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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2017

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: Common Stock, Par Value $0.0001 Per Share; Common stock traded on The Nasdaq Capital Market

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

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

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

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

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). YES ☒ NO ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a small reporting company)	Small reporting company	☒
Emerging growth company	☒		

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

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

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $4,064,074 as of June 30, 2017, based upon the closing sale price on The Nasdaq Global 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 9, 2018, was 17,763,340.

INCORPORATION BY REFERENCE

None.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K, or this 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 document, including statements regarding our business, operations and financial performance and conditions, as well as our plans, objectives and expectations for our business operations and financial performance and condition, are forward-looking statements. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "predict," "project," "potential," "should," "target," "will," "would," or the negative of those terms and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Annual Report include, among other things, statements about:

- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues and capital requirements;
- our ability to continue as a going concern;
- our need to raise substantial additional capital to fund our operations;
- our ability to develop our lead product candidate, Amphora® (L-lactic acid, citric acid, and potassium bitartrate), as a contraceptive;
- our ability to develop our Multi-purpose Prevention Technology, or MPT, vaginal gel product candidates for additional indications;
- our ability to select and capitalize on the most scientifically, clinically or commercially promising indications or therapeutic areas for our MPT vaginal gel product candidates in light of our limited financial resources;
- the success, cost and timing of our clinical trials;
- our dependence on third parties in the conduct of our clinical trials;
- our ability to obtain the necessary regulatory approvals to market and commercialize Amphora, our MPT vaginal gel product candidate and any other product candidate we may seek to develop;
- the potential that results of pre-clinical studies and clinical trials indicate that our MPT vaginal gel product candidates or any future product candidate we may seek to develop are unsafe or ineffective;
- the potential for us to incur substantial costs resulting from product liability lawsuits against us and the potential for these product liability lawsuits to cause us to limit our commercialization of our MPT vaginal gel product candidates or any future product candidate we may seek to develop;
- market acceptance of our product candidates, the size and growth of the potential markets for our MPT vaginal gel and any future product candidate we may seek to develop, and our ability to serve those markets;
- the results of market research conducted by us or others;
- our ability to obtain and maintain intellectual property protection for our MPT vaginal gel and any other product candidate we may seek to develop;
- our reliance on licenses granted to us by third parties, our ability to preserve our rights to licenses granted to us under these license agreements and our reliance on these third-party licensors to protect the intellectual property licensed to us;
- our ability to protect our intellectual property rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our intellectual property rights;
- the possibility that a third party may claim we have infringed, misappropriated or otherwise violated their intellectual property rights and that we may incur substantial costs and be required to devote substantial time defending against these claims;
- the successful development of our commercialization capabilities, including sales and marketing capabilities;
- our reliance on third-party suppliers and manufacturers;
- the success of competing therapies and products that are or become available;

- the potential for changes to current regulatory mandates requiring health insurance plans to cover Food and Drug Administration-cleared or approved contraceptive products without cost sharing and our reliance on the willingness of patients to pay out-of-pocket absent full or partial insurance coverage; and
- our ability to expand our organization to accommodate potential growth and our ability to retain and attract key personnel.

Our MPT vaginal gel product candidates are undergoing clinical development and have not been, nor may they ever be, approved for marketing by any regulatory agency or competent authorities 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. Forward-looking statements should be regarded solely as our current plans, estimates and beliefs. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this document, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that 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. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

PART I

Item 1. Business.

Merger of Neothetics, Inc. and Evofem Biosciences Operations, Inc.

On January 17, 2018, Neothetics, Inc., or Neothetics, and privately-held Evofem Biosciences Operations, Inc., or Private Evofem, completed the merger and reorganization, or the Merger, in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated October 17, 2017, or the Merger Agreement, by and among Neothetics, Private Evofem and Nobelli Merger Sub, Inc., a wholly owned subsidiary of Neothetics, or Merger Sub, whereby Merger Sub merged with and into Private Evofem, with Private Evofem surviving as a wholly owned subsidiary of Neothetics. The Merger was structured as a reverse capitalization and Private Evofem was determined to be the accounting acquirer based on the terms of the Merger and other factors.

On January 17, 2018, in connection with the Merger, the Company filed a certificate of amendment to its amended and restated certificate of incorporation to affect a six-for-one reverse stock split of its common stock, or the Reverse Split, which caused the Company not to be governed by Section 203 of the Delaware General Corporation Law, or the DGCL, and to change its name from "Neothetics, Inc." to "Evofem Biosciences, Inc." The name change and the Reverse Split were both effected on January 17, 2018. Shares of the Company's common stock commenced trading on The Nasdaq Capital Market under the new name and ticker symbol "EVFM" as of market open on January 18, 2018. ***Unless otherwise noted, all references to share amounts in this Annual Report, including references to shares or options issued in connection with the Merger and the Financing (as defined below), reflect the Reverse Split.***

On January 17, 2018, immediately following the completion of the Merger, the Company issued in a private placement transaction, or the Financing, an aggregate of 1,614,289 shares of its common stock to certain accredited investors for an aggregate purchase price of $20 million pursuant to the terms of the Securities Purchase Agreement, dated October 17, 2017, by and among the Company, Private Evofem and certain accredited investors, or the Securities Purchase Agreement. Upon consummation of the Financing, the Company terminated its existing Fourth Amended and Restated Investors' Rights Agreement, dated September 22, 2014, by and between the Company and the investors listed therein, or the Existing Investors. Additionally, the Company entered into a registration rights agreement with the accredited investors participating in the Financing and certain previous investors of Private Evofem and the Company, or the Registration Rights Agreement, pursuant to which the Company is, among other things, obligated to file a registration statement with the SEC within 60 days following completion of the Merger. The shares of Company common stock issued in the Financing were exempt from registration under Section 4(a)(2) under the Securities Act of 1933, as amended, or the Securities Act, and the rules promulgated thereunder.

In addition, pursuant to the Merger Agreement, the Company assumed Private Evofem's Amended and Restated 2012 Equity Incentive Plan, or the Private Evofem Equity Incentive Plan, and all of the stock options outstanding under the Private Evofem Equity Incentive Plan, with such stock options now representing the right to purchase shares of the Company's common stock. The Company also assumed warrants to purchase Private Evofem capital stock which were immediately amended and restated to be warrants, or the Post-Merger Warrants, to purchase up to an aggregate of 2,000,000 shares of the Company's common stock. The Post-Merger Warrants will have an exercise price equal to the average of the closing sale prices of shares of the Company's common stock as quoted on The Nasdaq Capital Market for the 30 consecutive trading day period immediately following January 17, 2018, and will be exercisable commencing on January 17, 2019, and until the earlier of January 17, 2022, or immediately prior to the completion of an Acceleration Event (as defined in the Post-Merger Warrants). The Post-Merger Warrants were issued as a unit with one share of the Company's common stock, or the Unit Share. Per the terms of the Post-Merger Warrants, the Unit Shares may not be transferred separately from the Post-Merger Warrants.

Following the completion of the Reverse Split, the Merger and the Financing, there were approximately 17,757,167 shares of the Company's common stock outstanding. The former Private Evofem stockholders owned approximately 87% of the issued and outstanding common stock of the Company, or 15,448,737 shares, and the Company's stockholders immediately prior to the Merger and Financing, whose shares of the Company's common stock remained outstanding after the Merger and Financing, owned approximately 13% of the issued and outstanding common stock of the Company, or 2,308,430 shares.

Prior to the Merger, Neothetics was originally incorporated in Delaware in February 2007 as Lipothera, Inc. In September 2008, Neothetics changed its name to Lithera, Inc. and in August 2014, Neothetics again changed its name to Neothetics, Inc.

Unless the context requires otherwise, references in this Annual Report to "Evofem", "EVFM", "we", "us", the "Company" and "our" refer to Evofem Biosciences, Inc. (formerly known as Neothetics).

Our principal corporate offices 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, or 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, or SEC. 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 document.

Overview

Prior to the Merger, we were a clinical-stage specialty pharmaceutical company developing therapeutics for the aesthetic market. After the Merger, we became a clinical-stage biotechnology company committed to improving the health and well-being of women throughout the world by addressing women's unmet medical needs through the discovery, development and commercialization of innovative, next-generation women's healthcare products. We utilize our multi-purpose prevention technology, or MPT, in two vaginal gel product candidates that are being developed for multiple indications, including contraception, sexually transmitted infections, or STIs, and bacterial vaginosis, or BV.

Our lead product candidate, Amphora® (L-lactic Acid, citric acid, and potassium bitartrate) is a hormone-free, on demand, woman-controlled vaginal gel currently in a Phase 3 clinical trial with contraceptive efficacy as the primary endpoint, and in a Phase 2b/3 trial with a primary endpoint for the prevention of urogenital chlamydia in women. Additionally, this second trial evaluates the efficacy of Amphora for the prevention of urogenital gonorrhea as a second endpoint. In addition, we recently completed a Phase 1 trial of our MPT vaginal gel product candidate for the reduction of recurrent BV and we are currently designing a Phase 2b/3 trial for this indication.

Based on our market research, we believe a majority of women seeking birth control are concerned about exposure to hormones. While hormone-based contraception is the current standard in female birth control, our research indicates that women are actively seeking alternative methods of contraception, but have limited options to reduce exposure to hormones. As a result, women are dissatisfied with current products on the market. Amphora is designed to empower women by offering a hormone-free, on demand, woman-controlled contraceptive.

Our MPT vaginal gels have also demonstrated a broad spectrum of antimicrobial activity *in vitro*, including on chlamydia-, gonorrhea-, and bacterial vaginosis- causing microbes, the three most common causes of reproductive tract infection. There are currently no products indicated for the prevention of urogenital chlamydia or gonorrhea or the reduction of recurrent BV. We believe our MPT vaginal gel product candidates offer a significant opportunity to address these important unmet medical needs for women.

Amphora has been granted Fast Track designation by the FDA for the prevention of acquisition of urogenital chlamydia. A drug that receives Fast Track designation will have opportunities to expedite development and review, such as more frequent interactions with the FDA and eligibility for priority review. A priority review designation means FDA's goal is to act on the marketing application within six months of receipt compared with 10 months under standard review.

Amphora has also been granted designation as a Qualified Infectious Disease Product, or QIDP, by the FDA for prevention of acquisition of urogenital gonorrhea infection in women and for reduction of recurrent BV. A drug that receives QIDP designation can also qualify for the FDA's Fast Track program. QIDP designations also provide an additional five years of marketing exclusivity for an approved product.

We have an exclusive worldwide license to our MPT vaginal gel from Rush University, a nationally recognized research institution. Our MPT vaginal gel was initially developed by the Program for Topical Prevention of Conception and Disease, an organization led by Rush University dedicated to the discovery and creation of topical products that can prevent pregnancy and the spread of STIs.

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:

- ***Actively monitor the completion of the Phase 3 clinical trial for the purpose of seeking approval of and subsequently commercializing Amphora for contraception.*** Our initial focus is the development and commercialization of Amphora as a hormone-free, on demand, woman-controlled contraceptive. We believe this will create a platform for us to advance our supplemental indications and allow us to effectively deploy investor capital for the benefit of all stakeholders.
- ***Leverage our MPT vaginal gel technology platform to develop and commercialize novel, first-in-class products for women.*** We intend to expand on our contraceptive indication by being the first company to market a contraceptive product with additional indications for the prevention of urogenital chlamydia and gonorrhea. In addition, we intend to develop a product for the reduction of recurrent BV.
- ***Expand our intellectual property position by pursuing opportunities to extend the exclusivity of our highly differentiated and proprietary MPT vaginal gel.*** We intend to aggressively pursue additional and new patent applications to broaden our

intellectual property portfolio. We will continue to seek to obtain domestic and international patent protection and endeavor to promptly file patent applications for new commercially valuable inventions.

- ***Expand our product pipeline.*** We intend to opportunistically acquire additional products or product candidates from third parties that enhance our offerings and complement our core competencies in women's healthcare.
- ***Build a world class organization committed to the discovery, development and commercialization of products that address 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 healthcare. We intend to continue to build on our leadership position and grow a culture dedicated to the development and commercialization of medicines that address the unmet medical needs of women.

The Contraceptive Market Overview

In 2016, the global revenue for contraceptive products was $21.2 billion and projected to grow at 6.8% per annum to $35.8 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 and Europe where favorable government policies aimed at preventing unwanted pregnancies are in place. The number of women using contraception is projected to grow through 2030.

Current contraceptive options include devices designed to prevent pregnancy through physical means such as condoms, diaphragms and intrauterine devices, or IUDs, and pharmaceutical means such as a variety of hormonal-based approaches, including oral contraceptives, vaginal rings containing hormones, intramuscular injections, subcutaneous implants and transdermal patches.

Existing contraceptive options can have significant side effects or other limitations. Long-acting options such as IUDs, hormonal 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 and mood changes, which may lead women to seek alternative contraceptive technologies or decide to not use any form of the contraceptive options currently available. Several spermicidal products currently available over-the-counter for use as vaginal contraceptives are based on surfactants, which can cause genital irritation and inflammation that may increase the risk of contracting human immunodeficiency virus, or HIV, or other STIs from an infected partner. For example, spermicides containing the active ingredient nonoxynol-9, or N-9, have been required by the FDA to carry a label warning for the risk of contracting HIV. Unlike other vaginal contraceptives currently on the market, Amphora is free of surfactants such as N-9.

The unmet medical needs of the contraception market and the shift away from traditional methods of contraception such as oral contraceptives make the entry of a non-hormonal contraceptive option such as Amphora timely and desirable. Currently, the only non-hormonal prescription contraceptive methods approved in the U.S. market are a copper IUD, which requires an invasive medical procedure and could remain in the user's body for up to 10 years and a diaphragm, which can be difficult to insert and must be used with contraceptive gel.

Additionally, we believe that growing concern associated with the increasing prevalence of sexually transmitted diseases along with growing demand for new innovative contraception options will drive further growth in the global contraceptive market.

Market Opportunity

We believe our key market strengths are as follows:

- Our MPT vaginal gel is potentially disruptive to the existing contraceptive landscape and is designed to address underserved and unmet needs in the women's healthcare market;
- We expect to benefit from favorable trends away from the daily use of oral forms of hormonal contraception to more innovative technologies that underpin the large and growing global contraceptive market;
- We have robust proprietary technology protected by an intellectual property portfolio currently extended to 2033; and
- We intend to add indications to our lead product candidate, Amphora, and to add complementary products or product candidates to our pipeline expected to provide future growth opportunities within the global contraceptive market.

We believe our product candidates are well positioned to fulfill unmet needs within the existing contraceptive market and to compete with existing contraceptive options. Market penetration requires development and implementation of a tailored strategy, involving healthcare policy officials and healthcare providers for each country or territory.

Innovation and new product introduction in women's reproductive healthcare and contraception has been limited when compared to other leading therapeutic categories. There were no approvals in women's contraception during 2017 as compared to, for example, oncology, where there have been more than 40 approvals in the same period, demonstrating a unique opportunity in this underdeveloped field.

According to the Centers for Disease Control and Prevention, or the CDC, reducing the percentage of all unintended pregnancies has been one of the National Health Promotion Objectives since they were first established in 1980. Despite the efforts to reduce their prevalence, over 2.0 million unintended pregnancies occur in the U.S. annually. Following decades of minimal change or increase, the percentage of unintended pregnancies in the U.S. decreased slightly in the period from 2008-2011. Despite this recent decrease, 45% of pregnancies in the U.S. are still unintended. Nearly all women with sexual experience in the U.S. have used contraception at some time in their lives, but many women may not use contraception consistently or correctly and subsequently become pregnant when not intending to have a child at that time. 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 an average 30 plus years of fertility. As such, women utilizing contraception consider the most appropriate methods for their purposes and intended use. The following information outlines expected trends in contraceptive usage in different regions of the world and outlines differences between the U.S. and European Union, or EU, contraceptive markets.

Women of Reproductive Age (millions) (2016 Projected)	**U.S.**	**EU**	***BRIC**
All females, age 18-49	61.0	63.8	420.9
At risk for pregnancy	70.4%	67.0%	55.0%
Relevant population for contraception	**43.0**	**43.1**	**231.5**

* *Brazil, Russia, India, China*

The U.S. Contraceptive Market

The total U.S. contraceptive market was valued at $5.5 billion in 2016 with the prescription contraceptive market expected to grow at a compound annual growth rate of 5.4% from 2013 to 2024 and reach a value of approximately $8.4 billion in 2024. The U.S. contraceptive market represented the largest segment of the global contraceptives market in 2016 at 29.4% and is currently dominated by hormonal methods including birth control pills and other reversible methods such as IUDs and injectables. Approximately four of every five women with sexual experience in the U.S. have used the pill at least one time with this percentage remaining stable since 1995.

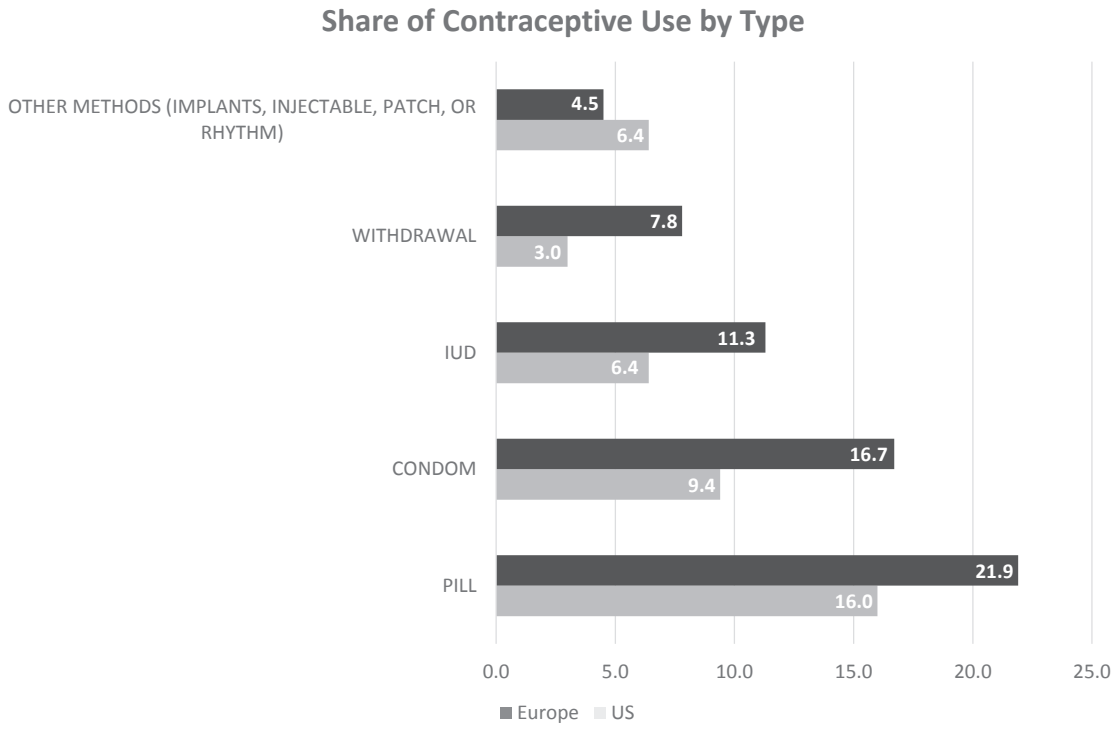
More than 12 million women in the U.S. rely on condoms, or some other form of non-hormonal contraception (e.g. copper IUD, diaphragm, rhythm, withdrawal) as their method of choice.

We conducted market research with women of reproductive age (ages 18 to 49) and healthcare providers in the U.S. to evaluate potential interest in Amphora. Of the more than 1,400 women surveyed, approximately one-third expressed interest in learning more about Amphora. Amphora's most motivating attributes for women surveyed included lack of hormones, ease of use and the ability to use on demand. Physicians also expressed interest in Amphora, indicating they see many patients for whom they would recommend use of Amphora.

Additionally, this market research indicated that an Amphora user would receive approximately seven refills of Amphora per year based on reported frequency of intercourse.

The EU Contraceptive Market

The EU contraceptive market was valued at approximately $5.0 billion in 2016, or 24.5% of the global market, and is expected to grow at an average compound annual growth rate of 5.4% from 2013 to 2024 to reach an estimated value of approximately $7.6 billion in 2024. The EU accounted for the second largest market share in the global contraceptives market in 2016. Contraceptive use in the EU varies from region to region. As the table below shows, approximately 30% of women use no contraception and the use of male condoms is significantly higher than the U.S. population (9.4%). Permanent sterilization is also substantially lower than the U.S. (female and male sterilization rates of 14.3% and 4.5%, respectively) and among newer innovations only IUDs are in double digit market share:



Product Candidates

Amphora as a Contraceptive

We believe Amphora, our lead product candidate, addresses significant gaps in the contraceptive market. If approved by the FDA, Amphora will be the only hormone-free, on demand, women-controlled contraceptive drug product available by prescription in the United States that does not require in-office placement by a healthcare provider.

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

Key Attributes	Potential Benefits
Hormone-free	Amphora is hormone-free and designed to avoid known side effects of hormonal-based contraceptives, which include 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	Amphora can be used as needed - no daily, weekly, or monthly routine. Amphora may be used immediately before or up to one hour before intercourse at a woman's discretion.
No Surgical Procedures	No physician insertion or removal required. The use of Amphora is private and discrete and avoids the need for recurring doctor appointments, clinical or surgical procedures.
Cost Effective	We anticipate coverage in the United States under the Affordable Care Act, or the ACA. Amphora is only used when needed thus eliminating cost for daily use methods.
Surfactant-free	Amphora can be used by women who experience allergy, sensitivity, or side effects to N-9.
Personal Lubricant Properties	Amphora has benefits for vaginal use, as a personal lubricant, beyond the primary contraceptive function. Amphora reduces friction and eases penetration.
Bioadhesive Properties	Amphora has bioadhesive 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.
Ease of Use	The pre-filled Amphora applicator is designed for convenience and to be stored at room temperature for ease of handling and use.

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

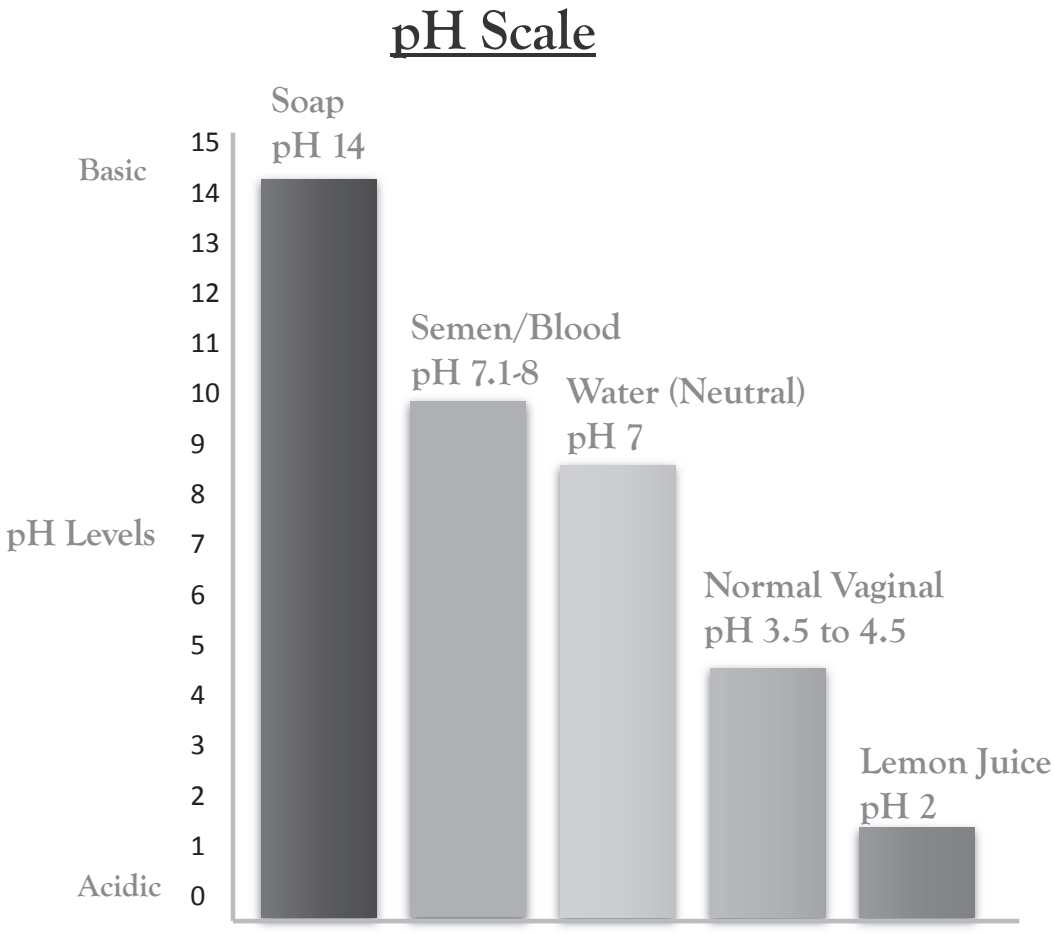
Category 4 (a condition that represents an unacceptable health risk if the contraceptive method is used)

- 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 CV 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)

Mechanism of Action in Contraception

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 spermatozoa, or sperm, as well as certain viral and bacterial pathogens. Amphora was developed to have acid-buffering (pH 3.5), bioadhesive, and viscosity-retaining properties to provide effective acidification of the male ejaculate in the vagina and to form a long-lasting layer of gel over the vaginal and cervical surfaces. Typically, the introduction of semen (pH = 7.2-8.0) into the vagina causes a rise in pH above 6.0 due to the alkalinity of the ejaculate, which neutralizes the normally acidic vaginal environment and allows the survival of sperm. Amphora acts as a vaginal contraceptive 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 Amphora's active pharmaceutical ingredients. Other properties contributing to the contraceptive effect of Amphora are its capacity to reduce/inhibit cervical mucus penetration, to maintain sufficient viscosity even upon dilution with the introduction of semen into the vagina and its bioadhesive strength. After proper use of Amphora, postcoital testing shows Amphora remains protective for up to 10 hours based on a lack of progressively motile sperm.

