unclear how this decision, subsequent appeals including potentially to the U.S. Supreme Court, and other efforts to repeal and replace the ACA will affect the implementation of that law and our business. We continue to evaluate the potential impact of the ACA and its possible repeal or replacement on our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. For 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 or 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 healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny in the United States of 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. At the federal level, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Notably, under the Trump Administration's Safe Importation Plan, at the end of December 2019, the FDA issued a notice of proposed rulemaking to establish a system whereby state governmental entities could lawfully import and distribute prescription drugs sourced from Canada, although the impact of such future programs is uncertain. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product 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.

Coverage, Pricing, and Reimbursement

Sales of Evofem's products approved for marketing by the FDA and foreign regulatory authorities will depend, in part, on the extent to which they will be covered by third-party payors, 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 payor-by-payor basis. 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 payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The United States 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, 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, or 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 and President Trump have expressed their 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 receives regulatory approval for commercial sale may suffer if the government and third-party payors 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, or HTA) in order to obtain reimbursement or pricing approval. For example, the European Union 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 European Union 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 on Form 10-K, 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 such material 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.

On January 17, 2018, we completed a business combination in accordance with the terms of an Agreement and Plan of Merger and Reorganization (the Merger Agreement), 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 (the Merger). On January 17, 2018, in connection with and prior to the consummation of the Merger, we effected a 6:1 reverse stock split of our common stock. See Item 7- Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report and Note 3- Merger and Related Transactions of our financial statements for the year ended December 31, 2018 included in Item 15 of this Annual Report for more information regarding the Merger.

Employees

As of February 28, 2020, we had a total of 53 employees, all of which are full-time employees, and we engage consultants and contract workers on an as-needed basis. We believe the relations with our employees and consultants are good.

Emerging Growth Company

We were an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. We remained an emerging growth company until December 31, 2019. We refer to the Jumpstart Our Business Startup Act of 2012 herein as the "JOBS Act," and references herein to "emerging growth company" shall have the meaning associated with it in the JOBS Act.

For periods when we were an "emerging growth company," we may have taken advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and financial statements in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote to approve executive compensation and stockholder approval of any golden parachute payments not previously approved. We may take advantage of one or more of these reporting exemptions until we are no longer an "emerging growth company."

Item 1A. Risk Factors.

An investment in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should carefully consider the risks described below together with the information included in this Annual Report on Form 10-K (Annual Report) including our financial statements and the related notes appearing in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations". If any of these risks occur, our business, financial condition, results of operations or cash flow could be harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. There may be additional risks we do not presently know of or we currently believe are immaterial which could also impair our business and financial position.

Risks Related to Our Financial Condition and Capital Requirements

We must raise significant additional funds to finance our operations to remain a going concern. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights.

Based on our cash balance, recurring losses since inception and the inadequacy of existing capital resources to fund planned operations during the next 12 months, we will require significant additional funding to continue operations and to complete the development of Phexxi for the prevention of certain sexually transmitted infections (STIs), and we will be unable to initiate the Phase 2 trial of our BV product candidate until we raise additional funds. If we are unable to raise additional funds when needed, we may be unable to commercialize Phexxi as a contraceptive if approved by FDA, continue development of Phexxi for prevention of certain STIs, may be required to delay, scale back or eliminate some or all our development programs, planned commercialization strategies or 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 rights of our stockholders. Debt financing, if available at all, would likely involve agreements with 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.

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

We are a clinical-stage biopharmaceutical company with a limited operating history. We have incurred yearly losses since inception, including net losses of $80.0 million and $125.7 million for the years ended December 31, 2019 and 2018 respectively. As of December 31, 2019, we had an accumulated deficit of $513.2 million. Negative cash flows from our operations are expected to continue for the foreseeable future. Our utilization of cash has been and will continue to be highly dependent on our product development programs, particularly our programs for the development of our lead Multipurpose Vaginal pH Regulator (MVP-R™) product candidate, Phexxi, for several potential indications. Our cash expenses will be highly dependent on the product development programs we choose to pursue, 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 candidate or any future product candidates we may choose to develop, the terms and conditions of our contracts with service providers and license partners, and the rate of recruitment of patients in our clinical trials. In addition, the continuation of our clinical trials, and quite possibly our entire business, will depend on our financial resources at the time. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidates.

We have devoted substantially all our financial resources to the development of our product candidates, including conducting clinical trials and providing general and administrative support for our operations. To date, we have financed our operations primarily through the sale of equity securities and related-party funding. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations or grants. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future and our expenses will increase substantially if and as we:

- seek to obtain regulatory approval for Phexxi as a contraceptive;
- continue the clinical development of our MVP-R product candidates for the prevention of certain STIs;
- undertake the manufacturing of our product candidates or increase volumes manufactured by third parties;
- advance our programs into larger, more expensive clinical trials;
- initiate additional preclinical, clinical, or other trials for our product candidates or any product candidates we may choose to develop in the future;

- seek regulatory and marketing approvals and reimbursement for our product candidates or any product candidates we may choose to develop in the future;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval and market for ourselves;
- continue 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;
- seek to attract and retain skilled personnel; and
- experience any delays or encounter issues with the development and regulatory approval of our product candidates such as safety issues, clinical trial accrual delays, longer follow-up for planned trials, additional major trials or supportive studies necessary to support marketing approval.

Further, 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, 2019, the report of our independent registered public accountant on our financial statements as of and for the years ended December 31, 2019 and 2018 filed in this Annual Report included explanatory language describing the existence of substantial doubt about our ability to continue as a going concern. There have been no adjustments in the accompanying financial statements to reflect this uncertainty.

We have never generated any revenue from product sales and may never be profitable.

We have no products approved for commercialization and have never generated any material amount of revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaborators, to successfully complete the development of, and obtain necessary regulatory and marketing approvals to commercialize one or more of our current or future product candidates. We do not anticipate generating revenue from product sales until the second half of 2020. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including, but not limited to:

- obtaining regulatory and marketing approval of Phexxi for prevention of pregnancy and successfully developing one or more of our other product candidates;
- hiring and training a qualified sales force to execute on our commercialization strategy in the United States;
- manufacturing one or more product candidates and establishing and maintaining supply and manufacturing relationships with third parties that are commercially feasible, meet regulatory requirements and meet our supply needs in sufficient quantities to meet market demand for our product candidates, if approved;
- marketing, launching and commercializing product candidates for which we obtain regulatory and marketing approval, either directly or with a collaborator or distributor;
- gaining market acceptance of our product candidates as treatment options;
- addressing any competing products;
- 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;
- obtaining reimbursement or pricing for Phexxi and our other product candidates in amounts that support profitability; and
- attracting, hiring and retaining qualified personnel.

Even if Phexxi or our other product candidates are approved for commercial sale, we anticipate incurring significant costs associated with launching and commercializing any approved product candidate. We also will have to develop or acquire manufacturing capabilities or continue to contract with contract manufacturers for continued development and potential commercialization of our product candidates. If we are not able to generate revenue from the sale of any approved products, we may never become profitable.

We are heavily reliant on our ability to access funding through capital market transactions. Due to our small public float, limited operating history and lack of revenue, it may be difficult and expensive for us to raise additional funds.

We are heavily reliant on our ability to raise funds through the issuance of shares of our common stock or securities linked to our common stock. Our ability to raise these funds may be dependent on several factors, including the risk factors further described in this Annual Report. The stocks of small cap companies in the biotechnology sector similar to us tend to be highly volatile. Even if we expand our portfolio of products and product candidates, we may never successfully commercialize or monetize our current product candidates or any future product candidates we may seek to develop.

As a result, we may be unable to access funding through sales of our common stock or other equity-linked securities. Even if we are able to access funding, the cost of capital may be substantial. The terms of any funding we are able to obtain may not be favorable to us and may be highly dilutive to our stockholders.

We may be unable to access capital due to unfavorable market conditions or other market factors outside of our control. There can be no assurance we will be able to raise additional capital when needed. The failure to obtain additional capital when needed would have a material adverse effect on our business.

Our limited operating history makes it difficult to evaluate the success of our business to date and to assess our future viability.

To date, our activities have been largely limited to staffing, business planning, raising capital, developing our MVP-R gel product candidates, identifying potential new product candidates and undertaking preclinical and clinical trials of our current product candidates. We have a limited operating history which makes it difficult to evaluate our business and prospects. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. As a clinical-stage company, we have not yet demonstrated our ability to obtain regulatory approvals, generate significant revenue or conduct biopharmaceutical marketing activities necessary for successful product commercialization. In addition, given our limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. Our likelihood of success must be evaluated in light of such challenges and variables associated with a clinical-stage biopharmaceutical product development company and we may not be successful in our commercialization efforts or may incur greater costs than expected, both of which would materially and adversely affect our business, results of operations or financial condition.

Risks Related to the Development of Our Product Candidates

Our success will depend heavily on whether we can obtain FDA approval for and then commercialize, our lead product candidate, Phexxi, for prevention of pregnancy. Failure to obtain approval for, or to successfully commercialize Phexxi for prevention of pregnancy would likely cause our business to fail.

We currently have a single platform technology, our MVP-R gel, from which we intend to create multiple product candidates. However, we will rely primarily on Phexxi for prevention of pregnancy for our commercial success. Our second Phase 3 clinical trial intended to demonstrate efficacy for prevention of pregnancy had its last patient exit the study on November 8, 2018. We released top-line results from this trial on December 17, 2018, and we resubmitted our NDA for Phexxi for the prevention of pregnancy on November 25, 2019. While we believe our MVP-R gel product candidate may also be useful in other indications, currently our business depends almost entirely on the successful clinical development and regulatory approval of Phexxi for prevention of pregnancy, which may never occur. We have never received regulatory approval for any product. Even though we were able to successfully complete our clinical trial for Phexxi for prevention of pregnancy, we may be unable to obtain regulatory approval for Phexxi for prevention of pregnancy, which would have a material adverse effect on our business, financial position, results of operations and prospects.

Our inability to develop our MVP-R gel product candidates for additional indications could have an adverse effect on our business and our ability to successfully market Phexxi for prevention of pregnancy.

We believe Phexxi may also be useful in certain other indications. In August 2019, we completed a Phase 2b clinical trial designed to assess the product candidate for the prevention of urogenital *Chlamydia trachomatis* infection (chlamydia) in women and for the prevention of urogenital *Neisseria gonorrhoeae* infection (gonorrhea) in women. Top-line results from this clinical trial, reported in December 2019, demonstrated that the trial met both its primary and secondary endpoints, with a 50% relative risk reduction in chlamydia infection and a 78% relative risk reduction in gonorrhea infection compared to placebo. We do not know if we will successfully complete the clinical development of either of these product candidates. Even if we do complete such 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 impede our ability to market Phexxi for prevention of pregnancy because all our product candidates are based on the same active ingredients and technology. 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 these product liability or other health related claims, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims 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 potential approval and commercialization of Phexxi for prevention of pregnancy and for the preventative of certain STIs, 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 sexually transmitted infections. 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, 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 approval at each clinical trial site;
- failure to obtain or delays in obtaining a permit from regulatory authorities to conduct 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;
- 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 Institutional Review Board to suspend or terminate a clinical trial or for the FDA, or comparable foreign regulatory authority, to put an Investigational New Drug Application or comparable foreign 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.

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 must obtain regulatory approval prior to marketing or commercializing our product candidates. 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 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. While we have received a Qualified Infectious Disease Product (QIDP) designation for certain of our product candidates based on their current formulations, we may be required to reapply for this designation should we alter the formulations of these product candidates.

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. We may never receive such approvals, and we must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of our product candidates 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 (1) we are required to conduct additional clinical trials or other nonclinical testing of our product candidates beyond the trials and testing we currently contemplate, (2) we are unable to successfully complete clinical trials of our product candidates or other testing, (3) the results of these clinical trials or tests are unfavorable, uncertain or are only modestly favorable or (4) 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, 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 to market Phexxi or any other MVP-R product candidate for any indication from the FDA or regulatory authorities in other jurisdictions. We have limited experience in filing and supporting the applications necessary to obtain marketing approvals for product candidates. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and effectiveness. 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 Phexxi or any potential future product candidate of ours 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 or that prevent or limit 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 are 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.

On November 25, 2019, we resubmitted our NDA that seeks approval from the FDA to market Phexxi for the prevention of pregnancy. The Phexxi NDA resubmission included full results from the Phase 3 AMPOWER study, which was designed with guidance and input from the FDA to address the issues raised in the Complete Response Letter issued in April 2016. According to the FDA's classification, this application will be considered a Class 2 resubmission. The FDA has assigned a six-month review period with a Prescription Drug User Fee Act (PDUFA) goal date of May 25, 2020.

On December 2, 2019 we reported top-line data for our AMPREVENCE clinical trial. These top-line data may differ from complete trial results once additional data are received and evaluated by the FDA.

The reported results of our AMPREVENCE clinical trial consist of only top-line data. 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, 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, and we have not received or had an opportunity to evaluate all of data from the AMPREVENCE trial. 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 AMPREVENCE data analyses, our ability to obtain or maintain approval for, and commercialize, Phexxi for prevention of chlamydia and gonorrhea in women may be harmed, which could materially adversely affect our business, financial condition, results of operations and prospects and the value of our common stock.

*Phexxi is a drug/device combination and the process for obtaining regulatory approval for Phexxi in the United States will require compliance with requirements of two divisions of the FDA. A change in the FDA's primary oversight responsibility would adversely impact our development timeline and significantly raise our cost**s.***

Phexxi is composed of both drug and device components and is considered a combination product by the FDA. It is a method of self-applied contraception that uses a pre-filled applicator to apply a semi-solid bio-adhesive gel. The key active ingredient has been shown to be an active anti-inflammatory and anti-infective that works in combination with other active ingredients to stabilize the pH levels in the vagina without altering the vaginal microbiome, which results in both the inhibition and the immobilization of sperm. Other properties contributing to the birth control effect of Phexxi are its capacity to reduce/inhibit cervical mucus penetration, its ability to maintain sufficient viscosity even on dilution, and its bio-adhesive strength.

The FDA has different divisions responsible for assessing and approving devices and drugs. The Center for Drug Evaluation and Research (CDER) has responsibility for drug products, while the Center for Devices and Radiological Health (CDRH) has oversight responsibility for medical devices. Phexxi previously underwent a request for designation process with the FDA that determined the CDER would lead the review and that the product should be submitted for marketing authorization

pursuant to an NDA. If the designation of the lead center were to be changed to CDRH, or if either division or the FDA Office of Combination Products were to institute additional requirements for the approval of Phexxi, we could be required to complete clinical trials with more patients and over longer periods of time than is currently anticipated or comply with regulatory requirements that are not currently anticipated. This would likely require us to raise additional funds and would cause us to miss anticipated timelines. The impact of either a change in lead agency center for pre-market review or the imposition of additional requirements for approval would be significant to us and would have a material adverse effect on the prospects for the development of Phexxi, our business and our financial condition.

Serious adverse events arising post marketing or during clinical trials of our product candidates could have a material, adverse effect on our product development timeline or our ability to develop and market our MVP-R gel product candidates, including our lead product candidate, Phexxi.

If serious adverse events or undesirable side effects occur during the clinical investigation of our product candidates or post marketing, the following events could materially and adversely affect our business:

- 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;
- regulatory authorities may require the addition of specific warnings or contraindications to product labeling or the issuance of alerts to physicians and pharmacies;
- we may be required to change the way the product candidates are administered or to revise the labeling of the 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 our product candidates;
- we may be required to limit the patients who can receive our product candidates;
- we may be subject to promotional and marketing limitations on our product candidates;
- sales of approved products, if any, may decrease significantly;
- regulatory authorities may require us to take approved products, if any, off the market;
- 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 our product candidates, or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from our product candidates.

If FDA approval is received for our MVP-R gel product candidates, including Phexxi, or any other future product candidates we may develop, serious adverse events or side effects could require the product to be taken off the market, may require the product to be packaged with safety warnings or may otherwise limit our sales of the product.

Even if we receive approval from the FDA in the United States to market our product candidates, 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. Further, we may be unable to obtain rights to the necessary clinical data and may be required to generate our own. 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 may be different and 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 fail 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 our product candidate will be harmed, which could have a materially adverse effect on our business, financial condition, results of operations and prospects.

Our development and commercialization strategy for our product candidates depends, in part, on published scientific literature and the FDA's prior findings regarding the safety and efficacy of approved products based on data developed by others that the FDA may rely on in reviewing our NDA.

The Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Amendments) added section 505(b)(2) to the Federal Food, Drug and Cosmetic Act (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 submitted an NDA for Phexxi in late 2019 under section 505(b)(2) of the FDCA that relies, in part, on the FDA's previous findings of safety and efficacy from investigations for approved products and published scientific literature for which we have not received a right of reference. We also plan to use the 505(b)(2) NDA pathway for future applications. We have made certifications against patents in the Orange Book covering reference products identified in the resubmission of our Phexxi NDA, which could result in patent litigation and delay of approval for our NDA.

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.

Risks Related to Our Post-Marketing Legal and Regulatory Compliance

Even if we obtain regulatory approval for a product candidate, we will remain subject to ongoing regulatory requirements.

If our product candidates are approved, we 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.

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 current good manufacturing practices (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 marketing authorization application.

Any regulatory approvals we receive for any of our product candidates may be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for a product candidate was obtained through an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm the clinical benefit for our products. An unsuccessful post-marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a 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 us, including requiring withdrawal of the product from the market. If we fail 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 failure 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 our products.

Even after regulatory approval, 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 scrutiny in 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 adverse 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 any of our product candidates following its 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.

In addition, certain health authorities, regulators and other governmental agencies have increased their focus on safety when assessing the balance of benefits and risks of drugs. Some health authorities appear to have become more cautious when making decisions about approvability of new products and are re-reviewing select products that are already marketed, adding further to the uncertainties in the regulatory processes post-approval. There is also greater regulatory scrutiny, especially in the United States, on the advertising and promotion (in particular, direct-to-consumer advertising and the use of influencers in
advertising campaigns), as well as the pricing and coverage, of prescription drug products.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our product candidates.

We face an inherent risk of product liability exposure in conducting clinical trials and face similar risks with our current product candidates or other product candidates we may seek to develop or commercialize. 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 our product candidates, or, 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 seek to conduct and continue to conduct clinical trials for our product candidates. Such insurance may become increasingly expensive and difficult to procure. In the future, such 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, we will likely need to increase our liability insurance coverage in connection with the commercialization of our product candidates, if 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 supplier's activities may involve the controlled storage, use, and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. 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 our MVP-R gel product candidates, including our lead product candidate, 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 our MVP-R gel product candidates including our lead product candidate, Phexxi, for the prevention of pregnancy, 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 development of our MVP-R gel product candidates. For example, and as discussed in the section entitled *"Business"* of this Annual Report, our amended and restated license agreement with Rush University (the Rush License Agreement) includes intellectual property rights to our MVP-R gel product candidates, including Phexxi for the prevention of pregnancy. 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. Our obligations under this in-license agreement impose significant financial and logistical burdens upon our ability to carry out our business plan. Furthermore, if we do not meet such obligations in a timely manner, and, in the case of milestone payment requirements, if we were unable to obtain an extension of the deadlines for meeting such payment requirements, we could lose the rights to this proprietary technology, which would have a material adverse effect on our business, financial condition and results of operations.

There is no assurance the existing Rush License Agreement covering the rights related to our MVP-R gel product candidates, including Phexxi for the prevention of pregnancy, will not be terminated due to a material breach of the underlying agreement. This would include a failure on our part to make the milestone and royalty payments, our failure to obtain applicable approvals from governmental authorities, or the loss of rights to the underlying intellectual property by any such licensors. Under the current circumstances and as we have not paid royalties to date, the Rush License Agreement may be terminated at Rush University's option. While we believe we will be able to negotiate an extension, if needed, there is no assurance we will be able to renew or renegotiate an extension to the Rush License Agreement or that we will be able to do so on acceptable terms. The termination of this license agreement or our inability to enforce our rights under this license agreement would materially and adversely affect our ability to commercialize our MVP-R gel product candidates, including Phexxi.

In addition, with respect to our MVP-R gel product candidates, 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 our MVP-R gel product candidates. While our license agreement with Rush University 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 our MVP-R gel product candidates.

Finally, the patent rights licensed to us under the Rush University License expire in 2021. If we are unable to obtain extensions of the patent rights, these patent rights will no longer protect our product candidates, and we will be relying solely on our directly owned patent formulas and patent application families for patent protection for our product candidates.

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 our product candidates, including our lead product candidate, Phexxi for the prevention of pregnancy, and 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 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, our BV product candidate and other proprietary technologies we may develop. If we or our licensors are unable to obtain or maintain patent protection with respect to Phexxi, our BV product candidate 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.

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 fail 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 our MVP-R gel product candidates 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 our product candidates 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 preissuance 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 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 development, testing, and regulatory review of our product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. 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 are, and 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 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 it initiates, 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 United States and non-United States 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 United States 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 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 our product candidates, including 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 United States 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 United States 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 United States 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 our product candidates 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 our product candidates, including Phexxi, and 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 our product candidates, including 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 patent term extension (PTE) and data exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidate we may develop, one or more of our owned or in-licensed United States patents may be eligible for limited PTE under the Drug Price Competition and Patent Term Restoration Action of 1984 (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 ability to obtain PTE on the patents licensed from Rush University, which currently expire in 2021. However, we may not be granted an extension, such as PTE for the United States patent and SPC for the European patents because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time or the scope of patent protection afforded could be less than our request. If we 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.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents relating to our product candidate 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 product candidate, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize our product candidate 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.

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 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 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 patents for our product candidates, including 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 our product candidates, 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 our product candidates 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 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 our MVP-R gel product candidates. 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 our MVP-R gel product candidates 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 of the relevant program 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, misappropriation or other violation against us or our collaborators may prevent or delay the development and commercialization of our product candidates and other proprietary technologies we may develop.

The contraceptive and/or anti-STIs market is competitive and dynamic. Due to the significant research and development activities that are taking place by several companies, including us and our competitors, in this field, 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, 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 United States 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 United States 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 our product candidates 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 developing our product candidate, 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 candidate. 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 product candidates and other proprietary technologies we may develop, could be found to be infringed by our 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 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 or product candidate. 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 product candidate 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 candidate 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 candidate and commercialize our product and product candidate, 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, 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.

We 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 may infringe our patents or the patents of our licensing partners, or we may be required to defend against claims of infringement. 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 such claims can be 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. Such 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.

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 may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. During trademark registration proceedings, including those for Phexxi, 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, it 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 candidate 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, there could be 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. 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 related to 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 product candidate 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 failure to successfully perform and comply with regulatory requirements, could negatively impact our business and our ability to develop and market our 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, and as such we will be subject to inherent uncertainties related to product safety, availability and security. We currently have only one contract manufacturer, 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. The Manufacturing Agreement may be terminated by either party at any time upon the occurrence of either the material failure of the other party to comply with its material obligations pursuant to the contract, and such failure is not remedied within 60 days of written notice thereof, or written notice if any bankruptcy event has occurred with respect to the other party. If DPT does not perform as agreed 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 our MVP-R gel product candidates, 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.

Moreover, we do not expect to control the manufacturing processes for the production of Phexxi, our any other product candidates we may seek to develop, 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 our product candidates, we could experience delays in research, planned clinical trials 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, 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 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, if any of our product candidates by the FDA or the commercialization of our product candidates 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 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 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 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. Even if we could otherwise obtain regulatory approval for any product candidate, there is no assurance that our manufacturers will be able to manufacture the approved product 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 internal distribution capabilities and intend to engage third-party distributors for distribution of products outside 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.

Although we currently plan to market and sell our lead product candidate, Phexxi, directly in the United States, we do intend to enter into distribution agreements with one or more distributors of Phexxi outside the United States. We currently have not entered into any such distribution agreement with any such distributor, and we cannot guarantee that we will be able to enter into any such distribution agreement on commercially reasonable terms, or at all. If we were to enter into such a product distribution agreement, 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 United States 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. 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 for distribution outside of the United States. Further, third-party distributors may not perform as agreed or may terminate their agreements with us. Any significant problem that our distributors experience 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. 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. Failure of these third parties to provide services of a suitable quality 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, 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.

If we fail to enter into or maintain strategic relationships or collaborations with respect to 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.

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 (for convenience if permitted) 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 candidates.

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 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 Commercialization of Our Product Candidates

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

Although some of our employees may have marketed, commercialized and sold other pharmaceutical products, including contraceptives, in the past while employed at other companies, we have no experience selling and marketing our product candidates, and we currently have no marketing or sales organization. We expect to hire internal sales representatives to market and sell Phexxi for use as contraception, if approved; however, we have not yet identified or hired any such sales representatives at this time. To successfully commercialize any products that may result from our development programs, we will need to find one or more collaborators to commercialize our products or invest in and develop these capabilities, either on our own or with others, which would be expensive, difficult and time consuming. Any failure or delay in the timely development of our internal commercialization capabilities could adversely impact the potential for success of our products.

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. We may be competing with companies that currently have extensive and well-funded marketing and sales operations, particularly in the markets our product candidates are intended to address. Without appropriate capabilities, whether directly or through third-party collaborators, we may be unable to compete successfully against these more established companies.

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

The medical device, biotechnology and biopharmaceutical industries 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. In addition, new products developed by others could emerge as competitors to Phexxi, if it is approved for our lead indication, the prevention of pregnancy. Such products could offer an alternative form of non-hormonal contraceptive that provides protection over longer periods of time. 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. 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. There are other contraceptive product candidates in development that, if approved, would potentially compete with Phexxi, including hormonal patches and hormonal vaginal rings.

Our product candidates, may not gain acceptance among physicians, patients or the medical community, thereby limiting our potential to generate revenue, which will undermine our future growth prospects.

Even if our 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, health care professionals and third-party payers will depend on a number of factors, including:

- demonstrated evidence of efficacy and safety;
- sufficient third-party insurance coverage and adequate reimbursement;
- effectiveness of our or our collaborators' sales and marketing strategy;
- the willingness of consumers, without third-party insurance coverage and adequate reimbursement, to pay for the product;
- the willingness of pharmacy chains to stock the products;
- the prevalence and severity of any adverse side effects; and
- availability of alternative products.

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

The success of Phexxi or any future contraceptive product candidate we may seek to develop 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 other future contraceptive product candidate we may seek to develop will depend upon the contraceptive market as well as market acceptance of our new form of prevention of pregnancy. Risks related to market acceptance include, among other things:

- minimum acceptable contraceptive efficacy rates;
- perceived safety differences of hormonal and/or non-hormonal contraceptive options;
- changes in healthcare laws and regulations, including implementation of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the ACA) and its effect on pharmaceutical coverage, reimbursement and pricing, and the coverage of preventable services (including contraception under certain conditions) and future new executive orders, legislation or agency rulemaking;
- competition from new lower dose hormonal contraceptives with more favorable side effect profiles; and
- new generic contraceptive options including the possibility of a future potential generic version of Phexxi as a contraceptive (if it is approved for marketing by the FDA).

The occurrence of one or more of 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 our product candidates will depend in significant measure on the label claims that the FDA or other regulatory authorities approve for the product.

The commercial success of our product candidates will depend in significant measure upon our ability to obtain approval from the FDA or other regulatory authorities of labeling describing a product candidate's expected features or benefits. 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.

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.

We have received conditional approval from the FDA for the use of Phexxi as the proprietary name for our product candidate for the prevention of pregnancy, L-lactic acid, citric acid, and potassium bitartrate. However, this approval is conditional upon a further and final review by the FDA at the time of NDA approval. Additionally, any name we intend to use for our other 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 the Phexxi mark 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 our products in development, our reputation could be harmed and we may be forced to cease development of such products.

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

We rely, and expect to continue to rely, on market research conducted on our behalf to evaluate the potential commercial acceptance of Phexxi, our BV product candidate, and other future product candidates.

We have contracted with and expect to continue to contract with third parties to perform market research on our behalf. Based on the results of our market research to date, we believe that Phexxi, if approved, would be an attractive alternative to hormonal birth control to certain women. However, 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 another product candidate or future product candidates we may develop.

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.

The proportion of the United States market that is made up of generic products has been increasing over time. This trend is consistent in the women's health segment, as well, where many of the most popular oral contraceptive pills (OCP) brands have experienced genericization. Currently, only two branded OCPs remain and both have a relatively low market share. Assuming this trend continues, it may be more challenging to introduce Phexxi, if approved by the FDA, 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 Phexxi or any future approved product candidate at a price that is commensurate with that of current branded products, or 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.

Risks Related to Our Commercialization of Healthcare Products

If approved for commercial marketing in the United States, our lead product candidate Phexxi and our other product candidates may face generic competition sooner than anticipated.