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



Amphora Clinical Trials

Amphora: Phase 3 Clinical Trial (AMP001)

A key stage in the development of Amphora was the completion of a large-scale Phase 3 clinical trial comparing the contraceptive effectiveness, safety and acceptability of Amphora to Conceptrol®, a surfactant-based spermicidal gel containing 4% N-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 Trial Design and Implementation

During 2011 through 2014, the AMP001 Amphora Phase 3 clinical trial enrolled 3,389 women at approximately 70 research centers located within the United States and Russia. It was an open-label, randomized, non-inferiority trial of repeated use of Amphora compared to Conceptrol over seven cycles of use. After completing the first seven cycles, some of the women randomized to Amphora continued for up to a total of 13 cycles. 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.

Results of AMP001 Phase 3 Clinical Trial

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 the Modified Intent-to-Treat population, otherwise known as 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%. 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%.

AMP001 Safety data

Of the 30 subjects who experienced at least one serious adverse event, or SAE, 11 were treated with Amphora (0.8%) and 19 were treated with Conceptrol (1.3%). The adverse event, or AE, reporting for the 13-cycle extension did not identify additional SAEs; therefore, no subject treated with Amphora experienced an SAE with an additional six cycles of exposure to Amphora. Significantly more subjects liked Amphora than Conceptrol and significantly more Amphora users would use the product again if it were available ($p<0.05$ for both comparisons).

The table below sets out the adverse events in the AMP001 Phase 3 clinical trial.

Adverse events in greater than 2% of Amphora gel treated subjects in the AMP001 Phase 3 Clinical Trial in the seven-cycle study by decreasing order of frequency in all subjects:

	Amphora	Conceptrol	All Subjects
System organ class	(N=1458)	(N=1477)	(N=2935)
Preferred term	**n(%)**	**n(%)**	**n(%)**
Total number (%) of subjects with at least one AE	833 (57.1)	857 (58.0)	1690 (57.6)
Urinary tract infection	160 (11.0)	193 (13.1)	353 (12.0)
Vaginitis bacterial	176 (12.1)	170 (11.5)	346 (11.8)
Vulvovaginal mycotic infection	169 (11.6)	168 (11.4)	337 (11.5)
Headache	104 (7.1)	80 (5.4)	184 (6.3)
Vulvovaginal pruritus	60 (4.1)	76 (5.1)	136 (4.6)
Nasopharyngitis	79 (5.4)	48 (3.2)	127 (4.3)
Vulvovaginal discomfort	48 (3.3)	53 (3.6)	101 (3.4)
Vulvovaginal candidiasis	49 (3.4)	46 (3.1)	95 (3.2)
Vulvovaginal burning sensation	52 (3.6)	41 (2.8)	93 (3.2)
Vaginal discharge	44 (3.0)	46 (3.1)	90 (3.1)
Dysmenorrhea	34 (2.3)	34 (2.3)	68 (2.3)
Influenza	39 (2.7)	20 (1.4)	59 (2.0)

Summary of Initial NDA Submission (Contraceptive Indication)

On July 2, 2015, pursuant to section 505(b)(2) of the Federal Food and Drug Cosmetic Act, or FDCA, we submitted a new drug application, or NDA, for Amphora 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 Complete Response Letter, or CRL, was issued by the FDA on April 28, 2016. A CRL is issued if the agency determines that the 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 U.S. and Russian cohorts. Although the study met its primary endpoint when the combined U.S. 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 U.S. 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 that were <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, at 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 that 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 (AMP002).

Amphora: AMP002 Confirmatory Phase 3 Trial (AMPOWER)

We are conducting a confirmatory, 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 Amphora Contraceptive Vaginal Gel." We refer to this trial as AMPOWER or AMP002. This study was designed to enroll approximately 1,350 women aged 18 to 35 at up to 115 sites in the United States. The first subject enrolled in this trial on July 28, 2017, and enrollment was completed in February 2018.

The primary endpoint for this trial is a seven-cycle cumulative pregnancy rate. In addition to our primary outcome for efficacy and secondary safety outcomes, we also included an exploratory endpoint of sexual satisfaction. Since Amphora also has lubricant properties, we anticipate a positive result for the sexual satisfaction outcome, which could be further explored in future studies and potentially utilized in its labeling and marketing materials. We believe this is the first contraception registration trial to include sexual satisfaction as an outcome.

Scientific Advice Process in the European Union

We previously conducted a regulatory gap analysis with Pharmalex GmbH to determine how the EU regulatory bodies were likely to view its marketing authorization application, or 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 the scientific advice process and seek marketing authorization for Amphora in the EU through a decentralized procedure.

Amphora for STI Prevention

In the U.S., the CDC reports that there were 1.6 million new cases of chlamydia and approximately 468,000 new cases of gonorrhea in 2016. We believe this represents a significant commercial opportunity for Amphora.

Pre-clinical tests conducted in the early developmental stages by Rush University, and later by us, suggest that our MPT vaginal gel 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. We are advancing Amphora into a pivotal Phase 2b/3 trial to determine the extent to which the gel prevents sexual transmission of two common STIs, urogenital chlamydia (primary endpoint) and gonorrhea (secondary endpoint) and intend to conduct additional clinical trials to determine whether the microbicide potential shown in pre-clinical results translates into protection for women. As of January 2018, the first subjects are enrolled in the Phase 2b/3 trial. Should this trial meet its primary endpoint, the FDA has indicated that it may be considered as one of two pivotal trials required for approval.

Amphora has been granted Fast Track designation by the FDA for the prevention of acquisition of urogenital chlamydia. A drug that receives Fast Track designation will have opportunities to expedite development and review, such as more frequent interactions with the FDA and eligibility for priority review. A priority review designation means FDA's goal is to act on the marketing application within 6 months of receipt compared with 10 months under standard review.

Amphora has been designated as a QIDP by the FDA for the prevention of urogenital gonorrhea infection in women. A drug that receives QIDP designation may qualify for an additional five years of marketing exclusivity and is eligible for the FDA's Fast Track program, intended to facilitate development and expedite review of drugs so an approved product can reach the market expeditiously. An additional benefit is that the program allows for a priority review, with a goal of FDA action on the NDA within six months.

MPT Vaginal Gel for Recurrent Bacterial Vaginosis

The prevalence of BV in the United States is estimated to affect 21 million women, or 29.2% of women ages 14 to 49, and is considered to be the most common reproductive tract infection for women ages 15 to 44. There are currently no FDA approved products indicated for the reduction of recurrent BV.

Pre-clinical tests have shown our MPT vaginal gel kills many microbes responsible for recurrent BV while not affecting lactobacilli, a normal and beneficial bacterium found in a healthy vagina. The inhibitory mechanism comprises the MPT vaginal gel's buffered acidity and the presence of active pharmaceutical ingredients in the MPV vaginal gel. Clinical studies are on-going to determine whether the anti-pathogen potential shown in the laboratory translates into protection for women.

We filed an Investigational New Drug, or IND, with the FDA in March 2016 to study the ability of our MPT vaginal gel for the reduction of recurrent BV. Following submission of the IND, we conducted a Phase 1 trial (EVO-002) examining the ability of a single vaginal administration of the vaginal gel at three different doses to reduce vaginal pH. The trial was completed in late 2016 and revealed that the highest dose of the MPT vaginal gel (5-gram) reduced vaginal pH for up to seven days following a single administration compared to placebo gel or no gel. We are currently designing a Phase 2b/3 trial to examine the ability of a 5-gram dose of our MPT vaginal gel product candidate compared to placebo gel to reduce recurrent BV over a 16-week intervention period.

Commercialization Strategy

We intend to implement a global strategy to commercialize Amphora. 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 Amphora.

While awaiting the decision from the FDA as to the approval of Amphora, we plan to conduct pre-commercialization activities including:

- the selection of commercial suppliers, which includes agency of record for the Amphora brand, hiring of sales and sales support personnel to support the anticipated Amphora launch, 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 that the U.S. market is the largest commercial opportunity for our product candidates. If Amphora is approved for commercialization by the FDA, we intend to establish a commercial sales force to market Amphora directly to obstetricians and gynecologists, or OB/GYNs, who write the majority of prescriptions for contraceptive products.

The American Congress of Obstetricians and Gynecologists, or ACOG, reports there are approximately 36,000 fellows currently practicing in the United States. However, the top 30% of this group represents 85% of the contraceptive prescription volume. We intend to target the top 30% by deploying a sales force of approximately 85 sales representatives. Our direct sales force 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. During the pre-launch phase for Amphora, we intend to assemble 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 ACOG and the Society of Family Planning), clinical publications, and additional market development activities. Launch and post-launch commercial 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-U.S. Markets

In markets outside of the United States, if a 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 to 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 that cover approximately 70% of covered lives within the United States to better understand viable access and pricing strategies for Amphora. 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 Amphora for all their reproductive aged women's lives they are managing at the end of the first year of commercialization of Amphora. 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 Amphora like that of branded oral contraceptives. Healthcare plans interviewed during market research expected Amphora to be priced between $100 to $200 for a monthly supply of a 12-applicator box (comparable to branded contraceptives), believing Amphora would ultimately offset other costs the payer may incur (i.e. unwanted pregnancies).

Third-party Payers

We expect any sales of our product candidates will depend, in part, on the extent to which the costs of the applicable product candidates will be covered by healthcare plans, including government health programs in the United States such as Medicare and Medicaid. The process for determining whether a healthcare plan will provide coverage for a product is separate from the process for setting the price or reimbursement rate the plan will pay for the product once coverage is approved. We are also aware many healthcare plans may limit coverage to specific products on an approved list, or formulary, which might not include all the approved products for a particular indication. We intend to target those healthcare plans managing the largest number of covered lives to achieve optimal access for our product portfolio.

In March 2010, the ACA became law with the goals of broadening access to health insurance, reducing or constraining the growth of healthcare spending, enhancing remedies against fraud and abuse, adding new transparency requirements for health care and health insurance industries and imposing additional health policy reforms. The ACA mandates that certain preventative services that have strong scientific evidence of health benefits, including contraception, must be fully covered and reimbursement plans may no longer require a patient co-payment, coinsurance or deductible (i.e., no patient out-of-pocket expenses) for these services when they are delivered by an in-network provider. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, including the contraceptive coverage mandate. Congress and President Trump have expressed their intentions to repeal or replace the ACA. The President has issued at least one Executive Order and both chambers of Congress passed bills all with the goal of fulfilling these intentions. If full or partial repeal of the ACA is enacted, many if not all of the provisions of the ACA may no longer apply.

European Union

In our market research, it was found that EU consumers were interested in the unique benefits of Amphora product profiles, especially since Amphora 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

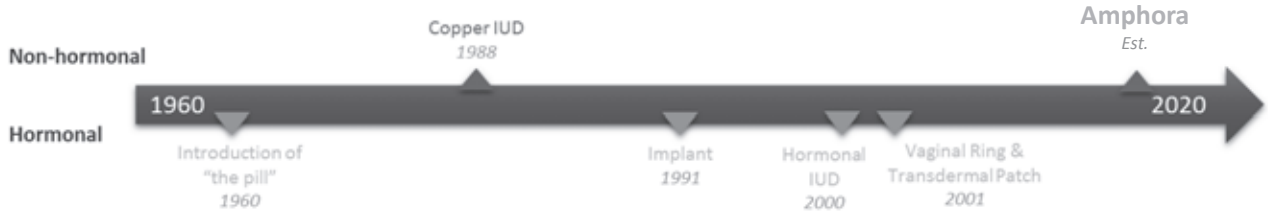
medicinal products for human use. EU member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of offering a drug product on the market. Other member states allow companies to fix their own prices for drug products, 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.

Amphora Manufacturing

We intend to outsource the manufacturing of Amphora (and our other potential product candidates) to third parties. Currently, we have contracted with Swiss-American CDMO, LLC in Carrollton, Texas, or Swiss-American, to manufacture our clinical supplies of Amphora. Swiss-American has agreed to manufacture Amphora and potential other product candidates in accordance with cGMP regulations, as well as in compliance with all applicable laws and other relevant regulatory agency requirements for manufacture of pharmaceutical drug products.

Competition

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 U.S. 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 non-hormonal 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, Amphora would compete for market share in at least four categories: 1) oral contraception, 2) Long-Acting Reversible Contraception, or LARC, comprised of IUDs, implants, and injectables, 3) short-term non-oral contraceptives, comprised of the weekly or monthly synthetic hormonal options including the patch and vaginal ring, and 4) over-the-counter, or OTC, methods, dominated primarily by the condom.

Oral Contraceptives (the "pill")

The pill is the most commonly used form of birth control in the U.S. today. Birth control pills are marketed under a variety of brand names. 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 in order 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 $141 million.

Injectables

The primary injectable hormonal contraceptive on the market is Depo-Provera® offered by Teva Pharmaceutical Industries Ltd. 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 U.S. of approximately $211 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® and has annual sales in the U.S. of approximately $290 million. The hormonal IUD is principally offered under the brand names, Kyleena®, Skyla® and Mirena®, a family of products from Bayer Pharmaceuticals, and has annual sales in the U.S. of approximately $1.2 billion. All IUDs must be inserted or removed by a physician.

The LARCs are not dependent on user adherence, thus making this method appealing 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.

Short-term Hormonal, Non-oral

Contraceptive Patch

The weekly contraceptive patch was introduced in 2000 by Johnson & Johnson's Janssen division; however, deaths resulting from venous thromboembolism, or VTE, 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.

Vaginal Ring

The hormonal vaginal ring by Merck & Co. was introduced to the market in 2001 and has annual sales in the U.S. of approximately $650 million. 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.

Non-prescription Over-the-Counter (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 U.S. for male condoms in 2016 was over $900 million.

Global Sales by Leading Contraceptive Companies:

	Bayer	Merck	Allergan	Cooper Surgical	Church & Dwight
Oral Contraceptive	Natazia		Lo Loestrin® Fe		
Short-term Non-Oral		Nuvaring			
IUD/Implant	Kyleena, Mirena, Skyla	Nexplanon	Liletta	Paragard	
OTC					Trojan Condoms

The adoption of Amphora, if approved, is expected to come equally from each category discussed, as interest in Amphora falls into two distinct segments: 1) those women seeking an alternative to hormonal contraception; and 2) those women who are expected to utilize Amphora 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 Amphora makes it an attractive option across the entire competitive set.

Rush License

As discussed above, we entered into an Amended and Restated License Agreement with Rush University, dated March 27, 2014, or the Rush License Agreement, pursuant to which Rush University granted us an exclusive, worldwide license of certain patents and know-how, or the Rush Licensed IP, related to our MPT vaginal gel 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 royalty payments 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 of 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; 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.

Intellectual Property

We believe we have a strong and growing intellectual property portfolio. We strive to protect the proprietary technology that we believe is important to our business, including seeking and maintaining 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 seek to obtain domestic and international patent protection, and endeavor to promptly 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 2018, regarding our MPT technology, we own or have exclusively licensed approximately 27 issued patents and allowed applications in the U.S. and other countries and jurisdictions, and have approximately 29 applications pending in the U.S. and other countries and jurisdictions. Furthermore, we own two pending Patent Cooperation Treaty applications that can be converted into national stage applications in U.S. 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 Amphora, 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 multiple patent families relating to the composition and therapeutic use of Amphora, which, upon grant, would expire at the earliest in 2033. We believe that our licensed and solely owned non-hormonal contraceptive gel patent filings, 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, as Amphora is a product that acts locally in the vagina, we believe that a generic version of Amphora gel cannot be evaluated for bioequivalence with the comparative pharmacokinetic blood testing that is commonly used to establish bioequivalence of systemic generic drugs. The comparative clinical endpoint studies that are generally conducted to establish bioequivalence of a locally-acting generic drug would not likely be adequately sensitive for detecting differences in performance between the generic drug and its reference listed drug.

In addition to patents, we 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 Amphora 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 any breach. In addition, our trade secrets and know-how may otherwise become known or may be independently discovered by competitors. To the extent that 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 Amphora. Our logos and trademarks are the property of Evofem Biosciences, Inc. All other brand names or 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 or trade dress owners.

Healthcare Laws and Regulations

Healthcare providers and third-party payers play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with third-party payers and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations, include 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;

False Claims Act — the federal False Claims Act imposes criminal and civil penalties, which can be enforced by private citizens through civil whistleblower and qui tam actions, against individuals or entities for 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, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or for making any false statements relating to healthcare matters; as in the case of the federal healthcare Anti-Kickback Statutes, 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;

False Statements Statute — the federal False Statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

Stark Law — the federal ban on physician self-referrals, which 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 with the 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, requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services, or the DHHS, information related to physician payments and other transfers of value and physician ownership and investment interests;

State Transparency Laws

Some U.S. state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to healthcare providers and other healthcare providers or marketing expenditures, and 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.

State and Foreign Regulatory Concerns

Analogous State and foreign laws and regulations, such as *State Anti-Kickback and False Claims* laws, 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 information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Government Regulation and Product Approval

United States — FDA Process

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. 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 NDA 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 comprised 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. Amphora is subject to review by the FDA, and it is anticipated that Amphora will be a drug/device combination product under NDA standards.

FDA Drug Approval Process

Amphora 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:

- pre-clinical laboratory tests, animal studies, and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND for human clinical testing;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication to the FDA's satisfaction;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP regulations; and
- FDA review and approval of the NDA.

Pre-clinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies. The results of the pre-clinical 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 U.S. 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. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Our first IND submitted in 2011 relates to Amphora for the prevention of pregnancy (AMP001). Our second IND relates to the MPT vaginal gel for the prevention of recurrent BV (EVO-002). We have also been allowed to conduct a clinical trial relating to prevention of urogenital chlamydia and gonorrhea (AMPREVENCE) under this IND, and the first subject was enrolled in this trial on January 23, 2018.

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. Clinical trials necessary for product approval are typically conducted in three sequential phases, but the phases may overlap. The trial protocol and informed consent information for trial subjects in clinical trials must also be approved by an Institutional Review Board, or IRB, for each institution where the trials will be conducted, and each IRB must monitor the trial until completion. 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.

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and of the clinical trials, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. 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. 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. Even if the NDA is filed, companies cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to an appropriate advisory committee, typically a panel of clinicians, 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 follows such recommendations. We submitted our NDA for Amphora on July 2, 2015 via the 505(b)(2) regulatory pathway. No advisory committee was convened by the FDA on the first-round review and no advisory committee is expected upon resubmission of our NDA.

The FDA may require that certain contraindications, warnings or precautions be included in the product labeling, or may condition the approval of an NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing or clinical trials and surveillance programs to monitor the safety of approved products that have been commercialized.

Post-Approval Requirements

Oftentimes, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical trials. If such post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to (i) report certain adverse reactions to the FDA, (ii) comply with certain requirements concerning advertising and promotional labeling for their products, and (iii) continue to have quality control and manufacturing procedures conform to cGMP regulations after approval. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities. This latter effort includes assessment of ongoing compliance with cGMP regulations. We have used and intend to continue to use third-party manufacturers to produce active pharmaceutical ingredients for our products in clinical and commercial quantities, and for final, finished product, and future FDA inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, including withdrawal of the product from the market.

Hatch-Waxman Act

As part of the Drug Price Competition and Patent Term Restoration Act of 1984, Section 505(b)(2) of the FDCA was enacted, otherwise known as the Hatch-Waxman Amendments. 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. The Hatch-Waxman Amendments permit the applicant to rely upon certain pre-clinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product 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.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, which is referred to as the Reference Listed Drug, the applicant is required to certify to the FDA concerning any listed patents in the FDA's Orange Book publication that relate to the Reference Listed Drug. Specifically, the applicant must certify for all listed patents one of the following certifications: (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 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 505(b)(2) application. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the Referenced Listed Drug has expired.

A certification that the new product will not infringe the Reference Listed Drug's listed patents or that such patents are invalid is called a Paragraph IV certification. If the 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 Reference 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 Section 505(b)(2) NDA by imposing a 30-month automatic statutory injunction, which may be shortened by the court in a pending patent case if either party fails to reasonably cooperate in expediting the case. The 30-month stay terminates if a court issues a final order determining that the patent is invalid, unenforceable or not infringed. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant's NDA will not be subject to the 30-month stay.

The Hatch-Waxman Amendments provide five years of data exclusivity for new chemical entities which prevents the FDA from accepting Abbreviated New Drug Applications and 505(b)(2) applications containing the protected active ingredient. The Hatch-Waxman Amendments also provide three years of exclusivity for applications containing the results of new clinical investigations (other than bioavailability studies) essential to the FDA's approval of new uses of approved products such as new indications, delivery mechanisms, dosage forms, strengths, or conditions of use.

Pricing and Reimbursement

Sales of products that we may market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability and level of reimbursement from third-party payers such as state and federal governments, managed care providers and private insurance plans. If our products are approved by the FDA, we intend to work with payers to demonstrate the clinical benefits of our products over other delivery modalities to secure adequate and commercially favorable pricing and reimbursement levels.

Other Governmental Regulations, Healthcare Laws and Environmental Matters

The FDA regulates all advertising and promotion activities for products under its jurisdiction both prior to and after approval. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with applicable FDA requirements may subject a company to adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA.

In addition, under the Pediatric Research Equity Act, or the PREA, 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 FDA has indicated that Amphora 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 have requested a partial waiver of the PREA in our NDA.

Although we currently do not have any products on the market, we may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the United States and foreign jurisdictions in which we conduct business. Such laws include, without limitation, state and federal fraud and abuse laws such as anti-kickback statutes, physician self-referral prohibitions, and false claims laws, privacy and security, and the Sunshine Act, many of which may become more applicable to us if our product candidates are approved for commercialization. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to it, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

If we establish international operations, we will be subject to compliance with the Foreign Corrupt Practices Act, or 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.

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

We are currently assessing how Amphora is going to be regulated in the EU and expect that Amphora is going to be regulated as a drug. 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.

To obtain marketing approval of a drug in the EU, an applicant must submit a Marketing Authorization Application, or 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 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.

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. Even if authorized, 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 (amongst 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 medical device, seizure of promotional materials, fines and possible imprisonment.

Emerging Growth Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of our initial public offering, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.0 billion, (3) the day we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as measured as of each June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. 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.

As long as we remain an "emerging growth company," we may take 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.

Except for the historical information contained herein or incorporated by reference, this Annual Report and the information incorporated by reference contains forward-looking statements that involve risks and uncertainties. These statements include projections about our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. These statements are not guarantees of future performance or events. Our actual results may differ materially from those discussed here. Factors that could cause or contribute to differences in our actual results include those discussed in the following section, as well as those discussed in Part II, Item 7 entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this Annual Report and in any other documents incorporated by reference into this Annual Report. You should consider carefully the following risk factors, together with all of the other information included or incorporated in this Annual Report. Each of these risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock. There may be additional risks that we do not presently know of or that we currently believe are immaterial which could also impair our business and financial position.

Risks Related to Our Business

Risks Related to Our Financial Condition and Capital Requirements

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

We are a development-stage biotechnology company with a limited operating history. Neothetics and Private Evofem each incurred net yearly losses since their respective inceptions. Private Evofem incurred net losses of $105.3 million and $66.7 million for the years ended December 31, 2017 and 2016, respectively. As of December 31, 2017, Private Evofem had an accumulated deficit of $307.3 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 MPT vaginal gel and our lead product candidate, Amphora. 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 pre-clinical studies and clinical trials, the cost, timing and outcomes of regulatory decisions regarding potential approval for our product candidate or any future product candidate 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 results of upcoming clinical data analyses and 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 of our financial resources to develop 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. 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:

- continue the clinical development of our MPT vaginal gel and our lead product candidate, Amphora;
- continue efforts to discover new product candidates;
- 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 pre-clinical, clinical, or other trials or studies 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;
- seek 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 studies, additional major studies 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.

We must raise additional funds to finance our operations to remain a going concern.

Based on our cash balance, recurring losses since inception and inadequacy of existing capital resources to fund planned operations for a twelve-month period, we will, during the remainder of 2018, require significant additional funding to continue operations. If we are unable to raise additional funds when needed, we will not be able to continue development of our MPT vaginal gel or our lead product candidate, Amphora, or we will be required to delay, scale back or eliminate some or all of our development programs or cease operations. Any additional equity or debt financing that we are able to obtain may be dilutive to our current stockholders and debt financing, if available, may involve restrictive covenants or unfavorable terms. If we raise funds through collaborative or licensing arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize. 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 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 the regulatory and marketing approvals necessary to commercialize one or more of our current or future product candidates. We do not anticipate generating revenue from product sales until 2020. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including, but not limited to:

- completing research and development of our MPT vaginal gel, Amphora, our lead product candidate, and one or more of our current or future product candidates;
- obtaining regulatory and marketing approvals for one or more of our current or future product candidates;
- 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 our supply needs in sufficient quantities to meet market demand for our product candidates, if approved;
- marketing, launching and commercializing one or more product candidates for which we obtain regulatory and marketing approval, either directly or with a collaborator or distributor;
- gaining market acceptance of one or more 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 our MPT vaginal gel, our lead product candidate, Amphora, or one or more of our current or future product candidates that supports profitability; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates that we develop is 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 in order to continue 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 a number of factors, including the risk factors further described herein and the low trading volume and volatile trading price of our shares of common stock. The stocks of small cap companies in the biotechnology

sector similar to us tend to be highly volatile. We expect that the price of our common stock will be highly volatile for the next several years. Even if we expand our portfolio of products and product candidates, we may never successfully commercialize or monetize our current product candidate or any future product candidate that 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 that 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.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights.

In order to complete the development of our MPT vaginal gel and our lead product candidate, Amphora, we must raise significant additional capital. To the extent that 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 that include 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 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. We do not know if we will be able to obtain additional funding if and when necessary to fund our entire portfolio of product candidates to meet our projected plans. If we are unable to obtain funding on a timely basis, we may be required to delay or discontinue one or more of our development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on potential business opportunities, which could materially harm our business, financial condition, and results of operations.

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 technology, identifying potential products and undertaking pre-clinical and clinical studies of our product candidates. We have a limited operating history that 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 largely development 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 adversely affect our business, results of operations or financial condition.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, the President signed into law the "Tax Cuts and Jobs Act," or TCJA, that significantly reforms the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating loss carryforwards, allows for the expensing of capital expenditures, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. Our net deferred tax assets and liabilities will be revalued at the newly enacted U.S. corporate rate, and the impact, if any, will be recognized in our tax expense in the year of enactment. We continue to examine the impact this tax reform legislation may have on our business. The impact of this tax reform is uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

Risks Related to the Development of Our Product Candidates

Our success will depend heavily on whether we can develop our lead product candidate, Amphora, as a contraceptive. Failure to develop Amphora as a contraceptive would likely cause our business to fail.

We currently have a single platform technology, our MPT vaginal gel, from which we intend to create multiple product candidates. However, we will rely primarily on our lead product candidate, Amphora, for use as a contraceptive for our commercial success. Amphora is currently the subject of an ongoing Phase 3 clinical trial intended to demonstrate efficacy as a contraceptive. While we believe that our MPT vaginal gel may also be useful in preventing other indications, currently our business depends almost entirely on the successful clinical development and regulatory approval of Amphora for use as a contraceptive, which may never occur. We have never received a regulatory approval for any product. Accordingly, even if we are able to successfully complete our clinical trial for Amphora as a contraceptive, we may

be unable to obtain regulatory approval for Amphora as a contraceptive, which would have a material adverse effect on our business and operations.

Our ability to develop our MPT vaginal gel for additional indications could have an adverse effect on our business and our ability to successfully market Amphora as a contraceptive.

We believe that Amphora may also be useful in certain other indications and we are conducting a Phase 2b/3 clinical trial for the prevention of urogenital chlamydia and gonorrhea in women. In addition, we are currently designing a Phase 2b/3 trial of our MPT vaginal gel product candidate for the reduction of recurrent BV. We do not know if we will successfully complete either of these clinical trials. Even if we do complete these clinical trials, there is no assurance that we will obtain regulatory approval of Amphora or our MPT vaginal gel for additional indications. Such a failure could impede our ability to market Amphora as a contraceptive because these product candidates are based on the same active ingredients. Also, any failure to obtain regulatory approvals for additional indications will likely have a material adverse effect on the company's business and operations.

Indemnity claims from lawsuits or damages against our clinical trial sites could cause us to incur substantial liabilities and to limit commercialization of Amphora, and any future product candidate that we may develop.

In connection with our clinical trials, our third-party clinical sites face inherent risk of liability exposure from patients enrolled in our clinical trials. We have entered into indemnification agreements with each of these clinical trial sites obligating us to reimburse these sites should they incur certain liability in connection with our clinical trials. If we or our clinical trial sites cannot successfully defend against these product liability and other health related claims, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in decreased demand for our MPT vaginal gel and our lead product candidate, Amphora or, as applicable, any future product candidate 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 its 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 continued clinical testing, potential approval and commercialization of our MPT vaginal gel as a contraceptive, as a possible preventative for certain STIs and prevention of recurrent BV, 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. Research programs to identify new product candidates require substantial technical, financial and human resources. 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 pre-clinical 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 so that such 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 would have a material adverse effect on our business, financial condition or results of operations and could potentially cause us to cease operations. Moreover, even if we were able to obtain the rights to additional product candidates, there can be no assurance that 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 that any clinical trials will be conducted as planned or completed on schedule, if at all. In addition, our product candidates are targeted toward pregnancy prevention and the prevention of certain infectious diseases. Therefore, it may be especially difficult to recruit patients to participate in our clinical trials when doing so will require that patients refrain from other methods of contraception and 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 pre-clinical, 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, or 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, or IRB, 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 by clinical sites or 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 or applicable foreign regulatory guidelines;
- patients withdrawing from our clinical trials;
- adverse events or other issues of concern significant enough for the FDA, or comparable foreign regulatory authority, to put an IND on clinical hold;
- occurrence of adverse events associated with our product candidates;
- 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 nonclinical studies and/or clinical trials to show that the results obtained from such new formulation 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.

Contraception is a highly competitive healthcare niche. The success of Amphora and any other future contraceptive product candidate we may pursue will be related to our efficacy and safety outcomes during clinical trials.

Today, there are a variety of hormonal and non-hormonal contraceptive options available to women, including oral contraceptive pills and intrauterine devices; newer hormonal contraceptive products including implants, injectables, vaginal rings, patches, and hormonal intrauterine systems; and non-hormonal methods such as female condoms, novel diaphragms, and new methods of female sterilization. Based

on our market research, clinical testing of Amphora may need to demonstrate efficacy for typical use of at least 80% to be commercially viable. Should Amphora fail to generate the safety and efficacy data expected, our business prospects would be materially damaged.

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 that 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 that we may in the future choose to develop, through the regulatory and development processes. We may make incorrect determinations with regard to the indications and clinical trials on which to focus the available resources that we do have. The decisions to allocate our research, management and financial resources toward 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 and Other Legal Compliance Matters

We must obtain regulatory approval prior to marketing or commercializing our product candidates. In order to obtain regulatory approval, we must complete our clinical and pre-clinical trials in compliance with the regulatory approval requirements of the FDA and any applicable and comparable foreign regulators. If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy 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.

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 must complete extensive pre-clinical development and clinical trials to demonstrate the safety and efficacy of our product candidates before we will be able to obtain these approvals.

Any inability to complete pre-clinical 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 testing of our product candidates beyond the trials and testing that 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.

Amphora is a drug/device combination and the process for obtaining regulatory approval for Amphora 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 costs.

Amphora is comprised 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 topical gel. The key active ingredient has been shown to be an active anti-inflammatory and anti-infective and 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 contraceptive effect of Amphora are its capacity to reduce/inhibit cervical mucus penetration, its ability to maintain sufficient viscosity even on dilution, and its bioadhesive strength. The FDA has different divisions responsible for assessing and approving devices and drugs. The Center for Drug Evaluation and Research, or CDER, has responsibility for drug products, while the Center for Devices and Radiological Health, or CDRH, has oversight responsibility for medical devices. Amphora previously underwent a request for designation process with the FDA that determined that CDER would lead the review. If the designation were to be changed to CDRH, or if either division were to institute additional requirements for the approval of Amphora, we could be required to complete clinical studies with more patients and over longer periods of time than is 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 review agency 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 Amphora, our business and our financial condition.

Serious adverse events arising during clinical studies of our MPT vaginal gel product candidates or post marketing could have a material, adverse effect on our product development timeline or our ability to develop and market our MPT vaginal gel product candidates at all.

If serious adverse events or undesirable side effects occur during the clinical investigation of our MPT vaginal gel or our lead product candidate, Amphora, or post marketing, the following events could materially and adversely affect our business:

- regulatory authorities may impose a clinical hold, which could result in substantial delays and adversely impact our ability to continue development of our MPT vaginal gel and Amphora;
- regulatory authorities may require the addition of specific warnings or contraindications to product labeling or field alerts to physicians and pharmacies;
- we may be required to change the way the MPT vaginal gel and/or Amphora is administered or the labeling of the MPT vaginal gel and/or Amphora;
- we may be required to conduct additional clinical studies with more patients or over longer periods of time than anticipated;
- we may be required to implement a risk minimization action plan, which could result in substantial cost increases and have a negative impact on our ability to commercialize our MPT vaginal gel and/or Amphora;
- we may be required to limit the patients who can receive our MPT vaginal gel and/or Amphora;
- we may be subject to promotional and marketing limitations on our MPT vaginal gel and/or Amphora;
- sales of our MPT vaginal gel and/or Amphora may decrease significantly;
- regulatory authorities may require us to take an approved product 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 MPT vaginal gel or our lead product candidate, Amphora, or any future product candidate we may seek to develop, or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from our MPT vaginal gel or Amphora sales or the sales from any future product candidate.

If FDA approval is received for our MPT vaginal gel, our lead product candidate, Amphora, or any other future product candidate we may develop, serious adverse events or side effects could require the product to be taken off of the market, may require the product to be packaged with safety warnings or may otherwise limit our sales of the product.

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

If our MPT 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 that quality control and manufacturing procedures conform to current good manufacturing practices, or cGMP, regulations and corresponding foreign regulatory manufacturing requirements. As such, 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 marketing authorization application.

Any regulatory approvals that 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 in order 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 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.

Even if we receive approval from the FDA in the U.S. to market our MPT vaginal gel product candidates or a future product candidate we may seek to develop, we may fail to receive similar approval outside the U.S.

In order 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 of 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 develop 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 operation and prospects.

Our development and commercialization strategy for our MPT vaginal gel product candidates depend, 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 added section 505(b)(2) to the FDCA. Section 505(b)(2) of the FDCA permits the filing of a 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 candidate has been approved, as well as for any new indication sought by the section 505(b)(2) applicant. The applicant's product label, however, may require 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 additional limitations, contraindications, warnings or precautions. We have submitted a NDA for Amphora under section 505(b)(2) of the FDCA and as such the NDA relied, 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. In addition, 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 that we submit. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of our product candidates.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our MPT vaginal gel product candidates and any future product candidate that we may develop.

We face an inherent risk of product liability exposure should we commercialize Amphora. We will face similar risks with any other future indications for our MPT vaginal gel or other product candidates that we may 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 MPT vaginal gel, Amphora or, as applicable, any future product candidate 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.

We will need to maintain liability insurance coverage as we seek to conduct and continue to conduct clinical trials for our MPT vaginal gel and Amphora. 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 that we may incur. In addition, we may need to increase our liability insurance coverage in connection with the commercialization of our MPT vaginal gel, Amphora or any other product candidate we may commercialize. 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 manufacturers' and suppliers' activities involve the controlled storage, use, and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are 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 are stored at our and our 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 that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that 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

If we are unable to obtain and maintain patent protection for our MPT vaginal gel product candidates and other proprietary technologies we 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 ours, and our ability to successfully commercialize Amphora, other MPT vaginal gel 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 MPT vaginal gel, our lead product candidate, Amphora, 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 our MPT vaginal gel, our Amphora 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 our MPT vaginal gel, our Amphora 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 that 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 behind 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 pharmaceutical 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 Amphora product candidate and other proprietary technologies we may 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 that we own or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether our MPT vaginal gel, Amphora product candidate 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 United States Patent and Trademark Office, or 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 our MPT vaginal gel, Amphora product candidate 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 MPT vaginal gel, Amphora product candidate 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 MPT vaginal gel and Amphora product candidate, 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.

Our rights to develop and commercialize our MPT vaginal gel product candidates are subject, in part, to the terms and conditions of licenses granted to us by others.

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 Amphora product candidate. For example, our license agreement with Rush University includes intellectual property rights to our MPT vaginal gel and our Amphora product candidate. 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 that the existing Rush License Agreement covering the rights related to our MPT vaginal gel or our Amphora product candidate 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. There is no assurance that we will be able to renew or renegotiate a license agreement on acceptable terms if the agreement is terminated. We cannot guarantee that any license agreement will be enforceable. 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 MPT vaginal gel and our Amphora product candidate.

In addition, with respect to our MPT vaginal gel and our Amphora product candidate, 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 MPT vaginal gel and our Amphora product candidate. 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 MPT vaginal gel or Amphora product candidate.

In addition, 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 that 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-licensed. 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.

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

Filing, prosecuting, and defending patents on our MPT vaginal gel 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 technologies 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 biotechnology 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 U.S., 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 U.S. 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 that we develop or license.

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

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

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

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

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that 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, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that 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 of time 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 MPT vaginal gel, our Amphora product candidate 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 of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Issued patents covering our MPT vaginal gel 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 MPT vaginal gel, our Amphora product candidate 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 MPT vaginal gel, our Amphora product candidate 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 Amphora product candidate 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 and data exclusivity for our MPT vaginal gel 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 U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term, or PTE, of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension 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, or the SPC.

An important part of our patent strategy is reliant on our ability to obtain patent term extension on the patents licensed from Rush University. However, we may not be granted an extension, such as PTE for the U.S. 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 period or the scope of patent protection afforded could be less than our request. If we are unable to obtain patent term extension 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 MPT vaginal gel 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 MPT vaginal gel and Amphora product candidate, 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 Amphora product candidate 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 Amphora product candidate 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 MPT vaginal gel, our Amphora product candidate 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 MPT vaginal gel and our Amphora product candidate, 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, the trade secrets and know-how in connection with our MPT vaginal gel and our Amphora product candidate 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 that 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 Amphora 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 MPT vaginal gel, our Amphora product candidate and other proprietary technologies we may develop. Other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. In order 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 MPT vaginal gel, our Amphora product candidate 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 that 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 pharmaceutical 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 MPT vaginal gel product candidates and other proprietary technologies we may develop.

The field of contraceptive and/or anti-STDs vaginal gel is competitive and dynamic. Due to the significant research and development that is 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, in addition to the ongoing interference 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 pharmaceutical 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 U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we intend to commercialize Amphora and our MPT vaginal gel product candidate and in which we are developing other proprietary technologies. As the biotechnology and pharmaceutical 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 MPT vaginal gel, our Amphora product candidate 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 candidate, 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 MPT vaginal gel, our Amphora product candidate 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 claim that use of our technologies or the manufacture, use or sale of our MPT vaginal gel or our Amphora product candidate infringes upon these patents. In the event that any third-party claims that we infringe 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 technologies 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 technologies 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 technologies. 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 technologies, 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 technologies, 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 that 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 into 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 that 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 that 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 Amphora, 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. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. 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 technologies 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 manufacturers. Any failure by such third parties, including failure to successfully perform and comply with regulatory requirements, could negatively impact our business and our ability to develop and market Amphora and potential future 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 on third parties to make our products, and as such we will be subject to inherent uncertainties related to product safety, availability and security. To date, our contract manufacturer, Swiss-American, has only produced a small quantity of our MPT vaginal gel for clinical testing. Furthermore, we have only a single source of supply for some of the key raw materials and components of our MPT vaginal gel and alternate sources of supply may not be readily available.

Moreover, we do not expect to control the manufacturing processes for the production of our MPT vaginal gel or any of our other future products or product candidates, which must be made in accordance with relevant regulations, and includes, 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, all of which would result in suspension or prevention of commercialization and/or manufacturing of our products or product candidates, including our MPT vaginal gel and our lead product candidate, Amphora, 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 studies or commercialization. We might be unable to find alternative suppliers or manufacturers with FDA approval, of acceptable quality, 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 operation and prospects.

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

- we may be unable to identify 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;
- Contract 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 inspection 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 agreement 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 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, 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 of time 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. 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.

We have no internal distribution capabilities and intend to engage third-party distributors for distribution of products outside the United States. The 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, Amphora, directly in the United States, we do intend to enter into distribution agreements with one or more distributors of Amphora outside the United States. We currently have not entered into any such distribution agreement with any such distributor, and we cannot guaranty that we will be able to enter into any such distribution agreement on commercially reasonable terms, or at all. If we were to outsource product distribution, including the distribution of Amphora or any future product candidate or product, this outsourcing would also 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 relevant regulations, which includes, among other things, compliance with current good documentation practices, the maintenance of records and documentation and compliance with other regulations, including, without limitation, the FCPA. Failure to comply with these requirements could result in significant remedial action, including improvement of facilities, suspension of distribution or recall of product. Additionally, any failure by us to forecast demand for finished product, including Amphora, 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. 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 MPT vaginal gel product candidates and our potential future product candidates. Failure of these third parties to provide services of a suitable quality and within acceptable timeframes 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. In terms of Amphora, we have engaged PAREXEL International Corporation as CRO to run substantially all aspects of the AMPOWER clinical trial. 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 MPT vaginal gel product candidates or any future product candidates, may be delayed, prevented or cost significantly more than expected, all of which would have a material adverse effect on our business, financial conditions, results of operation 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 studies, 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 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 have to 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, 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 the good faith performance of their services.

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

We currently have limited marketing and sales experience. 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, launched and sold other pharmaceutical products 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. 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 pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The medical device, biotechnology and pharmaceutical 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 with greater financial, technical and personnel resources than us. In order 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 Amphora, if approved. 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, Teva Pharmaceutical Industries Ltd., Bayer AG, Johnson & Johnson, Cooper 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 Amphora, including hormonal patches and hormonal vaginal rings.

Our MPT vaginal gel product candidates and any of our future potential 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 MPT vaginal gel, our lead product candidate, Amphora, or any of our future 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 or reimbursement;
- effectiveness of our or our collaborators' sales and marketing strategy;
- the willingness of uninsured consumers 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 our MPT vaginal gel product candidates that we may license, develop or sell 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 our MPT vaginal gel product candidates 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 this specific method of contraception.

The commercial success of our MPT vaginal gel, Amphora, or any other future contraceptive product candidate we may seek to develop, will depend upon the contraceptive market as well as market acceptance of this alternative method. 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 the ACA, and its effect on pharmaceutical coverage, reimbursement and pricing, and the birth control mandate;
- competition from new lower dose hormonal contraceptives with more favorable side effect profiles; and
- new generic contraceptive options including a generic version of Amphora as a contraceptive.

If one or more of these risks occur it could reduce the market potential for our MPT vagina gel, Amphora, or any future contraceptive product we may seek to develop, and place pressure on our business, financial condition, results of operation and prospects.

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 continue to expect to rely, on market research conducted on our behalf to evaluate the potential commercial acceptance our MPT vaginal gel product candidates 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 Amphora, 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 candidate we may develop.

The commercial success of our MPT vaginal gel product candidates and any future 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 MPT vaginal gel, our lead product candidate, Amphora, and any of our future 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 adequate information on features or benefits will prevent or substantially limit our advertising and promotion of such features in order to differentiate Amphora or any future product candidate from those products that already exist in the market. This failure would have a material adverse impact on our business, financial condition, results of operation and prospects.

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 U.S. market that is made up of generic products has been increasing over time. In 2005, generic contraceptive products held 47% of prescription volume and 34% of sales and, by 2011, those values had risen to 68% and 44%, respectively. For the year ended December 31, 2016, approximately 83% of the prescription volume and approximately 43% of sales of combined hormonal contraceptives in the United States were generated by generic products. If this trend continues, it may be more difficult to introduce Amphora, if approved, 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 Amphora in order to overcome the trend towards generics and to gain access to reimbursement by payers. If we are unable to introduce Amphora or any future approved contraceptive product candidate at a price that is commensurate with that of current branded contraceptive products, or we are unable to gain reimbursement from payers for Amphora, or if patients are unwilling to pay any price differential between Amphora and a generic contraceptive, our revenues will be limited.

Changes in healthcare laws and regulations may eliminate current requirements that health insurance plans cover and reimburse FDA-cleared or approved contraceptive products without cost sharing, which could reduce demand for products such as Amphora. Even if Amphora is approved for commercialization, our management expects that 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 Amphora, and if reimbursement is available, the amount of any such reimbursement. The ACA and subsequent regulations enacted by the DHHS require health plans to provide coverage for women's preventive care, including all forms of FDA-cleared or 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. However, after the 2016 election, the U.S. Federal Government is attempting to repeal the ACA and corresponding regulations, which would likely 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 under the Congressional Review Act. 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 Amphora, at all. As a result, we expect that our success will be dependent on the willingness of patients to pay out-of-pocket for Amphora in the event that either they do not have insurance or their insurance requires payment of a portion of Amphora by the patient, thus increasing the patient's overall cost to use Amphora. This could reduce market demand for Amphora 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 that we are successful in obtaining regulatory approval to market our MPT vaginal gel product candidates or a future product in the United States, revenues may be adversely affected if the product fails to obtain insurance coverage or adequate reimbursement from third-party payers and administrators in the United States.

Third-party payers and administrators, including state Medicaid programs and Medicare, have recently been 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. Third-party insurance coverage may not be available to patients for Amphora or any future product we may seek to commercialize. If such government and other third-party payers do not provide adequate coverage and reimbursement for Amphora or such products, 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. Private third-party payers, as well as governments, 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 our MPT vaginal gel, Amphora 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 operation and prospects.

The pharmaceutical and medical device industries are highly regulated and subject to various fraud and abuse laws, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act and the U.S. FCPA.