Even if we are successful in achieving regulatory approval to commercialize a product candidate, it may face competition from generic products earlier or more aggressively than anticipated, depending upon how well our future 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 abbreviated new drug applications, or ANDAs. An ANDA relies on the preclinical and clinical testing conducted for a previously approved reference listed drug (RLD), and must demonstrate to the FDA that the generic drug product is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug and also that it is "bioequivalent" to the RLD. The FDA is prohibited by statute from approving an ANDA when certain marketing or data exclusivity protections apply to the RLD.

If the FDA approves our resubmitted NDA for Phexxi for the prevention of pregnancy, we expect that it will be designated by the agency as an RLD and that it will be eligible for three years of data exclusivity based on our submission of new clinical data essential to the approval of the application. This three-year exclusivity period would block FDA from approving either a subsequent ANDA or 505(b)(2) NDA that rely in whole or in part on the Evofem's protected clinical data. If we do not receive such designation, we will not receive this three year data exclusivity. Further, we cannot predict the interest of potential generic 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 does not grant our products appropriate periods of data exclusivity before approving generic versions of our products, the sales of our products could be adversely affected.

With FDA approval of an NDA, the product covered by the application is specified as a "reference-listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," or the Orange Book. Manufacturers may seek approval of generic versions of reference-listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference-listed drug and that the generic version is bioequivalent to the reference-listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than a reference-listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any reference-listed drug may be typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference listed drug has expired. The Federal Food, Drug, and Cosmetic Act, or FDCA, provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity, or NCE. Specifically, in cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the product, in which case the applicant may submit its application four years following approval of the reference-listed drug. The FDCA also provides a period of three years of new clinical investigation, or NCI, data exclusivity in connection with the approval of a supplemental indication for the product for which a clinical trial is essential for approval.

In the event that a generic manufacturer is somehow able to obtain FDA approval without adherence to these periods of data exclusivity, the competition that our approved products may face from generic versions 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.

If we do not obtain protection under the Hatch-Waxman Act and similar legislation outside of the United States by extending the patent terms and obtaining marketing exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of Phexxi, our other product candidates or potential future product candidates, if any, one or more of our United States patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman). The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension if, for example, we fail to apply within applicable deadlines, we fail to apply prior to expiration of relevant patents or if we otherwise fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our products will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Changes in healthcare laws and regulations may eliminate current requirements for health insurance plans to cover and reimburse FDA-cleared or FDA-approved contraceptive products without cost sharing, which could reduce demand for products such as Phexxi. Even if Phexxi is approved for commercialization, our management expects our success will be dependent on the willingness or ability of patients to pay out-of-pocket 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 be available for Phexxi if it is approved for the prevention of pregnancy in 2020, or if reimbursement is available, the amount of any such reimbursement. The Patient Protection and Affordable Care Act (ACA) and subsequent regulations enacted by the United States Department of Health and Human Services (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. However, the Trump administration and Congress are attempting 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 under the Trump Administration, which in 2017 altered the mandate to allow certain employers and insurers to opt-out of birth control coverage for religious or moral reasons. 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 healthcare 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 co-payments 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

In the event we are successful in obtaining regulatory approval to market our STI product candidates in the United States, revenues may be adversely affected if the product fails to obtain coverage and adequate reimbursement from third-party payers in the United States.

Market acceptance and sales of any product candidates that we commercialize, even if approved by the FDA or foreign regulatory authorities, 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 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. The United States 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 for the prevention of chlamydia and gonorrhea, 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, healthcare providers may not prescribe them or patients may ask their healthcare providers 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 healthcare laws, including, without limitation, the United States Federal Anti-Kickback Statute, the United States Federal False Claims Act and the FCPA.

Healthcare providers 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 healthcare professionals, principal investigators, consultants, third-party payers, customers and other organizations may expose us to broadly applicable fraud and abuse and other healthcare 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, the False Claims Act, False Statements Statute, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the FDCA, the Physician Self-Referral Law (Stark Law), the Physician Payments Sunshine Act, transparency laws and regulations and analogous state and foreign laws and regulations.

The scope and enforcement of these laws and regulations is uncertain and subject to rapid change. 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. 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, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare 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.

Healthcare 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 healthcare 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 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 healthcare systems with the stated goals of containing healthcare 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 or collectively, the ACA, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the United States pharmaceutical industry. The ACA, among other things: (i) mandated that preventative services which have strong scientific evidence of health benefits, including in some cases contraception, must be fully covered by certain private third-party payers when they are delivered by an in-network provider; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (iii) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs; (iv) expanded the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; (v) increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price; (vi) expanded the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (vii) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (and 75%, commencing January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; (viii) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and (ix) established a Center for Medicare Innovation at the Centers for Medicare and Medicaid Services (CMS) to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drugs.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 repealed the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018 (the BBA), 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". We continue to evaluate the potential impact of the ACA and its possible repeal or replacement on our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws

may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

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.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

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. 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. 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 individually identifiable health information from a covered entity in a manner that is not authorized or permitted by the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) or for aiding and abetting the violation of HIPAA.

In particular, 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 California Consumer Privacy Act of 2018 (the CCPA) which will come into effect beginning in January 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.

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.

Effective May 25, 2018, the European Union implemented the GDPR which is a broad data protection framework that expanded the scope of EU data protection law to non-EU entities that process, or control the processing of, the personal information of EU subjects, including clinical trial data. The GDPR allows for the imposition of fines and/or corrective action on entities that improperly use or disclose the personal information of EU subjects, including through a data security breach. Accordingly, data security breaches experienced by us, our collaborators or contractors could lead to significant fines, required corrective action, loss of trade secrets or other intellectual property, or could lead to the public exposure of personally identifiable information (including sensitive personal information) of our employees, collaborators, clinical trial patients, and others. The GDPR imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU to the United States and 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.

Our business may be adversely affected by unfavorable macroeconomic conditions.

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.

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 fail 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, 2020, we had a total of 53 employees, all of which are full-time employees, and 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 develop, we expect that we will expand the size of our employee base for managerial, operational, sales, marketing, financial, regulatory affairs and other resources. For example, we expect to hire internal sales representatives for the purpose of selling Phexxi for the prevention of pregnancy, if approved, in the United States. 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 and medical device industries 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 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, it 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 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 healthcare 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 healthcare 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, security 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, and telecommunication and electrical failure. 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 product development programs. For example, the loss of clinical study data from future clinical trials could result in 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. 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 development of our products may be delayed. Furthermore, we may incur additional costs to remedy the damage caused by these disruptions or security breaches.

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. We expect that these expenses will further increase after we are no longer an emerging growth company. 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 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.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404), we will be required to furnish a report by our management on our internal controls over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company in 2019, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 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, Kelly Culwell, M.D., our Chief Medical Officer and Russell Barrans, our Chief Commercial Officer 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 healthcare, 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 United States 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 United States Export Administration Regulations, United States Customs regulations, various economic and trade sanctions regulations administered by the United States Treasury Department's Office of Foreign Assets Controls, the FCPA, the United States domestic bribery statute contained in 18 United States C. § 201, the United States 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.

Risks Related to Our Common Stock

We expect the price of our common stock may be volatile and may fluctuate substantially.

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 discover, develop, acquire or in-license product candidates or products, if any;
- the results of our efforts to commercialize any product candidates, if approved;
- failure or discontinuation of any of our research programs;
- 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. novel coronavirus epidemic in China), boycotts and other business restrictions;
- regulatory or legal developments in the United States and other countries;
- changes in the structure of healthcare 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;
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock; and
- other factors described in this "Risk Factors" section.

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.

Three of our stockholders own a significant percentage of our issued and outstanding common stock and will be able to exercise significant influence over matters submitted to stockholders for approval.

As of February 28, 2020, funds affiliated with or discretionarily managed by Invesco Ltd., funds affiliated with or discretionarily managed by Woodford Investment Management, and PDL BioPharma, Inc. (PDL) hold approximately 23.8% 18.4%, and 26.9%, respectively, of our outstanding common stock. If each of these stockholders were to exercise all of the warrants to purchase our common stock held by such stockholders, then their ownership percentages would be 24.7%, 18.4% and 31.5%, respectively, of our outstanding common stock. We have entered into voting agreements with certain funds managed by Woodford Investment Management that the shares held by such holders in excess of 19.5% of our issued and outstanding common stock shall be voted in the same proportion as the shares voted by all other stockholders. Notwithstanding the voting agreements, if the funds managed by Woodford Investment Management, Invesco Ltd. and PDL were to choose to act together, they would be able to exert a significant degree of influence over matters submitted to our stockholders for approval, as well as our management and affairs. This concentration of voting power could delay or prevent an acquisition on terms that other stockholders may desire. For example, these entities, if they choose to act together, would be able to have significant influence on the election of directors, approval of any increase in the number of shares reserved under equity incentive plans, approval of new equity incentive plans, and approval of any merger, consolidation or sale of all or substantially all our assets. For more information see the section entitled "*Description of Capital Stock Voting Agreements*" of this Annual Report.

In addition, and per the terms of our amended and restated certificate of incorporation, we are not subject to or governed by Section 203 of the Delaware General Corporation Law (the DGCL), which prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder," and we are able to enter into transactions with our principal stockholders. A concentration of ownership may have the effect of delaying, preventing or deterring a change of control of a company, could deprive its stockholders of an opportunity to receive a premium for their common stock as part of a sale of a company and may materially adversely affect the market price of its common stock.

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. Outstanding shares of our common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act of 1933, as amended (the Securities Act) or to the extent such shares have already been registered under the Securities Act and are held by non-affiliates.

As of December 31, 2019, there were 6,419,383 shares of our common stock subject to outstanding options, which have been registered on registration statements on Form S-8. Shares registered on a Form S-8 can be freely sold in the public market upon exercise, except to the extent they will be held by our affiliates, in which case such shares will become eligible for sale in the public market as permitted by Rule 144 under the Securities Act. Furthermore, as of December 31, 2019, there were 5,305,377 shares subject to outstanding warrants to purchase our common stock, of which 849,056 were registered pursuant to a Registration Statement on Form S-1 (No. 333-224958), which became effective on May 21, 2018, 1,666,667 were registered pursuant to a Registration Statement on Form S-3 (No. 333-231126), which became effective on May 7, 2019, and 2,777,779 were registered pursuant to a Registration Statement on Form S-3 (No. 333-232303), which became effective on July 2, 2019. Moreover, holders of 15,026,968 shares of our common stock, subject to conditions, may require us to file registration statements covering the resale of these shares or to include these shares in registration statements that we may file. In connection with these obligations, we filed a Registration Statement on Form S-3 (No. 333-223731) which became effective on April 3, 2018.

In November 2019, the Company entered into an equity distribution agreement with Piper Sandler & Co. (Piper Sandler), pursuant to which the Company may offer and sell shares of its common stock in at the market offerings (as defined in Rule 415 of the Securities Act) having an aggregate offering price up to $50 million in gross proceeds from time to time through Piper Sandler acting as sales agent. During the year ended December 31, 2019, we received proceeds of approximately $3.3 million (including $3.0 million in cash and cash equivalents and $0.3 million in other receivable), net of commissions, from the sale of 515,019 shares of our common stock.

We were an emerging growth company, and 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 remained an emerging growth company until December 31, 2019 under the JOBS Act. We are a "smaller reporting company" under SEC regulations. For periods when we were an emerging growth company, or 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 emerging growth companies or smaller reporting companies. These exemptions include:

- for so long as we are an emerging growth company, not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved for so long as we are an Emerging Growth Company.

We may choose to take advantage of some, but not all, of the available exemptions. Emerging growth companies may take advantage of an extended transition period for complying with new or revised accounting standards, allowing emerging growth companies to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

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. 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 fail to regularly publish 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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate headquarters are located in San Diego, California, where we lease approximately 16,000 square feet of office space. This existing lease will expire on March 31, 2020.

On October 9, 2019, the Company entered into an office lease for approximately 24,474 square feet pursuant to a non-cancelable lease agreement. This new lease will commence on April 1, 2020 and 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.

We believe that our existing facilities and the new lease 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. Prior to November 20, 2014, there was no public market for our common stock. On January 17, 2018, we completed a merger with privately-held Evofem Biosciences Operations, Inc. (Private Evofem) in accordance with the terms of the 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 (the Merger). 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, 2020, there were 49,594,477 shares of our common stock outstanding and 35 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 fourth quarter of 2019, we did not issue any securities that were not registered under the Securities Act of 1933, as amended.

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

The table below is a summary of purchases of our common stock we made during the quarter covered by this report. Other than as indicated in the table below, no such purchases were made in any other month during the quarter. We do not have any publicly announced repurchase plans or programs.

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares That May Yet be Purchased Under the Plans or Programs
October 1 - October 31	18,427	$5.01	—	—
November 1 - November 30	132,624	$5.98	—	—
December 1 - December 31	5,406	$6.27	—	—

(1) These shares were surrendered to the Company to satisfy tax withholdings obligations in connection with the vesting of restricted stock awards.

Item 6. Selected Financial Data.

As a "smaller reporting company" as defined in Rule 12b-2 of the Exchange Act, we are not required to provide the information required by this item.

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 or set forth elsewhere in this 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 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 clinical-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health. We exist to advance the lives of women by developing innovative solutions, such as woman-controlled contraception and potential protection from certain sexually transmitted infections (STIs). Our lead Multipurpose Vaginal pH Regulator (MVP-R™) product candidate, Phexxi (L-lactic acid, citric acid, and potassium bitartrate), is in development for multiple potential indications: prevention of pregnancy, prevention of urogenital transmission of *Chlamydia trachomatis* infection (chlamydia) in women and prevention of urogenital transmission of *Neisseria gonorrhoeae* infection (gonorrhea) in women.

We conducted a second, single-arm Phase 3 trial for Phexxi for the prevention of pregnancy in approximately 1,400 healthy women in the United States (AMPOWER). We have reported top-line data from AMPOWER, which demonstrated a cumulative pregnancy rate of 13.7% over seven cycles of use (95% CI 9.9, 17.4) in the modified intention-to-treat population (referred to as "typical use") which met the pre-determined endpoint of the clinical trial. This corresponds to an 86.3% efficacy rate. We resubmitted the New Drug Application (NDA) to the United States Food and Drug Administration (FDA) in November 2019. Subject to acceptance and timely approval of the NDA by the FDA, we plan to commercialize Phexxi in June 2020.

We recently concluded a Phase 2b clinical trial of Phexxi for prevention of urogenital transmission of chlamydia and gonorrhea (primary and secondary endpoint, respectively) in women. We refer to this trial as AMPREVENCE. The primary endpoint of AMPREVENCE is incidence of chlamydia in women treated with Phexxi versus placebo. Top-line results from AMPREVENCE, reported in December 2019, demonstrated that the study met both its primary and secondary endpoints, with a 50% relative risk reduction in chlamydia infection and a 78% relative risk reduction in gonorrhea infection compared to placebo. We envision our STI program as developing label expansion opportunities to further differentiate Phexxi from other contraceptive products on the market.

Since inception, we have devoted substantially all of our efforts to developing MVP-R product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. We do not have any approved products and have not generated any revenue from product sales. Although we have released top-line and final results from the Phase 3 AMPOWER trial of Phexxi for prevention of pregnancy, the product has not yet been approved for this or any other targeted indications. Additionally, Phexxi is still in mid- stage clinical development for the prevention of certain STIs. We do not expect to generate any revenues prior to June 2020. To finance our current strategic plans, including the conduct of future clinical trials, further research and development activities and anticipated pre-commercialization activities in 2020, we will require significant capital. Assuming we have sufficient liquidity, we will incur significantly higher costs in the foreseeable future.

Merger

As previously discussed, on January 17, 2018 (the Closing Date), Neothetics, Inc. (Neothetics), now known as Evofem Biosciences, Inc., completed its reverse merger (the Merger) with privately-held Evofem Biosciences Operations, Inc. (Private Evofem) in accordance with the terms of an agreement and plan of merger and reorganization, dated October 17, 2017. Since Private Evofem was determined to be the accounting acquirer in connection with the Merger, it recorded Neothetics' assets and liabilities at fair value as of the Closing Date. To reflect the close of the Merger, we recorded the following items:

- Recorded Neothetics' assets and liabilities at fair value as of the Closing Date, including $1.9 million of cash and cash equivalents, $0.5 million in prepaid and other current assets, $0.4 million in current and noncurrent liabilities and $1.9 million in common stock (Neothetics had 2,308,430 shares of common stock outstanding as of the Closing Date on a post-split basis at par value of $0.0001 per share) and additional paid-in capital (including the reclassification of Neothetics' historical accumulated deficit into additional paid-in capital);
- Reclassified the net proceeds from Private Evofem's issuance of an aggregate of 40,016,067 shares of Private Evofem's convertible preferred stock to 1,027,079 shares of the Company's common stock, effecting the merger exchange ratio of 0.1540, subject to adjustment for the Reverse Stock Split (as defined below) (the Exchange Ratio) and the 6:1 reverse stock split of our common stock (the Reverse Stock Split), and additional paid-in capital, net of par value, upon conversion to the Company's common stock immediately prior to the closing of the Merger;

- Recorded the cancellation of 122,149 shares of the Company's unvested restricted common stock upon closing of the Merger;
- Recorded the issuance of 3,968,473 shares of the Company's common stock upon the cashless exercise of warrants (the Invesco Warrants) issued to funds affiliated with Invesco Ltd., immediately prior to the closing of the Merger and recognized the fair value of the Invesco Warrants upon issuance;
- Adjusted for the final change in fair value of Private Evofem's Series D 2X liquidation preference and reclassified the Series D 2X liquidation preference to additional paid-in capital upon conversion of 80 shares of Private Evofem's Series D redeemable convertible preferred stock (Series D) to 6,878,989 shares of the Company's common stock;
- Recorded the fair value of the warrants issued to funds affiliated with Woodford Investment Management Ltd (WIM) to purchase up to 2,000,000 shares of the Company's common stock (the WIM Warrants) and related capital contribution upon issuance of the WIM Warrants;
- Recorded cash dividends between January 6, 2018 and the Closing Date, paid upon closing of the Merger to WIM;
- Adjusted common stock and additional paid-in capital associated with shares in connection with the Merger due to the 6:1 reverse stock split;
- Assumed options to purchase Private Evofem common stock that were outstanding and unexercised as of immediately prior to the Merger (the Private Evofem Plan Options). The Private Evofem Plan Options, were converted into options to purchase 159,325 shares of our common stock, as adjusted for the Exchange Ratio and Reverse Stock Split, at a weighted average price of $56.72; and
- Recorded $20.0 million in proceeds from the sale of 1,614,289 shares of our common stock in a private placement completed immediately after the closing of the Merger.

We historically have funded our operations primarily through the sale of our common stock, convertible preferred stock, related-party advances and a note payable from Cosmederm Biosciences, Inc., a prior related party.

Private Placement

As described in Note 10- Private Placement, on April 10, 2019, we entered into a Securities Purchase Agreement with PDL BioPharma, Inc., a Delaware corporation (PDL), funds discretionally managed by Invesco and funds managed by WIM (collectively, the Purchasers), pursuant to which we agreed to issue and sell an aggregate of $80 million of our common stock, par value $0.0001 per share at a purchase price of $4.50 per share, and warrants to purchase shares of common stock with an exercise price of $6.38 per share in a private placement (the Private Placement) that was funded in two separate
closings.

The first closing was completed on April 11, 2019 (the First Closing), pursuant to which we (i) issued and sold to PDL 6,666,667 shares of our common stock and warrants to purchase up to 1,666,667 shares of our common stock (the First Closing Warrants) and (ii) provided to the Purchasers an option to purchase an aggregate of up to 11,111,111 shares of our common stock and warrants to purchase up to an aggregate of 2,777,779 shares of our common stock as specified in the aforementioned Securities Purchase Agreement (the Second Closing Securities) during the period beginning on April 10, 2019 and ending on June 10, 2019 (the Purchase Rights). The total consideration for the First Closing was $30 million.

The second closing was completed on June 10, 2019 (the Second Closing), pursuant to which we issued and sold the Second Closing Securities to the Purchasers for an aggregate purchase price of $50 million.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from our lead product candidate, Phexxi. We do not expect to generate any revenue from any product candidates we develop unless, and until we obtain regulatory approval and commercialize our products or enter into collaborative agreements with third parties. In the future, if Phexxi is approved for commercial sale in the United States, we may generate revenue from product sales. If Phexxi is approved for commercial sale outside of the United States, we expect to out-license commercialization rights to Phexxi to global pharmaceutical companies or other qualified potential partners or enter into collaborations for the commercialization and distribution of Phexxi, from which we may generate licensing revenue. However, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and overall capital requirements. We expect to commercialize Phexxi in June 2020, if approved by the FDA.

Operating Expenses

Research and development expenses

Our research and development expenses primarily consist of costs associated with the clinical and preclinical development of our MVP-R product candidates. Our research and development 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;
- employee-related expenses, including salaries, benefits, travel and 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 costs as incurred. The following table summarizes research and development expenses by product candidate (in thousands):

	Years Ended December 31,	
	2019	**2018**
Allocated third-party development expenses:		
Phexxi for prevention of pregnancy	$ 988	$ 23,650
Phexxi for prevention of chlamydia/gonorrhea	7,735	10,162
Candidate for recurrent bacterial vaginosis	—	608
Total allocated third-party development expenses	8,723	34,420
Unallocated internal research and development expenses:		
Stock-based compensation expenses	1,131	3,193
Payroll related expenses	4,168	2,942
Outside services costs	7,172	1,887
Other	1,036	973
Total unallocated internal research and development expenses	13,507	8,995
Total research and development expenses	**$ 22,230**	**$ 43,415**

Completion dates and costs for our clinical development programs can vary significantly for each current and any future product candidate and are difficult to predict. We anticipate that we will make determinations as to 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 as to the commercial potential of each current or future product candidate. With the anticipation of conducting a phase 3 clinical trial of Phexxi for prevention of chlamydia in women in 2020 in connection with the expected commercial launch of Phexxi for prevention of pregnancy, if approved by the FDA, we expect our research and development expenses to increase in 2020. We will need to raise substantial additional capital in the future to complete clinical development for our current and 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 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.

General and administrative expenses

Our general and administrative expenses consist primarily of pre-commercialization sales and marketing expenses, salaries, benefits, travel, business development expense, stock-based compensation expense, and other related costs for our employees and consultants in executive, administrative, finance and human resource functions. Other general and administrative expenses include facility-related costs not otherwise included in research and development and professional fees for accounting, auditing, tax and legal fees, and other costs associated with obtaining and maintaining our patent portfolio, and conducting commercial assessments for our product candidates.

We expect our general and administrative expenses to increase significantly, specifically sales and marketing expenses, as we hire additional personnel to support the growth of our business and pre-commercialization activities, and as we engage third parties to assist in the preparation of the anticipated launch of Phexxi in June 2020, if approved by the FDA.

Other Income (Expense)

Other income (expense) consists primarily of interest income, other income recognized for the concession received upon the settlement of outstanding accrued sublicense fees and interest expense with WCG Cares as described in Note 6- Commitments and Contingencies, loss on issuance of warrants and Purchase Rights, the change in fair value of warrants and Purchase Rights, and the change in fair value of the Series D 2X liquidation preference, which for each share of Series D is equal to two times the issuance price per share of Series D, plus accrued and unpaid dividends.

Loss on issuance of warrants was recognized upon issuance of warrants to investors as they were determined to be free-standing financial instruments. The change in fair value of warrants was recognized as a result of the modifications to the warrants from change of the exercise price and mark-to-market adjustments for the liability-classified warrants.

Loss on issuance of Purchase Rights was recognized upon issuance the Purchase Rights as they were determined to be free-standing liability-classified financial instruments. The change in fair value of Purchase Rights was recognized as a result of mark-to-market adjustments for the Purchase Rights.

The Series D 2X liquidation preference expired at the Closing Date, at which time the final fair value of the Series D 2X liquidation preference was estimated. The final change in fair value of the Series D 2X liquidation preference of $0.1 million was recognized within change in fair value of the Series D 2X liquidation preference within the consolidated statement of operations for the year ended December 31, 2018. The Series D 2X liquidation preference liability was reclassified to additional paid-in capital within the consolidated balance sheet. Prior to the closing of the Merger, the Series D 2X liquidation preference was revalued at each reporting date and changes in fair value were recognized as increases in or decreases to other income (expense).

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the applicable periods. 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 estimated used in the preparation of our consolidated financial statements, which, in turn, could materially change our results from those reported. Management evaluates its 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 also 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 to this report for our additional accounting policies.

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 year ended December 31, 2019, there were approximately $1.1 million in adjustments to the Company’s previous estimates of accrued expenses for AMPOWER upon final billings. There were no material adjustments to accrued expenses for clinical trials during the year ended December 31, 2018.

Fair Value of Series D 2X Liquidation Preference

Prior to completion of the Merger, the Company valued its Series D 2X liquidation preference in accordance with Accounting Standards Codification No. 815 — Derivatives and Hedging, using a PWERM, which is sensitive to changes in assumptions regarding the timing of additional financings, potential exit scenarios and revisions in our financial forecast. Changes in any one of the assumptions could have had a material impact on the estimated fair value of the Series D 2X liquidation preference. Management used the most reliably available information at each valuation date to determine the fair value of the Series D 2X liquidation preference. Due to the nature of the assumptions and the sensitive nature of the PWERM, management could not reliably provide sensitivity analysis around the impact of changes in assumptions utilized in the PWERM used to estimate the fair value of the Series D 2X liquidation preference.

Fair Value of Stock Options and Warrants

The fair value of stock options, and each of (i) the WIM and Invesco Warrants issued in connection with the Merger, (ii) Reload Warrants issued in February 2019, (iii) warrants issued in the second quarter of 2019 in connection with the Private Placement, and (iv) the change in fair value of warrants as a result of the modification and mark-to-market for liability-classified warrants 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.

Fair Value of Purchase Rights

The fair value of the Purchase Rights issued with the Private Placement were determined using a combination of a lattice model and BSM option-pricing model. The lattice model was used to determine the future value of the Company's common stock as of the Second Closing. The BSM option-pricing model was used to determine the fair value of the warrants issued at the First Closing and Second Closing and the existing warrants subsequently canceled at the Second Closing (see discussion of the warrants canceled in Note 10- Private Placement) based on the applicable assumptions.

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. Operating leases are included in operating lease right-of-use (ROU) assets and operating lease liabilities in its consolidated balance sheets. ROU assets represent the Company's right to use an underlying asset for the lease term and 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 used 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 considered 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 financing. 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.

Results of Operations

Year Ended December 31, 2019 Compared to Year Ended December 31, 2018 (in thousands):

Research and development expenses

	Year Ended December 31,		2019 vs. 2018	
	2019	2018	$ Change	% Change
Research and development	$ 22,230	$ 43,415	$ (21,185)	(49)%

The overall decrease in research and development expenses during the year ended December 31, 2019 was due to a $24.9 million decrease in clinical trial costs primarily related to completion of the clinical phase of AMPOWER in December 2018 and AMPREVENCE in December 2019 as compared to the prior year period. In addition, there was a $2.1 million decrease in noncash stock-based compensation mainly associated with stock-based awards granted in March and July 2018, the majority of which vested during the year of grant, offset by stock-based compensation associated with stock-based awards granted subsequent to December 31, 2018. These aggregate decreases were partially offset by a $4.5 million increase in costs incurred for outside services associated with preparing the Phexxi NDA resubmission for the prevention of pregnancy and a $1.1 million increase in payroll related expenses due to increased headcount.

General and administrative expenses

	Year Ended December 31,		2019 vs. 2018	
	2019	2018	$ Change	% Change
General and administrative	$ 30,512	$ 34,227	$ (3,715)	(11)%

The overall decrease in general and administrative expenses during the year ended December 31, 2019 was primarily due to a $7.2 million decrease in noncash stock-based compensation mainly associated with RSAs granted in July 2018, the majority of which vested at grant, and stock options granted in March 2018, the majority of which vested during the first year after grant, offset by stock-based compensation associated with stock-based awards granted subsequent to December 31, 2018. There was also a $3.8 million decrease in professional services and personnel costs attributable to the one-time costs associated with the Merger in 2018. These decreases were partially offset by a $3.4 million increase in pre-commercialization advertising agency fees, public relations and sales support related expenses, a $2.3 million increase in payroll related expenses due to increased headcount and a $1.4 million increase in costs incurred associated with pre-commercialization consulting services.