Healthcare fraud and abuse 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 other things:

- the federal healthcare programs' anti-kickback law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce 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 federal healthcare programs such as the Medicare and Medicaid programs;
- false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- the Health Insurance Portability and Accountability Act of 1996, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and
- the U.S. FCPA, which prohibits corrupt payments, gifts or transfers of value to non-U.S. officials.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. 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.

Our business may be adversely affected by unfavorable macroeconomic conditions.

Various macroeconomic factors could adversely affect our business, our results of operations and 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) 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 Amphora 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 9, 2018, we had a total of 23 full-time employees and use 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. 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 of the objectives that we otherwise would seek to accomplish.

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, including our President and Chief Executive Officer, Saundra Pelletier, our Chief Financial Officer, Justin J. File, Kelly Culwell, M.D., our Chief Medical Officer and Russell Barrans, our Chief Commercial Officer. The loss of the services of any of these individuals 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, pharmaceutical 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 failures 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 studies, 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, including the imposition of significant fines or other sanctions, and our reputation.

We may be vulnerable to disruption, damage and financial obligations as a result of information technology system failures.

Despite the implementation of security measures, 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, terrorism, war, 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 studies could result in delays in our or our partners' regulatory approval efforts and significantly increase our costs in order 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 that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur resulting liability, 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, or 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," 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.

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 the operating performance of particular companies. 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;
- 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 technologies;
- 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;
- 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
- the 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.

If we were to be delisted from Nasdaq, it could reduce the visibility, liquidity and price of our common stock.

There are various quantitative listing requirements for a company to remain listed on The Nasdaq Capital Market, including maintaining a minimum bid price of $1.00 per share and Nasdaq equity standards. There is no guarantee that we will be able to continue complying with the minimum bid price rule, the minimum equity standard or other Nasdaq requirements.

Delisting from The Nasdaq Capital Market could reduce the visibility, liquidity and price of our common stock.

Two 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.

Funds affiliated with or discretionarily managed by Invesco Asset Management and funds affiliated with or discretionarily managed by Woodford Investment Management hold approximately 39.6% and 42.0%, respectively, of our outstanding common stock. We have entered into voting agreements with certain funds affiliated with Woodford Investment Management providing 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 affiliated with Woodford Investment Management and Invesco Asset Management 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 of our assets.

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 DGCL, which prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder," and the combined entity will be 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 the Company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the Company and may materially adversely affect the market price of our 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 at any time. 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 or to the extent such shares have already been registered under the Securities Act and are held by non-affiliates.

As of February 9, 2018, there were 399,962 shares of our common stock subject to outstanding options, 240,637 shares of 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 February 9, 2018, there were 2,011,875 shares subject to outstanding warrants to purchase common stock. These shares will become eligible for sale in the public market, to the extent such warrants are exercised, as permitted by Rule 144 under the Securities Act. Moreover, holders of approximately 15,026,968 shares of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act and may remain an emerging growth company through 2019. For so long as we remain an emerging growth company, we will be permitted to and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- 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.

We may choose to take advantage of some, but not all, of the available exemptions. 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 capital stock. We currently plan to retain all of our future earnings, if any, and any cash received as a result of 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 that 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 that 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 into 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 do not publish 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 that 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. We have two five-year renewal options, but the sub-lessor is not expected to renew its lease. We believe that our existing facilities are adequate for our current needs.

Item 3. Legal Proceedings.

From time to time we may be involved in various disputes and litigation matters that arise in the ordinary course of business. 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 trading symbol "NEOT". Prior to November 20, 2014, there was no public market for our common stock. On January 17, 2018, Neothetics and Private Evofem completed the Merger. In connection with the Merger, we changed the name of the Company to Evofem Biosciences, Inc. and changed the trading symbol for our common stock to "EVFM". Shares of our common stock began trading on The Nasdaq Capital Market under the ticker EVFM on January 18, 2018. The table below provides the high and low sales prices of our common stock for the periods indicated, as reported by The Nasdaq Global Market and The Nasdaq Capital Market (as adjusted for the Reverse Split effected on January 17, 2018).

	High	Low
Year ended December 31, 2017		
Fourth Quarter	$ 12.84	$ 2.52
Third Quarter	$ 3.83	$ 1.80
Second Quarter	$ 15.78	$ 3.02
First Quarter	$ 11.88	$ 6.18
Year ended December 31, 2016		
Fourth Quarter	$ 8.64	$ 4.80
Third Quarter	$ 9.00	$ 4.32
Second Quarter	$ 9.36	$ 3.37
First Quarter	$ 9.72	$ 3.19

The last sale price for our common stock as reported by The Nasdaq Capital Market on February 9, 2018, was $7.20 per share.

Holders of Common Stock

As of February 9, 2018, there were 17,763,340 shares of our common stock outstanding and 31 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 year ended December 31, 2017, we did not issue any securities that were not registered under the Securities Act. Information describing the Financing is incorporated herein by reference to the section entitled "Merger of Neothetics, Inc. and Evofem Biosciences Operations, Inc." in Part I, Item 1 of this Annual Report.

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

None.

Item 6. Selected Financial Data.

The following table shows selected financial data as of, and for the periods ended on, the dates indicated. Our historical results are not necessarily indicative of the results to be expected in the future and results of interim periods are not necessarily indicative of the results for the entire year. You should read the following selected financial data in conjunction with our financial statements, the notes to the financial statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this report. The selected financial data included in this section are not intended to replace the financial statements and the related notes included elsewhere in this report.

The financial information included in this Selected Financial Data is that of Neothetics prior to the Merger because the Merger was consummated after the period covered by the financial statements in this Annual Report. Accordingly, the historical information included in this Annual Report, unless otherwise indicated or as the context otherwise requires, is that of Neothetics prior to the Merger.

	Year Ended December 31,		
	2017	2016	2015
	(in thousands, except share and per share data)		
Statement of Operations Data:			
Operating expenses:			
Research and development	$ 3,946	$ 6,579	$ 34,410
General and administrative	6,099	5,463	7,639
Total operating expenses	10,045	12,042	42,049
Loss from operations	(10,045)	(12,042)	(42,049)
Interest income	52	59	26
Interest expense	—	(1,036)	(1,134)
Net loss	$ (9,993)	$ (13,019)	$ (43,157)
Net loss per share, basic and diluted[(1)]	$ (4.33)	$ (5.66)	$ (18.91)
Weighted average shares used to compute basic and diluted net loss per share[(1)]	2,305,817	2,300,167	2,282,672

(1) Please see Note 2 of our financial statements included elsewhere in this document for an explanation of the calculations of our actual basic and diluted net loss per share.

	As of December 31,		
	2017	2016	2015
		(in thousands)	
Balance sheet data:			
Cash and cash equivalents	$ 3,417	$ 11,478	$ 37,749
Working capital	$ 2,613	$ 11,605	$ 30,626
Total assets	$ 4,119	$ 12,817	$ 40,112
Long-term debt, less current portion	$ —	$ —	$ 7,205
Accumulated deficit	$ (135,844)	$ (125,850)	$ (112,832)
Total stockholders' equity	$ 2,707	$ 11,915	$ 23,807

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 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 document, 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.

Recent Developments

On January 17, 2018, Neothetics and Private Evofem completed the Merger in accordance with the terms of the Merger Agreement, whereby the Merger Sub merged with and into Private Evofem, with Private Evofem surviving as a wholly owned subsidiary of Neothetics. Immediately following the Merger, Neothetics changed its name to "Evofem Biosciences, Inc." In connection with the closing of the Merger and on January 18, 2018, our common stock began trading on The Nasdaq Capital Market under the ticker symbol "EVFM".

Effective January 17, 2018, we completed a six-for-one reverse stock split, which we refer to as the Reverse Split, of shares of our common stock. Share and per share amounts this Management's Discussion and Analysis of Financial Condition and Results of Operations reflect the Reverse Split.

The financial information included in this Management's Discussion and Analysis of Financial Condition and Results of Operations is that of Neothetics prior to the Merger because the Merger was consummated after the period covered by the financial statements included in this Annual Report. Accordingly, the historical financial information included in this Annual Report, unless otherwise indicated or as the context otherwise requires, is that of Neothetics prior to the Merger.

Neothetics Overview

As a result of the Merger, our historic business operations ceased and our going forward operations will be those of Private Evofem. Accordingly, the results of operations reported for the years ended December 31, 2017 and 2016, in this Management's Discussion and Analysis are not indicative of the results of operations expected in 2018 and future years due to the termination of our historic business operations.

Prior to the Merger, we were a clinical-stage specialty pharmaceutical company that developed therapeutics for the aesthetic market. Our initial focus was on localized fat reduction and body contouring.

We have never been profitable and, as of December 31, 2017, we had an accumulated deficit of $135.8 million. We incurred net losses of $10.0 million and $13.0 million for the years ended December 31, 2017 and 2016, respectively.

Basis of Presentation

Revenue

Prior to the Merger, we did not generate revenue, and we have not generated revenue following the Merger.

Research and Development Expenses

Prior to the Merger, our research and development expenses consisted primarily of:

- fees paid to clinical consultants, clinical trial sites and vendors, including CROs in conjunction with implementing and monitoring our pre-clinical and clinical trials and acquiring and evaluating pre-clinical and clinical trial data, including all related fees, such as for investigator grants, patient screening fees, laboratory work and statistical compilation and analysis;
- expenses related to pre-clinical studies, clinical trials and related clinical manufacturing, materials and supplies;
- expenses related to compliance with drug development regulatory requirements in the United States and other foreign jurisdictions; and
- personnel costs, including cash compensation, benefits and share-based compensation expense.

Prior to the Merger, we expensed both internal and external research and development costs in the periods in which they were incurred. Substantially all our research and development expenses were related to the development of LIPO-202. For the years ended December 31, 2017, 2016 and 2015, we incurred costs of $3.9 million, $6.6 million and $34.4 million respectively, on research and development expenses.

Prior to the Merger, we did not allocate compensation expense to individual product candidates, as we were organized and recorded expense by functional department and our employees were able to allocate time to more than one development project. We did not utilize a formal time allocation system to capture expenses on a project-by-project basis.

General and Administrative Expenses

Prior to the Merger, our general and administrative expenses primarily consisted of personnel costs, including cash compensation, benefits and share-based compensation expense, associated with our executive, accounting and finance departments. Other general and administrative expenses included costs in connection with patent filings, director and officer insurance premiums to support our operations as a public company, facilities expenses, information technology costs and professional fees for legal, consulting, marketing, audit and tax services.

Interest Income

Prior to the Merger, our interest income consisted primarily of interest received or earned on our cash and cash equivalents. Prior to the Merger, our interest income was not significant in any individual period.

Interest Expense

Prior to the Merger, our interest expense consisted of cash and non-cash interest costs related to our borrowings.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements as well as the reported revenues and expenses during the reported periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and share-based compensation. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ materially from these estimates. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected.

While our significant accounting policies are described in the notes to our financial statements appearing elsewhere in this document, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

As a result of the Merger, our historic business operations ceased and our going forward operations will be those of Private Evofem. Accordingly, the results of operations reported for the years ended December 31, 2017 and 2016, in this Management's Discussion and Analysis are not indicative of the results of operations expected in 2018 and future years due to the termination of our historic business operations.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing contracts and purchase orders, reviewing the terms of our vendor agreements, communicating with our applicable personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time.

Examples of estimated accrued research and development expenses include:

- fees paid to CROs in connection with clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to vendors in connection with pre-clinical development activities; and
- fees paid to vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows and expense recognition. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. 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 our reporting changes in estimates in any particular period. Through December 31, 2017, there have been no material adjustments to our prior period estimates of accrued expenses for clinical trials. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Share-Based Compensation

Prior to the Merger, we accounted for all share-based compensation payments using an option pricing model for estimating fair value. Accordingly, share-based compensation expense for employees and directors was measured based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. Compensation expense was recognized for the portion that is ultimately expected to vest over the period during which the recipient renders the required services to us using the straight-line single option method. In accordance with authoritative guidance, the fair value of non-employee share-based awards was remeasured as the awards vest, and the resulting change in value, if any, is recognized as expense during the period the related services are rendered.

Prior to the Merger, we estimated the fair value of our share-based awards using the Black-Scholes option pricing model. The Black-Scholes model 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, which determine the fair value of share-based awards.

We will continue to use judgment in evaluating the fair value of the underlying common stock and expected term and expected volatility, related to our share-based compensation on a prospective basis. As we continue to accumulate additional data related to our common stock, we may make refinements to the estimates of our expected term and expected volatility, which could materially impact our future share-based compensation expense.

Results of Operations

Comparison of the Years Ended December 31, 2017 and 2016

	Year Ended December 31,		Change
	2017	2016	$
		(in thousands)	
Operating expenses:			
Research and development	$ 3,946	$ 6,579	$ (2,633)
General and administrative	6,099	5,463	636
Total operating expenses	10,045	12,042	(1,997)
Loss from operations	(10,045)	(12,042)	1,997
Interest income	52	59	(7)
Interest expense	—	(1,036)	1,036
Net loss	$ (9,993)	$ (13,019)	$ 3,026

Research and Development Expenses. Research and development expenses decreased by $2.6 million to $3.9 million for the year ended December 31, 2017 from $6.6 million for the year ended December 31, 2016. Approximately $2.3 million of the decrease was due to the completion of close out activities for our AbCONTOUR1 and AbCONTOUR2 U.S. Phase 3 clinical trials and related supplemental clinical trials, $1.4 million decrease from the reduction of other research and development activities, and $0.5 million decrease due to additional reduction in workforce. The decreases were offset by $1.5 million of expenses incurred in 2017 related to the Phase 2 proof-of-concept clinical trial for the reduction of localized fat deposits under the chin.

General and Administrative Expenses. General and administrative expenses increased by $0.6 million to $6.1 million for the year ended December 31, 2017, from $5.5 million for the year ended December 31, 2016. An increase of $1.9 million was due to legal, accounting, and banker fees associated with the Merger with Private Evofem. The increase was offset by a decrease of $0.9 million due to the reduction in workforce and a reduction of $0.2 million in patent expense.

Interest Income. Interest income decreased by $7,000 to $52,000 for the year ended December 31, 2017 from $59,000 for the year ended December 31, 2016. The decrease was due to lower cash balance in 2017, compared to prior year.

Interest Expense. Interest expense decreased by $1.0 million to $0 for the year ended December 31, 2017 from $1.0 million for the year ended December 31, 2016. The decrease in interest expense was due to the prepayment in full of the loan from Hercules Technology Growth Capital Inc., or Hercules, debt facility in September 2016.

Comparison of Years Ended December 31, 2016 and 2015

	Year Ended December 31,		Change
	2016	2015	$
		(in thousands)	
Operating expenses:			
Research and development	$ 6,579	$ 34,410	$ (27,831)
General and administrative	5,463	7,639	(2,176)
Total operating expenses	12,042	42,049	(30,007)
Loss from operations	(12,042)	(42,049)	30,007
Interest income	59	26	33
Interest expense	(1,036)	(1,134)	98
Net loss	$ (13,019)	$ (43,157)	$ 30,138

Research and Development Expenses. Research and development expenses decreased by $27.8 million to $6.6 million for the year ended December 31, 2016 from $34.4 million for the year ended December 31, 2015. Approximately $19.1 million of the decrease was due to the completion of our AbCONTOUR1 and AbCONTOUR2 U.S. Phase 3 clinical trials and $4.7 million of the decrease was due to the termination of the supplemental clinical trials. Approximately $1.1 million of the decrease was due to the reduction of consulting and other outside services, the elimination of the Corporate Advisory Board, as well as a decrease of $1.4 million due to a reduction in headcount in research and development. The remaining decrease of approximately $1.5 million was due to a reduction of regulatory, pre-clinical and CMC activities.

General and Administrative Expenses. General and administrative expenses decreased by $2.2 million to $5.5 million for the year ended December 31, 2016, from $7.6 million for the year ended December 31, 2015. The decrease of approximately $2.0 million was due to reduction in general legal fees, public and investor relation expenses, accounting fees and outside services expenses. The remaining decrease of $0.1 million was related to a reduction of headcount for the year ended December 31, 2016.

Interest Income. Interest income increased by $33,000 to $59,000 for the year ended December 31, 2016 from $26,000 for the year ended December 31, 2015. The increase resulted from higher rates of return during the year ended December 31, 2016.

Interest Expense. Interest expense decreased by $0.1 to $1 million for the year ended December 31, 2016 from $1.1 million for the year ended December 31, 2015. The decrease in interest expense was due to the prepayment in full of the Hercules debt facility in September 2016.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operating activities for the years ended December 31, 2017 and 2016. As of December 31, 2017, we had an accumulated deficit of $135.8 million. We anticipate that we will continue to incur net losses for the foreseeable future as we continue the development and potential commercialization of our product candidates and incur additional costs associated with being a public company.

At December 31, 2017, we had cash and cash equivalents of approximately $3.4 million.

On December 1, 2015, we entered into a Controlled Equity Offering Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or Canter Fitzgerald, as a sales agent, pursuant to which we may offer and sell from time to time, through Cantor Fitzgerald, shares of our common stock, par value $0.0001 per share, having an aggregate offering price of up to $20.0 million. As of December 31, 2017, no shares were issued pursuant to the Sales Agreement.

On January 17, 2018, immediately following the completion of the Merger, we issued, in the Financing, an aggregate of 1,614,289 shares of its common stock to certain accredited investors for an aggregate purchase price of $20 million pursuant to the terms of the Securities Purchase Agreement, dated October 17, 2017, by and among us, Private Evofem and certain investors.

Management believes that there is substantial doubt about our ability to continue as a going concern for twelve months after the date that the financial statements for the year ended December 31, 2017, are issued. We plan to continue to fund our operating expenses and capital expenditure requirements through additional debt or equity financing or through collaborations and partnerships with other entities. Debt or equity financing or collaborations and partnerships with other entities may not be available on a timely basis, on acceptable terms, or at all. In addition, the Company may be required to scale back or discontinue the advancement of product candidates, reduce headcount or reduce other operating expenses. This could have an adverse impact on the Company's ability to achieve certain of its planned objectives during 2018, and thus, materially harm the Company's business. Our ability to successfully transition to profitability will be dependent upon obtaining additional financing and achieving a level of product sales adequate to support our cost structure. We cannot be assured that we will ever be profitable or generate positive cash flow from operating activities.

Summary Statement of Cash Flows

The following table sets forth a summary of the net cash flow activity for each of the periods set forth below (in thousands):

	Year Ended December 31,		
	2017	2016	2015
Net cash used in operating activities	$ (8,201)	$ (16,255)	$ (37,911)
Net cash provided by (used in) investing activities	7	3	(226)
Net cash provided by (used in) financing activities	26	(10,019)	139
Net decrease in cash, cash equivalents, and restricted cash	$ (8,168)	$ (26,271)	$ (37,998)

Cash Flows from Operating Activities.

Net cash used in operating activities was $8.2 million, $16.3 million and $37.9 million for the years ended December 31, 2017, 2016 and 2015, respectively. The primary use of cash was to fund our operations related to the development of our product candidates in each of these periods.

Cash Flows from Investing Activities.

Net cash provided by investing activities was $7,000 and $3,000 for the years ended December 31, 2017 and December 31, 2016, respectively. Net cash used in investing activities was $226,000 for the year ended December 31, 2015. Cash provided by investing activities consisted of proceeds from the sale of equipment and furniture for the years ended December 31, 2017 and December 31, 2016. Cash used for investing activities consisted primarily of the purchase of equipment and furniture during the year ended December 31, 2015.

Cash Flows from Financing Activities.

Financing activities provided cash of $26,000 for the year ended December 31, 2017, from the issuance of common stock from the exercise of stock options.

Net cash used in financing activities was $10.0 million for the year ended December 31, 2016, primarily from the prepayment of debt of $9.5 million and principal payments on debt of $0.5 million.

Financing activities provided cash of $139,000 for the year ended December 31, 2015, was from the issuance of common stock from the exercise of stock options and employee stock purchase plan.

Operating and Capital Expenditure Requirements

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic partnerships and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic partnerships or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, our other technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market them ourselves.

Contractual obligations and commitments

The following table summarizes our contractual obligations at December 31, 2017:

	Payments Due by Period						
	Total	2018	2019	2020	2021	2022	More than 5 Years
Operating lease	$ 951,648	$ 410,848	$ 431,507	$ 109,293	$ —	$ —	$ —
Total	$ 951,648	$ 410,848	$ 431,507	$ 109,293	$ —	$ —	$ —

Off-balance sheet arrangements

We do not have any off-balance sheet arrangements (as defined by applicable regulations of the SEC) that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

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

As a "smaller reporting company", 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 report beginning on page F-1.

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

None.

Item 9A. Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of the end of the period covered by this Annual Report, or December 31, 2017, our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of December 31, 2017. 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.

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, 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 control. 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.

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, 2017, 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 year ended December 31, 2017, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The following table lists the names, ages as of February 9, 2018, and positions of the individuals who serve as our executive officers and directors:

Name	Age	Position(s)
Executive Officers		
Saundra Pelletier	48	Chief Executive Officer and Class III Director
Justin J. File	47	Chief Financial Officer
Kelly Culwell, M.D.	43	Chief Medical Officer
Russ Barrans	58	Chief Commercial Officer
Alexander A. Fitzpatrick, Esq.	51	General Counsel and Secretary
Non-Employee Directors		
Thomas Lynch	61	Class III Director, Chairman of the Board
Gillian Greer, Ph.D.	73	Class II Director
William Hall, Ph.D., M.D.	68	Class II Director
Kim P. Kamdar, Ph.D.	50	Class I Director
Tony O'Brien	54	Class II Director
Colin Rutherford	59	Class I Director

As noted above, our Board currently consists of seven members and is divided into three classes each serving staggered three-year terms until their respective successors are duly elected and qualified and their terms expire on a staggered basis as set forth below:

- Class I directors' terms expire at the annual meeting of our stockholders in 2018;
- Class II directors' terms expire at the annual meeting of stockholders in 2019; and
- Class III directors' terms expire at the annual meeting of stockholders in 2020.

Executive Officers

Saundra Pelletier

Saundra Pelletier has served as Private Evofem's President and CEO since February 2013 and has served as our President and Chief Executive Officer since January 2018. From 2009 to 2016, Ms. Pelletier was the founding Chief Executive Officer of WomenCare Global International, or WCGI, an international non-profit organization focused on empowering, educating and enabling women and girls to make informed choices about their health. Under her leadership, WCGI secured approximately $68 million in committed funding from major foundations and governmental organizations, and launched an innovative U.S. educational campaign with American actress/activist Jessica Biel. Since November 2017, Ms. Pelletier has served as the Chair of the board of WCG Cares, a non-profit California corporation whose 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 also served as WCG Cares' Chief Executive Officer and President from 2013 until November 2017. From 2005 to 2009, Ms. Pelletier was founder and Chief Executive Officer of Saundra Pelletier International, where she served as a management consultant, executive coach, entrepreneur, author and keynote speaker. From 2000 until 2004, Ms. Pelletier served as Vice President, Pharmaceuticals at Women First Healthcare, a specialty healthcare company dedicated to improving the health of women in mid-life, and

from 1992 until 2000 she was Global Franchise Leader (Vice President), with G.D. Searle, developer of the first female birth control pill and now a wholly owned trademark of Pfizer. In her capacity as a corporate vice president and global franchise leader, Ms. Pelletier managed a $250 million business unit, reorganized companies from the ground up, raised $40 million in capital, managed worldwide partnerships, negotiated cost saving licensing agreements, assessed country infrastructures, developed commercialization plans and hired full scale teams, including contract sales forces, to support women's healthcare initiatives. Ms. Pelletier has launched pharmaceutical brands worldwide and expanded indications on female healthcare brands in multiple countries. She has had oversight and accountability for Sales, Marketing, Operations, Medical Affairs, Regulatory Affairs, Manufacturing, Customer Service, Business Development and Strategic Partnerships. In 2015, Ms. Pelletier was profiled by the United Nations Foundation as a New Champion for Reproductive Health, and in 2014 was awarded the Athena Pinnacle Award for Life Sciences, recognizing extraordinary leadership in the life sciences. She is a published author and an international keynote speaker on the economic return of investing in women and has spoken at the Clinton Global Initiative, Women Deliver, the Harvard School of Public Health, the Cavendish Global Health Impact Forum at Biocom, the University of Virginia's Darden School of Business; and was the keynote speaker at the June 2016 Women's Global Health Symposium. Her accomplishments have been frequently profiled in various media, including The New York Times, Inc. Magazine, Cosmopolitan, Devex, Refinery 29, Bustle, CNN, NBC News, Glamour, Marie Claire, BBC Radio, Global Grind and Vogue. Ms. Pelletier is the Chair of the Women Deliver Board of Directors and she is on the board of directors of ClearFast. We believe Ms. Pelletier's service as our Chief Executive Officer and extensive professional experience in women's healthcare qualifies her to serve as a member of our board of directors.

Justin J. File

Justin J. File has served as Private Evofem's Chief Financial Officer since July 2015 and has served as our Chief Financial Officer since January 2018. He has approximately 25 years of diverse accounting and finance experience within a variety of both public and private biotechnology companies. Most recently, he provided executive financial and accounting oversight services to various biotechnology companies in San Diego, California, assisting in their initial public offering process and helping to establish and improve their accounting and finance operations as publicly-traded entities. Prior to this, Mr. File was Senior Director and Controller of Sequenom, Inc., a diagnostic company that developed and commercialized molecular diagnostics testing services for the women's health market. During that time, he served as Treasurer of their diagnostic subsidiary and providing assistance in the raise of over $400 million in combined equity and convertible note offerings. He also assisted in the commercial launch of four diagnostic tests in a two-year period, which included Sequenom's revolutionary noninvasive prenatal test for Down syndrome. Earlier in his career he worked for approximately ten years in public accounting, primarily with Arthur Andersen LLP, where he worked with a variety of clients assisting with attestation and periodic reporting requirements, public offerings and acquisitions. He graduated from Central Washington University with a Bachelor's of Science in Accounting and International Business and is a Certified Public Accountant (inactive).

Kelly Culwell, M.D.

Dr. Kelly Culwell is an Obstetrician/Gynecologist with over 16 years specializing in women's health and contraceptive research. She has served as our Chief Medical Officer since January 2018 and has served as Private Evofem's Chief Medical Officer since April 2015. Prior to joining Evofem Biosciences, she was a trainer Merck and maintained an academic clinical practice as the Director of Family Planning and Associate Clinical Professor at University of California, Davis. She previously served as a Medical Officer with the World Health Organization where she developed global guidelines for clinical practice and is widely published in peer reviewed journals. Dr. Culwell received a Bachelor's of Science from California Lutheran University, a Medical Doctorate from the University of California, Davis and a Masters of Public Health from Northwestern University. She completed her post-graduate training in Obstetrics and Gynecology at University of California San Diego and her Family Planning Fellowship at Northwestern University. Dr. Culwell maintains appointments as Volunteer Assistant Clinical Professor in the Departments of Obstetrics and Gynecology at the University of California, Davis and San Diego campuses. She is qualified as a Diplomat from the American Board of Obstetrics and Gynecology.

Russ Barrans

Russ Barrans has served as our Chief Commercial Officer since January 2018 and has served as Private Evofem's Chief Commercial Officer since 2016. Mr. Barrans has over 25 years in the women's healthcare pharmaceuticals and biotechnology space. As the Chief Commercial Officer, he is responsible for the commercial launch and lifecycle management of the Evofem Biosciences product portfolio, oversees manufacturing and supply chain, and provides executive leadership to the sales and marketing team. Prior to joining Evofem Biosciences, Mr. Barrans was the Senior Director of Women's Healthcare Marketing for TEVA Pharmaceuticals. With significant tenure in life sciences and pharmaceutical companies, he has held senior level positions at global and domestic companies including Bayer Healthcare and Wyeth Pfizer (formerly Wyeth), as well as, being Chief Executive Officer of FusionRx, a strategic consulting firm servicing biotech and pharmaceutical brands of which Russ was the founding partner. He has overseen directed the launch of over half a dozen brands worldwide including the launch of Mirena®, and Plan B One-Step® OTC. He graduated from California Coast University with a Bachelor's of Science in Business Administration and holds an MBA from California Coast University. Mr. Barrans is an Accredited Pharmaceutical Manufactures Representative of Canada in General Healthcare and Oncology, and has earned his certification as a Business Coach from Brian Tracy International.

Alexander A. Fitzpatrick, Esq.

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

Non-Employee Directors

Thomas Lynch

Mr. Lynch has served as the Chairman of the Board since January 2018 and served as the Chairman of the Board of Private Evofem from November 2015 until January 2018. Mr. Lynch also currently serves as Chairman of the Boards of Profectus Biosciences Inc. and Adherium Inc. and as a non-executive director of GW Pharmaceuticals where he serves as Chairman of both its remuneration and nomination committees. Mr. Lynch is also the non-executive chairman of the Ireland East Hospital Group and the Mater Misericordiae University Hospital, a non-profit charitable foundation providing acute hospital services to both public patients funded by the HSE (defined below) and private patients. Mr. Lynch serves on the board of a number of other privately held biotechnology companies. Mr. Lynch previously served as Chairman of ICON plc and was a member of its board for 22 years. Mr. Lynch has also worked in a variety of capacities in Amarin Corporation plc, Elan Corporation plc and Warner Chilcott plc. From 2001 to 2010, Mr. Lynch was a member of the Board of IDA Ireland (an Irish government investment agency). Mr. Lynch received his B.Sc. in Economics from Queen's University of Belfast in 1978, and qualified as a chartered accountant with KPMG in 1983 and served as a partner in that firm from 1990 to 1993. We believe Mr. Lynch is qualified to serve as a member of our board of directors because of his decades of business, operational and board of director experience with pharmaceutical and life sciences companies and because of his prior experience as Chairman of Private Evofem's board of directors.

Gillian Greer, Ph.D.

Dr. Gillian Greer has served as a member of our Board since January 2018 and most recently served, from 2011 – 2017, as the Chief Executive Officer of Volunteer Service Abroad, a New Zealand non-profit organization that sends volunteers to work with partner organizations in the Pacific and Asia region. She is currently Chief Executive Officer of the National Council of Women of New Zealand. From 2006-2011 Dr. Greer served as Director General of the International Planned Parenthood Federation, or IPPF, the world's largest international sexual and reproductive health non-profit organization, working in 172 countries providing advocacy, education and sexual and reproductive health services, including maternal health, HIV/AIDS, family planning and adolescent health. During this time she also worked closely with UN agencies and governments to advocate for investment in health and human rights and served on the Board of ICON plc. Prior to her work with IPPF, Dr. Greer served as Executive Director of the Family Planning Association of New Zealand where she was involved in international and regional advocacy training and initiatives, including chairing the Asia Pacific Alliance, and was made a Member of the New Zealand Order of Merit for services to family planning in 2005. From 1996-1998 Dr. Greer was Assistant Vice Chancellor Equity and Human Resources, Victoria University of Wellington, New Zealand. Her early career was in education at secondary and tertiary levels. Throughout her career Dr. Greer has demonstrated an ongoing commitment to health, education, sustainable development, women's empowerment, and human rights. She is passionate about strengthening civil society and building high performing organizations that are effective, ethical, and accountable and can clearly demonstrate their impact. She has also served in a governance capacity for a number of charities and a university Council, as well as advisory panels to New Zealand Ministers of Foreign Affairs and Trade. Dr. Greer was made a Commander of the British Empire (CBE) for services to international health and women's rights in 2012. She continues to be in high demand as a speaker, facilitator, chairperson, and board member. Dr. Greer holds a B.A. in English from the University of Auckland and a Ph.D. in New Zealand Literature from the Victoria University of Wellington. We believe Dr. Greer's long experience as an executive officer and board member of organizations dedicated to women's sexual health qualifies her to serve as a member of our board of directors.

William Hall, Ph.D., M.D.

Professor Hall has served as a member of our Board since January 2018 and is a renowned expert in infectious diseases and virology. He currently serves as Distinguished Professor in Hokkaido University in Japan and is Professor Emeritus of Medical Microbiology and the Centre for Research in Infectious Diseases at University College Dublin's, or UCD, School of Medicine and Medical Science. He is also Executive Chairman of the UCD National Virus Reference Laboratory and is a Consultant Microbiologist at St. Vincent's University Hospital Dublin. Professor Hall also serves as a consultant to the Minister of Heath and Children in the Republic of Ireland, providing input on a range of topics including influenza pandemic preparedness and bioterrorism. Prior to his tenure at UCD, Professor Hall was Professor and Head of the Laboratory of Medical Virology, Senior Physician and Director of the Clinical Research Centre at the Rockefeller University

in New York. He previously served as an Assistant and Associate Professor of Medicine at Cornell University. Professor Hall is a Board member of The Atlantic Philanthropies and is a co-founder of the Global Virus Network. Professor Hall has served as a non-executive director of ICON plc, based in Dublin, Ireland, since February 2013. He is a member of its audit committee and the compensation committee and is chair of the nominating and governance committee. Professor Hall holds a B.Sc.(Honors.) in Biochemistry and a Ph.D. in Biochemistry/Virology from Queen's University Belfast. He received his M.D. from Cornell University Medical College, New York and a Diploma of Tropical Medicine and Hygiene from the London School of Hygiene and Tropical Medicine in London, England. We believe Dr. Hall is qualified to serve on our board of directors based on his extensive experience working in infectious diseases and virology and prior experiences on other board of directors.

Kim P. Kamdar, Ph.D.

Dr. Kamdar has served as a member of our Board since April 2011. Dr. Kamdar is a Managing Member of Domain Associates, LLC, a life sciences venture capital firm, which she joined in 2005.

Dr. Kamdar is currently Chair of the board of directors of Obalon (Nasdaq: OBLN). She also serves on the board of directors of several private companies including Epic Sciences, Omniome, ROX Medical, Sera Prognostics and Singular Genomics. Dr. Kamdar is founder and Chairman of the board of directors, and was formerly acting CEO of Truvian Sciences, a consumer-focused health and wellness company. Past investments include Ariosa (acquired by Roche), Corthera (acquired by Novartis), BiPar Sciences (acquired by Sanofi-Aventis) and Achaogen (Nasdaq: AKAO).

Formerly, Dr. Kamdar was a Kauffman Fellow with MPM Capital. Prior to joining MPM, she was a research director at Novartis, where she built and led a research team that focused on the biology, genetics and genomics of model organisms. Dr. Kamdar is the author of ten papers as well as the inventor on seven patents. She received her B.A. from Northwestern University and her Ph.D. in biochemistry and genetics from Emory University. Dr. Kamdar serves as an advisory board member of Dr. Eric Topol's NIH supported Clinical and Translational Science Award for Scripps Medicine and is also on the non-profit board for Access Youth Academy, an organization that is transforming the lives of underserved youth through academic enrichment, health and wellness, social responsibility and leadership through squash. We believe Dr. Kamdar is qualified to serve on our board of directors based on her extensive experience working and serving on the boards of directors of life sciences companies and her experience working in the venture capital industry.

Tony O'Brien

Mr. O'Brien has served as a member of our board of directors since January 2018 and as the Director General of Ireland's Health Service Executive, or HSE, an organization responsible for the provision of health and personal social services for the residents of Ireland, since July 2012. Prior to his role as Director General, Mr. O'Brien was the Chief Operating Officer of the Department of Health's Special Delivery Unit and a member of the Department's Management Board. From May 2011 to September 2011 Mr. O'Brien was Director of Clinical Strategy and Programs in the HSE. From December 2011 until October 2012 he held the post of Chief Executive Officer of the National Treatment Purchase Fund. He served as Chief Advisor to the HSE on the implementation of the National Cancer Control Strategy, Project Director for the National Plan for Radiation Oncology and is a former Chairman of the National Cancer Registry Board. He was the founding Chief Executive Officer of the National Cancer Screening Service, Director of BreastCheck, CervicalCheck and an Associate and Interim Director of the National Cancer Control Programme. Prior to joining the HSE, Mr. O'Brien served as Chief Executive of the Irish Family Planning Association and as the Chief Executive of the UK Family Planning Association. Mr. O'Brien is a Council Member of the Irish Management Institute, a Member of the Healthy Ireland Council and a Member of the Institute of Directors in Ireland. Mr. O'Brien holds a Master of Sciences in Management Practice from Trinity College, University of Dublin. He is Adjunct Ass. Professor in Health Strategy and Management at Trinity College Dublin. He is also Vice President of the Institute of Public Administration and a Council Member of the Irish Management Institute. In 2016, he was admitted as a Chartered Director by the Institute of Directors. We believe Mr. O'Brien's extensive experience as an executive and member of the boards of directors for healthcare and life sciences companies qualifies him to be a member of our board of directors.

Colin Rutherford

Mr. Rutherford has served as a member of our board of directors since January 2018 and served as a member of the board of directors of Private Evofem from November 2015 until January 2018. He currently serves as the audit committee chairman of Mitchells & Butlers' Plc., and Renaissance Services SAOG. Mr. Rutherford is also serving as the Chairman of Brookgate, Limited, TPG and Teachers Media Group Plc. Prior to this, Mr. Rutherford worked for European Healthcare Group as Non-Executive Chairman from 2012 to 2014 until its acquisition by two hedge funds. From 2008 to 2011, Mr. Rutherford also worked as Chief Executive Officer and Chairman to restructure MAM Funds Plc that had significant debt. From 2003 to 2006, Mr. Rutherford was Chairman and oversaw the restructuring of Noble House Group Limited which was sold in 2006. In 2002, as Chairman and Chief Executive Officer, he led the restructuring and sale of Euro-Sales Plc. with 18 offices across Europe. While a director of Private Evofem, Mr. Rutherford was Chair of its audit committee and a member of its remuneration committee. Mr. Rutherford graduated in Accountancy and Finance from Heriot Watt University and qualified as a chartered accountant with Touche Ross in 1984. Mr. Rutherford is a Harvard Business School Alumni. We believe that Mr. Rutherford is qualified to

serve as a member of our board of directors because of his prior experience as a member of Private Evofem's board of directors and his many years of finance and operations leadership experience in the healthcare and life sciences industries.

Audit Committee and Financial Expert

The audit committee of our board was established by our board of directors in accordance with Section 3(a)(58)(A) of the Exchange Act. The current members of our audit committee are Mr. Rutherford, Dr. Kamdar and Mr. O'Brien. Mr. Rutherford serves as Chairperson of the committee. Our board of directors has determined that all of the members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. Our board of directors has determined that Mr. Rutherford is an audit committee financial expert as defined under the applicable rules of the SEC and has the requisite financial sophistication as defined under the applicable rules and regulations of Nasdaq. Our board of directors has determined that all of the members of our audit committee are independent directors as defined under the applicable rules and regulations of the SEC and Nasdaq.

Stockholder Recommendations for Director Nominees

In nominating candidates for election as a director, the Nominating and Corporate Governance Committee will consider a reasonable number of candidates for director recommended by a single stockholder who has held over 0.1% of our common stock for over one year and who satisfies the notice, information and consent provisions set forth in our Bylaws and corporate governance guidelines. Stockholders who wish to recommend a candidate may do so by writing to the Nominating and Corporate Governance Committee in care of the Corporate Secretary, Evofem Biosciences, Inc., 12400 High Bluff Drive, Suite 600, San Diego, CA 92130. Our amended and restated bylaws state the procedures for a stockholder to bring a stockholder proposal or nominate an individual to serve as a director of the Board. Our amended and restated bylaws provide that advance notice of a stockholder's proposal or nomination of an individual to serve as a director must be delivered to our Corporate Secretary at our principal executive offices not earlier than the one hundred twentieth (120th) day, nor later than the close of business on the ninetieth (90th) day, prior to the anniversary of the previous year's annual meeting of stockholders. However, our amended and restated bylaws also provide that in the event that the date of the annual meeting is advanced by more than thirty (30) days, or delayed by more than seventy (70) days, from the anniversary date of the preceding year's annual meeting, notice must be received no earlier than the one hundred twentieth (120th) day prior to such annual meeting and not later than the close of business on the later of the ninetieth (90th) day prior to such annual meeting or, if the first public announcement of the date of such annual meeting is less than one-hundred (100) days prior to the date of such annual meeting, the tenth (10th) day following the day on which the public announcement of the date of such meeting is first made. In addition to meeting the advance notice provisions mentioned above, the stockholder in its notice must provide the information required by our Bylaws to bring a stockholder proposal or nominate an individual to serve as a director of the Board.

A copy of the full text of the provisions of our Bylaws dealing with stockholder nominations and proposals is available to stockholders from our Corporate Secretary upon written request. The Nominating and Corporate Governance Committee will use the same evaluation process for director nominees recommended by stockholders as it uses for other director nominees.

Section 16 (a) Beneficial Ownership Reporting Compliance

Under Section 16(a) of the Exchange Act and SEC rules, the Company's directors, executive officers and beneficial owners of more than 10% of any class of equity security are required to file periodic reports of their ownership, and changes in that ownership, with the SEC. Based solely on its review of copies of reports provided to the Company pursuant to Rule 16a-3(e) of the Exchange Act and representations of such reporting persons, the Company believes that during fiscal year 2017, such SEC filing requirements were satisfied.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees, which is available on our website at www.evofem.com. The Code of Business Conduct and Ethics contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics and is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Item 11. Executive Compensation.

Our named executive officers, which consisted of our principal executive officer and our only other executive officer were:

- Susan A. Knudson, Former Principal Executive Officer and Chief Financial Officer; and
- Maria Feldman, Former Vice President, Clinical Operations, Regulatory Affairs and Quality Assurance

We have also included the principal executive officer and the two most highly compensated officers of Private Evofem during 2017 below:

- Saundra Pelletier, Chief Executive Officer[(1)]
- Justin J. File, Chief Financial Officer[(1)]
- Kelly Culwell, M.D., Chief Medical Officer[(1)]

(1) Pursuant to the closing of the Merger as described within this Form 10-K, this individual became an executive officer of the Company in January 2018.

Summary Compensation Table

The following table summarizes information concerning the compensation awarded to, earned by, or paid for services rendered in all capacities by our named executive officers and the principal executive officer and two most highly compensated officers of Private Evofem during the years ended December 31, 2017 and 2016. As our management team transitions from operating a private company to operating a publicly traded company, our Compensation Committee will evaluate our compensation practices, philosophy and arrangements to ensure alignment with our structure and the roles of the executives as they relate to managing and oversight of a public company. The compensation described in this table does not include medical or other benefits that are available generally to all our salaried employees:

Name and Principal Position	Year Ended December 31,	Salary ($)	Bonus ($)	Option Awards[1][2] ($)	All Other Compensation ($)	Total ($)
Susan A. Knudson	2017	317,000	190,200	130,102 [3]	1,010 [4]	638,312
Former Chief Financial Officer	2016	281,197	59,052	19,170 [5]	1,010 [4]	360,429
Maria Feldman	2017	273,980	136,995	197,794 [6]	539 [7]	609,308
Former Vice President, Clinical Research, Operations, Regulatory and Quality	2016	243,000	46,550	10,650 [8]	539 [7]	300,739
Saundra Pelletier	2017	731,364	922,700	—	810 [9]	1,654,874
Chief Executive Officer	2016	588,527	201,562	1,477,691 [10]	1,621 [9]	2,269,401
Justin J. File	2017	562,373	306,750	—	810 [11]	869,933
Chief Financial Officer	2016	478,113	163,281	822,510 [12]	1,185 [11]	1,465,089
Kelly Culwell, M.D.	2017	428,650	123,600	—	540 [13]	552,790
Chief Medical Officer	2016	425,275	90,000	274,170 [14]	675 [13]	790,120

(1) Amounts listed in this column for Ms. Knudson and Ms. Feldman represent the aggregate fair value of the option awards computed as of the grant date of each option award in accordance with Financial Accounting Standards Board Accounting Standards Codification No. 718, Compensation-Stock Compensation, or FASB ASC Topic 718, rather than amounts paid to or realized by the named individual. There can be no assurance that options will be exercised (in which case no value will be realized by the individual) or that the value on exercise will approximate the fair value as computed in accordance with FASB ASC Topic 718. The assumptions used in the valuation of these awards are set forth in Note 6 to our financial statements for the year ended December 31, 2017, which are included in this Annual Report.

(2) Amounts listed in this column for Ms. Pelletier, Mr. File and Dr. Culwell represent the aggregate fair value of Private Evofem option awards computed as of the grant date of each option award in accordance with FASB ASC Topic 718, rather than amounts paid to or realized by the named individual. The fair value of the stock-based payments for these awards was estimated on the date of grant using the Black-Scholes-Merton option-pricing model based on the following weighted-average assumptions for the year ended December 31, 2016:

Expected volatility	89.2%
Risk-free interest rate	1.3%
Expected dividend yield	0.0%
Expected term (years)	5.6

There can be no assurance that options will be exercised (in which case no value will be realized by the individual) or that the value on exercise will approximate the fair value as computed in accordance with FASB ASC Topic 718.

(3) In March 2017, Ms. Knudson received options to purchase up to 16,666 shares of the Company's common stock with a performance-based vesting schedule, all of which were vested by December 31, 2017. In June 2017, Ms. Knudson received options to purchase up to 10,832 shares of the Company's common stock with a two-year vesting schedule.

(4) All Other Compensation for Ms. Knudson in 2017 and 2016 includes premiums paid for group term life insurance of $1,010.

(5) In February 2016, Ms. Knudson received an option to purchase up to 7,500 shares of the Company's common stock with a four-year vesting schedule.

(6) In March 2017, Ms. Feldman received options to purchase up to 15,000 shares of the Company's common stock with a performance-based vesting schedule, all of which were vested on December 31, 2017. In June 2017, Ms. Feldman received options to purchase up to 23,332 shares of the Company's common stock with a two-year vesting schedule.

(7) All Other Compensation for Ms. Feldman in 2017 and 2016 includes premiums paid for group term life insurance of $539.

(8) In February 2016, Ms. Feldman received an option to purchase up to 4,166 shares of the Company's common stock with a four-year vesting schedule.

(9) All Other Compensation for Ms. Pelletier in 2017 and 2016 includes premiums paid for group term life insurance of $810 and $1,621, respectively.

(10) On September 28, 2016, Ms. Pelletier received (i) options to purchase up to 750,000 and 500,000 shares of Private Evofem common stock with a three-year vesting schedule and a four-year vesting schedule, respectively, pursuant to which the unvested shares under each option grant agreement will become fully vested and exercisable upon a "change in control" (as defined in the agreements) and (ii) a fully vested option to purchase up to 389,404 shares of Private Evofem common stock. Each such option has been exchanged for an option to purchase shares of the Company's common stock, equal to approximately 0.1540 multiplied by the number of Private Evofem common stock issuable upon the exercise of the option to purchase shares of Private Evofem's common stock, on the same terms, in accordance with the terms of the Merger Agreement.

(11) All Other Compensation for Mr. File in 2017 and 2016 includes premiums paid for group term life insurance of $810 and $1,185, respectively.

(12) On September 28, 2016, Mr. File received options to purchase up to 500,000 and 400,000 shares of Private Evofem common stock with a three-year vesting schedule and a four-year vesting schedule, respectively, pursuant to which the unvested shares under each option grant agreement will become fully vested and exercisable upon a "change in control" (as defined in the agreements). Each such option has been exchanged for an option to purchase shares of the Company's common stock, equal to approximately 0.1540 multiplied by the number of Private Evofem common stock issuable upon the exercise of the option to purchase shares of Private Evofem's common stock, on the same terms, in accordance with the terms of the Merger Agreement.

(13) All Other Compensation for Dr. Culwell in 2017 and 2016 includes premiums paid for group term life insurance of $540 and $675, respectively.

(14) On September 28, 2016, Dr. Culwell received an option to purchase up to 300,000 shares of Private Evofem common stock with a three-year vesting schedule, pursuant to which the unvested shares under such option grant agreement will become fully vested and exercisable upon a "change in control" (as defined in the agreement), and such option has been exchanged for an option to purchase shares of the Company's common stock, equal to approximately 0.1540 multiplied by the number of Private Evofem common stock issuable upon the exercise of the option to purchase shares of Private Evofem's common stock, on the same terms, in accordance with the terms of the Merger Agreement.