Total other income (expense), net

	Year Ended December 31,		2019 vs. 2018	
	2019	2018	$ Change	% Change
Total other expense	$ (27,287)	$ (48,068)	$ 20,781	(43)%

Total other expense for the year ended December 31, 2019 primarily included a $0.7 million loss on issuance of Purchase Rights provided to the Purchasers in connection with the First Closing of the Private Placement as described in Note 10- Private Placement, a $19.6 million change in fair value of Purchase Rights and a $3.4 million change in fair value of warrants associated with the First Closing Warrants as a result of mark-to-market due to their classification change from liability to equity upon stockholder approval of the Private Placement, and a $4.4 million change in fair value of warrants as a result of a modification to the WIM Warrants and common warrants exercised in February 2019 as described in Note 8- Convertible Preferred Stock and Note 9- Public Offering. These other expenses were offset by $0.5 million of interest income and $0.3 million of other income for the concession received upon the settlement of outstanding accrued sublicense fees and interest expense with WCG Cares as described in Note 6- Commitments and Contingencies.

The total other expense for the year ended December 31, 2018 primarily included a $47.9 million loss on issuance of warrants related to the Invesco Warrants issued immediately prior to the Closing Date of the Merger, and a $0.1 million change in fair value of the Series D 2X liquidation preference upon a final valuation when all 80 shares issued and outstanding Series D were converted into the Company' common stock in January 2018 as described in Note 3- Merger and Related Transactions.

Liquidity and Capital Resources

As of December 31, 2019, we had working capital of $13.8 million, and an accumulated deficit of $513.2 million. We have financed our operations to date primarily through the sale of preferred stock, common stock, preferred units, payments received under our collaboration agreements, interest earned on investments, and cash received in the Merger. At December 31, 2019, we had approximately $23.8 million in cash and cash equivalents, and short-term investments. Our cash and cash equivalents include amounts held in checking accounts, money market funds, and investments in fixed income debt securities with original maturities less than three months. Our short-term investments consist of held-to-maturity securities that will be due in one year or less. 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. In February 2019, we received gross proceeds of approximately $6.3 million from the exercise of warrants to purchase 2,376,062 shares of our common stock held by certain shareholders at an exercise price of $2.64 per share. In the second quarter of 2019, we received proceeds of approximately $75.4 million, net of financial advisory fees, upon completion of the Private Placement. In December, we received proceeds of approximately $3.3 million (including $3.0 million in cash and cash equivalents and $0.3 million in other receivable), net of commissions, from the sale of 515,019 shares of our common stock.

We anticipate that we will continue to incur net losses for the foreseeable future and incur additional costs associated with being a public company. We expect research and development expenses to increase in 2020 compared to 2019 as we are planning to conduct a phase 3 clinical trial of Phexxi for prevention of chlamydia in women in 2020 in connection with the expected commercial launch of Phexxi for prevention of pregnancy, if approved by the FDA. We expect general and

administrative expenses to increase significantly in 2020, specifically sales and marketing expenses, as we deploy a sales force of approximately 140 sales representatives and leaders, hire additional personnel to support the growth of our business and pre-commercialization activities and engage third parties to assist in the preparation for the anticipated launch of Phexxi in June 2020, if approved by the FDA. According to management estimates, our liquidity resources as of December 31, 2019 are not sufficient to maintain our planned level of operations for the next 12 months. In addition, the uncertainties associated with our ability to (i) obtain additional equity financing on terms that are favorable to us, (ii) enter into collaborative agreements with strategic partners and (iii) succeed in our future operations, raise substantial doubt about our ability to continue as a going concern.

The opinion of our independent registered public accounting firm on our audited financial statements as of and for the years ended December 31, 2019 and 2018 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, 2019 and 2018 included in this 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.

If we are not able to obtain required additional funding in the near term, through equity financings or other means, or are not able to obtain funding on terms favorable to us, these circumstances will have a material adverse effect on our operations and strategic development plan for future growth. If we cannot successfully raise additional funding and implement our strategic development plan, we may be forced to make reductions in spending, suspend or terminate development programs, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these could materially and adversely affect our liquidity, financial condition and business prospects and we would not be able to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements.

At the Market Program

In November 2019, the Company entered into an equity distribution agreement with Piper Sandler & Co. (Piper Sandler), pursuant to which the Company may offer and sell shares of its common stock in at the market (ATM) offerings (as defined in Rule 415 of the Securities Act) having an aggregate offering price up to $50 million in gross proceeds from time to time through Piper Sandler acting as sales agent. During the year ended December 31, 2019, we received proceeds of approximately $3.3 million (including $3.0 million in cash and cash equivalents and $0.3 million in other receivable), net of commissions, from the sale of 515,019 shares of our common stock. Subsequent to December 31, 2019, we received net proceeds of approximately $1.1 million, net of commissions, from the sale of 202,098 shares of our common stock.

Promissory Note

On December 5, 2018, the Company entered into a promissory note with our CRO for AMPOWER, where the Company agreed to pay invoiced amounts totaling approximately $4.0 million for clinical trial related services and had a due date of February 15, 2019 (CRO Note). Any matured and unpaid amounts pursuant to this CRO Note bear an annual interest rate of the lesser of 1% per month or the maximum amount permitted by the Laws of the State of Massachusetts.

In late February 2019, the Company amended the CRO Note, which extended the due date to April 15, 2019. In April 2019, the Company paid the CRO Note in full.

Summary Statements of Cash Flows

The following table sets forth a summary of the net cash flow activity for the years ended December 31, 2019 and 2018 (in thousands):

	Year Ended December 31,		2019 vs. 2018	
	2019	2018	$ Change	% Change
Net cash, cash equivalents and restricted cash used in operating activities	$ (55,097)	$ (56,500)	$ 1,403	(2)%
Net cash, cash equivalents and restricted cash (used in) provided by investing activities	(8,115)	2,143	(10,258)	(479)%
Net cash, cash equivalents and restricted cash provided by financing activities	78,076	54,417	23,659	43 %
Net decrease in cash, cash equivalents and restricted cash	$ 14,864	$ 60	$ 14,804	24,673 %

Cash Flows from Operating Activities. Since inception, the primary use of cash, cash equivalents and restricted cash has been to fund development of our lead MVP-R product candidate, Phexxi, for prevention of pregnancy as well as potential other indications and to support pre-commercialization activities and other general and administrative operations.

Cash Flows from Investing Activities. Net cash, cash equivalents and restricted cash used in investing activities for theyear ended December 31, 2019 was primarily the purchase of short-term investments of $8.2 million. Net cash, cash equivalents and restricted cash provided by investing activities for the year ended December 31, 2018 was primarily due to $1.9 million non-recurring cash acquired from Neothetics in connection with the Merger as described in Note 1- Description of Business and Basis of Presentation.

Cash Flows from Financing Activities. During the year ended December 31, 2019, the primary source of cash, cash equivalents and restricted cash was the issuance of 2,376,062 shares of common stock upon the exercise of warrants in February 2019 for gross proceeds of $6.3 million, the issuance of an aggregate of 17,777,779 shares of common stock and common warrants to purchase 4,444,446 shares of common stock pursuant to the Private Placement as described in Note 10-Private Placement during the second quarter of 2019 for proceeds of $75.4 million, net of financial advisory fees, the sales of 515,019 shares of common stock with proceeds of approximately $3.0 million in cash and cash equivalents, net of commissions, under the ATM program, and the issuance of 88,074 shares of common stock with proceeds of approximately $0.3 million from the ESPP purchase and stock option exercises. The cash inflow was offset by the $4.0 million repayment for the CRO Note during the second quarter of 2019, $1.3 million in payments for financing costs and $1.6 million payments for tax withholdings related to vesting of restricted stock awards.

During the year ended December 31, 2018, the primary source of cash, cash equivalents and restricted cash was the sale of 1,614,289 shares of the Company’s common stock for gross proceeds of $20.0 million in a private placement transaction with Invesco, the sale of 7,436,171 shares of common stock, pre-funded warrants to purchase 1,063,829 shares of common stock and common warrants to purchase 1,700,000 shares of common stock for net proceeds of $37.5 million in connection with the Offering, offset by $1.6 million in payments for tax withholdings related to vesting of restricted stock awards, $1.4 million in payments for financing costs and $0.2 million in payments for Series D dividends upon conversion of Series D into Neothetics’ common stock.

Operating and Capital Expenditure Requirements

Our future capital requirements are difficult to forecast. For example, we expect to incur additional capital expenditures for serialization equipment to be utilized in the manufacturing of Phexxi prior to commercialization, but cannot adequately predict the cost of the equipment in the future or other potential capital expenditure requirements, if any.

We expect research and development expenses to increase in 2020 compared to 2019 as we are planning to conduct a phase 3 clinical trial of Phexxi for prevention of chlamydia in women in 2020 in connection with the expected commercial launch of Phexxi for prevention of pregnancy, if approved by the FDA. In addition, we expect to incur costs as we make improvements to our manufacturing process. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming and we may never succeed in achieving regulatory approval for any of our product candidates. The probability of success for each product candidate will be affected by numerous factors, including preclinical data, clinical trial data, competition, manufacturing capability and commercial viability. We are responsible for all research and development costs for our programs.

We expect general and administrative expenses to increase significantly, specifically sales and marketing expenses, as we deploy a sales force of approximately 140 sales representatives and leaders, hire additional personnel to support the growth of our business and pre-commercialization activities and engage third parties to assist in the preparation for the anticipated launch of Phexxi in June 2020, if approved by the FDA. We also anticipate increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with stock exchange listing and SEC requirements, and directors' and officers' liability insurance premiums.

When we believe regulatory approval of a product candidate appears likely, we expect to incur significant costs as we establish a sales and marketing infrastructure for its expected distribution, promotion and sale.

Off-Balance Sheet Arrangements

As of December 31, 2019 and 2018, we did not have any off-balance sheet arrangements, as such term is defined under Item 303 of Regulation S-K, that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Contractual Obligations and Commitments

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 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, 2019, 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 Securities and Exchange Act of 1934, as amended (Exchange Act) as of December 31, 2019. 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 (2013 Framework). Based on this assessment, our management concluded that, as of December 31, 2019, our internal control over financial reporting was effective based on those criteria.

Attestation Report on Internal Control over Financial Reporting

This Annual Report does not include an attestation report of our independent registered public accounting firm due to the deferral allowed under the JOBS Act for emerging growth companies.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2019 that has materially affected, or is 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.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The response to the information required by this item is incorporated by reference from the discussions set forth under the headings “ELECTION OF DIRECTORS (Notice Item 1)”, “EXECUTIVE OFFICER AND DIRECTOR COMPENSATION”, “SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE”, and “MANAGEMENT AND CORPORATE GOVERNANCE” in our proxy statement for the 2020 Annual Meeting of Stockholders.

Item 11. Executive Compensation.
The response to the information required by this item is incorporated by reference from the discussions set forth under the heading “EXECUTIVE OFFICER AND DIRECTOR COMPENSATION” in our proxy statement for the 2020 Annual Meeting of Stockholders.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.
The response to the information required by this item is incorporated by reference from the discussions set forth under the headings “SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT” and “EXECUTIVE OFFICER AND DIRECTOR COMPENSATION” in our proxy statement for the 2020 Annual Meeting of Stockholders.

Item 13. Certain Relationships and Related Transactions, and Director Independence.
The response to the information required by this item is incorporated by reference from the discussions set forth under the headings “CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS” and “ELECTION OF DIRECTORS (Notice Item 1)” in our proxy statement for the 2020 Annual Meeting of Stockholders.

Item 14. Principal Accounting Fees and Services.
The response to the information required by this item is incorporated by reference from the discussions set forth under the headings “INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM (Notice Item 5)” in our proxy statement for the 2020 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed as part of this Annual Report

1. Financial Statements.

The following financial statements of Evofem Biosciences, Inc., together with the report thereon of Deloitte & Touche LLP, an independent registered public accounting firm, are included in this Annual Report:

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.		10-K	001-36754	2/26/2018
3.2	Amended and Restated Bylaws of the Registrant.		8-K	001-36754	1/17/2018
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 between 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	Form of Voting Agreement.		S-4	333-221592	11/15/2017
4.9	Form of Common Warrant.		S-1	333-224958	5/16/2018
4.10	Form of Pre-funded Warrant.		S-1	333-224958	5/16/2018
4.11	Form of Reload Warrant.		8-K	001-36754	02/11/2019
4.12	Form of Reload Warrant.		8-K	001-36754	02/11/2019
4.13	Form of Warrant.		8-K	001-36754	04/11/2019
4.14	Form of Warrant for Woodford.		8-K	001-36754	04/11/2019
4.15*	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	04/11/2019
10.1	Form of Merger Lock-Up Agreement.		8-K	001-36754	10/17/2017
10.2	Twelfth Amendment, dated as of December 4, 2017, by and between the Registrant and LJ Gateway Office LLC.		8-K	001-36754	12/8/2017
10.3Δ	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
10.4Δ	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
10.5	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
10.6	Lease, dated as of July 3, 2008, by and between the Registrant and WW&LJ Gateways, LTD.		S-1	333-199449	10/17/2014
10.7	Ninth Amendment to Lease, dated as of April 21, 2014, by and between the Registrant and LJ Gateway Office LLC (as successor in interest to WW&LJ Gateways, LTD).		S-1	333-199449	10/17/2014

10.8	Tenth Amendment, dated as of January 20, 2015, by and between the Registrant and LJ Gateway Office LLC (as successor in interest to WW&LJ Gateways, LTD).	10-K	001-36754	3/29/2015
10.9	Eleventh Amendment, dated as of January 31, 2017, by and between the Registrant and LJ Gateway Office LLC (as successor in interest to WW&LJ Gateways, LTD).	8-K	001-36754	2/14/2017
10.1	Sublease, dated as of January 27, 2017, by and between the Registrant and Abacus Data Systems, Inc.	8-K	001-36754	2/14/2017
10.11Δ	Letter Agreement, dated as of July 3, 2014, by and between the Registrant and Martha J. Demski.	S-1	333-199449	10/17/2014
10.12Δ	Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers.	S-1	333-199449	10/17/2017
10.13Δ	Amended and Restated 2007 Stock Plan, as amended.	S-1/A	333-199449	11/10/2014
10.14Δ	Form of Stock Option Agreement under 2007 Stock Plan.	S-1	333-199449	10/17/2014
10.15Δ	Amendment to 2014 Equity Incentive Plan.	10-Q	001-36754	8/11/2016
10.16Δ	Amended and Restated 2014 Equity Incentive Plan.	8-K	001-36754	5/8/2018
10.17Δ	Form of Stock Option Agreement under 2014 Equity Incentive Plan.	S-1/A	333-199449	11/10/2014
10.18Δ	Form of Restricted Stock Units Agreement under the 2014 Equity Incentive Plan.	S-1/A	333-199449	11/10/2014
10.19Δ	Form of Restricted Stock Agreement under the 2014 Equity Incentive Plan.	S-1/A	333-199449	11/10/2014
10.20Δ	Form of Notice of Grant of Restricted Stock Units under the 2014 Equity Incentive Plan.	S-1/A	333-199449	11/10/2014
10.21Δ	Form of Notice of Grant of Restricted Stock under the 2014 Equity Incentive Plan.	S-1/A	333-199449	11/10/2014
10.22Δ	Form of Notice of Grant of Stock Option under the 2014 Equity Incentive Plan.	S-1/A	333-199449	11/10/2014
10.23Δ	2014 Employee Stock Purchase Plan.	S-1/A	333-199449	11/10/2014
10.24Δ	Amended and Restated Non-Employee Director Compensation Policy.	10-K	001-36754	2/26/2018
10.25	Consulting Agreement, dated as of April 1, 2017, by and between Evofem Biosciences Operations, Inc. and Thomas Lynch.	S-4	333-221592	11/15/2017
10.26Δ	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
10.27Δ	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
10.28Δ	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
10.29Δ	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
10.30Δ	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
10.31Δ	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
10.32Δ	Evofem Biosciences Operations, Inc. Amended and Restated 2012 Equity Incentive Plan.	S-4	333-221592	11/15/2017
10.33Δ	Form of Notice of Option Grant and Option Agreement under the Evofem Biosciences Operations, Inc. 2012 Equity Incentive Plan.	S-4	333-221592	11/15/2017

10.34Δ	Form of Notice of Grant of Restricted Stock Award under the Evofem Biosciences Operations, Inc. 2012 Equity Incentive Plan.		S-4	333-221592	11/15/2017
10.35†	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
10.36	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
10.37	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
10.38	Office Sublease, dated as of January 30, 2015, by and between Evofem, Inc. and Relational Investors LLC.		S-4	333-221592	11/15/2017
10.39	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
10.40	Sublease, dated as of January 30, 2015, by and between Evofem, Inc. and WomanCare Global Trading, Inc.		S-4	333-221592	11/15/2017
10.41Δ	Executive Employment Agreement, dated as of October 15, 2014, by and between the Registrant and Susan Knudson.		S-1	333-199449	10/17/2014
10.42	Form of Registration Rights Agreement.		8-K	001-36754	10/17/2017
10.43Δ	Executive Employment Agreement, dated as of July 2, 2018, by and between the Registrant and Saundra Pelletier.		8-K	001-36754	7/3/2018
10.44Δ	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
10.45Δ	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
10.46Δ	Executive Employment Agreement, dated as of July 2, 2018, by and between the Registrant and Russell Barrans.		8-K	001-36754	7/3/2018
10.47Δ	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
10.48Δ	2018 Inducement Equity Incentive Plan.		10-Q	001-36754	8/2/2018
10.49Δ	Form of Notice of Grant of Stock Option under the 2018 Inducement Equity Incentive Plan.		10-Q	001-36754	8/2/2018
10.50	Form of Repricing Letter Agreement.		8-K	001-36754	02/11/2019
10.51	Form of Repricing Letter Agreement.		8-K	001-36754	02/11/2019
10.52	Securities Purchase Agreement.		8-K	001-36754	04/11/2019
10.53	Registration Rights Agreement.		8-K	001-36754	04/11/2019
10.54	Consulting Agreement, dated as of April 1, 2019, by and between Evofem Biosciences Operations, Inc. and Thomas Lynch.		10-Q	001-36754	5/7/2019
10.55	Evofem Biosciences, Inc. Amended and Restated 2014 Equity Incentive Plan.		8-K	001-36754	06/05/2019
10.56	Evofem Biosciences, Inc. 2019 Employee Stock Purchase Plan.		8-K	001-36754	06/05/2019
10.57	Lease, entered into October 9, 2019, by and between the Registrant and Kilroy Realty, L.P.		10-Q	001-36754	11/7/2019
10.58††	Supply and Manufacturing Agreement, dated November 4, 2019, by and between the Registrant and DPT Laboratories, Ltd.	X			
16.1	Letter from Ernst & Young LLP dated as of January 25, 2018.		8-K	001-36754	1/25/2018
21.1	List of Registrant Subsidiaries.		10-K	001-36754	2/26/2018

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.

†† 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.

* Furnished herewith. This certification is being furnished solely to accompany this 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, 2019 filed on March 12, 2020 formatted in XBRL (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 report to be signed on its behalf by the undersigned hereunto duly authorized.

EVOFEM BIOSCIENCES, INC.

Date: March 12, 2020

By: /s/ Saundra Pelletier
Name: Saundra Pelletier
Title: *President and Chief Executive Officer*

Pursuant to the requirements of the Securities Exchange Act of 1934, this 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 and Chief Executive Officer and Director (*Principal Executive Officer*)	March 12, 2020
/s/ Justin J. File Justin J. File	Chief Financial Officer (*Principal Financial Officer and Principal Accounting Officer*)	March 12, 2020
/s/ Thomas Lynch Thomas Lynch	Chairman of the Board	March 12, 2020
/s/ Gillian Greer, Ph.D. Gillian Greer, Ph.D.	Director	March 12, 2020
/s/ William Hall, Ph.D. William Hall, Ph.D., M.D.	Director	March 12, 2020
/s/ Kim P. Kamdar, Ph.D. Kim P. Kamdar, Ph.D.	Director	March 12, 2020
/s/ Tony O'Brien Tony O'Brien	Director	March 12, 2020
/s/ Colin Rutherford Colin Rutherford	Director	March 12, 2020
/s/ Lisa Rarick Lisa Rarick	Director	March 12, 2020

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, 2019 and 2018, the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, 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 and negative cash flows from operations since inception. These conditions raise substantial doubt about the Company’s 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.

/s/ Deloitte & Touche LLP

San Diego, CA
March 12, 2020

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, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 15,571	$ 1,330
Restricted cash	304	431
Short-term investments	8,233	—
Prepaid and other current assets	2,313	717
Total current assets	26,421	2,478
Property and equipment, net	394	593
Operating right-of-use assets	160	—
Other noncurrent assets	1,320	939
Total assets	$ 28,295	$ 4,010
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 6,008	$ 8,882
Note payable	—	4,010
Accrued expenses	2,784	11,513
Accrued compensation	3,670	2,924
Operating lease liabilities	197	—
Total current liabilities	12,659	27,329
Deferred rent	—	37
Total liabilities	12,659	27,366
Commitments and contingencies (Note 6)		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized; no shares issued and outstanding	—	—
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 300,000,000 shares authorized; 48,137,880 and 25,867,248 shares issued and outstanding at December 31, 2019 and 2018, respectively	5	3
Additional paid-in capital	528,810	409,787
Accumulated deficit	(513,179)	(433,146)
Total stockholders' equity (deficit)	15,636	(23,356)
Total liabilities and stockholders' equity (deficit)	$ 28,295	$ 4,010

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,	
	2019	**2018**
Operating expenses:		
Research and development	$ 22,230	$ 43,415
General and administrative	30,512	34,227
Total operating expenses	52,742	77,642
Loss from operations	(52,742)	(77,642)
Other income (expense):		
Interest income	458	127
Other income (expense), net	301	(145)
Loss on issuance of warrants	—	(47,920)
Loss on issuance of Purchase Rights	(674)	—
Change in fair value of warrants	(7,755)	—
Change in fair value of Purchase Rights	(19,617)	—
Change in fair value of Series D 2X liquidation preference	—	(130)
Total other expense	(27,287)	(48,068)
Loss before income tax	(80,029)	(125,710)
Income tax expense	(4)	(2)
Net loss	(80,033)	(125,712)
Accretion of Series D redeemable convertible preferred stock dividends	—	(66)
Net loss attributable to common stockholders	$ (80,033)	$ (125,778)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.99)	$ (5.74)
Weighted-average shares used to compute net loss attributable to common stockholders, basic and diluted	40,228,517	21,900,574

See accompanying notes to the consolidated financial statements.

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share data)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C-1 Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2017	12,618,279	$ 23,848	13,801,318	$ 43,616	8,558,686	$ 34,382	5,037,784	$ 19,469	80	$ 68,556	2,082,053	$ —	$ 17,731	$ (307,277)	$ (289,546)
Conversion of convertible preferred stock into Private Evofem common stock, excluding Series D (see Note 8)	(12,618,279)	(23,848)	(13,801,318)	(43,616)	(8,558,686)	(34,382)	(5,037,784)	(19,469)	—	—	1,027,079	—	121,315	—	121,315
Cancellation of restricted stock awards (see Note 11)	—	—	—	—	—	—	—	—	—	—	(122,149)	—	—	—	—
Issuance of common stock upon cashless exercise of Invesco Warrants (see Note 10)	—	—	—	—	—	—	—	—	—	—	3,968,473	1	47,919	—	47,920
Accretion and payment of Series D dividends (see Note 8)	—	—	—	—	—	—	—	—	—	66	—	—	(66)	(157)	(223)
Conversion of Series D dividends and Series D (see Note 8)	—	—	—	—	—	—	—	—	(80)	(5,226)	6,878,989	1	5,225	—	5,226
Redemption of Series D 2X liquidation preference upon conversion of Series D (see Note 8)	—	—	—	—	—	—	—	—	—	—	—	—	80,000	—	80,000
Deemed contribution upon conversion of Series D (see Note 8)	—	—	—	—	—	—	—	—	—	(49,334)	—	—	49,334	—	49,334
Issuance of common stock and WIM Warrants (see Note 8)	—	—	—	—	—	—	—	—	—	(14,062)	3	—	14,062	—	14,062
Private placement of common stock (see Note 3)	—	—	—	—	—	—	—	—	—	—	1,614,289	—	20,000	—	20,000
Record pre-merger Neothetics' stockholders' equity and elimination of Neothetics' historical accumulated deficit (see Note 3)	—	—	—	—	—	—	—	—	—	—	2,308,430	—	1,946	—	1,946
Issuance of common stock, pre-funded warrants and common warrants in connection with the Offering, net of underwriting discounts, commissions and offering costs (see Note 9)	—	—	—	—	—	—	—	—	—	—	7,436,171	1	36,029	—	36,030
Issuance of common stock - exercise of stock options	—	—	—	—	—	—	—	—	—	—	6,173	—	42	—	42
Restricted stock awards/units issued	—	—	—	—	—	—	—	—	—	—	1,305,399	—	—	—	—
Shares withheld to cover taxes related to vesting of restricted stock awards	—	—	—	—	—	—	—	—	—	—	(637,662)	—	(1,592)	—	(1,592)
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	17,842	—	17,842
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(125,712)	(125,712)
Balance at December 31, 2018	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**25,867,248**	**$ 3**	**$ 409,787**	**$ (433,146)**	**$ (23,356)**
Issuance of common stock upon cash exercise of warrants and issuance of Reload Warrants (see Note 11)	—	—	—	—	—	—	—	—	—	—	3,438,133	—	10,618	—	10,618
Issuance of common stock in connection with the Private Placement (see Note 10)	—	—	—	—	—	—	—	—	—	—	17,777,779	2	68,262	—	68,264
Issuance of common stock in connection with ATM (see Note 11)	—	—	—	—	—	—	—	—	—	—	515,019	—	3,012	—	3,012
Issuance of common stock - ESPP and exercise of stock options	—	—	—	—	—	—	—	—	—	—	88,074	—	392	—	392
Restricted stock awards issued/restricted stock units released	—	—	—	—	—	—	—	—	—	—	720,333	—	—	—	—
Shares withheld to cover taxes related to vesting of restricted stock awards	—	—	—	—	—	—	—	—	—	—	(268,706)	—	(1,566)	—	(1,566)
Reclassification of warrant and Purchase Rights liability to equity	—	—	—	—	—	—	—	—	—	—	—	—	29,726	—	29,726
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	8,579	—	8,579
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	0	(80,033)	(80,033)
Balance at December 31, 2019	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**48,137,880**	**$ 5**	**$ 528,810**	**$ (513,179)**	**$ 15,636**

See accompanying notes to the consolidated financial statements.

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended December 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (80,033)	$ (125,712)
Adjustments to reconcile net loss to net cash, cash equivalents and restricted cash used in operating activities:		
Loss on issuance of warrants	—	47,920
Loss on issuance of Purchase Rights	674	—
Change in fair value of warrants	7,755	—
Change in fair value of Purchase Rights	19,617	—
Change in fair value of Series D 2X liquidation preference	—	130
Stock-based compensation	8,579	17,842
Depreciation	263	262
Loss from sale of property and equipment	79	—
Noncash lease expenses	642	—
Changes in operating assets and liabilities:		
Prepaid and other assets	(952)	(11)
Accounts payable	(2,931)	3,799
Accrued expenses and other liabilities	(8,775)	(795)
Accrued compensation	746	307
Operating lease liabilities	(761)	—
Deferred rent, net of current portion	—	(242)
Net cash, cash equivalents and restricted cash used in operating activities	(55,097)	(56,500)
Cash flows from investing activities:		
Proceeds from sale of property and equipment	32	—
Proceeds from sale of Softcup line of business	250	250
Cash acquired in connection with the Merger	—	1,900
Purchases of property and equipment	(164)	(7)
Purchase of short-term investments	(8,233)	—
Net cash, cash equivalents and restricted cash (used in) provided by investing activities	(8,115)	2,143
Cash flows from financing activities:		
Proceeds from issuance of common stock- exercise of warrants	6,273	—
Proceeds from issuance of common stock, warrants and Purchase Rights in connection with Private Placement, net of financial advisory fees	75,400	20,000
Proceeds from issuance of common stock, net of commissions- ATM transactions	2,960	—
Proceeds from issuance of common stock, pre-funded warrants and common warrants in connection with the Offering, net of underwriting discounts and commissions	—	37,542
Proceeds from issuance of common stock - ESPP and exercise of stock options	305	42
Repayment of Note Payable	(4,010)	—
Payment of cash dividends for Series D redeemable convertible preferred stock	—	(157)
Cash paid for financing costs	(1,286)	(1,418)
Payments of tax withholdings related to vesting of restricted stock awards	(1,566)	(1,592)
Net cash, cash equivalents and restricted cash provided by financing activities	78,076	54,417
Net change in cash, cash equivalents and restricted cash	14,864	60
Cash, cash equivalents and restricted cash, beginning of period	1,761	1,701
Cash, cash equivalents and restricted cash, end of period	$ 16,625	$ 1,761
Supplemental cash flow information:		
Cash paid for taxes	$ 4	$ 2
Supplemental disclosure of noncash investing and financing activities:		
Right-of-use assets obtained in exchange for operating lease liabilities	$ 802	$ —
Financing costs included in accounts payable and accrued expenses	$ 306	$ 94
Purchases of property and equipment included in accounts payable and accrued expenses	$ 10	$ —
Reclassification of warrants and Purchase Rights liability to equity	$ 6,120	
Proceeds from issuance of common stock included in other receivable	$ 416	$ —
Net assets acquired in connection with the Merger	$ —	$ 46
Conversion of convertible preferred stock into common stock (excluding Series D)	$ —	$ 121,315

Conversion of Series D redeemable convertible preferred stock into common stock	$	—	$	68,622
Redemption of Series D 2X liquidation preference upon conversion of Series D redeemable convertible preferred stock into common stock	$	—	$	80,000
Issuance of Promissory Note	$	—	$	4,010

See accompanying notes to the consolidated financial statements.