Employment, Severance and Separation Agreements

Susan A. Knudson Employment Agreement and Golden Parachute Compensation

On October 15, 2014, the Company entered into an executive employment agreement with Ms. Knudson which provided that, if Ms. Knudson was terminated by us without cause or if she resigned for good reason, she was entitled to a severance package consisting of (a) a payment equal to six months of her then in effect base salary payable in accordance with our regular payroll cycle beginning on the first regular payday occurring 60 days following the termination date and (b) payment by us of the premiums required to continue Ms. Knudson's group health coverage for a period of six months following termination.

On January 31, 2018, after the Merger, Ms. Knudson's employment with us was terminated, pursuant to the Separation and Release Agreement entered into by the Company and Ms. Knudson on January 17, 2018, which provided that in the event that Ms. Knudson was terminated within 12 months following a change in control, she was entitled to a severance package consisting of (a) a lump sum payment equal to $317,000, or 12 months of her then in effect base salary, (b) payment by us of the premiums required to continue Ms. Knudson's group health coverage for a period of 12 months following termination, valued at $24,939 and (c) full acceleration of all unvested equity awards under the 2007 Stock Plan and 2014 Plan, which had an intrinsic value of $11,344. Ms. Knudson was also entitled to receive a $150,000 cash bonus in connection with the consummation of the Merger, as approved the board of directors in July 2017. The exercise period for all options held by Ms. Knudson was extended to the earlier of (i) the expiration of the stock option pursuant to its terms or (ii) March 31, 2019.

Maria Feldman Compensation and Severance and Separation Agreement

On February 28, 2014, the Company entered into an employment agreement with Maria Feldman and on February 15, 2018, Ms. Feldman's employment with us was terminated. Pursuant to the Separation and Release Agreement entered into by the Company and Ms. Feldman on February 6, 2018, upon Ms. Feldman's termination without cause following the Merger, which constituted a change of control, she was entitled to a severance package consisting of (a) a lump sum payment equal to $136,990, or six (6) months of her then in effect base salary, (b) payment by us of the premiums required to continue Ms. Feldman's group health coverage for a period of six (6) months following termination, valued at $8,326 and (c) full acceleration of all unvested equity awards under the 2007 Stock Plan and 2014 Plan, which had an intrinsic value of $2,575. The exercise period for all options held by Ms. Feldman was extended to the earlier of (i) the expiration of the stock option pursuant to its terms or (ii) March 31, 2019.

Pelletier, File and Culwell Private Evofem Employment and Severance Arrangements

Saundra Pelletier

Ms. Pelletier's employment with the Company is at-will and she is party to a Severance Agreement, dated April 27, 2015, by and between Private Evofem and Ms. Pelletier, or the Pelletier Severance Agreement. Ms. Pelletier is also eligible to participate in the Company's 401K plan, to receive paid vacation each year and to participate in other benefit plans and programs generally available to the Company's employees.

Pursuant to the terms of the Pelletier Severance Agreement, if Ms. Pelletier's employment is terminated other than for "Cause" or "Good Reason" (as defined in the Pelletier Severance Agreement), death, or disability, then, subject to Ms. Pelletier signing and not revoking a separation and release of claims agreement, Ms. Pelletier would be entitled to receive the following, regardless of whether the termination occurs within or outside the change of control period:

- an amount equal to Ms. Pelletier's Highest Monthly Salary (as defined in the Pelletier Severance Agreement) with such amount payable in each month following the date of termination of employment for a period of 12 months.
- payments for the employer share of any applicable COBRA premiums for a period of 12 months following the date of termination.

Justin J. File

Mr. File's employment with the Company is at-will and he is party to a Severance Agreement, dated November 16, 2015, by and between Private Evofem and Mr. File, or the File Severance Agreement. Mr. File is also eligible to participate in the Company's 401K plan, to receive paid vacation each year and to participate in other benefit plans and programs generally available to the Company's employees.

Pursuant to the terms of the File Severance Agreement, if Mr. File's employment is terminated other than for "Cause" or "Good Reason" (as defined in the File Severance Agreement), death, or disability, then, subject to Mr. File signing and not revoking a separation and release of claims agreement, Mr. File would be entitled to receive the following, regardless of whether the termination occurs within or outside the change of control period:

- an amount equal to Mr. File's Highest Monthly Salary (as defined in the File Severance Agreement) with such amount payable in each month following the date of termination of employment for a period of 12 months.
- payments for the employer share of any applicable COBRA premiums for a period of 12 months following the date of termination.

Kelly Culwell, M.D.

Dr. Culwell's employment with the Company is at-will. Dr. Culwell is eligible to participate in the Company's 401K plan, to receive paid vacation each year and to participate in other benefit plans and programs generally available to the Company's employees.

The Merger did not constitute a "change in control" for the purposes of the above described Private Evofem employment arrangements. The Private Evofem offer letters and severance agreements described above are currently in effect and will remain in effect until amended by our board of directors.

Outstanding Equity Awards at December 31, 2017

The following table presents the outstanding equity awards held by our named executive officers as of December 31, 2017, and includes outstanding equity awards held by the principal executive officer and the two most highly compensated executive officers of Private Evofem as of December 31, 2017, giving retroactive effect to the Merger.

	Option Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable[1]	Number of Securities Underlying Unexercised Options Unexercisable[2]	Option Exercise price	Option Expiration date
Susan A. Knudson	5,119[3]	—	$7.32	2/11/2020
	5,544[3]	—	$8.05	2/6/2024
	4,160[3]	—	$27.45	7/17/2024
	2,454[3]	—	$40.74	2/10/2025
	5,146[3]	—	$40.74	2/10/2025
	7,500[3]	—	$5.82	2/4/2026
	11,655[3]	—	$8.58	3/2/2027
	5,011[3]	—	$8.58	3/2/2027
	5,249[3]	—	$13.62	6/22/2027
	5,583[3]	—	$13.62	6/22/2027
Maria Feldman	3,583[3]	—	$8.05	3/10/2024
	2,454[3]	—	$40.74	2/10/2025
	545[3]	—	$40.74	2/10/2025
	4,166[3]	—	$5.82	2/4/2026
	11,655[3]	—	$8.58	3/2/2027
	3,345[3]	—	$8.58	3/2/2027
	4,724[3]	—	$13.62	3/22/2027
	18,608[3]	—	$13.62	3/22/2027
Saundra Pelletier	6,719[4]	—	$79.87	6/3/2023
	9,994[5]	—	$46.36	9/28/2026
	10,821[6]	8,428[6]	$46.36	9/28/2026
	4,009[7]	8,824[7]	$46.36	9/28/2026
Justin J. File	7,209[8]	5,624[8]	$46.36	9/28/2026
	3,205[9]	7,061[9]	$46.36	9/28/2026
Kelly Culwell, M.D.	4,322[10]	3,377[10]	$46.36	9/28/2016

(1) The number of shares under the option that have vested.

(2) The number of shares under the option that have not vested.

(3) Pursuant to the 2014 Plan, all options issued under the 2014 Plan are immediately exercisable regardless of whether they have vested.

(4) The share numbers and exercise prices reflected are those of options issued to the executive upon completion of the Merger in January 2018. These options were issued upon completion of the Merger in exchange for options to purchase 261,784 shares of Private Evofem common stock, which were fully vested upon grant, at an exercise price of $2.05 per share awarded to the executive by Private Evofem in 2013.

(5) The share numbers and exercise prices reflected are those of options issued to the executive upon completion of the Merger in January 2018. These options were issued upon completion of the Merger in exchange for options to purchase 389,404 shares of Private Evofem common stock, which were fully vested upon grant, at an exercise price of $1.19 per share awarded to the executive by Private Evofem in 2016.

(6) The share numbers and exercise prices reflected are those of options issued to the executive upon completion of the Merger in January 2018. These options were issued upon completion of the Merger in exchange for options to purchase 750,000 shares of Private Evofem common stock at an exercise price of $1.19 per share awarded to the executive by Private Evofem in 2016. Twenty-five percent of the award vested upon grant and the remaining 75% vests monthly over three years.

(7) The share numbers and exercise prices reflected are those of options issued to the executive upon completion of the Merger in January 2018. These options were issued upon completion of the Merger in exchange for options to purchase 500,000 shares of Private Evofem common stock, which vests over four years, with 25% vesting after one year and the remaining vesting monthly, at an exercise price of $1.19 per share awarded to the executive by Private Evofem in 2016.

(8) The share numbers and exercise prices reflected are those of options issued to the executive upon completion of the Merger in January 2018. These options were issued upon completion of the Merger in exchange for options to purchase 500,000 shares of Private Evofem common stock at an exercise price of $1.19 per share awarded to the executive by Private Evofem in 2016. Twenty-five percent of the award vested upon grant and the remaining 75% vests monthly over three years.

(9) The share numbers and exercise prices reflected are those of options issued to the executive upon completion of the Merger in January 2018. These options were issued upon completion of the Merger in exchange for options to purchase 400,000 shares of Private Evofem common stock, which vests over four years, with 25% vesting after one year and the remaining vesting monthly, at an exercise price of $1.19 per share awarded to the executive by Private Evofem in 2016.

(10) The share numbers and exercise prices reflected are those of options issued to the executive upon completion of the Merger in January 2018. These options were issued upon completion of the Merger in exchange for options to purchase 300,000 shares of Private Evofem Common stock at an exercise price of $1.19 per share awarded to the executive by Private Evofem in 2016. Twenty-five percent of the award vested upon grant and the remaining 75% vests monthly over three years.

Employee Benefit and Equity Incentive Plans

Stock Compensation Plans

The Company initially adopted the 2007 Plan in March 2007, under which 211,893 shares of common stock were reserved for issuance to employees, non-employee directors, and consultants of the Company. The Company ceased granting any additional awards under our 2007 Plan, and presently grants equity awards under the 2014 Plan Equity Incentive Plan, or 2014 Plan.

Our standard option awards provide for a "double trigger" acceleration of vesting upon certain terminations occurring within eighteen months following a termination of service after a change of control or similar transaction.

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

A total of 166,666 shares of our common stock was initially authorized and reserved for issuance under the 2014 Plan. This reserve will automatically increase on each January 1 through 2024, by an amount equal to the smaller of:

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

As of February 9, 2018, a total of 458,586 shares of our common stock were reserved and available for issuance under the 2014 Plan.

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

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

The 2014 Plan authorizes the Compensation Committee, without further stockholder approval, to provide for the cancellation of stock options or stock appreciation rights with exercise prices in excess of the fair market value of the underlying shares of common stock on the date of grant in exchange for new options or other equity awards with exercise prices equal to the fair market value of the underlying common stock on the date of grant or a cash payment.

In the event of a change in control as described in the 2014 Plan, the acquiring or successor entity may assume or continue all or any awards outstanding under the 2014 Plan or substitute substantially equivalent awards. The Compensation Committee may provide for the acceleration of vesting of any or all outstanding awards upon such terms and to such extent as it determines, except that the vesting of all awards held by members of the board of directors who are not employees will automatically be accelerated in full. Any awards that are not assumed, continued, or substituted for in connection with a change in control or are not exercised or settled prior to the change in control will terminate effective as of the time of the change in control. Notwithstanding the foregoing, except as otherwise provided in an award agreement governing any award, as determined by the Compensation Committee, any award that is not assumed, continued, or substituted for in connection with a change in control shall, subject to the provisions of applicable law, become fully vested and exercisable and/or settleable immediately prior to, but conditioned upon, the consummation of the change in control. The 2014 Plan also authorizes the Compensation Committee, in its discretion and without the consent of any participant, to cancel each or any outstanding award denominated in shares upon a change in control in exchange for a payment to the participant with respect to each share subject to the cancelled award of an amount equal

to the excess of the consideration to be paid per share of common stock in the change in control transaction over the exercise price per share, if any, under the award. The vesting schedules of all outstanding options of the Company were fully accelerated in connection with the Merger and termination of employment or service arrangement with the Company.

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

Private Evofem Equity Incentive Plan

The Private Evofem Equity Incentive Plan was assumed by the Company in connection with the Merger and shares of Private Evofem common stock issuable pursuant to options previously granted under the Private Evofem Equity Incentive Plan became options to purchase our common stock upon completion of the Merger. No new awards may be granted under the Private Evofem Equity Incentive Plan. As of February 9, 2018, a total of 159,325 shares of our common stock were reserved for issuance upon the exercise of outstanding options under the Private Evofem Equity Incentive Plan.

Perquisites, Health and Retirement Benefits

Health, Welfare and Retirement Benefits

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

Director Compensation

The following table sets forth the compensation (cash and equity) received by our non-employee directors and the Private Evofem non-employee directors during the year ended December 31, 2017. Ms. Demski, Mr. Gorbachev, and Mr. Nugent resigned as members of our board of directors on January 17, 2018, in connection with the Merger.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[1][2]	All other Compensation ($)	Totals ($)
Kim P. Kamdar, Ph.D.	67,500	68,853	—	136,353
Maxim Gorbachev	43,500	11,683	—	55,183
Martha J. Demski	58,500	68,853	—	127,353
Jeffrey M. Nugent	52,500	68,853	—	121,353
Thomas Lynch[3][4]	60,000	—	640,000	700,000
Colin Rutherford[3]	65,402	24,891	—	90,293

(1) With respect to awards granted to Dr. Kamdar, Mr. Gorbachev, Ms. Demski and Mr. Nugent, amounts listed in this column represent the aggregate fair value of the option awards computed as of the grant date of each option award in accordance with FASB ASC Topic 718, rather than amounts paid to or realized by the named individual. There can be no assurance that options will be exercised (in which case no value will be realized by the individual) or that the value on exercise will approximate the fair value as computed in accordance with FASB ASC Topic 718. The assumptions used in the valuation of these awards are set forth in Note 6 to our financial statements for the year ended December 31, 2017, which are included in this Annual Report.

(2) With respect to an award granted to Mr. Rutherford, amounts listed in this column present the aggregate fair value of the Private Evofem option awards on the issuance date of these awards in accordance with FASB ASC Topic 718, rather than amounts paid to or realized by Mr. Rutherford. The fair value of the stock-based payments for Mr. Rutherford's award was estimated on the date of grant using the Black-Scholes-Merton option-pricing model based on the following weighted-average assumptions for the years ended December 31, 2017:

Expected volatility	91.2 %
Risk-free interest rate	2.2 %
Expected dividend yield	0.0 %
Expected term (years)	5.7

There can be no assurance that options will be exercised (in which case no value will be realized by the individual) or that the value on exercise will approximate the fair value as computed in accordance with FASB ASC Topic 718.

(3) Pursuant to the closing of the Merger as described within this Form 10-K, this individual became a director of the Company in January 2018, and the amounts reported for this individual, if applicable, represent equity awarded for services rendered to Private Evofem.

(4) Mr. Lynch's fees earned include $60,000 payable as board fees under his Consulting Agreement. Mr. Lynch's other compensation consists of $290,000 in consulting fees payable under his Consulting Agreement and a $350,000 bonus earned by Mr. Lynch in connection with consulting services provided during 2017. Mr. Lynch did not receive an equity award in 2017 in his capacity as a member of Private Evofem's board of directors.

In June 2015, our board of directors approved a compensation policy for our non-employee directors to adjust compensation based upon current market rates. This policy remained in effect for the fiscal year ended December 31, 2017, and provided the following compensation:

- Each non-employee director will receive an annual cash retainer in the amount of $35,000 per year.
- The Lead Independent Director will receive an additional annual cash retainer in the amount of $17,500 per year.
- The chairperson of the audit committee will receive additional annual cash compensation in the amount of $15,000 per year for such chairperson's service on the audit committee. Each non-chairperson member of the audit committee will receive additional annual cash compensation in the amount of $7,500 per year for such member's service on the audit committee.
- The chairperson of the compensation committee will receive additional annual cash compensation in the amount of $10,000 per year for such chairperson's service on the compensation committee. Each non-chairperson member of the compensation committee will receive additional annual cash compensation in the amount of $5,000 per year for such member's service on the compensation committee.
- The chairperson of the nominating and corporate governance committee will receive additional annual cash compensation in the amount of $7,500 per year for such chairperson's service on the nominating and corporate governance committee. Each non-chairperson member of the nominating and corporate governance committee will receive additional annual cash compensation in the amount of $3,500 per year for such member's service on the nominating and corporate governance committee.
- Each non-employee directors will receive a stock option grant with an initial grant equal to a cash value of $125,000 in shares of the Company's common stock upon a director's initial appointment or election to the board of directors, vesting quarterly over a three-year period and an annual stock option grant equal to a cash value of $65,000 in shares of the Company's common stock on the date of each annual stockholder's meeting thereafter, fully vesting in one year from the date of grant.

In January 2018, our Board amended our Non-Employee Director Compensation Policy to provide the compensation set forth below:

- Each non-employee director will receive an annual cash retainer in the amount of $50,000 per year.
- The Chairman of the Board will receive an additional annual cash retainer in the amount of $17,500 per year.
- The chairperson of the Audit Committee will receive additional annual cash compensation in the amount of $10,000 per year for such chairperson's service on the Audit Committee. Each non-chairperson member of the Audit Committee will receive additional annual cash compensation in the amount of $5,000 per year for such member's service on the Audit Committee.
- The chairperson of the Compensation Committee will receive additional annual cash compensation in the amount of $10,000 per year for such chairperson's service on the Compensation Committee. Each non-chairperson member of the Compensation Committee will receive additional annual cash compensation in the amount of $5,000 per year for such member's service on the Compensation Committee.
- The chairperson of the Nominating and Corporate Governance Committee will receive additional annual cash compensation in the amount of $7,500 per year for such chairperson's service on the Nominating and Corporate Governance Committee. Each non-chairperson member of the Nominating and Corporate Governance Committee will receive additional annual cash compensation in the amount of $3,500 per year for such member's service on the Nominating and Corporate Governance Committee. Each non-employee director will receive a stock option grant with an initial grant equal to a cash value of $180,000 in shares of our common stock upon a director's initial appointment or election to our board of directors, vesting quarterly over a three-year period and an annual stock option grant equal to a cash value of $90,000 in shares of our common stock on the date of each annual stockholder's meeting thereafter, beginning in 2018, fully vesting in one year from the date of grant.

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

Security Ownership of Certain Beneficial Owners

The following table sets forth certain information concerning the ownership of our common stock as of February 9, 2018, by (i) those persons who are known to us to be the beneficial owner(s) of more than five percent of our common stock, (ii) each of our directors and named executive officers and (iii) all of our directors and named executive officers as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership generally includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of February 9, 2018, through the exercise of stock options, warrants or other rights. Unless otherwise indicated in the footnotes to this table, we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned.

Name and Address of Beneficial Owner	Shares Beneficially Owned	Percent of Shares Beneficially Owned
5% Stockholders		
Entities affiliated with Invesco Asset Management Limited[(1)†] Perpetual Park Henley-on-Thames Oxfordshire, RG9 1HH, United Kingdom	7,037,498	39.6%
Entities affiliated with Woodford Investment Management Limited[(2)†] 9400 Garsington Road Oxford, OX4 2HN, United Kingdom	7,465,538	42.0%
Directors and Named Executive Officers		
Thomas Lynch[(3)]	3,850	*
Gillian Greer, Ph.D.	—	*
William Hall, Ph.D., M.D.	—	*
Kim Kamdar, Ph.D.[(4)]	551,560	3.1%
Tony O'Brien	—	*
Colin Rutherford[(5)]	770	*
Saundra Pelletier[(6)]	33,547	*
Justin J. File[(7)]	11,857	*
Kelly Culwell, M.D.[(8)]	4,802	*
Directors and executive officers as a group (12 Persons)[(9)]	612,290	3.4%

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

† Party to the Support Agreement, pursuant to which stockholder agreed to vote shares of Evofem stock owned by stockholder or over which stockholder has voting control in a certain manner.

(1) Includes (i) 3,519,366 shares of common stock held by Invesco Perpetual High Income Fund, or PHIF, and (ii) 3,518,132 shares of common stock held by Invesco Perpetual Income Fund, or PIF. Invesco Asset Management Limited acts as agent for and on behalf of PHIF and PIF, each as a discretionary managed client. Invesco Asset Management Limited has the power to direct the vote and disposition of the common stock held by the PHIF and PIF. Accordingly, Invesco Asset Management Limited may be deemed to be the beneficial owner of an aggregate amount of 7,037,498 shares of common stock, consisting of the shares held directly by PHIF and PIF, as described above.

(2) Includes (i) 5,620,952 shares of common stock held by CF Woodford Equity Income Fund, a sub fund of CF Woodford Investment Fund, or WEIF, (ii) 171,195 shares of common stock held by Omnibus Income & Growth Fund, a sub fund of Omnis Portfolio Investments ICVC, or OIGF, and (iii) 1,672,611 shares of common stock held by Woodford Patient Capital Trust Plc., or WPCT. Woodford Investment Management Limited acts as agent for and on behalf of WEIF, OIGF and WPCT, each as a discretionary managed client. Woodford Investment Management Limited has the power to direct the vote and disposition of the common stock held by WEIF, OIGF and WPCT. Accordingly, Woodford Investment Management Limited may be deemed to be the beneficial owner of an aggregate amount of 7,465,538 shares of common stock, consisting of the shares held by WEIF, OIGF and WPCT, as described above.

(3) Includes 3,850 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of February 9, 2018.

(4) Consists of (1) 515,273 shares of common stock owned by Domain Partners VII, L.P., (2) 8,004 shares of common stock owned by DP VII Associates, L.P, (3) 655 shares of common stock owned by Domain Associates, LLC and, with respect to Dr. Kamdar, options to purchase (4) 27,628 shares currently exercisable or exercisable within 60 days of February 9, 2018. One Palmer Square Associates VII,

LLC, or One Palmer Square, is the general partner of Domain Partners VII and DP VII Associates. Dr. Kamdar is a member of One Palmer Square. The managing members of One Palmer Square are James Blair, Jesse Treu, Brian Dovey, Brian Halak and Nicole Vitullo. Each of James Blair, Jesse Treu, Brian Dovey, Brian Halak and Nicole Vitullo share voting and investment power with respect to the securities held by Domain Partners VII and DP VII Associates. The managing members of Domain Associates are James Blair, Brian Dovey, Nicole Vitullo, Brian Halak and Dr. Kamdar. Each of James Blair, Brian Dovey, Nicole Vitullo, and Brian Halak share voting and investment power with respect to the securities held by Domain Associates. Each of James Blair, Jesse Treu, Brian Dovey, Brian Halak and Nicole Vitullo disclaims beneficial ownership of the securities held by Domain Partners VII and DP VII Associates except to the extent of his or her pecuniary interest therein, if any. Each of James Blair, Brian Dovey, Nicole Vitullo, Brian Halak, and Dr. Kamdar disclaims beneficial ownership of the securities held by Domain Associates except to the extent of his or her pecuniary interest therein, if any. Dr. Kamdar is a member of our board of directors.

(5) Includes 770 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of February 9, 2018.

(6) Includes 33,547 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of February 9, 2018.

(7) Includes 11,857 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of February 9, 2018.

(8) Includes 4,802 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of February 9, 2018.

(9) Includes (1) 515,273 shares of common stock owned by Domain Partners VII, L.P., but deemed to be beneficially owned by Dr. Kamdar, (2) 8,004 shares of common stock owned by DP VII Associates, L.P, but deemed to be beneficially owned by Dr. Kamdar, (3) 655 shares of common stock owned by Domain Associates, LLC, but deemed to be beneficially owned by Dr. Kamdar. Dr. Kamdar has a pecuniary interest in the securities held by Domain Associates as described in note 4, (ii) 88,358 shares of common stock that may be acquired by our current executive officers and directors pursuant to the exercise of stock options within 60 days of February 9, 2018.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides certain aggregate information with respect to all of our equity compensation plans in effect as of December 31, 2017:

Plan Category	Number of Securities to be Issued Upon Exercise of Awards (a)		Weighted Average Exercise Price of Outstanding Awards	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))	
Equity compensation plans approved by stockholders	407,058	(1)	$ 30.98	536,370	(2)
Total:	407,058		$ 30.98	536,370	

(1) Includes our 2007 Plan, 2014 Plan and the Private Evofem Equity Incentive Plan.