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business and Basis of Presentation

Merger

On January 17, 2018, Neothetics, Inc., a Delaware corporation (Neothetics), now known as Evofem Biosciences, Inc. (the Company), completed its merger (the Merger) with privately-held Evofem Biosciences Operations, Inc. (Private Evofem), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated October 17, 2017 (the Merger Agreement), whereby Nobelli Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Neothetics, merged with and into Private Evofem, with Private Evofem surviving as Neothetics' wholly-owned subsidiary.

In connection with the Merger, Neothetics filed a certificate of amendment to the amended and restated certificate of incorporation to, among other things, affect a 6:1 reverse stock split of its common stock (the Reverse Stock Split) and change its name from "Neothetics, Inc." to "Evofem Biosciences, Inc." Both the name change and the Reverse Stock Split were effective on January 17, 2018 (the Closing Date). Shares of the Company's common stock commenced trading on The Nasdaq Capital Market under the ticker symbol "EVFM" as of January 18, 2018. See discussions of the transactions in connection with the Merger at Note 3- Merger and Related Transactions.

Evofem Biosciences, Inc.'s operations include those of its wholly-owned subsidiaries, Evofem Biosciences Operations, Inc., a Delaware corporation, Evofem Inc., a Delaware corporation, Evofem North America, Inc., a Delaware corporation (ENA), Evofem Limited, LLC, a Delaware limited liability company and Evofem Ltd., a limited company registered in England and Wales and those of its partially owned subsidiary, Evolution Pharma, a Dutch limited partnership (EP) with 99% of the outstanding partnership interests held by Evofem Inc. and 1% of the outstanding partnership interests held by Evofem Limited, LLC. Evofem Limited, LLC and Evofem Ltd. are currently inactive.

Unless otherwise noted, (i) references in this report to "Evofem" and the "Company" refer to Evofem Biosciences, Inc. and its subsidiaries following the closing of the Merger on the Closing Date, (ii) references to "Private Evofem" refer to Evofem Biosciences Operations, Inc. and its subsidiaries prior to the closing the Merger on the Closing Date, (iii) references to "Neothetics" refer to Neothetics, Inc. and its subsidiaries prior to the closing of the Merger on the Closing Date, and (iv) references to share amounts, figures (other than exchange ratios) and other information have been adjusted to reflect the Reverse Stock Split.

Description of Business

Evofem is a San Diego-based clinical-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health. Evofem exists to advance the lives of women by developing innovative solutions, such as woman-controlled contraception and potential protection from certain sexually transmitted infections (STIs). The Company is leveraging its proprietary Multipurpose Vaginal pH Regulator (MVP-R™) platform to develop product candidates for several potential indications, including prevention of pregnancy and prevention of certain STIs.

Evofem's pipeline also includes an MVP-R product candidate for reduction of recurrent BV. The Company anticipates conducting a Phase 2 clinical trial for this indication, building on favorable Phase 1 trial results.

Basis of Presentation and Principles of Consolidation

Since Private Evofem was determined to be the accounting acquirer in connection with the Merger, it recorded Neothetics' assets and liabilities at fair value as of the Closing Date. Therefore, for periods prior to the Merger, the consolidated financial statements were prepared on a stand-alone basis for Private Evofem and did not include the combined entities' financial position. Subsequent to the Merger, the consolidated financial statements as of and for the year ended December 31, 2018 from the Closing Date included Neothetics' assets and liabilities.

The Company prepared the consolidated financial statements in accordance with accounting principles generally accepted in the U.S. (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 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 do 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 (R&D), including development of Phexxi, as well as raising capital, recruiting personnel and establishing a corporate infrastructure to support a commercial product. The Company has no revenues and, as such, has incurred operating losses and negative cash flows from operating activities since inception. As described in the notes to the consolidated financial statements, the Company received gross proceeds of approximately $6.3 million upon the exercise of warrants in February 2019, proceeds of approximately $75.4 million, net of financial advisory fees, upon the sale and issuance of common stock pursuant to a Private Placement with certain investors in the second quarter of 2019, and proceeds of approximately $3.0 million from its at the market (ATM) program in December 2019, net of commissions. As of December 31, 2019, the Company had cash and cash equivalents of $15.6 million, working capital of $13.8 million and an accumulated deficit of $513.2 million.

The Company is subject to risks common to other life science companies in the development stage including, but not limited to, uncertainty of product development and commercialization, lack of marketing and sales history, development by its competitors of new technological innovations, dependence on key personnel, market acceptance of products, product liability, protection of proprietary technology, ability to raise additional financing, and compliance with U.S. Food and Drug Administration (FDA) and other government regulations. If the Company does not successfully commercialize any product candidates, it will be unable to generate recurring product revenue or achieve profitability. Management's plans to meet its short- and long-term operating cash flow requirements include obtaining additional funding, such as through the issuance of its common stock, from other equity or debt financings, or through collaborations or partnerships with other companies.

The Company anticipates it will continue to incur net losses for the foreseeable future and incur additional costs associated with being a public company. R&D expenses are expected to increase in 2020 in anticipation of conducting a Phase 3 clinical trial of Phexxi for the prevention of urogenital chlamydia and gonorrhea in women in 2020 in connection with the expected commercial launch of Phexxi for the prevention of pregnancy, if approved by the FDA. Sales and marketing expenses are expected to increase significantly in 2020 due to anticipated pre-commercialization activities in the first half of 2020 in preparation for the anticipated launch of Phexxi in June 2020, if approved by the FDA. According to management estimates, liquidity resources as of December 31, 2019 are not sufficient to maintain its planned level of operations for the 12 months from the date of issuance of the consolidated financial statements.

These circumstances and the uncertainties associated with the Company's ability to (i) obtain additional equity or debt financing on terms that are favorable to Evofem, (ii) enter into collaborative agreements with strategic partners and (iii) 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 financings or other means, or is unable to obtain funding on terms favorable to the Company, this will have a material adverse effect on its operations and 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, 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 programs or cease operations entirely. Any of these could materially and adversely affect its 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 not limited to: the discount rate used in estimating the fair value of the lease right-of-use (ROU) assets and lease liabilities, the measurement of the Series D 2X liquidation preference, assumptions used in estimating the fair value of warrants and Purchase Rights issued, the useful lives of property and equipment, the recoverability of long-lived assets, clinical trial accruals, and assumptions used in estimating the fair value of stock-based compensation expense. The Company's assumptions regarding the measurement of the First Closing Warrants, the Purchase Rights, the Series D 2X liquidation preference, the lease ROU assets and lease liabilities, and stock-based compensation are more fully described in Note 5 — Fair Value of Financial Instruments, Note 6 — Commitments and Contingencies, and Note 12 — Stock-based Compensation, respectively. 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 and 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, who is 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 due to the financial position of the depository institutions in which these deposits are held.

Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents consist of readily available cash in checking accounts, money market funds, and investments in fixed income debt securities with original maturities less than three months. Restricted cash consists of cash held in monthly time deposit accounts and a letter of credit, which are collateral for the Company's credit cards and facility leases.

On October 9, 2019, the Company entered into an office lease for approximately 24,474 square feet pursuant to a non-cancelable lease agreement. This new lease will commence on April 1, 2020 and 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. The Company provided the landlord a $750,000 security deposit in the form of a letter of credit.

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,	
	2019	**2018**
Cash and cash equivalents	$ 15,571	$ 1,330
Restricted cash	304	431
Restricted cash included in other noncurrent assets	$ 750	$ —
Total cash, cash equivalents and restricted cash presented in the consolidated statements of cash flows	$ 16,625	$ 1,761

Investments in Marketable Securities

The Company's marketable investments are primarily money market funds and fixed income debt securities. Short-term investments consist of marketable fixed income debt securities with original maturities in excess of three months with remaining maturities of less than one year. Marketable fixed income debt securities where the Company has both the positive intent and ability to hold to maturity are classified as held-to-maturity and are carried at amortized cost. Unrealized gains or losses on held-to-maturity securities are not recognized until maturity, except other-than-temporary unrealized losses which are recognized in earnings in the period incurred. The Company evaluates securities with unrealized losses to determine whether such losses are other than temporary. Interest on investments in money market funds is reported in interest income.

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 and 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, note payable, accrued expenses and accrued compensation approximate their fair values due to their short-term nature. As of December 31, 2019 and 2018, 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.

Property and Equipment

Property and equipment generally consist of research equipment, computer equipment and software and office furniture, and 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, 2019 and 2018.

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 Series D 2X Liquidation Preference

Prior to completion of the Merger, the Company valued its Series D 2X liquidation preference in accordance with Accounting Standards Codification No. 815 — Derivatives and Hedging, using a PWERM, which is sensitive to changes in assumptions regarding the timing of additional financings, potential exit scenarios and revisions in our financial forecast. Changes in any one of the assumptions could have had a material impact on the estimated fair value of the Series D 2X liquidation preference. Management used the most reliably available information at each valuation date to determine the fair value of the Series D 2X liquidation preference. Due to the nature of the assumptions and the sensitive nature of the PWERM, management could not reliably provide sensitivity analysis around the impact of changes in assumptions utilized in the PWERM used to estimate the fair value of the Series D 2X liquidation preference.

Fair Value of Warrants

The fair value of each of (i) the WIM and Invesco Warrants issued in connection with the Merger, (ii) Reload Warrants issued in February 2019, (iii) warrants issued in April and June 2019 in connection with the Private Placement, and (iv) the change in fair value of warrants as a result of the modification and mark-to-market for liability-classified warrants were 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.

Fair Value of Purchase Rights

The fair value of the Purchase Rights issued in connection with the Private Placement were determined using a combination of a lattice model and BSM option-pricing model. The lattice model was used to determine the future value of the Company's common stock as of the Second Closing. The BSM option-pricing model was used to determine the fair value of the warrants issued at the First Closing and Second Closing and the existing warrants subsequently canceled at the Second Closing (see discussion of the warrants canceled in Note 10- Private Placement) based on the applicable assumptions.

Leases

On January 1, 2019 (Adoption Date), the Company adopted Accounting Standards Update (ASU) No. 2016-02, Leases *(Topic 842*) (ASU No. 2016-02), as amended, using the modified retrospective approach, which provides a method for recording existing leases at adoption and does not require recasting comparative financial information. The Company also elected the package of practical expedients permitted under the transition guidance under ASU No. 2016-02, which among other things, allowed the Company to not reassess the lease classification for any existing leases, whether any expired or existing contracts are or contain leases and initial direct costs for any existing leases. The Company did not elect the hindsight practical expedient to determine the lease term for existing leases. In addition, the Company elected the additional transition method permitted under ASU No. 2018-11 (Leases (Topic 842): Targeted Improvements, under which the Company initially applied the new lease standard, Accounting Standards Codification (ASC) 842, at adoption and there was no cumulative-effect adjustment to the opening balance of retained earnings on January 1, 2019. For the comparative period presented in these consolidated financial statements, lease related disclosures continue to be in accordance with the legacy GAAP, ASC 840.

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. Operating leases are included in operating lease right-of-use (ROU) assets and operating lease liabilities in its consolidated balance sheets. ROU assets represent the Company's right to use an underlying asset for the lease term and 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 used 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 considered 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 financing. 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 both $0.2 million at December 31, 2019. Adoption of the new standard did not materially impact the Company's consolidated statement of operations and cash flows. See Note 6 - Commitments and Contingencies for more detail discussions on leases and financial statements information under ASC 842.

Research and Development

R&D expenses include the costs associated with the Company's R&D activities, including, but not limited to, payroll and personnel-related expenses, stock-based compensation expense, materials, laboratory supplies, clinical studies and outside services. R&D 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.

Patent Expenses

The Company expenses all costs incurred relating to patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and 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.

Expensing

The following table summarizes the Company's stock-based awards expensing policies for employees and nonemployees:

	Employees and Nonemployee Consultants After Adopting ASU 2018-07	**Nonemployee Consultants Prior to Adopting ASU 2018-07**
Service only condition	Straight-line based on the grant date fair value	Re-value at each reporting date through the service commitment date
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	Re-value the award(s) once the performance criterion is considered probable of occurrence and recognize expense for the then fair value of the award(s)
Service criterion is not complete	Expense using an accelerated multiple-option approach[(1)] over the remaining requisite service period	Same as for employees, except the award will be marked-to-market through the performance commitment date
Performance criterion is not probable of being met and:		
Is not tied to the successful completion of an initial public offering of the Company's common stock (IPO)	No expense recognition is required until the performance criterion is considered probable at which point expense is recognized using an accelerated multiple-option approach	Same as for employees, except the award will be marked-to-market through the performance commitment date
Is tied to the successful completion of an IPO by the Company	Upon closing of an IPO by the Company, recognize the grant date fair value of the award(s)	Same as for employees, except expense is recognized based upon the fair value of the Company's common stock sold in the IPO

(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 and the re-measurement of the Company's consultant stock options were 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.

Forfeitures

The Company records forfeitures when they occur.

Performance-based Awards

For performance-based restricted stock awards (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.

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 attributable to common stockholders 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 attributable to common stockholders 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. For the year ended December 31, 2018, the shares in the table also included 1,013,375 shares of options granted out of the share reserve increase approved by the board of directors under the Amended and Restated 2014 Plan (as defined below) on November 28, 2018, and were subject to the Company obtaining the requisite stockholder approval (the Contingent Options) at the 2019 annual meeting. Such stockholder approval was obtained on June 5, 2019.

	Years Ended December 31,	
	2019	**2018**
Unvested restricted common stock subject to repurchase	110,000	—
Unvested restricted stock units	81,667	—
Common stock to be purchased under the 2019 ESPP	49,793	—
Options to purchase common stock	6,419,383	5,767,627
Warrants to purchase common stock	5,305,377	4,775,886
Total	11,966,220	10,543,513

Recently Adopted Accounting Pronouncements

The Company qualifies as an “emerging growth company” (EGC) pursuant to the provisions of the Jumpstart Our Business Startups (JOBS) Act from the fiscal year 2014 to 2019. Section 7(a)(2)(B) of the Securities Act of 1933, as amended, permits EGCs to defer compliance with new or revised accounting standards until non-issuers are required to comply with such standards. However, the Company elected not to take advantage of the extended transition period for implementation of new or revised financial accounting standards, and as a result, the Company will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

As described above, on January 1, 2019, the Company adopted ASU No. 2016-02, as amended, applying the practical expedients as a package allowed under the transition guidance.

Recently Issued Accounting Pronouncements — Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (ASU No. 2016-13), which requires credit losses relating to held-to maturity debt securities should be recorded through an allowance for credit losses. ASU No. 2016-13 was effective for the Company on January 1, 2020. The Company does not expect the adoption of this new standard to have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820) (ASU No. 2018-13), which removes, modifies and adds certain disclosure requirements on fair value measurements in Topic 820. ASU No. 2018-13 was effective for the Company on January 1, 2020. The Company does not expect the adoption of this new standard to have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, Intangibles—Goodwill and Other (Topic 350): Internal-Use Software (ASU No. 2018-15), which requires capitalizing implementation costs incurred to develop or obtain internal-use software in a cloud computing arrangement that is a service contract. ASU No. 2018-15 was effective for the Company on January 1, 2020. The Company does not expect the adoption of this new standard to have a material impact on its consolidated financial statements.

3. Merger and Related Transactions

As described in Note 1- Description of Business and Basis of Presentation, Private Evofem merged with the Company effective on the Closing Date. The Merger was accounted for as a reverse recapitalization with Private Evofem treated as the accounting acquirer pursuant to ASC 805- *Business Combinations.* Under reverse recapitalization accounting, the accounting acquirer shall measure the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree at their acquisition-date fair values.

The following transactions were completed with the Merger and recorded by the Company:

- Recorded Neothetics' assets and liabilities at fair value as of the Closing Date, including $1.9 million of cash and cash equivalents, $0.5 million in prepaid and other current assets, $0.4 million in current and noncurrent liabilities and $1.9 million in common stock (Neothetics had 2,308,430 shares of common stock outstanding as of the Closing Date on a post-split basis at par value of $0.0001 per share) and additional paid-in capital (including the reclassification of Neothetics' historical accumulated deficit into additional paid-in capital);

- Converted each share of Private Evofem’s capital stock including its Series A convertible preferred stock, Series B convertible preferred stock, Series C-1 convertible preferred stock and Series C convertible preferred stock into the Company's common stock on a one-for-one basis effecting the merger exchange ratio of 0.1540, subject to adjustment for the Reverse Stock Split (the Exchange Ratio) and the Reverse Stock Split for an aggregate of 1,027,079 shares. Upon such conversion, reclassified the net proceeds from issuance of these preferred stocks to common stock at par value and additional paid-in capital, net of par value;

- Cancelled 122,149 shares of unvested restricted common stock;

- Issued warrants for the purchase up to an aggregate of 3,980,437 shares of common stock to funds affiliated with Invesco Ltd. (the Invesco Warrants), which were immediately net exercised on a cashless basis for 3,968,473 shares of common stock;

- Converted 80 shares of Private Evofem's redeemable convertible preferred stock (Series D) into 6,878,989 shares of the Company's common stock, including:

  i. Adjustment for the final change in fair value of Private Evofem's Series D 2X liquidation preference;

  ii. Redemption of the Series D 2X liquidation preference upon conversion;

  iii. Private Evofem's Series D Warrant Rights (as defined below) were assumed by the Company and exchanged for three shares of the Company's common stock and warrants for the purchase of 2,000,000 shares of the Company's common stock (the WIM Warrants). The Company recorded the fair value of the WIM Warrants and related capital contribution upon issuance of the WIM Warrants; and

  iv. Recording cash dividends between January 6, 2018 and the Closing Date, which was paid upon closing of the Merger to Woodford Investment Management Ltd (WIM).

- The Company effected the Reverse Stock Split, and thus the Company adjusted common stock and additional paid-in capital associated with shares issued in connection with the Merger due to the 6:1 reverse stock split, which the Company has affected in the amounts described within this footnote;
- The Company assumed options to purchase Private Evofem common stock that were outstanding and unexercised as of immediately prior to the Merger (the Private Evofem Plan Options). The Private Evofem Plan Options, were converted into options to purchase 159,325 shares of our common stock, as adjusted for the Exchange Ratio and Reverse Stock Split, at a weighted average price of $56.72; and
- Sold 1,614,289 shares of the Company's common stock in a private placement for gross proceeds of $20.0 million.

4. Balance Sheet Details

Short-term Investments

Short-term investments consist of held-to-maturity securities that will be due in one year or less. The following table illustrates the held-to-maturity securities' amortized costs at purchase and the fair value at December 31, 2019 (in thousands):

	Amortized Cost Basis	Gross Unrealized Gains	Fair Value
Fixed income debt securities	$ 8,233	$ 42	$ 8,275
Total held-to-maturity securities	$ 8,233	$ 42	$ 8,275

Prepaid and Other Current Assets

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

	Years Ended December 31,	
	2019	2018
Flex note receivable [1]	$ 250	$ 250
Insurance	481	199
Marketing related costs	491	—
Other receivables	436	—
Other	655	268
Total	$ 2,313	$ 717

[1] In June 2016, Private Evofem's board of directors committed to a plan to sell its Softcup line of business (Softcup) and re-direct its available cash resources to further develop Phexxi. 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 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 Maturity Date.

The Flex Note is secured by the Softcup assets and has been recorded at present value. The Company's incremental borrowing rate and the stated interest rate of the Flex Note are materially consistent.

Property and Equipment, Net

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

		Years Ended December 31,	
	Useful Life	**2019**	**2018**
Research equipment	5 years	$ 608	$ 639
Computer equipment and software	3 years	13	13
Office furniture	5 years	205	205
Leasehold improvements	5 years or less	340	340
Construction in-process	—	77	—
		1,243	1,197
Less: accumulated depreciation		(849)	(604)
Total, net		$ 394	$ 593

Depreciation expense was $0.3 million for both the years ended December 31, 2019 and 2018.

Other Noncurrent Assets

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

	Years Ended December 31,	
	2019	**2018**
Flex note receivable, net of current portion	$ 250	$ 500
Prepaid Directors & Officers insurance	320	439
Restricted cash included in noncurrent assets	$ 750	$ —
Total	$ 1,320	$ 939

Note Payable

On December 5, 2018, the Company entered into a promissory note with its clinical research organization for AMPOWER, where the Company agreed to pay invoiced amounts totaling approximately $4.0 million for clinical trial related services and had a due date of February 15, 2019 (CRO Note). Any matured and unpaid amounts pursuant to this CRO Note bear an annual interest rate of the lesser of 1% per month or the maximum amount permitted by the Laws of the State of Massachusetts.

In late February 2019, the Company amended the CRO Note, which extended the due date to April 15, 2019. In April 2019, the Company paid the CRO Note in full.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	Years Ended December 31,	
	2019	**2018**
Clinical studies	$ 585	$ 9,153
Sublicense fees	—	1,117
Accrued interest on unpaid sublicense fees	—	174
Legal and other professional fees	1,652	549
Other	547	520
Total	$ 2,784	$ 11,513

5. Fair Value of Financial Instruments

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, investments in marketable fixed income debt securities classified as held-to-maturity and Flex Note receivable, measured on a recurring basis are summarized in the following tables, as applicable (in thousands):

	December 31, 2019	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]	7,064	7,064	—	—
Fixed income debt securities classified as cash and cash equivalents	6,749	—	6,749	—
Fixed income debt securities classified as short-term investments	8,275	—	8,275	—
Flex note receivable	500	—	500	—
Total assets	$ 22,588	$ 7,064	$ 15,524	$ —

	December 31, 2018	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]	$ 154	$ 154	$ —	$ —
Flex note receivable	750	—	750	—
Total assets (liabilities)	$ 904	$ 154	$ 750	$ —

[1] Included as a component of cash and cash equivalents on the accompanying consolidated balance sheet.

As discussed in Note 10- Private Placement, the First Closing Warrants and Purchase Rights were determined to be liability classified. Therefore, they were stated at fair value at issuance and marked to market at each reporting date until shareholder approval was obtained in June 2019 that changed their classification from liability to equity. Series D 2X liquidation preference issued in connection with the issuance of Series D in 2016 and 2017 was also stated at fair value.

The First Closing Warrants, Purchase Rights and Series D 2X liquidation preference were considered Level 3 instruments because the fair value measurement was based, in part, on significant inputs not observed in the market. The Company determined the fair value of these three instruments as described below.

The following table summarizes the changes in Level 3 financial liabilities measured at fair value on a recurring basis for the year ended December 31, 2019 and 2018 (in thousands).

	Warrant Liability
Balance at December 31, 2018	$ —
Initial warrant liability at issuance	3,611
Change in fair value of warrants	3,315
Reclassification from warrant liability to equity	(6,926)
Balance at December 31, 2019	$ —

	Purchase Rights Liability
Balance at December 31, 2018	$ —
Initial purchase rights liability at issuance	3,183
Change in fair value of purchase rights	19,617
Reclassification from purchase rights liability to equity	(22,800)
Balance at December 31, 2019	$ —

	Series D 2X Liquidation Preference Liability
Balance at December 31, 2017	$ 79,870
Change in fair value of Series D 2X liquidation preference	130
Redemption of Series D 2X liquidation preference upon conversion of Series D	(80,000)
Balance at December 31, 2018	$ —

First Closing Warrants

The fair value of the First Closing Warrants issued in April 2019 in connection with the Private Placement and the change in fair value of warrants as a result of mark-to-market were determined using the Black-Scholes-Merton (BSM) option-pricing model based on the following weighted-average assumptions for the period indicated.

	Year Ended December 31, 2019
Expected volatility	75.0%
Risk-free interest rate	2.2%
Expected dividend yield	—%
Expected term (years)	6.9

Series D 2X Liquidation Preference

As described in the Note 2- Summary of Significant Accounting Policies, under the terms of the Series D issued, in a liquidation transaction Private Evofem's Series D participated, prior and in preference to the other series of convertible preferred stock and common stock, at a rate of two times its initial investment, plus accrued and unpaid dividends (the Series D 2X Liquidation Preference). The Company determined the Series D 2X Liquidation Preference represented an embedded derivative, which required bifurcation and separate liability accounting and was initially recorded at fair value. See the *Series D Redeemable Convertible Preferred Stock* discussion in Note 8 — Convertible Preferred Stock for the terms of the Series D.

To determine the final fair value of the Series D 2X Liquidation Preference, the Company utilized a hybrid valuation model that considers the probability of achieving certain exit scenarios, the Company's cost of capital, the estimated period the Series D 2X Liquidation Preference would be outstanding, consideration received for the instrument with the Series D 2X Liquidation Preference and at what price and changes, if any, in the fair value of the underlying instrument to the Series D 2X Liquidation Preference. At December 31, 2017, the most significant assumption was the probability of occurrence, which was concluded to be high, and as a result the fair value as of December 31, 2017 approximated the final redemption value.

In connection with the Merger, Private Evofem converted 80 shares of Series D into the Company's common stock. The valuations resulted in a concluded fair value of the Series D 2X liquidation preference of $80.0 million as of the Closing Date, which was reclassified from a Series D 2X liquidation preference to additional paid-in capital upon the conversion into the Company' common stock.

The change in fair value of the Series D 2X liquidation preference for the years ended December 31, 2018 was $0.1 million. There was no such change for the year ended December 31, 2019 as the Series D was converted into common stock in connection with the Merger.

6. Commitments and Contingencies

Operating Leases

2015 Lease

Effective January 30, 2015, Private Evofem entered into a sublease for office space under a noncancelable lease agreement that expires in March 2020 (the 2015 Lease), which is the Company's primary office space. The sublease provides for two renewal periods of five years each, but the sub-lessor is not expected to renew its lease. In lieu of paying a security deposit directly to the sub-lessor, the Company maintains a time deposit in favor of the sub-lessor (the Deposit), which is included in restricted cash in the consolidated balance sheets. During months 13 through 58 of the 2015 Lease term, subject to certain restrictions, approximately $5,000 of the Deposit may be released each month through November 2019 and approximately $66,000 of the Deposit may be released each month between December 2019 and March 2020. As of December 31, 2019 and 2018, restricted cash maintained as collateral for the Company's Deposit was $0.3 million for both periods.

Concurrent with the execution of the 2015 Lease, Private Evofem entered into a sublease with WomanCare Global Trading, Inc. (WCGT) whereby WCGT agreed to sublease approximately 25% (subject to annual adjustment), as amended, of the Company's primary office space aforementioned (the WCG Sublease). The Company remains the primary obligor under the WCG Sublease and records all sublease income as a reduction of rent expense in the consolidated statements of operations. WCGT paid an initial security deposit of approximately $0.3 million (the WCG Security Deposit). Effective April 1, 2018, the WCG Sublease was reassigned from WCGT to WCG Cares, whereby WCG Cares agreed to pay the Company 20% of the overall lease payment under the 2015 Lease. All terms and conditions remain the same as the original WCG Sublease. The remaining WCG Security Deposit totaled approximately $0.2 million was repaid to WCGT in June 2018. The Company terminated the WCG Sublease in the fourth quarter of 2018. There were no sublease payments received pursuant to the WCG Sublease during the year ended December 31, 2019, and $0.1 million during the year ended December 31, 2018.

Leased Space

In August 2017, the Company entered into a manufacturing and supply agreement with an outside supplier for non-recoverable expenses incurred by the supplier during non-commercial periods for a term of one year from August 2017. This agreement was further renewed by both parties to cover the period from August 2018 to late 2019. Under the agreement, the supplier provides a dedicated packaging space for the Company with a fixed monthly cost. The Company determined that this dedicated space is accounted for as an operating lease under *ASC 842 Leases.* The lease for this Leased Space expired in September 2019.