(2) As of December 31, 2017, an aggregate of 366,249 shares of common stock were available for grant under the 2014 Plan and an aggregate of 95,741 shares were available for issuance under 2014 ESPP, and an aggregate of 74,380 shares available for grant under the Private Evofem Equity Incentive Plan. The 2014 Plan contains a provision for an automatic increase in the number of shares available for grant each January 1st until and including January 1, 2024, subject to certain limitations, by a number of shares equal to the lesser of 4% of the number of shares of our common stock issued and outstanding on the immediately preceding December 31 or a number of shares set by our board of directors. The ESPP contains a provision for an automatic increase in the number of shares available for issuance under the ESPP each January 1st and including January 1, 2024, subject to certain limitations, by a number of shares equal to the lesser of 1% of our common stock issued and outstanding on the immediately preceding December 31 or a number of shares set by our board of directors.

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

Company Policy Regarding Related Party Transactions

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

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

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

Financing and the Merger

As discussed in Item 1 of this Annual Report, which is hereby incorporated by reference, we issued shares of our common stock to certain investors in Private Evofem, including funds affiliated with Invesco Asset Management, at a purchase price of $12.389355 per share in the Financing. In addition, we issued shares of our common stock and, with respect to funds affiliated with Woodford Investment Management, the Post-Merger Warrants. As of February 9, 2018, and upon the closing of the Merger, the funds affiliated with Invesco Asset Management and the funds affiliated with Woodford Asset Management each beneficially owned more than 10% of our issued and outstanding capital stock. The issuances to funds affiliated with Invesco Asset Management and to funds affiliated with Woodford Asset Management in connection with the Merger and Financing are reflected below:

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

Post-Merger Voting Agreements

On January 17, 2018, the Company entered into Post-Merger Voting Agreements with funds affiliated with Woodford Investment Management, or the Voting Agreement Holders, regarding shares of our common stock then representing more than 19.5% of the then issued and outstanding shares of our common stock, or the Threshold. The Post-Merger Voting Agreements grant us or our designee 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 us by the Post-Merger Voting Agreements, the Proxy Shares shall be voted in the same proportions as the shares voted by all other stockholders voting on the Proxy Matters. The Post-Merger 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.

Private Evofem Series D Preferred Stock Issuance

Prior to the Merger in July 2017 and November 2017, Private Evofem issued additional shares of its Series D Preferred Stock and warrant rights to purchase shares of its capital stock to funds affiliated with Woodford Investment Management at a purchase price of $500,000 per share and an aggregate purchase price of $10 million in a private placement transaction in reliance upon Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder.

Registration Rights Agreement

As noted in Item 1 of this Annual Report, which is hereby incorporated by reference, we have entered into the Registration Rights Agreement, pursuant to which the Company is, among other things, obligated to file a registration statement with the SEC within 60 days following completion of the Merger. Funds affiliated with Invesco Asset Management, Domain Partners and Woodford Investment

Management are party to the Registration Rights Agreement. Funds affiliated with Domain Partners were beneficial owners of more than 10% of our issued and outstanding common stock at the time of the Merger.

Item 14. Principal Accounting Fees and Services.

The Audit Committee appointed Ernst & Young LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2017.

The following table presents the fees for professional audit services and other services rendered by Ernst & Young LLP, as of February 9, 2018, for fiscal year 2017 and 2016.

	Fiscal Year 2017	Fiscal Year 2016
Audit Fees[(1)]	$ 485,736	$ 256,209
Audit-Related Fees	N/A	N/A
Tax Fees	N/A	N/A
All Other Fees	N/A	N/A
Total	$ 485,736	$ 256,209

(1) Audit Fees represent fees and out-of-pocket expenses whether or not yet invoiced for professional services provided in connection with the audit of the Company's financial statements, the review of our registration statement on Form S-4, the review of the Company's quarterly financial statements, and audit services provided in connection with other regulatory filings.

Pre-Approval Policies and Procedures

The Audit Committee annually reviews and pre-approves certain audit and non-audit services that may be provided by our independent registered public accounting firm and establishes and pre-approves the aggregate fee level for these services. Any proposed services that would cause us to exceed the pre-approved aggregate fee amount must be pre-approved by the Audit Committee. All audit services for 2017 were pre-approved by the Audit Committee.

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 Neothetics, Inc., together with the report thereon of Ernst & Young 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-2, immediately following the signature pages of this Annual Report.

2. List of 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

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

EVOFEM BIOSCIENCES, INC.
EXHIBIT INDEX

Exhibit Number	Exhibit Title	Filed with this Form 10 K	Incorporated by Reference		
			Form	File No.	Date Filed
2. 1^	Agreement and Plan of Merger and Reorganization, dated October 17, 2017, by and among the Registrant, Evofem Biosciences Operations, Inc. and Nobelli Merger Sub, Inc.		8-K	001-36754-171139916	10/17/2017
2.2	Form of Support Agreement, by and between Evofem Biosciences Operations, Inc. and certain of its stockholders.		8-K	001-36754-171139916	10/17/2017
3.1	Amended and Restated Certificate of Incorporation.	X			
3.2	Amended and Restated Bylaws of the Registrant.		8-K	001-36754-18546687	01/17/2018
4.1	Form of Stock Certificate.	X			
4.2	Warrant to Purchase Stock, dated February 23, 2010, issued to Silicon Valley Bank.		S-1	333-199449	10/17/2014
4.3	Warrant to Purchase Stock, dated March 30, 2012, issued to Silicon Valley Bank.		S-1	333-199449	10/17/2014
4.4	Warrant to Purchase Stock, dated August 17, 2012, issued to Silicon Valley Bank.		S-1	333-199449	10/17/2014
4.5	Warrant Agreement, dated June 11, 2014, by and between the Registrant and Hercules Technology III, L.P.		S-1	333-199449	10/17/2014
4.6	Fourth Amended and Restated Investors' Rights Agreement, dated September 22, 2014, by and between the Registrant and the investors listed therein.		S-1	333-199449	10/17/2014
4.7	Letter Terminating Registrant's Fourth Amended and Restated Investors' Rights Agreement, dated January 17, 2018, by and between the Registrant and the investors listed therein.	X			
4.8	Form of Amended and Restated Warrant to Purchase Common Stock of the Registrant.		S-4	333-221592	11/15/2017
4.9	Form of Voting Agreement.		S-4	333-221592	11/15/2017
10.1	Form of Lock-Up Agreement.		8-K	001-36754-171139916	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	001-36754-171247758	12/08/2017
10.3†	Technology Transfer Agreement, dated December 12, 2012, by and between the Registrant and Domain Russia Investments Limited.		S-1	333-199449	10/17/2014
10.4Δ	Separation and Release Agreement, dated January 17, 2018, by and between the Registrant and Susan Knudson		8-K	001-36754-18546687	01/17/2018
10.5Δ	Separation and Release Agreement, dated January 29, 2018, by and between the Registrant and Maria Feldman	X			
10.6	Securities Purchase Agreement, dated October 17, 2017, by and among the Company, Evofem Biosciences Operations, Inc. and the investors listed therein.		8-K	001-36754-171139916	10/17/2017
10.7†	Assignment and Assumption Agreement, dated December 12, 2012, by and among the Registrant, Domain Russia Investments Limited and NovaMedica LLC.		S-1	333-199449	10/17/2014

Exhibit Number	Exhibit Title	Filed with this Form 10 K	Incorporated by Reference		
			Form	File No.	Date Filed
10.8†	Clinical Development and Collaboration Agreement, dated July 2, 2013, by and between the Registrant and NovaMedica LLC.		S-1	333-199449	10/17/2014
10.9†	Contract No. 0702/12, dated July 2, 2013, by and between the Registrant and NovaMedica LLC.		S-1	333-199449	10/17/2014
10.10	Lease, dated July 3, 2008, by and between the Registrant and WW&LJ Gateways, LTD.		S-1	333-199449	10/17/2014
10.11	Ninth Amendment to Lease, dated 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
10.12	Tenth Amendment, date January 20, 2015, by and between the Registrant and LJ Gateway Office LLC (as successor in interest to WW&LJ Gateways, LTD).		10-K	001-36754-161533653	03/29/2015
10.13	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	001-363754-17609634	02/14/2017
10.14	Sublease, dated as of January 27, 2017, by and between the Registrant and Abacus Data Systems, Inc.		8-K	001-363754-17609634	02/14/2017
10.15	Loan and Security Agreement, dated June 11, 2014, by and between the Registrant and Hercules Technology Growth Capital, Inc.		S-1	333-199449	10/17/2014
10.16Δ	Letter Agreement, dated July 3, 2014, by and between the Registrant and Martha J. Demski.		S-1	333-199449	10/17/2014
10.17Δ	Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers.		S-1	333-199449	10/17/2017
10.18Δ	Amended and Restated 2007 Stock Plan, as amended.		S-1/A	333-199449	11/10/2014
10.19Δ	Form of Stock Option Agreement under 2007 Stock Plan.		S-1	333-199449	10/17/2014
10.20Δ	2014 Equity Incentive Plan.		S-1/A	333-199449	11/10/2014
10.21Δ	Amendment to 2014 Equity Incentive Plan.		10-Q	001-36754-161823046	08/11/2016
10.22Δ	Form of Stock Option Agreement under 2014 Equity Incentive Plan.		S-1/A	333-199449	11/10/2014
10.23Δ	Form of Restricted Stock Units Agreement under the 2014 Equity Incentive Plan.		S-1/A	333-199449	11/10/2014
10.24Δ	Form of Restricted Stock Agreement under the 2014 Equity Incentive Plan.		S-1/A	333-199449	11/10/2014
10.25Δ	Form of Notice of Grant of Restricted Stock Units under the 2014 Equity Incentive Plan.		S-1/A	333-199449	11/10/2014
10.26Δ	Form of Notice of Grant of Restricted Stock under the 2014 Equity Incentive Plan.		S-1/A	33-199449	11/10/2014
10.27Δ	Form of Notice of Grant of Stock Option under the 2014 Equity Incentive Plan.		S-1/A	33-199449	11/10/2014
10.28Δ	2014 Employee Stock Purchase Plan.		S-1/A	33-199449	11/10/2014
10.29Δ	Amended and Restated Non-Employee Director Compensation Policy.	X			
10.30	Stockholder Agreement, dated as of November 25, 2015, by and among Evofem Biosciences Operations, Inc. and the stockholders listed therein.		S-4	333-221592	11/15/2017

Exhibit Number	Exhibit Title	Filed with this Form 10 K	Incorporated by Reference		
			Form	File No.	Date Filed
10.31	First Amendment to Stockholder Agreement, dated as of July 13, 2016, by and among Evofem Biosciences Operations, Inc. and the stockholders listed therein.		S-4	333-221592	11/15/2017
10.32	Second Amendment to Stockholder Agreement, dated as of July 28, 2017, by and among Evofem Biosciences Operations, Inc. and the stockholders listed therein.		S-4	333-221592	11/15/2017
10.33	Registration Rights Agreement, dated as of November 25, 2015, by and among Evofem Biosciences Operations, Inc. and the stockholders listed therein.		S-4	333-221592	11/15/2017
10.34	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
10.35Δ	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
10.36Δ	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
10.37Δ	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
10.38Δ	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
10.39Δ	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
10.40Δ	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
10.41Δ	Evofem Biosciences Operations, Inc. Amended and Restated 2012 Equity Incentive Plan.		S-4	333-221592	11/15/2017
10.42Δ	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
10.43Δ	Form of Grant of Restricted Stock Award under the Evofem Biosciences Operations, Inc. 2012 Equity Incentive Plan.		S-4	333-221592	11/15/2017
10.44†	Amended and Restated License Agreement, by and between Rush University Medical Center and Evofem, Inc. dated March 27, 2014.		S-4	333-221592	11/15/2017
10.45	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
10.46	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
10.47	Office Sublease, dated as of January 30, 2015, by and between Evofem, Inc. and Relational Investors LLC.		S-4	333-221592	11/15/2017
10.48	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
10.49	Sublease, dated as of January 30, 2015, by and between Evofem, Inc. and WomanCare Global Trading, Inc.		S-4	333-221592	11/15/2017
10.50	Series D Preferred Stock Purchase Agreement, dated as of July 13, 2016, by and between Evofem Biosciences Operations, Inc. and the investors set forth therein.		S-4	333-221592	11/15/2017

Exhibit Number	Exhibit Title	Filed with this Form 10 K	Incorporated by Reference		
			Form	File No.	Date Filed
10.51	First Amendment to Series D Preferred Stock Purchase Agreement, dated as of July 28, 2017, by and between Evofem Biosciences Operations, Inc. and the investors set forth therein.		S-4	333-221592	11/15/2017
10.52	Restricted Stock Cancellation Agreement, dated as of October 17, 2017, by and between Evofem Biosciences Operations, Inc. and Saundra Pelletier.		S-4	333-221592	11/15/2017
10.53	Restricted Stock Cancellation Agreement, dated as of October 17, 2017, by and between Evofem Biosciences Operations, Inc. and Justin J. File.		S-4	333-221592	11/15/2017
10.54	Restricted Stock Cancellation Agreement, dated as of October 17, 2017, by and between Evofem Biosciences Operations, Inc. and Kelly Culwell, M.D.		S-4	333-221592	11/15/2017
10.55	Restricted Stock Unit Award Cancellation Agreement, dated as of October 17, 2017 by and between Evofem Biosciences Operations, Inc. and Thomas Lynch.		S-4	333-221592	11/15/2017
10.56	First Amendment to Loan and Security Agreement, dated October 21, 2014, by and between the Registrant and Hercules Technology Growth Capital, Inc.		S-1/A	333-199449	11/10/2014
10.57	Second Amendment to Loan and Security Agreement, dated March 30, 2016, by and between the Registrant and Hercules Capital, Inc.		10-Q	001-36754-16164168	5/12/2016
10.58Δ	Executive Employment Agreement, dated October 15, 2014, by and between the Registrant and Susan Knudson.		S-1	333-199449	10/17/2014
10.59	Form of Registration Rights Agreement.		8-K	001-36754-171139916	10/17/2017
10.60Δ	Separation Agreement, dated January 21, 2016, by and between the Registrant and George W. Mahaffey.		10-K	001-36754-161533653	03/29/2016
16.1	Letter from Ernst & Young LLP dated January 25, 2018.		8-K	001-36754-18546687	01/25/2018
21.1	List of Registrant Subsidiaries.	X			
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.	X			
31.1	Certification of Chief Executive Officer.	X			
31.2	Certification of Chief Financial Officer.	X			
32.1	Certification 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 Taxonomy Extension Definition Linkbase Document	X			
101.LAB	XBRL Taxonomy Extension Label 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

^ 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.

Item 16. 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, thereunto duly authorized.

EVOFEM BIOSCIENCES, INC.

Date: February 26, 2018

By: /s/ Saundra Pelletier
Name: Saundra Pelletier
Title: 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	Chief Executive Officer and Director (Principal Executive Officer)	February 26, 2018
/s/ Justin J. File Justin J. File	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 26, 2018
/s/ Thomas Lynch Thomas Lynch	Chairman of the Board	February 26, 2018
/s/ Gillian Greer Gillian Greer, CBE, Ph.D.	Director	February 26, 2018
/s/ William Hall William Hall, Ph.D., M.D.	Director	February 26, 2018
/s/ Kim P. Kamdar Kim P. Kamdar, Ph.D.	Director	February 26, 2018
/s/ Tony O'Brien Tony O'Brien	Director	February 26, 2018
/s/ Colin Rutherford Colin Rutherford	Director	February 26, 2018

NEOTHETICS, INC.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Evofem Biosciences, Inc. (formerly Neothetics, Inc.)

Opinion on the Financial Statements:

We have audited the accompanying balance sheets of Evofem Biosciences, Inc. (formerly Neothetics, Inc.), or the Company, as of December 31, 2017 and 2016, the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2017, 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 at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a 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 from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding 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/ Ernst & Young LLP

We have served as the Company's auditor since 2011.
San Diego, California
February 26, 2018

NEOTHETICS, INC.

BALANCE SHEETS

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 3,416,960	$ 11,477,852
Prepaid expenses and other current assets	608,432	1,029,546
Total current assets	$ 4,025,392	$ 12,507,398
Restricted cash	93,382	200,000
Property and equipment, net	—	109,320
Total assets	$ 4,118,774	$ 12,816,718
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 566,253	$ 503,739
Accrued expenses	845,768	398,453
Total current liabilities	1,412,021	902,192
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock - $0.0001 par value; 300,000,000 shares authorized; 2,308,430 and 2,304,749 shares issued and outstanding at December 31, 2017 and 2016, respectively	231	230
Additional paid-in capital	138,550,328	137,764,651
Accumulated deficit	(135,843,806)	(125,850,355)
Total stockholders' equity	2,706,753	11,914,526
Total liabilities and stockholders' equity	$ 4,118,774	$ 12,816,718

See accompanying notes.

NEOTHETICS, INC.

STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2017	**2016**	**2015**
Expenses:			
Research and development	$ 3,945,757	$ 6,578,678	$ 34,409,664
General and administrative	6,098,944	5,463,622	7,639,427
Total operating expenses	10,044,701	12,042,300	42,049,091
Loss from operations	(10,044,701)	(12,042,300)	(42,049,091)
Interest income	51,250	59,465	26,033
Interest expense	—	(1,035,763)	(1,133,987)
Net loss	$ (9,993,451)	$ (13,018,598)	$ (43,157,045)
Net loss per share, basic and diluted	$ (4.33)	$ (5.66)	$ (18.91)
Weighted average shares used to compute basic and diluted net loss per share	2,305,817	2,300,167	2,282,672

See accompanying notes.

NEOTHETICS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2014	2,278,554	$ 228	$134,921,913	$ (69,674,712)	$ 65,247,429
Common stock issued upon exercise of options	8,027	1	96,503	—	96,504
Common stock issued upon purchase of the employee stock purchase plan	1,339	—	42,126	—	42,126
Issuance of restricted shares, net of shares repurchased for minimum tax liability	3,750	—	193,500	—	193,500
Share-based compensation	—	—	1,384,781	—	1,384,781
Net loss	—	—	—	(43,157,045)	(43,157,045)
Balance at December 31, 2015	2,291,670	$ 229	$136,638,823	$(112,831,757)	$ 23,807,295
Common stock issued upon exercise of options	4,883	—	33,542	—	33,542
Issuance of restricted shares, net of shares repurchased for minimum tax liability	8,196	1	—	—	1
Debt amendment warrant costs	—	—	9,417	—	9,417
Share-based compensation	—	—	1,082,869	—	1,082,869
Net loss	—	—	—	(13,018,598)	(13,018,598)
Balance at December 31, 2016	2,304,749	$ 230	$137,764,651	$(125,850,355)	$ 11,914,526
Common stock issued upon exercise of options	3,681	1	26,348	—	26,349
Share-based compensation	—	—	759,329	—	759,329
Net loss	—	—	—	(9,993,451)	(9,993,451)
Balance at December 31, 2017	2,308,430	$ 231	$138,550,328	$(135,843,806)	$ 2,706,753

See accompanying notes.

NEOTHETICS, INC.

STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2017	2016	2015
Operating activities			
Net loss	$ (9,993,451)	$ (13,018,598)	$ (43,157,045)
Adjustments to reconcile net loss to net cash used in operating activities:			
Loss on sale of assets	56,350	4,858	6,140
Depreciation and amortization	45,870	69,094	58,425
Non-cash interest expense on notes payable and debt	—	100,290	220,447
Share-based compensation	759,329	1,082,869	1,578,279
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	421,114	947,452	(1,051,224)
Accounts payable and accrued expenses	509,829	(5,440,958)	4,433,561
Net cash used in operating activities	(8,200,959)	(16,254,993)	(37,911,417)
Investing activities			
Proceeds from sale of property and equipment	7,100	3,100	—
Purchase of property and equipment	—	—	(226,128)
Net cash provided by (used in) investing activities	7,100	3,100	(226,128)
Financing activities			
Prepayment resulting in debt extinguishment	—	(9,514,058)	—
Principal payments on bank loan	—	(538,342)	—
Issuance of common stock from exercise of options	26,349	33,542	96,506
Issuance of common stock from employee stock purchase plan	—	—	42,126
Net cash provided by (used in) financing activities	26,349	(10,018,858)	138,632
Net decrease in cash, cash equivalents, and restricted cash	(8,167,510)	(26,270,751)	(37,998,913)
Cash, cash equivalents, and restricted cash beginning of period	11,677,852	37,948,603	75,947,516
Cash, cash equivalents, and restricted cash end of period	$ 3,510,342	$ 11,677,852	$ 37,948,603
Supplemental disclosure of cash flow activity			
Cash paid for interest	$ —	$ 973,115	$ 912,500

See accompanying notes.

1. Organization and Basis of Presentation

Neothetics, Inc. (the "Company" or "Neothetics"), was originally incorporated in Delaware on February 1, 2007, under the name Lipothera, Inc. In September 2008, Lipothera, Inc. changed its name to Lithera, Inc. In August 2014, Lithera, Inc. changed its name to Neothetics, Inc. Neothetics was a clinical-stage specialty pharmaceutical company that developed therapeutics for the aesthetic market.

Merger of Neothetics, Inc. and Evofem Biosciences Operations, Inc.

On January 17, 2018, Neothetics and privately-held Evofem Biosciences Operations, Inc., or Private Evofem, completed a merger and reorganization, or the Merger, in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated October 17, 2017, or the Merger Agreement, by and among Neothetics, Private Evofem and a wholly owned subsidiary of Neothetics, Nobelli Merger Sub, Inc., or Merger Sub, whereby Merger Sub merged with and into Private Evofem, with Private Evofem surviving as a wholly owned subsidiary of Neothetics.

In connection with the Merger, on January 17, 2018, the Company filed a certificate of amendment to its amended and restated certificate of incorporation to effect a six-for-one reverse stock split of its common stock, or the Reverse Split, cause the Company not to be governed by Section 203 of the Delaware General Corporation Law, or the DGCL, and change its name from "Neothetics, Inc." to "Evofem Biosciences, Inc." The name change and the Reverse Split were both effected on January 17, 2018. Shares of the Company's common stock commenced trading on The Nasdaq Capital Market under the new name and ticker symbol "EVFM" as of market open on January 18, 2018.

No fractional shares were issued in connection with the Reverse Split. The accompanying financial statements and notes to the financial statements give retroactive effect to the Reverse Split for all the periods presented. The Merger was structured as a reverse capitalization, and Private Evofem was determined to be the accounting acquirer based on the terms of the Merger and other factors.

The financial information included in the financial statements is that of Neothetics prior to the Merger because the Merger was consummated after the period covered by these financial statements.

As of December 31, 2017, Neothetics had devoted substantially all of its efforts to product development, raising capital, and building infrastructure and has not realized revenues from its planned principal operations.

Basis of Presentation and Liquidity

The Company has a limited operating history. The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction 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 expects to continue to incur net losses into the foreseeable future.

In accordance with ASU 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, management is required to perform a two-step analysis over its ability to continue as a going concern. Management must first evaluate whether there are conditions and events that raise substantial doubt about the Company's ability to continue as a going concern (step 1). If management concludes that substantial doubt is raised, management is also required to consider whether its plans alleviate that doubt (step 2).

The Company has incurred net losses from operations since inception and has an accumulated deficit of $135.8 million at December 31, 2017. Management has prepared cash flows forecasts which indicate that based on the Company's expected operating losses and negative cash flows, there is substantial doubt about the Company's ability to continue as a going concern for twelve months after the date that the financial statements for the year ended December 31, 2017, are issued. Even with the Merger that was completed on January 17, 2018, uncertainties associated with the Company's ability to obtain additional funding raise substantial doubt about the Company's ability to continue as a going concern. The Company plans to continue to fund its losses from operations and capital funding needs through debt and equity financing or through collaborations and partnerships with other entities. Debt or equity financing or collaborations and partnerships with other entities may not be available, on a timely basis on terms that are acceptable to the Company, or at all. In addition, the Company may be required to scale back or discontinue advancement of product candidates, reduce headcount or reduce other operating expenses. This could have an adverse impact on the Company's ability to achieve certain of its planned objectives during 2018, and thus, could materially harm the Company's business.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States, or GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of 90 days or less at the date of purchase to be cash equivalents. Cash and cash equivalents include cash in readily available checking and money market accounts.