Supplemental Financial Statement Information

Lease Assets and Liabilities (in thousands)	**December 31, 2019**
Operating right-of-use assets	$ 160
Operating lease liabilities	197

		Year Ended December 31,	
Lease Cost (in thousands)	**Classification**	**2019**	**2018**
Operating lease expense	Research and development	$ 307	$ 191
Operating lease expense	General and administrative	430	$ 387
Total		**$ 737**	**$ 578**

Lease Term and Discount Rate	**December 31, 2019**
Weighted Average Remaining Lease Term (in years)	0.25
Weighted Average Discount Rate	12%

Maturity of Operating Lease Liabilities (in thousands)	**December 31, 2019**
Year ending December 31, 2020	$ 201
Less: imputed interest	(4)
Total	**$ 197**

Maturity of Operating Lease Liabilities under the 2015 Lease (in thousands)	**December 31, 2018**
Year ending December 31, 2019	$ 777
Year ending December 31, 2020	201
Total	$ 978

Other information (in thousands)	**Year Ended December 31, 2019**
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash outflows in operating leases	$ 834

Other Contractual Commitments

In November 2019, the Company entered into a Supply and Manufacturing Agreement with a third party to manufacture Phexxi and potential other product candidates in accordance with all applicable current good manufacturing practices (cGMP) regulations, pursuant to which the Company has certain contractual commitments commencing 2020.

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. There were no claims or actions pending against the Company as of December 31, 2019 and 2018, which management believes would have, individually or in the aggregate, a material adverse effect on its business, liquidity, financial position, results of operations or cash flows. However, litigation is subject to inherent uncertainties and an adverse result in these or other matters may arise from time to time that may harm the Company's business.

Intellectual Property Rights

In 2014, Private Evofem entered into an amended and restated license agreement with Rush University (the Rush License Agreement) pursuant to which Rush University granted Private Evofem an exclusive, worldwide license of certain patents and know-how, related to its MVP-R technology authorizing Private Evofem 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.

The Company may be obligated to pay an earned royalty based upon a percentage of net sales in the range of mid-single digits. Commencing on January 1 of year three after a product has received regulatory approval and has been introduced to market, the Company may become obligated to pay minimum annual royalties, to the extent the earned royalty or sublicensing fees, as applicable, do not exceed the minimum annual royalties.

In October 2015, the Company entered into separate sublicense agreements (the Sublicenses) with WomanCare Global Trading CIC (WCGCIC) for a contraceptive vaginal ring for an aggregated consideration of (i) payments or potential payments to the licensor of (a) an upfront payment of $10.0 million, (b) potential regulatory and commercial milestone payments up to $32.0 million, (c) potential royalty payments on net product sales and (d) potential royalty payments on net sales of an equivalent generic product and (ii) $5.0 million in annual sublicense fees through October 1, 2019 to WCGCIC.

During the first quarter of 2019, the Sublicenses were reassigned to WCG Cares, upon which, the unpaid sublicense fees ceased accruing interest and all accrued sublicense fees and interest expense of $1.3 million were transferred and became payable to WCG Cares. During the year ended December 31, 2019, the Company and WCG Cares entered into a settlement agreement, whereby the Company paid $1.0 million to WCG Cares to settle the entire outstanding balance. The Company recorded the difference of $0.3 million as a concession recorded within other income (expense) in its consolidated statement of operations. As of December 31, 2018, the Company had accrued sublicense fees and accrued interest expense on unpaid sublicense fees of approximately $1.1 million and $0.2 million, respectively, which were included in the consolidated balance sheets. No such amounts were outstanding as of December 31, 2019 due to the settlement. See Note 7 – Related-party Transactions for a summary of the Company's transactions with WCGCIC, WomanCare Global International, a non-profit organization registered in England and Wales (WCGI) and related entities, and WCG Cares.

7. Related-party Transactions

Consulting Agreements

Effective April 1, 2016, Private Evofem entered into a one-year consulting agreement (the 2016 Consulting Agreement) with Thomas Lynch, the chairman of the Company's board of directors. Pursuant to the 2016 Consulting Agreement, Mr. Lynch provided consulting services with respect to investor relations and business development activities as requested from time to time. Pursuant to the 2016 Consulting Agreement, Mr. Lynch (i) received compensation of approximately $0.4 million, including $0.1 million related to his board services, (ii) received a stock option for the purchase of 3,850 shares of common stock with an exercise price of $46.36 per share, which vest over a one-year period through March 1, 2017 and (iii) was issued a restricted stock unit (RSU) for the rights to 2,566 shares of common stock. Upon the closing of the Merger, Mr. Lynch agreed to cancel unvested RSU received pursuant to the 2016 Consulting Agreement. See *Restricted Stock Units* discussion in Note 12 — Stock-based Compensation for the accounting treatment for Mr. Lynch's RSU granted in 2016. On July 2, 2018, under the Amended and Restated 2014 Plan (as defined below), the Company issued 75,000 RSU to Mr. Lynch in consideration for certain consulting services provided to the Company in connection with the 2016 Consulting Agreement. The RSU fully vested on the grant date.

In August 2017, Private Evofem and Mr. Lynch entered into a two-year consulting agreement (the 2017 Consulting Agreement), which was effective as of April 1, 2017. The 2017 Consulting Agreement expired in accordance with its terms on March 31, 2019. This 2017 Consulting Agreement provided for (i) annual compensation of $0.4 million, including $0.1 million related to his board services and (ii) a stock option for the purchase of 6,416 shares of common stock that was to vest quarterly through March 31, 2018, which remained unissued at the time of the Merger. On March 12, 2018, the Company issued a stock

option for the purchase of 225,000 shares of the Company's common stock with an exercise price of $7.29 per share in lieu of the unissued stock option pursuant to the 2017 Consulting Agreement, of which 125,000 vested on the grant date and the remaining shares vested in a series of twelve successive equal monthly installments upon completion of each additional month of service measured from April 1, 2018. The option was awarded in connection with Mr. Lynch's consulting services for the Company for the fiscal years 2016 to 2018. On July 31, 2018, the Company issued additional stock options for the purchase of 85,500 shares of the Company's common stock with an exercise price of $2.10 per share pursuant to the 2017 Consulting Agreement, which will vest in a series of 36 successive equal monthly installments upon completion of each additional month of service measured from the grant date. In addition, on July 31, 2018, the Compensation Committee, with the authorization of the board of directors, approved a one-time, discretionary cash bonus award to Mr. Lynch in the amount of $50,000.

Effective April 1, 2019, the Company entered into a new two-year consulting agreement with Mr. Lynch (the 2019 Consulting Agreement). The 2019 Consulting Agreement provides 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.

Consulting fees incurred under the 2017 and 2019 Consulting Agreements were approximately $0.6 million and $0.3 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019 and 2018, accrued compensation, excluding board fees, owed to Mr. Lynch was $0.4 million and $0.1 million, respectively.

Transactions with WCGI and Related Entities

From 2009 to 2016, Ms. Saundra Pelletier was the founding CEO of 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 of $4.0 million per year to WCGI.

From 2011 to 2017, Ms. Pelletier served as a director of the board of WCGT, a WCGI subsidiary. As described in Note 6 — Commitments and Contingencies, (i) effective in 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 WCGCIC, also a WCGI affiliate, and (b) the service and grant agreements were canceled.

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 charge the other company’s services provided by each entity on behalf of the other. The SSA also allows for netting of due to and due from shared-services fees. In July 2019, the SSA was terminated. Services provided under the SSA on behalf of WCGI totaled approximately $0.1 million for the year ended December 31, 2018. Such amounts were immaterial for the year ended December 31, 2019. As of December 31, 2019 and 2018, net shared-services due to the Company was minimal for both periods.

The following table summarizes receivables and payables related to the Company’s transactions with WCGI related entities for the periods indicated (in thousands). All accrued sublicense fees and interest expense related to the Sublicenses as of December 31, 2018 became payable to WCG Cares during the first quarter of 2019.

	December 31, 2019	December 31, 2018
Receivables	$ —	$ 3
Payables	$ —	$ 1,291

	Years Ended December 31,	
	2019	2018
Payments	$ —	$ 883
Expenses	$ —	$ 98

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 healthcare and healthcare products around the world. Ms. Pelletier served as the CEO and President of WCG Cares from 2013 to November 2017. She was a member of its board from November 2017 to March 1, 2020, and also 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. Dr. Kelly Culwell served as WCG Cares' Chief Medical Officer from November 2017 to December 2018. Dr. Culwell also was appointed to its board of directors in January 2019 with a term of three years until December 31, 2021. See shared-services agreement discussion below.

The Company agreed to be a corporate sponsor of WCG Cares' U.S. education campaign, the Tryst Network, which officially launched in February 2018. The Company paid WCG Cares a one-time payment of $0.3 million in March 2018 in connection with this corporate sponsorship of the Tryst Network. During the second quarter of 2018, the Company ceased its corporate sponsorship of the Tryst Network.

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. Services provided under the Cares Shared Services on behalf of WCG Cares were immaterial for the year ended December 31, 2019 and approximately $0.1 million for the year ended December 31, 2018. As of December 31, 2019 and December 31, 2018, net shared-services due to the Company was minimal for both periods.

The following table summarizes payments and expenses related to the Company's transactions with WCG Cares for the periods indicated (in thousands). There were no receivables or payables at December 31, 2019, and were immaterial at December 2018.

	Years Ended December 31,	
	2019	**2018**
Payments	$ 1,000	$ 302
Expenses	$ —	$ 127

Variable Interest Entity Considerations

Due to shared management and numerous agreements between the Company and WCGI and the Company and WCG Cares, management reviewed its relationship with both WCGI and its subsidiaries and WCG Cares in accordance with the authoritative guidance for variable interest entities within ASC 810 - *Consolidation*. The Company concluded that due to WCGI's and WCG Cares' status as not-for-profit entities, the scope exception from qualifying as a variable interest entity was met and, therefore, the Company is not required to consolidate WCGI or WCG Cares.

8. Convertible Preferred Stock

Immediately prior to the Merger, as described in Note 1- Description of Business and Basis of Presentation, each share of Private Evofem's capital stock (other than Private Evofem's Series D), including its Series A convertible preferred stock, Series B convertible preferred stock, Series C-1 convertible preferred stock and Series C convertible preferred stock was converted into shares of the Company's common stock on a one-for-one basis effecting the Exchange Ratio and the Reverse Stock Split for an aggregate of 1,027,079 shares. In addition, each share of Private Evofem's Series D was converted into approximately 85,987 shares of the Company's common stock for an aggregate of 6,878,989 shares. As of December 31, 2019 and 2018, no shares of convertible preferred stock were issued and outstanding.

Dividends on the Series D were payable (i) upon conversion, (ii) redemption or (iii) liquidation. As such, although the Company's board of directors had not declared dividends, the Company accrued dividends on the Series D. Upon closing of the Merger, the Company paid cash dividends of $0.2 million for the accrued dividends only for the period of January 6, 2018 to the Closing Date and the accrued and unpaid dividends of $5.2 million as of December 31, 2017 were reclassified to additional paid-in capital upon conversion of 80 shares of Series D into common stock.

The designated, issued and outstanding shares of convertible preferred stock, by series, as of December 31, 2017 were as follows (aggregate liquidation amount and proceeds, net of issuance costs, in thousands):

	Shares Designated	Original Issue Price	Shares Issued and Outstanding	Common Stock Equivalents [1]	Aggregate Liquidation Amount	Proceeds, Net of Issuance Costs
Series A	12,768,492	$ 1.9579445	12,618,279	12,618,279	$ 24,706	$ 23,848
Series B	31,034,696	$ 3.2222	13,801,318	13,801,318	44,471	43,616
Series C-1	8,660,572	$ 3.97	8,558,686	8,558,686	33,978	34,382
Series C	5,037,784	$ 3.97	5,037,784	5,037,784	20,000	19,469
Series D [2][3]	80	$ 500,000	80	—	85,160	39,739
Total	57,501,624		40,016,147		$ 208,315	$ 161,054

(1) The Series D shares were convertible into shares in the next equity financing (either preferred or common) at a 50% discount to the fair value price per share of the shares to be issued in the next financing, therefore, the Series D common stock equivalents and the totals for common stock equivalents have been left blank.

(2) Aggregate liquidation amount included accrued and unpaid dividends of $5.2 million as of December 31, 2017.

(3) Proceeds, net of issuance costs, included $35.0 million in cash and $5.0 million from the conversion of the Amended Cosmederm Note (see more discussions below) less issuance costs of approximately $0.3 million. This line excluded the Series D 2X liquidation preference net issuance price of $18.2 million, the loss on the issuance of Series D of $35.2 million, loss on extinguishment of related-party note payable of $6.7 million and accrued Series D dividends of $5.2 million.

Private Evofem and Cosmederm entered a promissory note during 2015, which was amended in July 2016 in conjunction with the Private Evofem's Series D financing (the Amended Cosmederm Note). Cosmederm assigned the Amended Cosmederm Note with the then outstanding principal balance of $10.0 million to WIM. As a condition to closing the Private Evofem's Series D, WIM immediately converted $5.0 million of the Amended Cosmederm Note into 10 shares of the Private Evofem's Series D and canceled the remaining $5.0 million.

Series D

In July 2016, Private Evofem entered into a Series D purchase agreement with WIM, which was subsequently amended in July 2017 to increase the number of authorized preferred stock for issuance (as amended, the Series D SPA). The Series D SPA authorized the issuance and sale of an aggregate of 80 shares of Series D, which was sold at an issuance price per share of $500,000. WIM also received the right to receive warrant shares to be determined in the next equity financing (Warrant Rights). See *Warrant Rights* discussion below.

Warrant Rights

Upon completion of the Merger, Private Evofem's Series D Warrant Rights were assumed by the Company and exchanged for an aggregate of three shares of the Company's common stock and the WIM Warrants to purchase up to 2,000,000 shares of the Company's common stock. The shares of common stock issued in connection with the WIM Warrants may not be transferred separately from the WIM Warrants. The WIM Warrants became exercisable on January 17, 2019 and remain exercisable until the earlier of January 18, 2022 or immediately prior to the completion of an acceleration event, as defined therein, and have an exercise price of $8.35 per share.

The Company determined that the WIM Warrants are free standing financial instruments and classified as equity in accordance with ASC 480—*Distinguish Liabilities from Equity.* To determine the fair value of the WIM Warrants, the Company utilized the BSM option-pricing model, where the warrants' exercise price was determined based on a Monte Carlo simulation. The valuations resulted in a concluded fair value of the WIM Warrants of $14.1 million as of January 18, 2018, which was recorded as additional paid-in capital in the consolidated balance sheet.

On February 5, 2019, the Company entered into letter agreements (the Repricing Letter Agreements) with WIM and certain other holders of outstanding warrants to purchase common stock of the Company by exercising certain outstanding warrants. Upon execution of the Repricing Letter Agreements, investment funds affiliated with WIM exercised certain WIM Warrants to purchase an aggregate of 1,525,000 shares of common stock at a reduced exercise price of $2.64 per share. The Company determined that the incremental fair value as a result of the modification to these WIM Warrants from change of the exercise price was approximately $1.4 million, which was recorded as change in fair value of warrants in the

consolidated statement of operations for the year ended December 31, 2019.

On June 10, 2019, upon the Second Closing of the Private Placement as discussed at Note 10- Private Placement, the remaining WIM Warrants to purchase up to 475,000 shares of common stock were canceled.

9. Public Offering

On May 24, 2018, the Company completed an underwritten public offering (the Offering), whereby the Company issued 7,436,171 shares of common stock at a public offering price of $4.69 per share and pre-funded warrants to purchase 1,063,829 shares of common stock at a public offering price of $4.68 per warrant and an exercise price of $0.01 per share. Each share of common stock and each pre-funded warrant was issued together with a common warrant to purchase one-fifth of a share of the Company's common stock at a public offering price of $0.01 per warrant and an exercise price of $7.50 per share. An aggregate of 8,500,000 common warrants were issued in connection with the Offering and are exercisable to purchase an aggregate of 1,700,000 shares of common stock. The common warrants issued to the three funds affiliated with WIM that participated in the Offering were issued as a unit with one share of common stock totaling three unit shares in the aggregate (the Unit Shares). Except with respect to the Unit Shares, the shares of common stock, pre-funded warrants and common warrants are separately transferable. The Company determined that the pre-funded warrants and common warrants are free standing financial instruments and equity classified in accordance with ASC 480- *Distinguish Liabilities from Equity*.

The Company received proceeds from the Offering of approximately $37.5 million, net of underwriting discounts and commissions, but before deducting the estimated offering costs of $1.5 million. The estimated offering costs were recorded as contra additional-paid in capital in the consolidated balance sheet. The common stock and warrants issued in the Offering were registered pursuant to a registration statement on Form S-1 filed with the SEC on May 16, 2018 and declared effective on May 21, 2018.

On June 26, 2018, the Company issued an additional 912 common warrants to purchase approximately 182 shares of common stock upon an underwriter's exercise of its overallotment option. The offering price and exercise price were the same as the common warrants issued on May 24, 2018. The net proceeds received from this issuance were immaterial.

In February 2019, per the terms of the Repricing Letter Agreements, certain holders of common warrants issued in the Offering exercised their common warrants to purchase an aggregate of 851,062 shares of common stock at a reduced exercise price of $2.64 per share. The Company determined that the incremental fair value as a result of the modification to these common warrants issued in the Offering from change of the exercise price was $0.5 million, which was recorded as change in fair value of warrants in the consolidated statement of operations for the year ended December 31, 2019.

During 2019, all pre-funded warrants to purchase 1,063,829 shares of common stock were exercised on a cashless basis, and as a result, the Company issued 1,062,004 shares of common stock. Additionally, common warrants to purchase 64 shares of common stock were exercised, from which the total cash received was immaterial.

10. Private Placement

On April 10, 2019, the Company entered into a Securities Purchase Agreement with PDL BioPharma, Inc., a Delaware corporation (PDL), funds discretionally managed by Invesco Ltd. (Invesco) and funds managed by WIM (collectively, the Purchasers), providing for the issuance and sale to the Purchasers of an aggregate of up to $80 million of the Company’s common stock, par value $0.0001 per share (the Shares) at a purchase price of $4.50 per share, and warrants to purchase shares of common stock with an exercise price of $6.38 per share (collectively, the Securities) in a private placement (the Private Placement) to be funded in up to two separate closings.

The first closing was completed on April 11, 2019 (the First Closing), pursuant to which the Company (i) issued and sold to PDL 6,666,667 shares of its common stock and warrants to purchase up to 1,666,667 shares of common stock (the First Closing Warrants) and (ii) provided to the Purchasers an option, but not an obligation, from the Company to issue and sell to each Purchaser the shares of common stock and warrants as specified in the aforementioned Securities Purchase Agreement during the period beginning on April 11, 2019 and ending on June 10, 2019 (the Purchase Rights). The total consideration for the First Closing was $30 million.

The second closing was completed on June 10, 2019 (the Second Closing), pursuant to which the Company issued and sold to PDL, Invesco and WIM (i) 6,666,667, 2,222,222 and 2,222,223 shares of its common stock (including one unit share associated with the common warrants issued to WIM), respectively and (ii) warrants to purchase up to 1,666,667, 555,556 and 555,556 shares of common stock (the Second Closing Warrants), respectively, for an aggregate purchase price of $50 million. Shares of common stock issued to WIM included one voting share issued in connection with the issuance of its warrants.

The Company's stockholders approved the Private Placement at its 2019 Annual Meeting of Stockholders held on June 5, 2019 (the Approval Date).

The warrants have a seven (7) year term and will become exercisable at any time on or after the date that is six (6) months following their respective issuance dates. The Company determined the First Closing Warrants were free standing financial instruments and liability classified in accordance with ASC 480- *Distinguish Liabilities from Equity* (ASC 480) due to the requirement to obtain stockholder approval pursuant to Nasdaq Listing Rule 5635(b). The Company utilized the BSM option-pricing model to calculate the fair value of warrants at issuance and on the Approval Date for the First Closing Warrants, and recorded the following in the consolidated financial statements: (i) $3.6 million warrant liability at issuance; (ii) $3.3 million change in fair value of warrants in the consolidated statement of operations as a result of mark-to-market on the Approval Date; and (iii) $6.9 million reclassification from warrant liability to additional paid-in capital in the consolidated balance sheet on the Approval Date.

The Second Closing Warrants were determined to be free standing financial instruments and equity classified in accordance with ASC 815- *Derivatives and Hedging* (ASC 815). The Company utilized the BSM option-pricing model to calculate the fair value of warrants at issuance and recorded an estimated fair value of $12.7 million as additional paid-in capital in the consolidated balance sheet.

The Company also determined the Purchase Rights were free standing financial instruments and liability classified in accordance with ASC 480 due to the stockholder approval provision noted above. As described in Note 5- Fair Value Financial Instruments, the Company utilized a combination of a lattice model and a BSM option-pricing model to calculate the fair value of the Purchase Rights at issuance and on the Approval Date. The Company recorded the following in the consolidated financial statements: (i) $3.2 million purchase rights liability at issuance for the Purchase Rights provided to PDL; (i) $0.7 million loss on issuance of purchase rights at issuance in the consolidated statement of operations for the Purchase Rights provided to Invesco and WIM; (iii) $19.6 million change in fair value of purchase rights in the consolidated statement of operations as a result of mark-to-market on the Approval Date; and (iii) $22.8 million reclassification from purchase rights liability to additional paid-in capital in the consolidated balance sheet on the Approval Date.

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

Additionally, upon completion of the Second Closing, the remaining WIM Warrants and all issued Reload Warrants to purchase up to 475,000 and 1,188,029 shares of common stock, respectively, were canceled. See Note 11- Stockholders' Equity (Deficit) for additional details on the Reload Warrants. The Company included such cancellation in valuing the Purchase Rights described above.

11. Stockholders' Equity (Deficit)

Warrants

As referenced in Note 8- Convertible Preferred Stock and Note 9- Public Offering, common warrants to purchase an aggregate of 2,376,062 shares of common stock were exercised at an exercise price of $2.64 per share in February 2019 per the Repricing Letter Agreements, and common warrants to purchase 64 shares of common stock were exercised at an exercise price of $7.50 per share in August 2019. The Company received gross proceeds of approximately $6.3 million from these exercises. In addition, as referenced in Note 9- Pubic Offering, all pre-funded warrants issued during the Public Offering were exercised on a cashless basis during the year ended December 31, 2019.

On February 8, 2019 and per the terms of the Repricing Letter Agreements, the Company issued warrants to purchase up to 1,188,029 shares of the Company's common stock (Reload Warrants) to the holders party to the Repricing Letter Agreements, at an exercise price of $5.20 per share. The Company determined the Reload Warrants were free standing financial instruments and equity classified in accordance with ASC 480— Distinguish Liabilities from Equity. Since these Reload Warrants were issued in addition to the reduced exercise price to induce Holders of WIM Warrants and common warrants to exercise their warrants, the Company determined the fair value of the Reload Warrants was also the incremental fair value as a result of the modification to the WIM warrants and common warrants exercised. To determine the fair value of the Reload Warrants, the Company utilized the BSM option-pricing model, which resulted in an estimated fair value of the Reload Warrants of $2.5 million, which was recorded as additional paid-in capital in the consolidated balance sheet and change in fair

value of warrants in the consolidated statement of operations. Upon completion of the Second Closing of the Private Placement as discussed in Note 10- Private Placement, all Reload Warrants were canceled.

In addition, as referenced in Note 10- Private Placement, warrants to purchase an aggregate of 4,444,446 were issued in connection with the Private Placement at an exercise price of $6.38 per share in April and June 2019.

As of December 31, 2019, warrants to purchase approximately 5,305,377 shares of the Company's common stock remain outstanding at a weighted average exercise price of $6.60 per share. These warrants are summarized below:

Type of Warrants	Underlying Common Stock to be Purchased	Exercise Price	Issue Date	Exercise Period
Common Warrants	2,020	$ 67.71	January 25, 2010	January 25, 2010- February 25, 2020
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	848,874	$ 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
Total	**5,305,377**			

Common Stock

Effective January 17, 2018 and in connection with the Merger, the Company amended and restated its certificate of incorporation, under which the Company is currently authorized to issue up to 300,000,000 shares of common stock, $0.0001 par value per share, and 5,000,000 shares of preferred stock, $0.0001 par value per share.

During the year ended December 31, 2019, the Company issued an aggregate of 3,438,133 shares of common stock upon the exercise of outstanding pre-funded and common warrants, 17,777,779 shares of common stock in connection with the Private Placement as discussed in Note 10- Private Placement, 515,019 shares of common stock under the at the market program as discussed below, 768,072 shares of common stock upon grant of RSAs, vesting of RSUs and the exercise of stock options pursuant to the Amended and Restated 2014 Plan (as defined below), and 40,335 shares of common stock pursuant to the employee stock purchase plan as discussed in Note 12 - Stock-based Compensation.

At the Market (ATM) Program

On December 1, 2015, the Company entered into a Controlled Equity Offering Sales Agreement (Sales Agreement) with Cantor Fitzgerald & Co. (Cantor Fitzgerald) as a sales agent, pursuant to which the Company may offer and sell from time to time, through Cantor Fitzgerald, shares of the Company's common stock, par value $0.0001 per share, having an aggregate offering price of up to $20.0 million. The minimum share price for this Controlled Equity Offering is selected at the discretion of the Company’s board of directors. This ATM program expired in early December 2018 and no shares of common stock have been sold pursuant to this Sales Agreement during 2018.

In November 2019, the Company entered into an equity distribution agreement with Piper Sandler & Co. (Piper Sandler), pursuant to which the Company may offer and sell shares of its common stock in ATM offerings (as defined in Rule 415 of the Securities Act) having an aggregate offering price up to $50 million in gross proceeds from time to time through Piper Sandler acting as sales agent. During the year ended December 31, 2019, we received proceeds of approximately $3.3 million (including $3.0 million in cash and cash equivalents and $0.3 million in other receivable), net of commissions, from the sale of 515,019 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, 2019:

Common stock issuable upon the exercise of stock options outstanding	6,419,383
Common stock issuable upon release of restricted stock units	81,667
Common stock issuable upon the exercise of common stock warrants	5,305,377
Common stock available for future issuance under the 2019 ESPP	459,665
Common stock available for future issuance under the Amended and Restated 2014 Plan	327,930
Common stock available for future issuance under the Inducement Plan	156,000
Total common stock reserved for future issuance	12,750,022

12. Stock-based Compensation

Equity Incentive Plans

In September 2012, Private Evofem adopted the 2012 Equity Incentive Plan (the 2012 Plan) that 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. Upon completion of the Merger, Private Evofem's 2012 Plan was assumed by the Company and awards outstanding under the 2012 Plan became awards for the Company's common stock. Effective as of the Merger, no further awards may be issued under the 2012 Plan.

On September 15, 2014, Neothetics' board of directors adopted, and stockholders approved, the 2014 Equity Incentive Plan (the 2014 Plan). In May 2018, the Company's board of directors adopted and stockholder approved, the amendment and restatement of the 2014 Plan of the Company (the Amended and Restated 2014 Plan), that, among other things, increased the number of authorized shares under the 2014 Plan from 749,305 to an aggregate of 5,300,000 shares. On November 28, 2018, the Company's board of directors approved, subject to stockholder approval, and recommended its stockholders approve at the 2019 Annual Meeting, an additional 2,500,000 authorized shares reserved for issuance under the Amended and Restated 2014 Plan to an aggregate of 7,800,000 shares. Such approval was obtained at the 2019 Annual Meeting held on June 5, 2019. 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 (1) 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31; or (2) an amount determined by our board of directors. This provision resulted in an additional 1,925,515 shares (Evergreen Shares) added to the total number of authorized shares on January 1, 2020. As of December 31, 2019, there were 327,930 shares available to grant under the Amended and Restated 2014 Plan.

On July 24, 2018, upon the recommendation by the Compensation Committee, the 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 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. As of December 31, 2019, there were 156,000 shares available to grant under the Inducement Plan.