Restricted Cash

Restricted cash as of December 31, 2017 represents a $93,382 restricted money market account used to secure the standby letter of credit issued in connection with a lease (see Note 5 “Debt”).

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the balance sheets that sum to the total of the same such amounts shown in the statement of cash flows.

	December 31,		
	2017	2016	2015
Cash and cash equivalents	$ 3,416,960	$ 11,477,852	$ 37,748,603
Restricted cash	93,382	200,000	200,000
Total cash, cash equivalents and restricted cash	$ 3,510,342	$ 11,677,852	$ 37,948,603

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash due to the financial position of the depository institution in which those deposits are held.

Fair Value of Financial Instruments

The carrying amounts of prepaid and other current assets, accounts payable and accrued expenses are reasonable estimates of their fair value because of the short term maturity of these items.

Property and Equipment

Property and equipment, which primarily consist of office furniture and equipment and computer equipment, are stated at cost and depreciated over the estimated useful lives of the assets (three to five years) using the straight-line method.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment. An impairment loss is recorded if and when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. While the Company's current and historical operating losses and negative cash flows are indicators of impairment, management believes that future cash flows to be received support the carrying value of its long-lived assets and, accordingly, has not recognized any impairment losses since inception.

Research and Development Costs

Research and development expenses consist primarily of salaries and related overhead expenses; fees paid to consultants and contract research organizations; costs related to acquiring and manufacturing clinical trial materials; and costs related to compliance with regulatory requirements.

All research and development costs are charged to expense as incurred.

Income Taxes

The Company uses the 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. Valuation allowances are recorded when the realizability of such deferred tax assets is not more likely than not.

The guidance on accounting 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. The Company's policy is to recognize interest expense and penalties related to income tax matters as a component of income tax expense. During 2017 and 2016, the Company had not recognized interest and penalties in the balance sheets or statements of operations. The Company is subject to taxation in the U.S. and state jurisdictions. The Company's tax years from inception are subject to examination by the United States and California authorities due to the carryforwards of unutilized net operating losses, or NOLs, and research and development credits.

Share-Based Compensation

Share-based compensation for the Company includes amortization related to all stock options, restricted stock awards and shares issued under the employee stock purchase plan, based on the grant-date fair value. The fair value of each option and restricted stock award is estimated on the date of grant using the Black-Scholes option pricing model. The expected life of the awards is based on the simplified method described in SEC Staff Accounting Bulletin No. 107. The expected volatility assumption is based upon the historical volatility of a number of publicly traded companies in similar stages of clinical development. The risk-free interest rate is based on the yield of U.S. Treasury bills with a life that approximates the expected life of the awards. The Company recognizes share-based compensation on a straight-line basis over the vesting term of the options and the actual forfeitures by reducing the employee share-based compensation expense in the same period as the forfeitures occur.

Option grants to non-employees are valued at fair value and are expensed over the period services are provided. These options are subject to periodic revaluation to reflect the current fair value at each reporting period until the non-employee completes the performance obligation or the date on which a performance commitment is reached. There were 10,000 and 41,666 shares issued to non-employee consultants during the years ended December 31, 2017 and 2016, respectively. There was no non-cash compensation to consultants for the year ended December 31, 2015.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common share equivalents outstanding during the period. Common stock equivalents are only included when their effect is dilutive. The Company's potentially dilutive securities, which include common stock warrants and outstanding stock options under the stock option plan, have been excluded from the computation of diluted net loss per share as they would be anti-dilutive. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding due to the Company's net loss position.

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because to do so would be anti-dilutive.

	December 31,		
	2017	2016	2015
Warrants for common stock	11,875	11,875	11,875
Common stock options and restricted stock awards issued and outstanding	246,810	145,188	227,157
	258,685	157,063	239,032

Recent Adopted Accounting Pronouncements

In March 2016, the FASB issued ASU 2016-09, *Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, or ASU 2016-09. ASU 2016-09 simplifies several aspects of the accounting for employee share-based payments, including accounting for income taxes, forfeitures, statutory tax withholding requirements, and classification on the statement of cash flows. The amendments in this ASU are effective for annual periods beginning after December 15, 2016. The Company adopted ASU 2016-09 during its fiscal year ended December 31, 2017, which did not have a material effect on the Company's financial statements and related disclosures.

In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments*, or ASU 2016-15. This pronouncement gives guidance to clarify how certain cash receipts and payments should be presented and classified in the statement of cash flows. The guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is permitted. The Company adopted ASU 2016-15 during its fiscal year ended December 31, 2017, which did not have a material effect on the Company's financial statements and related disclosures.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842),* or ASU 2016-02. ASU 2016-02 requires that lessees recognize assets and liabilities for the rights and obligations for leases with a lease term of more than one year. The amendments in this ASU are effective for annual periods ending after December 15, 2018. Early adoption is permitted. The Company is evaluating the impact of adoption on its financial statements.

In January 2017, the FASB issued ASU No. 2017-1, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, or ASU 2017-1. ASU 2017-1 clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. ASU 2017-1 will be effective for the Company beginning January 1, 2018. The adoption of this guidance is not expected to have a material impact on the Company's financial position or results of operations.

3. Fair Value Measurements

Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, accounts payable, accrued expenses, including warrants issued in connection with financing arrangements, and long-term debt. Fair value estimates of these instruments are made at a specific point in time based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. The carrying amount of cash and cash equivalents, accounts payable, and accrued expenses are generally considered to be representative of their respective fair values because of the short-term nature of these instruments. The Company believes that the fair value of long-term debt approximates its carrying value based on the borrowing rates currently available to the Company for loans with similar terms.

The authoritative guidance for fair value measurements defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers or sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact. The guidance prioritizes three levels of inputs into the following hierarchy:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value on a recurring basis as of December 31, 2017 and 2016 are as follows:

		Fair Value Measurements at Reporting Date Using		
	Balance as of December 31, 2017	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market fund[(1)]	$ 3,416,960	$ 3,416,960	$ —	$ —
Total assets	$ 3,416,960	$ 3,416,960	$ —	$ —

(1) Included as a component of cash and cash equivalents on accompanying balance sheet.

	Balance as of December 31, 2016	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market fund[(1)]	$11,477,852	$ 11,477,852	$ —	$ —
Total assets	$11,477,852	$ 11,477,852	$ —	$ —

(1) Included as a component of cash and cash equivalents on accompanying balance sheet.

4. Property and Equipment

Property and equipment consist of the following:

	December 31, 2017	December 31, 2016
Office furniture and equipment	$ 92,373	$ 254,049
Less accumulated depreciation and amortization	(92,373)	(144,729)
	$ —	$ 109,320

Depreciation and amortization expense related to furniture and equipment amounted to $45,870, $69,094, and $58,425, for the years ended December 31, 2017, 2016, and 2015 respectively.

5. Debt

Loans

In February 2010, and as amended during 2012, the Company entered into a loan and security agreement (2010 Loan and Security Agreement) with Silicon Valley Bank, or SVB, for borrowings of $3,750,000, collateralized by all assets of the Company. In connection with the borrowings, the Company issued warrants to the bank for the purchase of a total of 64,865 shares of Series B convertible preferred stock and warrants to purchase 75,000 shares of Series C convertible preferred stock. Effective upon the IPO, this was converted to a warrant to purchase 4,069 shares of common stock at a weighted average exercise price of $59.43 and expire ten years from the date of issuance. The 2010 Loan was paid in full in June 2014.

In June 2014, the Company entered into a Loan and Security Agreement, or the Loan Agreement, with Hercules Technology Growth Capital Inc. that provided for borrowings up to $10.0 million available to the Company in two tranches. Upon closing of the Loan Agreement, the Company borrowed $4.0 million. In October 2014, the Company entered into the first amendment of the Loan Agreement and borrowed the remaining $6.0 million available under the agreement.

In connection with the Loan Agreement, in June 2014, the Company issued warrants to purchase shares of Series C convertible preferred stock equal to 4% of the amount advanced under the loan. Effective upon the IPO, this was converted to a warrant to purchase 7,806 shares of common stock at $51.24, which expires on June 11, 2024. The fair value of the warrants issued was $207,429, based on the fair value of such Series C warrants at the date of issuance. The warrants' fair value and financing fees of approximately $133,000 were recorded as a debt discount.

In March 2016, the Company entered into the second amendment of the Loan Agreement that provided for a prepayment of the outstanding loan carrying amount of $5.5 million with a prepayment fee of $110,000. In connection with the second amendment, the Company re-priced the outstanding warrants to purchase 7,806 shares of common stock at a new exercise price of $3.72, which will expire in September 2022 unless exercised prior to such expiration date. The Company recorded a debt discount of $9,417 associated with the fair value of the warrants issued in connection with the amendment. In addition, the Company incurred loan amendment fees and legal fees of $52,400, which the Company recorded as a debt discount.

In September 2016, the Company prepaid the remaining outstanding balance under the Loan Agreement at a carrying amount of $4.0 million with a prepayment fee of $120,000 and an end of term fee of $300,000. Accordingly, the Loan Agreement was terminated on September 23, 2016. Upon termination of the Loan Agreement, the prepayment fees of $230,000 and unamortized end of term fee of $260,000 were recorded as interest expense

From June 2014 through payoff in September 2016, the Company paid interest equal to the greater of either 9.0%, plus the Prime Rate as reported in The Wall Street Journal, less 3.25% or 9.0%. The Company recorded total interest expense of $0, $1,035,763 and $1,133,987 for the twelve months ended December 31, 2017, December 31, 2016 and December 31, 2015, respectively.

Letter of Credit

In January 2015, the Company executed a lease amendment with LJ Gateway, LLC for new office space. In connection with this lease amendment the Company issued a stand-by letter of credit in the amount of $200,000 in lieu of a security deposit. Pursuant to the terms set forth in the lease amendment, as of March 31, 2017, the stand-by letter of credit was reduced to $93,382. The standby letter of credit is secured by a restricted money market account. The terms of the standby letter of credit expire in May 2020 and are subject to automatic yearly renewal prior to this date.

6. Convertible Preferred Stock and Stockholders' Equity

Common Stock

On December 1, 2015, the Company entered into a Controlled Equity Offering Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, as a sales agent pursuant to which the Company may offer and sell from time to time, through Cantor Fitzgerald shares of Neothetics 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 board of directors.

The Company cannot provide any assurances that it will issue any shares pursuant to the Sales Agreement. Subject to the terms and conditions of the Sales Agreement, Cantor Fitzgerald will use commercially reasonable efforts consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations and applicable Nasdaq rules to sell shares from time to time based upon Neothetics' instructions, including any price, time or size limits specified by Neothetics. Under the Sales Agreement, Cantor Fitzgerald may sell shares by any method deemed to be an "at-the-market" offering as defined in Rule 415 under the U.S. Securities Act of 1933, as amended, or any other method permitted by law, including in privately negotiated transactions. Neothetics will pay Cantor Fitzgerald a commission of 3.0% of the aggregate gross proceeds from each sale of shares and has agreed to provide Cantor Fitzgerald with customary indemnification and contribution rights. Neothetics has also agreed to reimburse Cantor Fitzgerald for legal fees and disbursements, not to exceed $50,000 in the aggregate, in connection with entering into the Sales Agreement.

The Sales Agreement may be terminated by Cantor Fitzgerald or Neothetics at any time upon notice to the other party, or by Cantor Fitzgerald at any time in certain circumstances, including the occurrence of a material and adverse change in Neothetics' business or financial condition that makes it impractical or inadvisable to market the shares or to enforce contracts for the sale of the shares. As of December 31, 2017, no shares were issued pursuant to the Sales Agreement.

Stock Compensation Plan

The Company adopted a Stock Option Plan in 2007, or the 2007 Plan under which 211,893 shares of common stock were reserved for issuance to employees, non-employee directors, and consultants of the Company. Effective upon the completion of the Company's IPO, the board of directors determined not to grant any further awards under the 2007 Plan.

In September 2014, the Company's board of directors and stockholders approved and adopted the 2014 Equity Incentive Plan, or the 2014 Plan. The 2014 Plan became effective immediately prior to the Company's IPO. A total of 166,666 shares of common stock were initially reserved for issuance under the 2014 Plan. This reserve automatically increased on January 1, 2015, and will continue to increase each subsequent anniversary through 2024, by an amount equal to the smaller of (a) 4% of the number of shares of common stock issued and outstanding on the date immediately preceding December 31 and (b) an amount determined by our board of directors. All shares that remained available, expired, or otherwise terminated without having been exercised in full and unvested shares that were forfeited to or repurchased by us under the 2007 Plan were rolled into 2014 Plan. The 2014 Plan provides for the grant of stock options, stock appreciation rights, restricted stock, restricted stock units, or RSU's, performance shares, and units and other cash-based or share-based awards. In addition, the 2014 Plan contains a mechanism through which we may adopt a deferred compensation arrangement in the future. Recipients of stock options shall be eligible to purchase shares of the Company's common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant.

The following table summarizes stock option and restricted stock award transactions under the 2014 Plan during the year ended December 31, 2017:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Contractual Life — Years	Total Intrinsic Value
Outstanding at December 31, 2016	145,188	$ 17.70	8.6	$ 18,363
Granted	145,877	$ 11.27		
Exercised	(3,681)	$ 7.15		$ 5,725
Forfeited	(40,574)	$ 16.20		
Outstanding and exercisable at December 31, 2017	246,810	$ 14.31	8.5	$ 539,259
Vested and options expected to vest at December 31, 2017	238,753	$ 14.33	8.4	$ 536,233

The 2014 Plan allows for the exercise of unvested options, which are subject to repurchase until vesting occurs. All options exercised to date were fully vested at date of exercise. No grants expired during the year ended December 31, 2017.

The weighted average fair value of options granted was $4.96 and $2.71 for the twelve months ended December 31, 2017 and 2016, respectively. The weighted average fair value of options vested was $5.43 at December 31, 2017. Total cash received upon the exercise of stock options was $26,349 for the year ended December 31, 2017. The unrecognized compensation cost related to non-vested stock options and restricted stock awards outstanding at December 31, 2017 and 2016, net of expected forfeitures, was $263,206 and $420,339, respectively, to be recognized over a weighted-average remaining vesting period of approximately 1.1 and 1.7 years, respectively.

Share-Based Compensation

The estimated fair value of each option award granted was determined on the date of grant using the Black-Scholes option-pricing valuation model with the following weighted-average assumptions for options grants.

	Year Ended December 31,		
	2017	2016	2015
Weighted Average Assumptions:			
Risk-free interest rate	1.74%	1.61%	1.69%
Expected dividend yield	0%	0%	0%
Expected volatility	55.17%	44.89%	43.72%
Expected term (in years)	5.8	5.4	5.8

The risk-free interest rate assumption was based on the yield of an applicable rate for U.S. Treasury instruments with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company never paying cash dividends and having no expectation of paying cash dividends in the foreseeable future. The weighted average expected term of options was calculated using the simplified method as permitted by accounting guidance for stock-based compensation. In addition, due to the Company's limited historical data, the estimated volatility was calculated based upon the historical volatility of comparable companies in the biotechnology industry whose share prices are publicly available for a sufficient period of time.

Employee Stock Purchase Plan

In November 2014, the Company adopted the 2014 Employee Stock Purchase Plan (the "ESPP"), which enables eligible employees to purchase shares of the Company's common stock using their after tax payroll deductions of up to 15% of their eligible compensation, subject to certain restrictions.

The 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 will continue 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, and (b) a number of Shares determined by the board of directors of the Company. The 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, or the Code.

The Company estimates the fair value of shares issued to employees under the ESPP using a Black-Scholes option-pricing model. The Black-Scholes model 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, which determine the fair value of share-based awards.

There were no shares issued under the ESPP during the years ended December 31, 2017 and 2016.

The weighted average assumptions used to estimate the fair value of shares issued under the ESPP in the year ended December 31, 2015, using the Black-Scholes option pricing model was as follows:

Weighted Average Assumptions:	
Risk-free interest rate	0.39%
Expected dividend yield	0%
Expected volatility	45.13%
Expected term (in years)	1.23

The Company recognized non-cash share-based compensation expense related to its ESPP, restricted stock awards and stock options granted to employees and directors in its research and development and its general and administrative functions as follows:

	Year Ended December 31,		
	2017	2016	2015
Research and development	$ 280,140	$ 163,996	$ 410,099
General and administrative	479,189	918,873	974,682
	$ 759,329	$ 1,082,869	$ 1,384,781

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance is as follows:

	December 31,	
	2017	2016
Warrants issued and outstanding	11,875	11,875
Stock options and restricted stock awards issued and outstanding	246,810	145,188
Authorized for future option grants	366,249	379,362
Reserved for employee stock purchase plan	95,741	72,694
	720,675	609,119

7. Income Taxes

As of December 31, 2017, the Company had federal and California tax NOL carryforwards available to reduce its future taxable income of approximately $139,064,000 and $62,808,000, respectively. The federal NOL begins to expire in 2027, unless previously utilized. At December 31, 2017, the Company has federal and state research tax credits of $3,976,000 and $2,786,000, respectively. The federal research credit expires in 2027 unless previously utilized. The California research credit will carry forward indefinitely until utilized.

Utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Section 382 of the Code as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders. Since the Company's formation, the Company has raised capital through the issuance of capital stock on several occasions, including the IPO in 2014, which on their own or combined with the purchasing stockholders' subsequent disposition of those shares, may have resulted in such an ownership change, or could result in an ownership change in the future.

The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since the Company's formation 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. If the Company has experienced an ownership change at any time since its formation, utilization of the NOL or R&D credit carryforwards would be subject to an annual limitation under Section 382 of the Code, 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 NOL or R&D credit carryforwards before utilization. Further, until a study is completed and any limitation known, no amounts are being considered as an uncertain tax position or disclosed as an unrecognized tax benefit. Due to the existence of the valuation allowance, future changes in the

Company's unrecognized tax benefits will not impact its effective tax rate. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets, with a corresponding reduction of the valuation allowance.

Until the study is completed, the Company has removed federal and state operating losses of approximately $33,590,000 and federal and state research and development credits of approximately $6,177,000 from its deferred tax asset schedule and has recorded a corresponding decrease to its valuation allowance.

Significant components of the Company's deferred tax assets for federal and state income taxes at December 31, 2017 and 2016 are shown below. A valuation allowance has been established as realization of such deferred tax assets is uncertain.

	December 31,	
	2017	2016
Deferred tax assets:		
Accrued compensation	51,000	46,000
Non-qualified Stock Options	195,000	173,000
Other, net	7,000	34,000
Total deferred tax assets	253,000	253,000
Valuation allowance	(253,000)	(253,000)
	$ —	$ —

There was no material income tax expense for the years ended December 31, 2017 and 2016.

A reconciliation of income tax expense as compared to the tax expense calculated by applying the statutory federal and state tax rate to income before taxes for the years ended December 31, is as follows:

	2017	2016	2015
Income tax at statutory rates	34.00%	39.80%	39.80%
State changes	(0.01%)	0.00%	0.00%
Transaction costs	(5.52%)	0.00%	0.00%
NOL not recorded due to 382 limitations	(25.78%)	(36.70%)	(39.30%)
Other	(1.14%)	(3.10%)	(0.50%)
Tax reform - tax rate change	(1.57%)	0.00%	0.00%
Total tax expense	(0.02%)	0.00%	0.00%

The Tax Cuts and Jobs Act, or the Act, was enacted on December 22, 2017. The Act reduces the U.S. federal and corporate tax rate from 35% to 21%. At December 31, 2017, the Company has not completed the accounting for the tax effects of enactment of the Act; however, in certain cases, we have made a reasonable estimate of the effects on our existing deferred tax balances. As part of the Act, we remeasured our deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%. Due to our full valuations, the remeasurement of our deferred tax assets and liabilities had no impact on the statement of operations. However, we are still analyzing certain aspects of the Act and refining our calculations, which could potentially affect the measurement of these balances or potentially give rise to new deferred tax amounts.

The Company follows the provisions under the Income Taxes topic of the Codification which addresses accounting for the uncertainty in income taxes. The evaluation of a tax position in accordance with this topic is a two-step process. The first step involves recognition. The Company determines whether it is more likely than not that a tax position will be sustained upon tax examination, including resolution of any related appeals or litigation, based on only the technical merits of the position. The technical merits of a tax position derive from both statutory and judicial authority (legislation and statutes, legislative intent, regulations, rulings, and case law) and their applicability to the facts and circumstances of the tax position. If a tax position does not meet the more-likely-than-not recognition threshold, the benefit of that position is not recognized in the financial statements. The second step is measurement. A tax position that meets the more-likely-than-not recognition threshold is measures to determine the amount of benefit to recognize in the financial statements. The tax position is measured as the largest amount of benefit that is greater than 50% likely of being realized upon ultimate resolution with a taxing authority.

The Company files income tax returns in the United States and California. The Company currently has no years under examination by any jurisdiction; however, the Company is subject to income tax examination by federal and state for years beginning in 2013 and 2012, respectively. However, to the extent allowed by law, the taxing authorities may have the right to examine prior periods where NOLs and tax credits were generated and carried forward, and make adjustment up to the amount of the carryforwards. The Company does not have any unrecognized tax benefits as of December 31, 2017 and does not anticipate that the amount of unrecognized tax benefits will significantly change within the next twelve months. The Company has not recognized interest or penalties in its consolidated statements of operations and comprehensive loss since inception.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest and/or penalties in the statements of operations for the years ended December 31, 2017, 2016, and 2015 or for the period from February 1, 2007 to December 31, 2017.

8. Commitments

Operating Leases

The Company entered into a non-cancelable operating lease for its facilities on January 20, 2015. The lease expires in March 2020.

On January 31, 2017, the Company entered into an Eleventh Amendment to the Lease with LJ Gateway Office LLC, or LJ Gateway. Concurrent with entering into the Lease Amendment, the Company entered into a Sublease with Abacus Data Systems, Inc., or Abacus, providing for the sublease of existing office space located at Suite No. 270. This Lease Amendment also provides the Company with additional office space located at Suite No. 250, 9171 Towne Centre Drive, San Diego California, which the Company occupies as its headquarters.

Upon occurrence of Abacus retaining possession of the original premises in February 2017, Abacus received rent abatement for months one, three, and four as well as a discount of 50% off the base rent for months five through nine. Abacus paid the Company a base rent of $27,768 for the second month's rent and $30,317 security deposit. The base rent will increase by three percent on each annual anniversary. In February 2017, the Company recorded $353,000 of sublease liability. The Company has recorded the rental income collected or accrued under the sublease as a reduction of rent expense. Rent expense and sublease rental income under the Lease Amendment and Sublease for the year ended December 31, 2017 were $326,000 and $264,000, respectively. Rent expense were $429,927 and $388,997 for the years ended December 31, 2016 and 2015, respectively. The payments escalate over the term of the lease; however, the Company recognizes the expense on a straight-line basis over the term of the lease.

In December 2017, the Company entered into the Twelfth Amendment to the Lease with LJ Gateway whereby upon the mutual execution and delivery of a new lease between LJ Gateway's affiliate and Abacus and Abacus vacates Suite No. 270, LJ Gateway and the Company agree that the Lease with respect to the office space located at Suite No. 270 shall be terminated. As of December 31, 2017, the sublease had not been terminated.

The following table summarizes the minimum lease payments and sublease receipts under the lease agreement.

	Lease Payments	Sublease Receipts
2018	$ 410,848	$ 342,374
2019	431,507	352,644
2020	109,293	90,143
Total	$ 951,648	$ 785,161

9. Subsequent Events

Per the discussion in Note 1 "Organization and Basis of Presentation", Neothetics and Private Evofem completed the Merger in accordance with the terms of the Merger Agreement whereby Merger Sub merged with and into Private Evofem, with Private Evofem surviving as a wholly owned subsidiary of Neothetics.