The following table summarizes stock-based compensation expense related to stock options, RSAs and RSUs granted to employees and nonemployees included in the consolidated statements of operations as follows (in thousands):

	Years Ended December 31,	
	2019	**2018**
Research and development	$ 1,131	$ 3,193
General and administrative	7,448	14,649
Total	$ 8,579	$ 17,842

Stock Options

The following table summarizes share option activity for the year ended December 31, 2019:

	Options	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Term (in Years)**	**Aggregate Intrinsic Value (in thousands)**
Outstanding as of December 31, 2018	5,767,627	$ 7.00	9.01	3,211
Granted	946,000	$ 5.27		
Exercised	(47,739)	$ 3.82		
Forfeited	(246,505)	$ 9.17		
Outstanding as of December 31, 2019	6,419,383	$ 6.68	8.44	$ 8,336
Options vested and expected to vest as of December 31, 2019	6,419,383	6.68	8.44	8,336
Options exercisable as of December 31, 2019	4,137,561	$ 8.11	8.13	$ 3,251

The following table summarizes certain information regarding stock options for the years ended December 31, 2019 and 2018 (in thousands, except per share data):

	2019	2018
Weighted average grant date fair value per share of options granted during the period	$ 3.50	$ 3.99
Fair value per share of options vested during the period	$ 3.94	$ 4.58
Cash received from options exercised during the period	$ 95	$ 42
Intrinsic value of options exercised during the period	$ 133	$ 12

The Company recognized $5.6 million and $14.7 million stock-based compensation expense related to stock options for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, unrecognized stock-based compensation expense for employees and non-employee stock options was approximately $7.1 million, which the Company expects to recognize over a weighted-average remaining period of 2.0 years, assuming all unvested options become fully vested.

Summary of Assumptions

The fair value of stock-based compensation for stock options granted to employees and nonemployees was estimated on the date of grant using the BSM option-pricing model based on the following weighted-average assumptions for options granted for the periods indicated.

	Years Ended December 31,	
	2019	2018
Expected volatility	76.3%	87.0%
Risk-free interest rate	1.8%	2.9%
Expected dividend yield	—%	—%
Expected term (years)	5.9	5.5

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*, which is the midpoint between the requisite service period and the contractual term of the option.

Restricted Stock Awards and Units

The following table summarizes RSAs and RSUs activity for the year ended December 31, 2019:

	Shares (RSAs)	Weighted Average Fair Value per Share	Shares (RSUs)	Weighted Average Fair Value per Share
Unvested as of December 31, 2018	45,000	$ 2.46	—	$ —
Granted	641,000	$ 4.15	161,000	$ 3.66
Canceled	—	$ —	—	$ —
Released	(576,000)	$ 3.87	(79,333)	$ 3.58
Unvested as of December 31, 2019	110,000	$ 4.91	81,667	$ 3.87

In September 2016, under the 2012 Equity Incentive Plan, Private Evofem issued an aggregate of 122,149 shares of restricted stock to members of management (the Management RSAs) with vesting terms subject to the completion of an initial public offering (IPO) by Private Evofem. In October 2016, as previously described in Note 7 — Related-party Transactions, Private Evofem issued a RSU for the right to 2,566 shares of common stock to the chairman of the Company's board of

directors (the Chairman RSUs). Upon closing of the Merger, as described in Note 1 – Description of Business and Basis of Presentation, the members of management and the chairman of the board of directors agreed to cancel their RSAs and RSUs. As a result, all 122,149 shares of unvested Management RSAs and 2,566 shares of unvested Chairman RSUs were canceled in January 2018, and there was no unrecognized stock-based compensation expense related to the canceled Management RSAs and Chairman RSUs.

There were 641,000 shares and 1,230,399 shares of RSAs granted under the Amended and Restated 2014 Plan during the years ended December 31, 2019 and 2018, respectively, to its executive management team and certain non-executive employees. Of the total RSAs granted during the year ended December 31, 2019, 460,500 shares vested in accordance with the Company's achievement of certain performance milestones in 2019 (Performance-based RSAs). There were 161,000 shares and 75,000 shares of RSUs granted during the years ended December 31, 2019 and 2018, respectively to the chairman of the Company's board of directors and certain non-employee consultants.

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 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. The non-performance based RSAs and RSUs are valued at the fair value of the Company's common stock on the grant date and the associated expenses will be recognized over the vesting period.

The Company recognized $2.9 million and $3.2 million stock-based compensation expense related to RSAs and RSUs for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, unrecognized stock-based compensation expense related to the unvested RSAs and RSUs was approximately $0.6 million, which the Company expects to recognize over a weighted-average remaining period of 1.1 year.

Employee Stock Purchase Plan

In November 2014, Neothetics 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.

The 2014 ESPP initially authorized the issuance of 28,333 shares of common stock pursuant to purchase rights granted to employees. The number of shares of common stock reserved for issuance automatically increased on January 1, 2015 and was subject to increase on each January 1 thereafter through January 1, 2024, by the smaller of (a) 1.0% of the total issued and outstanding shares on the preceding December 31, or (b) a number of shares determined by the board of directors of Neothetics. Therefore, an additional 258,672 shares were added to the total shares authorized under the 2014 ESPP on January 1, 2019. Following completion of the Merger, there was no enrollment in the 2014 ESPP. During the year ended December 31, 2019 and 2018, there were no shares of common stock purchased under the 2014 ESPP.

On May 7, 2019, the board of directors terminated the 2014 ESPP and approved a new 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 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. The first offering period under the 2019 ESPP commenced on June 17, 2019 and ended on December 15, 2019, and the second offering period commenced on December 16, 2019 and will end on June 15, 2020. During the year ended December 31, 2019, there were 40,335 shares of common stock purchased under the 2019 ESPP.

As of December 31, 2019, there were 459,665 shares of common stock reserved and available for issuance pursuant to the 2019 ESPP. In addition, the number of shares available for issuance under the 2019 ESPP will increase on January 1 of each year 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. Therefore, an additional 962,757 shares were added to the total shares authorized under the 2019 ESPP on January 1, 2020. 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 Code).

The Company recognized $0.1 million stock-based compensation expense for the shares to be issued under the 2019 ESPP for the year ended December 31, 2019. As of December 31, 2019, unrecognized stock-based compensation expense 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 BSM option-pricing model at the grant date, which requires the use of subjective and complex assumptions, including (a) the expected stock price volatility, (b) the calculation of the expected term of the award, (c) the risk-free interest rate and (d) 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, 2019
Expected volatility	81.4%
Risk-free interest rate	1.9%
Expected dividend yield	—%
Expected term (years)	0.5

13. Employee Benefits

The Company has a defined contribution 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 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, 2019 and 2018, the Company made safe-harbor contributions of approximately $0.2 million and $0.1 million, respectively.

14. Income Taxes

The Company is subject to taxation in the U.S., United Kingdom and various states jurisdictions. Tax years since Neothetics and Private Evofem's inception of 2007 and 2009, respectively, remain open to examination by the major taxing jurisdictions to which they are subject to. The Company's consolidated pretax loss for the years ended December 31, 2019 and 2018 were generated by domestic and foreign operations as follows (in thousands):

	2019	2018
United States	$ (80,029)	$ (125,670)
Foreign	—	(40)
Total	$ (80,029)	$ (125,710)

Income tax provision for the years ended December 31, 2019 and 2018 consisted of the following (in thousands):

	2019	2018
United States	$ —	$ —
State	(4)	(2)
Foreign	—	—
Total current tax provision	(4)	(2)
Total deferred tax provision	—	—
Total	$ (4)	$ (2)

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, 2019 and 2018 was as follows:

	2019	2018
Statutory rate	21.00 %	21.00 %
State income tax, net of federal benefit	0.37 %	0.21 %
Nondeductible expenses	(2.05)%	(0.56)%
Equity-based expenses	(0.58)%	(1.03)%
Loss on issuance of warrants	(0.18)%	(8.01)%
Change in fair value of warrants	(2.03)%	— %
Change in fiar value Purchase Rights	(5.15)%	— %
Change in fair value of Series D 2X liquidation preference	— %	(0.02)%
Return to provision	(0.26)%	0.03 %
Tax credits	1.35 %	1.60 %
Uncertain tax positions	(0.42)%	(0.57)%
Foreign rate differential	— %	(0.01)%
Rate adjustment	— %	0.19 %
Change in valuation allowance	(12.05)%	(12.83)%
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, 2019 and 2018 (in thousands):

	2019	2018
Deferred tax assets:		
Net loss carryforwards	$ 62,955	$ 53,933
Fixed assets and intangibles	591	672
Research and development credits	6,953	5,948
Stock-based compensation	3,367	3,905
Other	885	747
Total deferred tax assets	74,751	65,205
Deferred tax liabilities		
Lease asset	(34)	—
Less: valuation allowance	(74,717)	(65,205)
Net deferred tax assets	$ —	$ —

In assessing the realizability of 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, 2019, the Company had net operating loss (NOL) carryforwards for federal income tax purposes of approximately $272.2 million, which will begin to expire in 2029 if not utilized. As of December 31, 2019, the Company had NOL carryforwards in various states of approximately $107.6 million. The state carryforwards have varying expiration dates beginning in 2029. The Company has foreign NOLs of $0.6 million that do not expire.

As of December 31, 2019, the Company has federal and state R&D tax credit carryforwards of approximately $7.8 million and $1.8 million, respectively. As of December 31, 2018, the Company has federal and state R&D tax credit

carryforwards of approximately $6.8 million and $1.5 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, 2019 and 2018 (in thousands):

	2019	2018
Balance at the beginning of the year	$ 2,061	$ 1,335
Adjustments related to prior year tax positions	—	162
Increases related to current year tax positions	352	564
Decreases due to statute of limitation expiration	—	—
Balance at end of year	$ 2,413	$ 2,061

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, 2019. 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 IRC Sections 382 and 383, annual use of the Company's NOLs and R&D credit carryforwards may be limited in the event a cumulative change in ownership of more than 50.0% occurs within a three-year period. The Company has not completed an IRC Section 382/383 analysis regarding the limitation of NOLs and R&D credit carryforwards; due to the complexity and cost associated with such a study and the fact that there may be additional such ownership changes in the future. The Company does not expect this analysis to be completed within the next 12 months and as a result, the Company does not expect the unrecognized tax benefits will change within 12 months of this reporting date. Due to the existence of the valuation allowances, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate. If the Company has experienced an ownership change at any time since its formation, utilization of the NOLs or R&D tax credit carryforwards would be subject to an annual limitation under Section 382 of the IRC, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOLs or R&D tax credit carryforwards before utilization.

15. Selected Quarterly Financial Data (unaudited)

The following table contains quarterly financial information for 2019 and 2018. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair statement of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share data)			
Year Ended December 31, 2019				
Total operating expense	$ 13,632	$ 11,941	$ 14,297	$ 12,872
Other (income) expense	4,436	23,505	499	(155)
Net loss	(18,068)	(35,450)	(13,798)	(12,717)
Net loss attributable to common stockholders	(18,068)	(35,450)	(13,798)	(12,717)
Net loss per share attributable to common stockholders, basic and diluted	(0.67)	(0.97)	(0.30)	(0.27)
Year Ended December 31, 2018				
Total operating expense	$ 20,986	$ 23,242	$ 18,433	$ 14,981
Other (income) expense	48,070	—	(2)	—
Net loss	(69,056)	(23,244)	(18,431)	(14,981)
Net loss attributable to common stockholders	(69,122)	(23,244)	(18,431)	(14,981)
Net loss per share attributable to common stockholders, basic and diluted	(4.62)	(1.11)	(0.71)	(0.58)

16. Subsequent Events

Subsequent events were evaluated through the filing date of this Annual Report, March 12, 2020.

On February 5, 2020, upon the recommendation by the Compensation Committee, the Board of Directors approved, subject to stockholder approval, and recommended the stockholders of the Company approve at the annual meeting to be held on May 12, 2020, the Amended and Restated 2014 Plan, that, among other things, would increase the number of authorized shares under this plan from 9,725,515 to an aggregate of 11,725,515 shares. The Compensation Committee also approved the number of authorized shares under the Inducement Plan from 250,000 to an aggregate of 1,250,000 shares.

On February 5, 2020, the Company issued an aggregate of 1,245,000 shares of performance-based RSAs to its executive management team and 134,085 shares of stock options to certain non-executive employees and consultants 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 2020. In addition, on February 5, 2020, the Compensation Committee, with the authorization of the Board of Directors, approved a total of 1,027,400 shares of stock options to be granted to its executive management team, and were subject to the Company obtaining the requisite stockholder approval as discussed above.

Subsequent to December 31, 2019, the Company received proceeds of approximately $1.1 million, net of commissions, from the sale of 202,098 shares of its common stock and which consumed the remaining capacity under the ATM equity distribution agreement.

Exhibit 4.15

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

As of December 31, 2019, Evofem Biosciences, Inc. had one class 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 ("Common Stock").

Unless the context otherwise requires, all references to "we", "us", the "Company", or "Evofem" in this Exhibit 4.15 refer to Evofem Biosciences, Inc.

DESCRIPTION OF COMMON STOCK

The following description of our common stock summarizes the material terms and provisions of our common stock. The following description is only a summary and it may not contain all the information that is important to you. For the complete terms of our common 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 as exhibits to the Annual Report on Form 10-K. The terms of our common stock may also be affected by the Delaware General Corporation Law ("the DGCL").

General

Our amended and restated certificate of incorporation authorizes us to issue up to 300,000,000 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 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, the shares of common stock issued upon the conversion of any securities convertible into our common stock, the shares of common stock issued upon the conversion of any preferred stock or debt securities or exercise of any warrants are fully paid and non-assessable.

Stock Exchange Listing

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

Blank Check 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:

- to establish from time to time the number of shares to be included in each such series;
- to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon; and
- 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. 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.

Registration Rights Agreements

In connection with that certain Agreement and Plan of Merger, dated as of October 17, 2017, by and among the Company, Nobelli Merger Sub, Inc., our wholly owned subsidiary ("Merger Sub") and Evofem Biosciences Operations, Inc. ("Private Evofem"), pursuant to which the Merger Sub merged with and into Private Evofem, with Private Evofem surviving as our wholly owned subsidiary (the "Merger"), on January 17, 2018, 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, or 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, 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 (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 First Closing warrants (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 (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 Second Closing warrants (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. The foregoing description of the registration rights agreements does not purport to be complete, and is qualified in its entirety by the complete text of those agreements, which are attached as exhibits to the Annual Report on Form 10-K.

Voting Agreements

On January 17, 2018, in connection with a business combination event, we entered into voting agreements, or the Voting Agreements, with discretionary investment funds, managed by Woodford Investment Management Limited as discretionary investment manager, or the Voting Agreement holders, holding shares of our common stock then representing more than 19.5% of our issued and outstanding common stock, or the Threshold. The Voting Agreements grant the Chief Executive Officer and Chief Financial Officer of the Company, or any other designee of the Company, a proxy to vote on matters presented to our stockholders, or the Proxy Matters, any and all shares of our common stock held by a Voting Agreement Holder in excess of the Threshold, or the Proxy Shares. In accordance with the proxies granted to the Company by the Voting Agreements, the Proxy Shares shall be voted in the same proportions as the shares voted by all other stockholders excluding the discretionary investment funds managed by Woodford Investment Management Ltd as discretionary investment manager) voting on the Proxy Matters. The Voting Agreements may not be revoked by a Voting Agreement Holder so long as such holder holds shares of our common stock in excess of the Threshold.

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 2021. 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 2020. 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. 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 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 10.58

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

SUPPLY AND MANUFACTURING AGREEMENT

This Supply and Manufacturing Agreement (the "**Agreement**") is made as of this 4th day of November 2019 (the "**Effective Date**") by and between DPT Laboratories, Ltd., a Texas Limited Partnership with a place of business at 307 East Josephine Street, San Antonio, Texas 78215 (hereinafter "**DPT**") and Evofem, Inc, a Delaware corporation (and a wholly-owned subsidiary of Evofem Biosciences, Inc.), having principal offices at 12400 High Bluff Drive, Suite 600, San Diego, CA 92130 ("**COMPANY**"). COMPANY and DPT may be referred to herein by name or individually, as a "**Party**" and collectively, as the "**Parties**."

BACKGROUND

A. COMPANY is engaged in the development and commercialization of certain pharmaceutical products;

B. DPT owns and has a broad spectrum of technologies for the development, formulation, testing, control, manufacture, filling and supply of pharmaceutical, over-the-counter and cosmetic products; and

C. COMPANY desires DPT to manufacture and supply Product (as hereinafter defined) to COMPANY, and DPT desires to do so.

D. The Parties have also entered into that certain [***] setting forth specific responsibilities, procedures and guidelines for batch release, quality control testing, quality assurance review, acceptance testing and other quality-related aspects of DPT's manufacture and release of Products. In the event of any conflict between this Agreement and the Quality Agreement, this Agreement shall take precedence except as to quality matters.

NOW, THEREFORE, in consideration of the covenants, conditions and undertakings hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

AGREEMENT

ARTICLE 1 DEFINITIONS/INTERPRETATION

For the purposes of this Agreement, the following capitalized words and phrases shall have the following meanings**:**

1.1 "**Act**" means the Federal Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder.

1.2 "**Administrative Expenses**" means, in the context of any [***].

1.3 "**Affiliate**" means, with respect to a Party, any corporation, limited liability company or other business entity controlling, controlled by or under common control with such Party, for so long as such relationship exists. For the purposes of this definition, control means:
(a) to possess, directly or indirectly, the power to direct affirmatively the management and policies of such corporation, limited liability company or other business entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) ownership of more than fifty percent (50%) of the voting stock in such corporation, limited liability company or other business entity (or such lesser percent as may be the maximum that may be owned pursuant to Applicable Law of the country of incorporation or domicile), as applicable.

1.4 "**Annual Product Review**" means an analysis conducted by DPT personnel on a yearly basis which examines a multitude of subject matter areas, including, but not limited to, changes in cost of raw materials, API, packaging and shipping components, unit volume, production issues, and other similar such issues.

1.5 "**API**" means the active pharmaceutical ingredient identified on and having the chemical composition set forth in Schedule A attached hereto, that is contained in the Product(s).

1.6 "**Applicable Law**" means all laws, ordinances, rules, rulings, directives and regulations of any Governmental Authority that apply to the development, manufacture, supply or commercialization of any Product or the other activities contemplated under this Agreement, including (i) all applicable federal, state and local laws, rules and regulations; (ii) the Act;
(iii) regulations and guidelines of the FDA and other Regulatory Authorities, including cGMPs; and (iv) any applicable non-U.S. equivalents of any of the foregoing, including guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (as amended from time to time).

1.7 "**Bankruptcy Event**" means, with respect to a Party, (a) the making by it of a general assignment for the benefit of creditors, (b) the commencement by it of any voluntary petition in bankruptcy or suffering by it of the filing of an involuntary petition of its creditors,
(c) the suffering by it of the appointment of a receiver to take possession of all, or substantially all, of its assets, (d) the suffering by it of the attachment or other judicial seizure of all, or substantially all, of its assets, (e) the admission by it in writing of its inability to pay its debts as they come due, or (f) the making by it of an offer of settlement, extension or composition to its creditors generally.

1.8 "Batch" means a specific quantity of Product that is intended to have uniform character and quality within specified limits and is produced according to a single manufacturing order during the same cycle of manufacture.

1.9 "Batch Record" means Batch production and control records prepared for each Batch of Product, to be reproduced from approved Master Batch Records, and to include sufficient detail regarding location, equipment, operators, materials and processes to provide a complete and traceable record of the activity and participants.

1.10 "**Business Day**" means any day other than a Saturday, a Sunday or any day on which commercial banks located in New York City, New York, U.S.A. are authorized or required to remain closed.

1.11 "**cGMPs**" means current good manufacturing practices and standards as set forth (and as amended from time to time) in the current Good Manufacturing Practice Regulations of the U.S. Code of Federal Regulations, including 21 C.F.R. Sections 210 and 211, and any corresponding practices and standards under Applicable Law in the Territory, or the country in which the Product is manufactured hereunder, subject to any arrangements, additions or clarifications, and the respective roles and responsibilities, agreed from time to time between the Parties.

1.12 "**Change Control Request**" or "**CCR**" means the primary record in the TrackWise® system in which the overall details of a change are captured and monitored.

1.13 "Conform" or "Conforming" means, with respect to Product, that such Product:
(a) conforms, in all respects, to the Specifications, the Master Batch Record and the manufacturing requirements set forth herein; (b) is free from defects, material manufacture and workmanship; and (c) is manufactured according to the Quality Agreement.

1.14 "**FDA**" means the United States Food and Drug Administration, or any successor agency thereto performing similar functions.

1.15 "Facility" means the following DPT facility in which it will manufacture Product: 307 East Josephine St., San Antonio, TX 78215, or such other DPT-controlled facility as agreed in writing by COMPANY or as identified in the Quality Agreement.

1.16 "**Forecasted Needs**" [***].

1.17 "**Governmental Authority**" means any court, agency, department, authority or other instrumentality of any nation, state, country, city or other political subdivision, including any Regulatory Authority.

1.18 "**Label**", "**Labeled**", or "**Labeling**" means all labels and other written, printed, or graphic matter included or to be included upon: (i) the Product or any container or wrapper utilized with Product or (ii) any written material accompanying Product.

1.19 "**Launch Year**" means the period commencing on the first day following DPT's delivery of the initial invoice for Product to COMPANY and ending on December 31 of such calendar year.

1.20 [***] and Package each Product. The Manufacturing Fee is quoted in single final Product unit increments (i.e., by the bottle or tube). The Manufacturing Fee shall include services for [***].

The Manufacturing Fee does not include, without limitation, any technical or development services support, Package engineering studies, validation studies or support, FDA audit support, extensive reporting requirements, or additional laboratory testing performed by an outside testing laboratory or testing beyond that required in the Specifications. These services are in addition to the Manufacturing Fee and shall be billed by the hour at DPT's then-prevailing Technical and Development Hourly Rate (as hereinafter defined) in accordance with Article 7 contained herein. In addition, the Manufacturing Fee does not include warehousing or distribution of Product, any materials costs or costs associated with establishing or manufacturing new materials such as art charges, die costs, plate costs, and packaging equipment change parts. [***].

1.21 Deliberately omitted

1.22 "Master Batch Record" means a formal set of instructions for the manufacturing of the Product.

1.23 "**Material Safety Data Sheet**" or "**MSDS**" means written or printed material concerning a hazardous chemical which is prepared in accordance with the regulations promulgated by the Occupational Safety & Health Administration, or any successor entity thereto.

1.24 "**Materials Fee**" [***].

1.25 "**Minimum Order Quantity**" means the smallest amount or number of a chemical, device, excipient, Labeling or Packaging component that a vendor will supply to DPT when it submits a purchase order to such vendor for such chemical, device, excipient, Labeling or Packaging component.

1.26 "**Package**" or "**Packaging**" means all primary containers, cartons, shipping cases, inserts or any other like material used in packaging, or accompanying, a Product.

1.27 "**Person**" means an individual, a corporation, a partnership, an association, a trust or other entity or organization, including a government or political subdivision or an agency thereof.

1.28 "**Product**" means COMPANY's proprietary product (currently named Amphora®, but subject to a change in name before commercialization), NDA number 208352, in finished form, for which FDA approval is being sought and ready for clinical use and commercial sale and distribution.

1.29 "**Project Protocol**" means, in the event that COMPANY asks DPT to perform services related to any Development Product (as described in Section 7.1), a precise and detailed plan that is mutually agreed and executed by DPT and COMPANY which carefully describes the nature and scope of services to be rendered, Product to be delivered, and fees to be charged, including the relevant Specifications therefor.

1.30 "**Regulatory Authority**" means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity, including the FDA, with authority over the development, manufacture or commercialization of any Product(s) in any jurisdiction in any country where COMPANY may commercialize Product.

1.31 "**Specifications**" means the requirements and standards for each Product set forth on Schedule B, which may include (i) raw material specifications (including chemical, micro, and Labeling and Packaging specifications); (ii) sampling requirements (i.e., lab, chemical, and micro); (iii) compounding module, including compounding process and major equipment; (iv) intermediate specifications; (v) Packaging modules (including Packaging procedures, torque and fill weights); and (vi) finished Product specifications release criteria including DPT's Acceptable Quality Limits ("**AQLs**"). Specifications shall be established or amended from time to time upon the written agreement of both DPT and COMPANY via a Change Control Request in accordance with Article 6 below.

1.32 "**Standard Cost**" means, with respect to materials, the average actual cost to DPT of materials plus shipping and handling charges, incoming freight, scrap/yield loss adjustments and any other recurring costs directly attributable to acquiring such material(s).

1.33 "**Standard Operating Procedures**" or "**SOPs**" means DPT's detailed, written instructions to achieve uniformity of the performance of a specific process; the instructions usually cover more than one task or area covered by cGMP regulations.

1.34 "**Stock Keeping Unit**" or "**sku**" or "**SKU**" means a unique number assigned to a finished product one unit of which shall consist of 12 filled applicators in individual sealed foil pouches placed in serialized selling unit carton with package insert.

1.35 "**Technical and Development Hourly Rate**" means the hourly rate charged by DPT technical and development personnel for services provided to COMPANY by DPT at the time such services are provided.

1.36 "**Territory**" means those countries set forth in Schedule D.

1.37 "**Third Party**" means any Person other than DPT, COMPANY or their respective Affiliates.

1.38 "**Total Price**" means, for a unit of Product, the sum of the Manufacturing Fee and the Materials Fee.

1.39 "**TrackWise®**" means a global electronic record keeping system that is used for, but not limited to, issuing and monitoring the completion of activities related to change control.

1.40 Additional Definitions. Each of the following terms shall have the meaning described in the corresponding Section of this Agreement indicated below:

Term	Section
Agreement	Preamble
Anti-Corruption Laws	9.3.1
AQLs	1.31
COMPANY	Preamble
COMPANY Indemnitees	11.1.1
Confidential Information	10.1
Development Costs	7.1.2
Development Product	7.1.1
Disclosing Party	10.1
Dispute	13.1
DPT	Preamble
DPT Indemnitees	11.1.2
Effective Date	Preamble
Extended Term	12.1
Force Majeure	14.4
Indemnify	11.1.1
Initial Term	12.1
Laboratory	4.4.4
Liabilities	11.1.1
Party or Parties	Preamble
PPI	3.1.1
Prior CDA	10.1
Receiving Party	10.1
Recipients	10.2
Rejected Product	4.4.1
Term	12.1
Third-Party Claim	11.1.1
Trade Control Laws	9.4.1

1.41 Interpretations. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections, Schedules mean the particular Articles, Sections, Schedules to this Agreement and references to this Agreement include all Schedules hereto. Unless context clearly requires otherwise, whenever used in this Agreement: (i) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation;" (ii) the word "or" shall have its inclusive meaning of "and/or;" (iii) the word "notice" shall require notice in writing (whether or not specifically stated) and shall include

notices, consents, approvals and other written communications contemplated under this Agreement; (iv) the words "hereof," "herein," "hereunder," "hereby" and derivative or similar words refer to this Agreement (including any Schedules); (v) provisions that require that a Party or the Parties "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing; (vi) words of any gender include the other gender; (vii) words using the singular or plural number also include the plural or singular number, respectively; (viii) references to any specific law, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement thereof; and (ix) provisions that refer to Persons acting "under the authority of DPT" shall include DPT's Affiliates and those Persons acting "under the authority of COMPANY" shall include COMPANY's Affiliates; conversely, those Persons acting "under the authority of DPT" shall exclude COMPANY and its Affiliates and those Persons acting "under the authority of COMPANY" shall exclude DPT and its Affiliates.

ARTICLE 2 MANUFACTURE AND SUPPLY

2.1 Manufacture and Purchase. During the Term and subject to the terms and conditions of this Agreement, DPT agrees that it will manufacture and provide Product to COMPANY (or COMPANY's designed 3PL). [***] DPT shall use commercially reasonable efforts to manufacture each Product in accordance with the Specifications therefor, and in sufficient quantity to meet COMPANY's Forecasted Needs.

2.2 Commencement of Manufacturing for New Product. No later than [***] prior to the estimated first delivery date of a new Product (or a new sku of an existing Product), COMPANY agrees to notify DPT of its delivery requirements for such new Product (or sku of an existing Product). COMPANY shall provide Forecasted Needs covering the twelve (12) month period commencing on the first day of the Launch Year in order to ensure timely delivery of Product. Firm orders shall be issued for the [***] the COMPANY's Forecasted Needs with delivery dates based on the longest component lead time.

2.3 Supply of Materials.

2.3.1 Materials Supplied by COMPANY. The Specification and/or each purchase order shall set forth any material to be supplied by COMPANY to DPT for the manufacture and supply of Product thereunder. COMPANY shall, at COMPANY's cost and expense, provide DPT with such materials at a minimum of [***] prior to DPT's scheduled start of production of Product requiring said materials and in sufficient amounts for DPT's manufacture of Product but not to exceed quantities necessary to support twelve (12) months of the most recently supplied Forecasted Needs or the Minimum Order Quantity, whichever is greater. COMPANY-supplied material in excess of these amounts shall be either subject to storage fees or returned to COMPANY at COMPANY's expense. All COMPANY- supplied material shall be shipped to DPT's DDP (Incoterms 2010). In the event COMPANY ships or causes to ship such material freight collect, DPT shall invoice COMPANY for the cost of the freight plus a reasonable administrative fee which invoice shall be paid by COMPANY promptly upon receipt. DPT is hereby authorized by COMPANY to return to COMPANY, at COMPANY's cost and expense, any portion of COMPANY-supplied material for which no future production is planned. COMPANY shall be responsible for the quality of all COMPANY-supplied materials. COMPANY shall be responsible for the payment of all personal property and other taxes incident to the storage of COMPANY-supplied material at DPT. DPT warrants that, during the Term, it will maintain, for the benefit of COMPANY, complete and accurate records of the inventory of all such COMPANY-supplied materials. If requested by COMPANY, DPT will provide to COMPANY a monthly report of the ending monthly inventory balance of all COMPANY-supplied materials stored at DPT. This reporting will be supplied exclusively on DPT forms.

2.3.2 Materials Supplied by DPT. DPT shall be responsible for the supply, at the expense of COMPANY, of all other components necessary for the manufacture of Product. If the applicable Specification requires that DPT utilize supplier(s) for raw materials and components that are not validated and approved DPT supplier(s) as of the Effective Date, then materials and components from such supplier(s) shall be treated as COMPANY-supplied materials until such time as DPT can, using commercially reasonable efforts, validate and approve such new supplier(s) at its earliest reasonable opportunity. Following such validation and approval, such materials and components will be treated as DPT-supplied. In the event that DPT is unable to validate and approve such new supplier(s), such products and materials will remain COMPANY-supplied for purposes of this Agreement. Any cost associated with validating and approving new supplier(s) borne by COMPANY if the new supplier(s) is only used to make Product, but shall be borne by DPT if used for other DPT customers' products. Except as provided above, supplier qualification services are not part of the manufacturing services to be performed and DPT shall have no obligation to qualify new suppliers. All DPT-supplied materials will be billed to COMPANY on the respective invoice for Product, into which such DPT-supplied material was converted, as part of the Materials Fee.

2.3.3 Packaging and Labeling. COMPANY shall provide DPT with Specifications (including art proofs) for Packaging and Labeling of each Product, and DPT shall purchase, at the expense of COMPANY, such Packaging and Labeling in accordance with the Specifications. COMPANY assumes responsibility and liability for the content of all Labeling and Packaging and compliance with Applicable Laws.

2.3.4 Additional Charges. COMPANY shall be responsible for any additional charges (including, but not limited to, items such as brokerage fees, courier expenses, duty fees payable, etc.) that are incurred in the procurement of any materials, including Packaging and Labeling components, as detailed in the immediately preceding sub-sections 2.3.1, 2.3.2 and 2.3.3; required for the manufacture of each Product, irrespective of which Party to the Agreement is responsible for supplying such items.

2.4 Supply of Product.

2.4.1 Purchase of Product. COMPANY agrees to purchase from DPT all Product manufactured for COMPANY by DPT in accordance with COMPANY's purchase orders or Forecasted Needs. Product shall be ordered by COMPANY by the issuance of separate, pre- numbered purchase orders in increments of full Batches and in Minimum Order Quantities.

2.4.2 Forecasted Needs. COMPANY shall provide DPT with its [***] projection with specific data as to its Forecasted Needs on or before December 13, 2019. Such Forecasted Needs shall be updated by COMPANY monthly on or before the 10th day of each calendar month on a rolling twelve (12) month basis. It is understood and agreed that with respect to all Forecasted Needs issued to DPT by COMPANY pursuant to the terms hereof, the forecast for the first three (3) months thereof shall constitute a firm order for Product, to the extent not the subject of a previous firm order, regardless of receipt of COMPANY's actual purchase order. COMPANY shall provide DPT with a confirmatory purchase order on or before the 10th day of each calendar month. [***] prior to the requested delivery date in order to accommodate fluctuations in production demands. The remaining [***] of the Forecasted Needs shall be utilized by DPT for purposes of material acquisition on behalf of COMPANY and DPT production planning. DPT shall attempt to

minimize the material inventory purchased on behalf of COMPANY. Certain materials, however, may have long lead times or require a Minimum Order Quantity. Therefore, with the exception of alginic acid (which typically has only a nine-month shelf life, and which therefore should be purchased by DPT no later than six-months from its date of manufacture) DPT may order the chemical and Packaging components necessary to support up to six (6) months of COMPANY's Forecasted Needs, or the applicable Minimum Order Quantity, whichever is greater. Should COMPANY subsequently reduce its Forecasted Needs, COMPANY will be financially responsible for any material purchased by DPT on COMPANY's behalf; provided that COMPANY is not permitted to reduce COMPANY's Forecasted Needs for any three (3)-month period constituting a firm order. Any such material which is subsequently rendered in excess of that required to support up to [***] of COMPANY's Forecasted Needs may be subject to storage and inventory carrying fees. DPT may require a deposit for such materials.

2.5 Orders.

2.5.1 Time of Issuance. COMPANY shall issue written purchase orders for Product to DPT at [***] prior to the requested delivery dates if the requirements are at or below [***] of the applicable Forecasted Needs, and at least [***] prior to the requested delivery dates if the requirements exceed the Forecasted Needs by [***]. Each such written purchase order shall be subject to acceptance by DPT.

2.5.2 Contents of Purchase Orders. COMPANY's purchase orders shall designate the desired quantities of each Product, delivery dates and destinations, each in accordance with this Section 2.5. This Agreement allows for up to three (3) shipping destinations per batch of Product. Additional destinations can be accommodated for a shipping preparation fee to be negotiated by DPT and COMPANY.

2.5.3 Shipment. Shipment of Product shall be in accordance with COMPANY instructions, provided that such instructions comply with Applicable Law. Product will be shipped to COMPANY or its designated 3PL provider promptly following release, freight collect. If COMPANY requests DPT to make any miscellaneous small shipments of Product, material, or other items on COMPANY's behalf, COMPANY agrees to reimburse DPT for any shipping charges incurred by DPT.

2.5.4 Delivery Terms. All shipment of Product detailed in Schedule B hereof shall be EXW (Incoterms 2010) DPT's Facility. Title to, and risk of loss for, Product, shall transfer from DPT to COMPANY when DPT makes the Product available to COMPANY at DPT's Facility. COMPANY shall bear all risk of loss, delay, or damage in transit, as well as cost of freight and insurance.

2.6 No Conflicting Terms.. The terms and conditions of this Agreement shall be controlling over any conflicting terms and conditions stated in any purchase order or Specifications (unless otherwise stipulated in writing referencing this Section 2.6). The Parties acknowledge that SOPs are considered supplemental to Master Batch Records, Specification documents and standard methods of analysis. Specific instructions in Master Batch Records, Specification documents and standard methods of analysis will supersede instructions in SOPs (unless otherwise stipulated in the SOP document).

2.7 Supply Failure. Subject to the terms of this Agreement, and provided that such failure is not attributable to any inaction or action caused by COMPANY and accepting normal yield losses associated with the production of each Batch, in the event that DPT fails to deliver at [***] of the quantity of Product set forth in any purchase order: (i) on or before the date [***] or (ii) on or before the date [***] after the delivery date (but in the case of (ii) only if such late delivery occurs in [***] status. Without limiting its obligations herein, DPT shall, within two (2) business days of becoming aware (if commercially feasible), inform COMPANY of any known or anticipated events or conditions that may result in such a Supply Failure.

2.8 Consequences of and Remedies for a Supply Failure. In the event of a Supply Failure, and without limiting any other remedy available to the COMPANY at law or equity:
(i) [***].

2.9 Limited Nonexclusivity. [***].

2.10 Safety Stock. Any requested safety stock must be agreed upon via side letter between the parties. COMPANY shall take delivery of any remaining of safety stock upon termination or expiration of this Agreement.

ARTICLE 3 PRICING AND PAYMENT

3.1 Product Price

3.1.1 Manufacturing Fees. The initial Manufacturing Fees to be paid by COMPANY to DPT are set forth in Schedule C. DPT reserves the right to raise the Manufacturing Fees if change(s) to Applicable Law, including, but not limited to GMP or changes made under Article 6, increase the cost of manufacturing of the Product or of any other activities contemplated under this Agreement. In addition, the Parties hereto agree that increases to the Manufacturing Fees set forth in Schedule C shall be negotiated, in good faith, at the beginning of each calendar year. If the Parties are unable to agree on a re-negotiated price at [***].
[***].

In addition, Manufacturing Fees are based on annual volumes for Product. [***].

Prices for new Product or new Product sizes, new batch sizes or Product configuration changes not initially included in Schedule C, shall be negotiated and DPT and COMPANY shall arrive at a mutual agreement with respect to prices at the time said new Product or new Product sizes are added to Schedule B.

Costs associated with establishing, testing or manufacturing components or new materials such as reference standards, reagents, art charges, die costs, molding or tooling costs, plate costs, and packing equipment change parts will be invoiced to COMPANY at DPT's cost on a net thirty (30) basis and COMPANY agrees to reimburse DPT for any such authorized expenditures made on COMPANY's behalf.

3.1.2 Materials Fees and Other Costs. The initial Materials Fees to be paid by COMPANY to DPT are listed in Schedule C. For the Launch Year, the Materials Fee will be listed

in Schedule C [***]. After the Launch Year, the Materials Fee will be adjusted (up or down) once annually at the beginning of each calendar year and Schedule C shall be amended accordingly based on changes in DPT's Standard Cost for materials. In the event, however, the total underlying costs of Material Fee for a Product increases during any calendar year [***], DPT will provide documented cost justifications to COMPANY in connection with such cost change(s). Thereafter DPT may promptly upon the effective date of such increase, increase its Materials Fee for said Product to COMPANY to compensate for the increase in such costs.

Material Fees for new Product or new Product sizes, new batch sizes or Product configuration changes not initially included in Schedule C, shall be established prior to the time of first production.

3.1.3 [***].

3.2 Payment. Payment for all deliveries of Product and services shall be made in U.S. Dollars (USD), [***] days after the date of DPT's invoice therefor. Invoices shall be generated upon shipment of Product from DPT. Total invoice price shall be equal to the quantity of Product times the Total Price per unit of Product effective on the date of the Product release, as listed in Schedule B. Payments shall be made by check, wire transfer, electronic fund transfer or through other

instrument accepted by DPT. Payments by wire or electronic fund transfer should be made to the following: [***].

3.3 Late Payment. A late fee of [***] of total invoice can be added each month for late payments. DPT, at its sole discretion, has the right to discontinue COMPANY's credit on future orders and to put a hold on any production or shipment of Product if COMPANY is late in making payment [***]. Such hold on production or shipment shall not constitute a breach of this Agreement by DPT. In the event credit is discontinued, [***] material deposit paid by COMPANY to DPT will be required prior to DPT ordering any additional materials. In addition, [***] will be required prior to DPT manufacturing any Product and the balance of the invoice for such Product must be paid in full prior to shipment.

3.4 Destruction Costs. DPT reserves the right to invoice COMPANY for all of the costs of destruction of any Product, unless such destruction relates to a Rejected Product arising from DPT's failure to comply with applicable written procedures which renders the Product not Conforming or unmarketable. In either case DPT will supply a certificate of destruction without charge additional charge to COMPANY.

3.5 Taxes. COMPANY shall bear all taxes, whether direct or indirect (including, by way of example, corporate income, sales and transfer taxes, and VAT), levies, and duties (including customs duties) as may be imposed on COMPANY under Applicable Law (or for which COMPANY is required to act as withholding agent by any governmental body or authority on the subject matter of this Agreement), and COMPANY shall be responsible for the timely payment of such amounts to such governmental body or authority.

ARTICLE 4 PRODUCT TESTING

4.1 Certificates of Analysis/Conformance. Unless otherwise provided to the contrary in the Quality Agreement, DPT shall test each finished lot of Product purchased pursuant to this Agreement before delivery to COMPANY. Each Certificate of Analysis shall set forth the items tested, specifications and test results for each finished lot delivered. DPT shall send two (2) Certificates of Analysis and one (1) Certificate of Conformance to COMPANY at the time of the release of Product. Extraordinary reporting or documentation, outside this Agreement, may be subject to an additional charge by DPT.

4.2 Stability Testing. DPT shall perform its standard stability test program as defined in DPT's SOPs or as separately agreed to in accordance with a CCR for each Product contained herein. COMPANY shall receive a copy of the report generated in DPT's Annual Product Review for each Product in DPT's standard form as long as DPT is continuing to produce such Product for COMPANY and for as long as COMPANY's account is current. If COMPANY elects to perform

its own stability testing on Product, COMPANY agrees to provide DPT with a copy of the results from such testing on an annual basis.

4.3 Validation Studies or Additional Testing. It is understood and agreed by the Parties hereto that unless otherwise agreed, any validation studies shall be the sole responsibility of COMPANY except the validation of any equipment owned by DPT shall be at DPT's expense. The Parties agree that for any validation studies or additional testing to be performed by DPT in connection with the Product, DPT and COMPANY shall enter into a specific written Project Protocol establishing methodology and pricing for such services.

4.4 Rejected Product

4.4.1 Rejection of Product by COMPANY. COMPANY may reject any Product which fails to meet the Specifications in accordance with this Section 4.4 ("**Rejected Product**"). COMPANY shall, within thirty (30) days after its receipt of any shipment of Product and related Certificate of Analysis/Conformance of Product batch (as described in Section 4.1 hereof), notify DPT in writing of COMPANY's rejection of the Product, specifying why the Product batch failed to meet the Specifications, and any claim relating to the Rejected Product batch accompanied with the supporting analyses or documentation. COMPANY's failure to provide rejection such notification within the thirty (30) day period specified above will be deemed for purposes of the Agreement to constitute COMPANY's acceptance of such Product batch. COMPANY shall grant to DPT the right to inspect or test said Product batch. All necessary samples of Rejected Product shall be delivered to DPT and submitted for inspection and evaluation by DPT in accordance with DPT's SOPs to determine whether or not said Product meet the Specifications.

4.4.2 Replacement of Rejected Product. As to any Rejected Product agreed by the Parties as failing to meet the Specifications or determined by the Laboratory not to meet the Specifications, pursuant to Section 4.4.4 below (including in each case phases of or complete batches of bulk Product), DPT shall replace such Rejected Product (in an agreed upon batch order quantity, but in no event less than full batch increments) promptly after all requisite materials are available to DPT for the manufacture of replacement Product with costs allocated pursuant to Section 4.4.3 below.

4.4.3 Responsibility for Costs. For all of the validation batches of a Product produced by DPT, or in the event a Rejected Product fails to comply with the Specification due to COMPANY-supplied information, formulations or materials, or otherwise due to improper storage, transport or other mishandling by COMPANY, [***] Rejected Product including the cost of destruction of the Rejected Product, which shall be conducted and managed by DPT. Upon the completion of all necessary validation batches in the event a Rejected Product fails to comply with the Specification due to DPT's failure to comply with the applicable written procedures and such failure renders the Product non-Conforming or unmarketable, DPT shall bear [***]. In the event Rejected Product fails to comply with the Specification, but such failure is not due to either COMPANY-supplied information, formulations or materials or otherwise due to improper storage, transport or other mishandling by COMPANY, or DPT's failure to follow written procedures, [***]

related to such Rejected Product. Destruction of Rejected Product shall be in accordance with all Applicable Laws.

4.4.4 Resolution of Conflict. If DPT does not agree with COMPANY's determination that the Product fails to conform to the Specifications, then DPT shall so notify COMPANY within thirty (30) days of receipt of COMPANY's notice of non-conformity with respect to such Product and (if requested) Product sample. In the event of: (i) a conflict between the Parties with respect to the conclusions to be drawn from any test results or, (ii) a difference of opinion between the Parties regarding the rejection of any batch by DPT with respect to any shipment of Product in such batch, a sample of such Product batch shall be submitted by DPT to an independent testing organization, or to a consultant of recognized repute within the United States pharmaceutical industry, in either case mutually agreed upon by the Parties (such organization or consultant, the "**Laboratory**"), the appointment of which shall not be unreasonably withheld or delayed by either Party, for testing against the Specifications utilizing the methods set out in the Specifications. The determination of the Laboratory with respect to all or part of any shipment of Product shall be final and binding on the Parties. The fees and expenses of the Laboratory testing shall be borne entirely by the Party against whom such Laboratory's findings are made. If results from the Laboratory are inconclusive, final resolution will be settled in accordance with Article 13 below.

4.4.5 Product Recall. Each of DPT and COMPANY will immediately inform the other in writing if it believes one or more lots of any Product(s) should be subject to recall from distribution, withdrawal or some other field action. In the event it is determined that such a recall resulted from a breach by either Party of any of its representations, warranties, duties or obligations under the Agreement, such Party shall be responsible for the costs of the recall and shall reimburse the other Party as necessary; provided that if both Parties share responsibility with respect to such recall, the costs shall be shared in the ratio of the Parties' contributory responsibility. COMPANY shall, with respect to any recall of any Product, abide by all Healthcare Distribution Management Association published guidelines for product recall reimbursement in effect at the time of the recall. In the event that any such recall results solely from the breach of DPT's warranties under this Agreement, DPT shall be responsible for the [***] of such recall, in any case not to exceed [***] per Product recall incident, as well as for the cost [***].

ARTICLE 5
REGULATORY AND QUALITY RESPONSIBILITIES

5.1 Materials Testing. For each lot of materials supplied by COMPANY, DPT shall perform the quality control and inspection tests as set forth in the Specifications unless COMPANY has made arrangements in writing to supply pre-approved material. All materials and Packaging supplies shall, when received by DPT, be submitted for analysis and evaluation in accordance with DPT's SOPs to determine whether or not said materials or Packaging supplies meet the Specifications. DPT shall have the right to reject any pre-approved material which does not conform with the Specifications. The cost of all such analyses and evaluations shall be borne by DPT except as otherwise provided in Section 2.3 of this Agreement**.** DPT agrees to maintain and, if necessary, make available records of all such analyses and evaluations.

5.2 Material Safety Data Sheets. Prior to DPT's receipt and testing of any materials components or finished Product, and as a condition precedent of any testing or formulation work by DPT pursuant to this Agreement, COMPANY shall provide DPT with Certificates of Analysis and MSDS sheets for any materials supplied by COMPANY, as well as any finished Product and any components to be supplied by COMPANY which is necessary for the manufacture of each Product. Any materials, components or Product requiring disposal shall be presumed hazardous unless otherwise provided in the MSDS information provided.

5.3 Regulatory Inspection. DPT shall advise COMPANY if an authorized agent of the FDA, EMA or other Regulatory Authority or Governmental Authority visits DPT's manufacturing facility and requests or requires information or changes which specifically pertain to any Product. Any time spent on Regulatory Authority or Governmental Authority visits or requests specific to Products will be billed to COMPANY by DPT at DPT's standard hourly rates.

5.4 Regulatory Communications & Filings. COMPANY agrees to provide DPT with copies of any sections of NDA's, ANDA's, 510(k)'s or other regulatory filings and Regulatory Authority correspondence applicable to each Product manufactured or tested by DPT, and copies of any changes in or updates to the same as they, from time to time, hereafter occur.

5.5 Access to DPT's Facilities. During the Term, COMPANY shall have access to DPT's facilities at a mutually agreeable time for the sole purpose of auditing DPT's compliance with cGMP and the Act in the manufacture of Products hereunder. Such access shall in no way give COMPANY the right to any of DPT's confidential or proprietary information. Furthermore, such audits shall normally be limited in frequency to [***] employees of COMPANY who are subject to written obligations of confidentiality and non-use at least as protective of DPT and DPT's Confidential Information as the terms of this Agreement.

ARTICLE 6
CHANGES TO PROCESS OR PRODUCT

6.1 Changes by COMPANY. If COMPANY at any time requests a change to any Product and DPT agrees such change is reasonable with regard to Product manufacture; (i) such change shall be incorporated within the Master Batch Record or Specifications via a written CCR reviewed and agreed upon in writing by both DPT and COMPANY; (ii) the Parties shall adjust the Total Price of Product, if necessary, and Schedule B shall be amended accordingly; and (iii) COMPANY shall pay DPT for the costs associated with such change including, but not limited to, any additional development or validation studies required, charged at DPT's then-prevailing R&D rates.

6.2 Changes by DPT. DPT agrees that any changes to the Product developed by DPT, which may be incorporated into the Product shall require the written approval of COMPANY via a CCR prior to such incorporation. At the time of such incorporation, such changes shall become part of the Specifications. It is also agreed that any filings with any Regulatory Authority necessitated by any such change shall be the sole responsibility of COMPANY.

6.3 Changes or Fees by Regulatory Authorities. The Parties agree that any changes required by a Regulatory Authority, shall be incorporated into the Product as evidenced by the written approval of COMPANY via a CCR prior to such incorporation. Any actual or potential additional Product costs, fees or expenses, including but not limited to items such as regulatory user fees, serialization fees or similar such items shall be the sole responsibility of COMPANY. At the time of such incorporation, such changes shall become part of the Specifications. If DPT is required by Regulatory Authority to perform validation studies for purposes of validating new manufacturing process or cleaning procedures or new material and finished Product assay procedures with respect to Product in order to continue to engage in the manufacture of said Product for COMPANY, such studies shall be agreed to by the Parties and set forth in a new Project Protocol. In the event the Parties are unable to reach agreement with respect to such Project Protocol, then DPT shall be under no obligation to perform such studies or otherwise continue the manufacture of the Product affected by said regulation. Any costs to DPT resulting from the operation of this Section 6.3 shall be reimbursed by COMPANY by way of adjustments to the Manufacturing Fee, Materials Fee or via an annual charge.

6.4 Obsolete Inventory. Any COMPANY-specific inventory relating to a Product or Development Product (as defined below), including, but not limited to, materials, expired materials, work-in-process, bulk Development Product, waste by-products, testing supplies, stability samples, work-in-process, and any Product or finished good rendered obsolete as a result of formula, artwork, Minimum Order Quantities, or Labeling or Packaging changes requested by COMPANY or by changes required by a Regulatory Authority, or at the conclusion, revision or termination of the development project shall be reimbursed to DPT by COMPANY at DPT's Materials Fee and unless otherwise instructed by COMPANY and agreed to by DPT, will be shipped to COMPANY for destruction by COMPANY. COMPANY shall bear one hundred percent (100%) of all shipping and destruction costs related to said obsolete inventory. COMPANY shall destroy any such inventory in accordance with all Applicable Laws and COMPANY shall Indemnify (as hereinafter defined) DPT for any liability, costs or expenses, including attorney's fees and court costs, relating to COMPANY's failure to dispose of such inventory in accordance with such laws and regulations. COMPANY shall also provide DPT with all manifests and other applicable evidence of proper destruction as may be requested by DPT or required by applicable law. DPT shall provide written notification to COMPANY of its intent to dispose of or store obsolete inventory. If DPT does not receive disposition instructions from COMPANY within thirty (30) days from date of notification, obsolete inventory remaining at DPT's facilities shall be subject to a deposit covering the standard cost of the obsolete inventory and storage and or destruction fees at DPT's discretion.

ARTICLE 7
TECHNICAL & DEVELOPMENT SERVICES

7.1 Technical & Development Services

7.1.1 Development Product. From time to time, COMPANY may request, in writing, that DPT evaluate, develop, manufacture, test or provide price quotations for certain new items which may become Product (hereinafter referred to as "**Development Product**") on behalf of COMPANY. If DPT agrees to perform such services, DPT shall so notify COMPANY within thirty (30) days of its receipt of COMPANY's proposal. To the extent that DPT agrees to perform

any services hereunder for COMPANY, DPT shall only be obligated to act in good faith and to use reasonable efforts to accomplish the desired results as outlined in the relevant Project Protocol. Nothing herein shall obligate DPT to achieve any specific results and DPT makes no warranties or representations that it will be able to achieve the desired results.

7.1.2 Project Protocol. Should DPT agree to perform any services hereunder, DPT shall submit a written development proposal in the form of a Project Protocol to COMPANY identifying DPT's best estimate of the cost of such services (the "**Development Costs**"). This estimate shall include, but not be limited to, labor hours for development, testing, scale up, stability, report writing, etc., as well as all reasonably foreseeable associated tasks and expenses. If this estimate is acceptable to COMPANY and COMPANY so notifies DPT by approving the Project Protocol in writing, DPT shall begin work as outlined in the Project Protocol. It is understood between both Parties that during any development project unforeseen circumstances may evolve, including, but not limited to, termination of any further activity due to unacceptable results, significant reevaluation due to marginal results. DPT will promptly notify COMPANY of any such unforeseen circumstances before proceeding at which time either COMPANY or DPT may terminate the project or mutually agree to amend or completely revise the Project Protocol. In the case where the project is terminated or revised, COMPANY will be obligated to pay for all of the work performed by DPT up to that point plus any noncancellable expenses incurred by DPT in connection with the relevant Project Protocol.

7.1.3 Costs. Material costs involved will be billed to COMPANY [***]. The Development Costs shall be paid to DPT in accordance with DPT's standard invoicing procedures regardless of whether DPT is able to accomplish the results which COMPANY requested. All invoices shall be paid by COMPANY in accordance with Article 3 above.

7.2 Commercial Production of Development Project. . At or near the beginning of any development project, DPT agrees to send to COMPANY a written proposal which will provide a good faith estimate of Manufacturing Fees and Materials Fees along with related assumptions. It is agreed that such manufacturing requirements shall be binding upon any assignee, licensee, or other Third Party marketing any new Development Product. The price which COMPANY (or any such Third Party) shall pay to DPT for such Product shall be based upon the Manufacturing Fee and Material Fee estimate provided in good faith by DPT under this Section 7.2 subject to revision for final packaging configuration and final cost and Manufacturing Fee and Material Fee adjustment pursuant to Article 3. Once COMPANY completes the development of a finished product prototype (which shall include final primary container selection filled with Development Product), DPT will provide an updated estimate of the Manufacturing Fee. DPT may also provide an updated estimate of the Materials Fee, should specifications be known for these items at such time.

ARTICLE 8 INTELLECTUAL PROPERTY

8.1 No Licenses. COMPANY neither transfers nor licenses DPT by operation of this Agreement under any of its patent rights, copyrights or other proprietary rights, except as specifically set forth in this Agreement.

8.2 Ownership of Inventions. [***].

8.3 Licenses to COMPANY. DPT agrees that if, in the course of performing the services required of DPT to manufacture and Package each Product, DPT incorporates into any Project IP or Product or utilizes in the performance of the services required of DPT to manufacture and Package each Product any pre-existing invention, discovery, original works of authorship, development, improvements, trade secret, concept, or other proprietary information or intellectual property right owned by DPT or in which DPT has an interest (“Prior Inventions”), DPT hereby grants COMPANY a non-exclusive, royalty-free, perpetual, transferable, worldwide license (with the right to grant and authorize sublicenses) under such Prior Inventions to make, have made, use, import, offer for sale, sell, reproduce, distribute, modify, adapt, prepare derivative works of, display, perform, and otherwise exploit the Project IP and Product. DPT will not knowingly incorporate any invention, improvement, development, concept, discovery, work of authorship or other proprietary information owned by any third party into any Project IP or Product without COMPANY’s prior written permission.

ARTICLE 9 REPRESENTATIONS AND WARRANTIES

9.1 DPT Warranties and Representations. DPT represents and warrants the following:

9.1.1 DPT is a limited partnership duly organized, validly existing and in good standing under the laws of the State of Texas.

9.1.2 DPT has all requisite power and authority to enter into this Agreement. The Person signing this Agreement has the necessary corporate authority to legally bind DPT to the terms set forth herein.

9.1.3 DPT's execution of this Agreement and performance of the terms set forth herein will not cause DPT to be in conflict with or constitute a breach of its organizational documents nor any other agreement, court order, consent decree or other arrangement, whether written or oral, by which it is bound.

9.1.4 This Agreement is a legal, valid and binding obligation, enforceable against DPT in accordance with the terms and conditions hereof, except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by the principles governing the availability of equitable remedies.

9.1.5 To DPT's knowledge, the practice of any DPT Intellectual Property (as defined in Section 8.2) does not infringe any Third Party intellectual property right(s).

9.1.6 DPT will provide COMPANY with prompt written notice if any of the representations and warranties in this Section 9.1 become untrue.

9.2 COMPANY Warranties and Representations. COMPANY represents and warrants the following:

9.2.1 COMPANY is a corporation duly organized, validly existing and in good standing under the laws of Delaware.

9.2.2 COMPANY has all requisite power and authority to enter into this Agreement. The Person signing this Agreement has the necessary corporate authority to legally bind COMPANY to the terms set forth herein.

9.2.3 COMPANY's execution of this Agreement and performance of the terms set forth herein will not cause COMPANY to be in conflict with or constitute a breach of its organizational documents nor any other agreement, court order, consent decree or other arrangement, whether written or oral, by which it is bound.

9.2.4 To COMPANY's knowledge and belief, there are no suits, actions, claims, proceedings, or investigations pending or threatened by or before any court, by any Person relating to Product and matters set forth herein.

9.2.5 COMPANY's execution of this Agreement and performance hereunder are in, and will be in, compliance with any Applicable Law in all material respects.

9.2.6 This Agreement is a legal, valid and binding obligation, enforceable against COMPANY in accordance with the terms and conditions hereof, except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by the principles governing the availability of equitable remedies.

9.2.7 COMPANY shall bear sole responsibility for all material supplied by COMPANY to DPT, including the pre-approved material and the validity of all test methods and appropriateness of all Specifications. In addition, COMPANY shall bear sole responsibility for all regulatory approvals, filings, and registrations and adequacy of all validation, stability, and preservative efficacy studies. COMPANY further warrants that it has obtained (or will obtain before required by Applicable Law) any and all necessary approvals from all applicable Regulatory Authorities necessary to manufacture and distribute all Product under this Agreement.

9.2.8 As of the Effective Date, there are no claims, judgments or settlements against or owed by COMPANY or its Affiliates, or pending or threatened claims or litigation, relating to API, Products, Packaging and Labeling or any Company-supplied materials.

9.2.9 COMPANY will provide DPT with prompt written notice if any of the representations and warranties in this Section 9.2 become untrue.

9.3 Anti-Corruption.

9.3.1 COMPANY understands that DPT is required to and does abide by the United States Foreign Corrupt Practices Act, the United Kingdom Bribery Act and any other applicable anti-corruption laws (collectively, the "**Anti-Corruption Laws**"). COMPANY represents and warrants that no one acting on its behalf will give, offer, agree or promise to give, or authorize the giving directly or indirectly, of any money or thing of value to anyone as an inducement or reward or favorable action or forbearance from action or the exercise of influence
(a) to any governmental official or employee (including employees of government-owned and government-controlled corporations or agencies), (b) to any political party, official of a political party, or candidate, (c) to an intermediary for payment to any of the foregoing, or (d) to any other Person in a corrupt or improper effort to obtain or retain business or any commercial advantage, such as receiving a permit or license.

9.3.2 COMPANY understands that DPT may immediately suspend its manufacture and supply of Product, in its sole discretion and without notice, if the actions or inactions of COMPANY are found to be in violation of the Anti-Corruption Laws.

9.3.3 Each Party warrants that all Persons acting on its behalf will comply with all Applicable Laws in connection with all work under this Agreement, including the Anti- Corruption Laws if any, prevailing in the country(ies) in which such Party has its principal places of business.

9.3.4 Each Party further warrants and represents that should it learn or have reason to suspect any breach of any representation or warranty in this Section 9.3 it will immediately notify the other Party.

9.3.5 Upon receipt of such Notice refer to above (or upon determination that such Notice should have been given) DPT may appoint a certified public accounting firm to

perform a financial audit to determine whether COMPANY is in compliance with the terms of this Section 9.3. COMPANY hereby agrees to grant the certified public accounting firm commercially reasonable access to its books, records, systems and accounts to the extent they pertain to transactions covered by this Agreement and are necessary for such purpose.

9.4 Trade Control Laws.

9.4.1 Each Party will fully comply with all applicable export control, economic sanctions laws and anti-boycott regulations of the United States of America and other governments, including the U.S. Export Administration Regulations (Title 15 of the U.S. Code of Federal Regulations Part 730 et seq.) and the economic sanctions rules and regulations implemented under statutory authority or President's Executive Orders and administered by the
U.S. Treasury Department's Office of Foreign Assets Control (Title 31 of the U.S. Code of Federal Regulations Part 500 et seq.) (collectively, "**Trade Control Laws**").

9.4.2 Each Party acknowledges and confirms that Trade Control Laws apply to its activities, its employees and Affiliates under this Agreement.

9.4.3 COMPANY acknowledges that it shall be solely and exclusively responsible for the preparation of all import and export documentation and compliance with all applicable Trade Control Laws, except as otherwise agreed by the Parties in writing. COMPANY represents and warrants that is shall not take any unilateral action to identify or otherwise name DPT as the importer or exporter of record for any of the aforementioned items.

9.4.4 No Product will be directly or indirectly shipped by the other Party to any country subject to U.S. or U.N. economic sanctions without the necessary licenses, even for transfer to non-sanctioned countries, and only after the express written consent of DPT, in its sole discretion.

9.4.5 DPT shall not be required by the terms of this Agreement to be directly or indirectly involved in the provision of goods, services or technical data that may be prohibited by applicable Trade Control Laws if performed by DPT. It shall be in the sole discretion of DPT to refrain from being directly or indirectly involved in the provision of goods, services or technical data that may be prohibited by applicable Trade Control Laws.

9.4.6 Each Party hereby represents and warrants that it is not included on any of the restricted party lists maintained by the U.S. Government, including the Specially Designated Nationals List administered by the U.S. Treasury Department’s Office of Foreign Assets Control; the Denied Persons List, Unverified List or Entity List maintained by the U.S. Commerce Department’s Bureau of Industry and Security; or the List of Statutorily Debarred Parties maintained by the U.S. State Department’s Directorate of Defense Trade Controls.

9.4.7 Each Party shall commit to maintaining awareness of the importance of Trade Control Laws throughout its organization. Each Party shall take such actions as are necessary and reasonable to prevent Product from being exported or re-exported to any country, entity or individual subject to U.S. trade sanctions, unless prior approval of the other Party, and relevant permission or license from the U.S. government has been obtained.

9.4.8 Each Party will keep accurate and consistent records of all transactions under this Agreement covered by the Trade Control Laws for a minimum of five (5) years from the date of export or re-export; the date of expiration of any applicable license; or, other approval or reliance on any application of license exception or exemption.

9.4.9 COMPANY shall be the importer or exporter of record for all such import or export activities. COMPANY shall cooperate with DPT as reasonably necessary to permit DPT to comply with the laws and regulations of the United States, including Trade Control Laws and Anti-Corruption Laws, and the laws and regulations other country relating to the control of import or export of Product, Active Pharmaceutical Ingredient, chemical, Labeling or Packaging components (or related technical information or data).

9.5 DPT Product Warranties. DPT represents and warrants that:

9.5.1 All Product delivered by DPT shall have been manufactured by DPT in substantial compliance with applicable FDA regulations and current Good Manufacturing Practices as that term is defined under the Act.

9.5.2 All Product sold pursuant to this Agreement by DPT during the Term, at the time of pick-up by COMPANY, will have been manufactured in accordance with the Specifications for the release of the Product or pursuant to exceptions approved by COMPANY at the time of manufacture. Notwithstanding the foregoing, however, no warranty is made by DPT for Product that is rendered non-Conforming by reason of a COMPANY-supplied material, provided that such material has been tested and cleared by DPT as provided in Section 5.1 or the Quality Agreement.

9.6 COMPANY Product Warranties. COMPANY represents and warrants that:

9.6.1 All Labeling, copy and artwork approved, designated or supplied by COMPANY shall be in compliance with all Applicable Laws. Compliance with all Applicable Laws concerning Packaging and Labeling shall be the sole responsibility of COMPANY, provided that DPT purchases such Packaging and Labeling as provided in Section 2.3.3.

9.6.2 No COMPANY designated formulas, components or artwork related to the Product violate or infringe any patent, copyright or trademark laws.

9.6.3 COMPANY has either: (i) an Investigational New Drug (IND) designation; or (ii) the approval of the FDA to manufacture, sell and distribute the Product into the consumer marketplace and COMPANY assumes any and all responsibility for the manufacture, sale and distribution of the Product in the event that such approval was never provided by the FDA, or was initially provided but subsequently withdrawn by the FDA.

9.6.4 The manufacture, sale, offer for sale, use, import and commercialization of Product will not infringe or misappropriate the patent or other proprietary rights of any Third Parties.

9.7 Disclaimer. EACH PARTY AGREES AND ACKNOWLEDGES THAT, EXCEPT AS SET FORTH IN THIS ARTICLE 9, NEITHER PARTY MAKES ANY

REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, IMPLIED OR STATUTORY, AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, IMPLIED OR STATUTORY, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AGAINST NON-INFRINGEMENT OR THE LIKE, OR ARISING FROM COURSE OF PERFORMANCE.

ARTICLE 10 CONFIDENTIALITY

10.1 Definition. "**Confidential Information**" means the terms and provisions of this Agreement (each of which shall be the Confidential Information of both Parties) and all other information and data, including all notes, books, papers, diagrams, documents, reports, e-mail, memoranda, visual observations, oral communications and all other data or information in whatever form, that one Party or any of its Affiliates or representatives (the "**Disclosing Party**") has supplied or otherwise made available to the other Party or its Affiliates or representatives (the "**Receiving Party**") hereunder, including those made prior to the Effective Date of this Agreement. This Article 10 shall supersede the confidentiality provisions in any prior agreements between the Parties, including those dated [***] (the "**Prior CDAs**"), and all Confidential Information disclosed pursuant to the Prior CDAs shall be deemed to have been disclosed hereunder.

10.2 Obligations. The Receiving Party shall protect all Confidential Information of the Disclosing Party against unauthorized use and disclosure to Third Parties with the same degree of care as the Receiving Party uses for its own similar information, but in no event less than a reasonable degree of care. The Receiving Party shall be permitted to use the Confidential Information of the Disclosing Party solely as reasonably necessary to exercise its rights and fulfill its obligations under this Agreement (including any surviving rights), including (a) in prosecuting or defending litigation, (b) complying with Applicable Law, or (c) otherwise submitting information to tax or other Governmental Authorities. The Receiving Party shall not disclose the Confidential Information of the Disclosing Party to any Third Party other than to its Affiliates and its and their respective directors, officers, employees, and in the case of either party, to its subcontractors, sublicensees, consultants, and attorneys, accountants, banks and investors (collectively, "**Recipients**") who have a need to know such information for purposes related to this Agreement and who are made aware of the confidentiality obligations set forth in this Agreement or are bound by obligations of confidentiality at least as protective of such Confidential Information as those set forth in this Agreement. The Receiving Party shall be responsible for any disclosures made by its Recipients in violation of this Agreement.

10.3 Exceptions

10.3.1 Restriction Limitations. The restrictions related to use and disclosure under this Article 10 shall not apply to any information to the extent the Receiving Party can demonstrate by competent evidence that such information:

(1) is (at the time of disclosure by the Disclosing Party) or becomes (after the time of such disclosure by the Disclosing Party) known to the public or part of the public

domain through no breach of this Agreement by the Receiving Party, or any Recipient to whom the Receiving Party disclosed such information, of its confidentiality obligations to the Receiving Party; or

(2) was known to, or otherwise in the possession of, the Receiving Party prior to the time of disclosure by the Disclosing Party;

(3) is disclosed to the Receiving Party on a non-confidential basis by a Third Party who is not, to the actual knowledge of the Receiving Party, prohibited from disclosing it without breaching any confidentiality obligation to the Disclosing Party; or

(4) is independently developed by or on behalf of the Receiving Party or any of its Affiliates, as evidenced by its written records, without use of or access to the Confidential Information.

10.3.2 Disclosure Required by Law. The restrictions set forth in this Article 10 shall not apply to the extent that the Receiving Party is required to disclose any Confidential Information under law or by an order of a Governmental Authority; provided that the Receiving Party: (a) provides the Disclosing Party with prompt written notice of such disclosure requirement if legally permitted, (b) affords the Disclosing Party an opportunity, and cooperates with the Disclosing Party's efforts, to oppose or limit, or secure confidential treatment for such required disclosure (at the Disclosing Party's expense), and (c) if the Disclosing Party is unsuccessful in its efforts pursuant to subsection (b), discloses only that portion of the Confidential Information that the Receiving Party is legally required to disclose as advised by the Receiving Party's legal counsel.

10.4 Nondisclosure of Terms. Each Party agrees not to issue any press releases, reports, or other statements in connection with this Agreement intended for use in the public or private media or otherwise disclose the terms of this Agreement to any Third Party without the prior written consent of the other Party hereto, which consent shall not be unreasonably withheld, except to such Party's attorneys, advisors and others on a need to know basis in each case consistent with customary practice under circumstances that protect the confidentiality thereof. Notwithstanding the foregoing, each Party may make announcements concerning the subject matter of this Agreement if required by Applicable Law or any securities exchange or Governmental Authority or any tax authority to which any Party is subject or submits, in which case the Party making such announcement shall provide the other Party with a copy of such announcement at least five (5) Business Days prior to issuance, to the extent practicable under the circumstances, and shall only disclose information required by Applicable Law or such exchange or authority.

10.5 Right to Injunctive Relief. Each Party agrees that breaches of this Article 10 may cause irreparable harm to the other Party and shall entitle such other Party, in addition to any other remedies available to it (subject to the terms of this Agreement), to the right to seek injunctive relief enjoining such action.

10.6 Ongoing Obligation for Confidentiality. The Parties' obligations of confidentiality, non-use and non-disclosure under this Article 10 shall survive any expiration or termination of this Agreement for five (5) years.

10.7 DPT Business Model. [***].

ARTICLE 11 INDEMNIFICATION AND INSURANCE

11.1 Indemnification.

11.1.1 Indemnification by DPT. DPT hereby agrees, at its sole cost and expense, to defend, hold harmless and indemnify, to the extent permitted by Applicable Law, (collectively, "**Indemnify**") COMPANY and its Affiliates and their respective directors, officers and employees of such Persons and the respective successors and assigns of any of the foregoing (the "**COMPANY Indemnitees**") from and against any and all liabilities, damages, penalties, fines, costs and expenses (including, reasonable attorneys' fees and other expenses of litigation) (collectively, "**Liabilities**") resulting from suits, claims, actions and demands, in each case brought by a Third Party (each, a "**Third-Party Claim**") against any COMPANY Indemnitee and arising from or occurring as a result of: (a) any material breach of any of DPT's obligations, representations, warranties or covenants under this Agreement; or (b) the gross negligence or willful misconduct of a DPT Indemnitee. DPT's obligations to Indemnify COMPANY Indemnitees pursuant to this Section 11.1.1 shall not apply to the extent any such Liabilities are the result of a material breach by COMPANY of its obligations, representations, warranties or covenants under this Agreement or any COMPANY Indemnitee's gross negligence or willful misconduct. Notwithstanding the foregoing, under no circumstances shall DPT have any responsibility for product liability or personal injury claims of such third parties which arise from the sale, marketing, promotion, distribution or any use of Product which meets the Specifications.

11.1.2 Indemnification by COMPANY. COMPANY hereby agrees to Indemnify DPT and its agents, directors, officers and employees and the respective successors and assigns of any of the foregoing (the "**DPT Indemnitees**") from and against any and all Liabilities resulting from Third-Party Claims against any DPT Indemnitee arising from or occurring as a result of: COMPANY's gross negligence, willful misconduct or any material breach of COMPANY's obligations, representations, warranties or covenants provided for herein or which arise out of the marketing promotion, distribution, use, testing or sales of any Product, including, without limitation, any Third Party Claim, express, implied or statutory, made as to the efficacy, safety, or use to be made of Product, and Third Party Claims made by reason of any Product Labeling or any Packaging containing Product. COMPANY's obligations to Indemnify DPT Indemnitees pursuant to this Section 11.1.2 shall not apply to the extent any such Liabilities are the result of a material breach by DPT of its obligations, representations, warranties or covenants under this Agreement or any DPT Indemnitee's gross negligence or willful misconduct.

11.1.3 Procedure. To be eligible to be Indemnified hereunder, the indemnified Person shall provide the indemnifying Party with prompt written notice of the Third-Party Claim giving rise to the indemnification obligation pursuant to this Section 11.1.3 and the right to control the defense (with the reasonable cooperation of the indemnified Person) or settlement any such claim; provided, however, that the indemnifying Party shall not enter into any settlement that admits fault, wrongdoing or damages without the indemnified Person's written consent, such consent not to be unreasonably withheld or delayed. The indemnified Person shall have the right to join, but not to control, at its own expense and with counsel of its choice, the defense of any claim or suit that has been assumed by the indemnifying Party.

11.2 Product Liability Insurance. Each Party shall, during the Term and for two (2) years after termination or expiration of this Agreement, obtain and maintain at its own cost and expense from a qualified insurance company (provided however that DPT may satisfy all or part of its obligation through its insurance captive or self-insurance) product liability insurance providing protection against any and all claims, demands, and causes of action arising out of any defects, alleged or otherwise, of the Product(s) or their use, design or manufacture, or any material incorporated in the Product(s). The amount of coverage shall be a minimum of [***] combined single limit coverage for each occurrence for bodily injury or for property damage and shall be provided from an insurance company qualified to write global product liability coverage. Each Party agrees, upon request, to furnish the other Party with a certificate of insurance evidencing such insurance coverage (at the execution of this Agreement and at each subsequent renewal) and shall provide the other Party with a thirty (30) day notice of cancellation or non-renewal of such coverage. COMPANY shall provide its current certificate of insurance evidencing such insurance coverage as of the Effective Date. COMPANY shall name DPT as an additional insured on its insurance policies maintained pursuant to this Section 11.2.

11.3 LIMITATION OF LIABILITY. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, OR ANY OTHER THEORY OR FORM OF ACTION, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY THEREOF. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, WITH RESPECT TO ALL CLAIMS MADE BY COMPANY AGAINST DPT UNDER THIS AGREEMENT, THE TOTAL LIABILITY OF DPT TO COMPANY DURING THE TERM [***].

ARTICLE 12
TERM AND TERMINATION

12.1 Term. The initial term of this Agreement shall commence on the Effective Date hereof and will continue until [***] calendar year following the Launch Year, unless sooner terminated pursuant to Section 12.2 below (the "**Initial Term**"). This Agreement shall thereafter automatically renew for periods of [***], unless any Party shall give notice to the other to the contrary at least [***] prior to the expiration of the Initial Term or any renewal term of the Agreement (such renewal term, the "**Extended Term**" and, together with the Initial Term, the "**Term**").

12.2 Termination. In addition to any other termination right provided for herein, this Agreement may be terminated in its entirety by either Party at any time upon the occurrence of either of the following events:

12.2.1 The material failure of the other Party to comply with its material obligations herein, which failure is not remedied within [***] days after written notice thereof.

12.2.2 Written notice to the other if any Bankruptcy Event has occurred with respect to such other Party.

12.3 Effects of Termination. In the event of the termination or cancellation of this Agreement for any reason, and without prejudice to any other rights and remedies available to DPT hereunder, COMPANY agrees to reimburse DPT, within thirty (30) days of such termination or cancellation, for: (i) the Materials Fee for all DPT-supplied materials ordered by DPT for the manufacture of Product based on COMPANY's Forecasted Needs, (ii) the Total Price per unit of Product, with a prorated adjustment for percent completed for work-in-process Product, and (iii) the Total Price per unit of Product for finished Product. The Parties agree to return one another's Confidential Information (except that each Party may maintain one archival copy of same). If COMPANY has not already set up an alternative manufacturing facility as provided in Sections 2.7-2.9, then DPT agrees to provide all reasonable and necessary non-financial assistance and cooperation in any COMPANY-requested technology transfer to an alternative manufacturing facility.

12.4 Nonexclusive Remedy. Exercise of any right of termination afforded to either Party under this Agreement (i) shall not prejudice any other legal rights or remedies either Party have against the other in respect of any breach of the terms and conditions of this Agreement, and
(ii) shall be without any obligation or liability arising from such termination other than such obligations expressly arising from termination.

12.5 Survival. Termination of this Agreement (for any reason) shall not affect any accrued rights or liabilities of either Party. Article 1 (Definitions/Interpretation), Article 9 (Representations and Warranties), Article 10 (Confidentiality), Article 11 (Indemnification and Insurance), Article 13 (Disputes; Governing Law) and Article 14 (Miscellaneous), Sections 2.3.3 (Packaging and Labeling) (last sentence only), 3.4 (Destruction Costs), 4.4.5 (Product Recall), 6.4 (Obsolete Inventory), 12.3 (Effect of Termination), 12.4 (Nonexclusive Remedy) and 12.5 (Survival) shall survive the termination or cancellation of this Agreement.

ARTICLE 13 DISPUTES; GOVERNING LAW

13.1 Discussion by Executives. Except as otherwise provided herein, any dispute, controversy or claim arising under, out of or in connection with this Agreement, including any subsequent amendments, or the validity, enforceability, construction, performance or breach hereof (and including the applicability of this Article 13 to any such dispute, controversy or claim) (each a "**Dispute**") shall be first submitted to an executive officer of each of the Parties having authority to resolve such Dispute for attempted resolution by good faith negotiations within ten (10) Business Days. In such event, each Party shall cause its designated executive officer to meet and be available to attempt to resolve such issue. If the Parties should resolve such Dispute, a memorandum setting

forth their agreement will be prepared and signed by both Parties if requested by either Party. The Parties shall cooperate in an effort to limit the issues for consideration in such manner as narrowly as reasonably practicable in order to resolve the Dispute.

13.2 Governing Law. This Agreement and all rights and obligations of the Parties arising out of or relating to this Agreement shall be governed by, construed and enforced in accordance with the laws of the State of New York, U.S.A without giving effect to conflicts of laws principles. The Parties hereby expressly agree that the U.N. Convention on Contracts for the International Sale of Goods shall not apply.

13.3 Jurisdiction. The Parties agree that any Dispute that is not resolved pursuant to Section 13.1 shall be subject to the exclusive jurisdiction of the state and federal courts in [***] and each Party hereby submits to such jurisdiction.

ARTICLE 14 MISCELLANEOUS

14.1 Relationship of the Parties. The Parties agree that the relationship of COMPANY and DPT established by this Agreement is that of independent contractors. Furthermore, the Parties agree that this Agreement does not, is not intended to, and shall not be construed to, establish a partnership or joint venture, and nor shall this Agreement create or establish an employment, agency or any other relationship. Except as may be specifically provided herein, neither Party shall have any right, power or authority, nor shall they represent themselves as having any authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other Party, or otherwise act as an agent for the other Party for any purpose.

14.2 Expenses. Except as otherwise expressly provided herein, each Party shall bear its own costs, fees and expenses incurred by such Party in connection with this Agreement.

14.3 Licenses and Permits. Each Party shall, at its sole cost and expense, maintain in full force and affect all necessary licenses, permits, and other authorizations required by Applicable Law in order to carry out its duties and obligations hereunder.

14.4 Force Majeure. No Party shall be liable for a failure or delay in performing any of its obligations under this Agreement if, but only to the extent that such failure or delay is due to causes beyond the reasonable control of the affected Party, including: (a) acts of God; (b) fire, explosion, or unusually severe weather; (c) war, invasion, riot, terrorism, or other civil unrest; (d) governmental laws, orders, restrictions, actions, embargo or blockages; (e) national or regional emergency; (f) strikes or industrial disputes at a national level which directly impact the affected Party's performance under this Agreement; or (g) other similar cause outside of the reasonable control of such Party ("**Force Majeure**"); provided that the Party affected shall promptly notify the other of the Force Majeure condition and shall use reasonable efforts to eliminate, cure or overcome any such causes and resume performance of its obligations as soon as possible. If the performance of any such obligation under this Agreement is delayed owing to such a Force

Majeure for any continuous period of more than one hundred eighty (180) days, DPT shall have the right to terminate this Agreement.

14.5 Notices. Any notice required or permitted to be given hereunder shall be in writing and shall be delivered in person, by a nationally recognized overnight courier, or by registered or certified airmail, postage prepaid to the addresses given below or such other addresses as may be designated in writing by the Parties from time to time, and shall be deemed to have been given upon receipt.

In the case of COMPANY:	**With a required copy (which shall not constitute Notice) to:**
Evofem, Inc. c/o Evofem Biosciences, Inc. 12400 High Bluff Drive, Suite 600 San Diego, CA 92130 Attn: General Counsel	Mintz, Levin, Cohen, Ferris, Glovsky & Popeo, P.C. 3580 Carmel Mountain Road #300 San Diego, CA 92130 Attn: Adam Lenain
[***]	[***]
[***]	[***]

14.6 Assignment. Neither Party shall at any time, without obtaining the prior written consent of the other Party, assign or transfer this Agreement or subcontract its obligations hereunder to any Person. Notwithstanding the foregoing, both Parties shall be permitted, without the consent of the other, to assign this Agreement to its Affiliates or to perform this Agreement, in whole or in part, through its Affiliates, and assign this Agreement to any successor or Third Party that acquires all or substantially all of the assets to which this Agreement relates by sale, transfer, merger, reorganization, operation of law or otherwise; provided that the assignee agrees in writing to be bound to the terms and conditions of this Agreement. In the event of an assignment permitted under this Section 14.6, the assigning Party shall notify the other Party in writing of such assignment. This Agreement shall be binding upon and shall inure to the benefit of the Parties and their successors and permitted assigns. Any assignment not in accordance with this Section 14.6 shall be null and void.

14.7 Entire Agreement and Amendment. This Agreement (including, for clarity, its Schedules and Exhibits and the Quality Agreement incorporated herein by reference), constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior and contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. Notwithstanding the foregoing, except as expressly set forth in Section 2.6, to the extent the terms and conditions of the body of this Agreement conflict with the terms and conditions of any Schedule or Exhibit hereto, the terms and conditions of the body of this Agreement shall govern. No terms or provisions of this Agreement will be varied or modified by any prior or subsequent statement, conduct or act of either of the Parties, except that the Parties may amend this Agreement by written instruments specifically referring to and executed in the same manner as this Agreement.

14.8 No Third Party Beneficiaries. Except for the rights to indemnification provided for under Article 11 above, all rights, benefits and remedies under this Agreement are solely intended for the benefit of DPT and COMPANY. Except for such rights to indemnification expressly provided pursuant to Article 11, no Third Party shall have any rights whatsoever to (a) enforce any obligation contained in this Agreement; (b) seek a benefit or remedy for any breach of this Agreement; or (c) take any other action relating to this Agreement under any legal theory, including actions in contract, tort (including negligence, gross negligence and strict liability), or as a defense, setoff or counterclaim to any action or claim brought or made by the Parties.

14.9 Severability. Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement, and the Parties agree to negotiate in good faith a valid and enforceable provision therefor which, as nearly as possible, achieves the desired economic effect and mutual understanding of the Parties under this Agreement.

14.10 No Waiver. A waiver by any Party of any of the terms and conditions of this Agreement in any instance will not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement will be cumulative and none of them will be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

14.11 Compliance with Law. Both COMPANY and DPT shall perform their obligations under this Agreement in accordance with Applicable Law and each Party shall bear its own costs in ensuring compliance therewith. No Party shall, or shall be required to, undertake any activity under or in connection with this Agreement that violates, or which it reasonably believes may violate, any Applicable Law.

14.12 English Language. This Agreement shall be written and executed in the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

14.13 Review by Legal Counsel. Each Party agrees that it has read and had the opportunity to review this Agreement with its legal counsel. Accordingly, the rule of construction that any ambiguity contained in this Agreement shall be construed against the drafting Party shall not apply.

14.14 Further Acts. Each Party shall do, execute and perform and shall procure to be done and performed all such further acts, deeds, documents and things as the other Parties may reasonably require from time to time to give full effect to the terms of this Agreement.

14.15 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but which together shall constitute one and the same document. This Agreement and any amendments hereto, to the extent signed and delivered by means of electronic reproduction (e.g., portable document format (.pdf)), shall be treated in all manner and respects as an original and shall be considered to have the same binding legal effects as if it were the original signed version thereof delivered in person. At the request of a Party, the other Party shall reexecute original forms thereof and deliver them to the Party who made said request.

The remainder of this page is left intentionally blank; signature page follows.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized officers as of the Effective Date, each copy of which will for all purposes be deemed to be an original.

EVOFEM, INC.	DPT LABORATORIES LIMITED
By:	By:
Name:	Name:
Title:	Title:

Schedule A

API

- Citric Acid
- Lactic Acid
- Potassium Bitartrate

Schedule B

Product & Specifications

[***]

Schedule C

Fees

[***]

Schedule D

Territory

The United States and such other countries as COMPANY may subsequently designate by notice to DPT (subject to DPT's acceptance of such designation).

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-234769, 333-230191, 333-231126, 333-232303, and 333-223731 on Form S-3 and Registration Statement Nos. 333-231993, 333-231991, 333-226517, 333-225366, 333-203059, and 333-200409 on Form S-8 of our report dated March 12, 2020, relating to the financial statements of Evofem Biosciences, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ DELOITTE & TOUCHE LLP

San Diego, California
March 12, 2020

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 12, 2020 By: /s/ Saundra Pelletier

Saundra Pelletier
President and Chief Executive Officer
(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 12, 2020 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, 2019, 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 12, 2020 By: /s/ Saundra Pelletier

Saundra Pelletier
President and Chief Executive Officer
(principal executive officer)

Date: March 12, 2020 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.