UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2017

Commission File Number 001-00100

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Nevada	**87-0233535**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*

6800 Broken Sound Parkway NW
Third Floor
Boca Raton, Florida 33487
(561) 961-1900
(Address, including zip code, and telephone number, including area code, of Principal Executive Offices)

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	The Nasdaq Stock Market LLC

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 Section 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 Website, 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 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, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐
(Do not check if a smaller reporting company)	Emerging growth Company ☐

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

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

The aggregate market value of common stock held by non-affiliates of the registrant (169,430,175 shares) based on the closing price of the registrant's common stock as reported on NYSE American on June 30, 2017, which was the last business day of the registrant's most recently completed second fiscal quarter, was $892,897,022.

As of February 20, 2018, there were outstanding 216,439,483 shares of the registrant's common stock, par value $0.001 per share.

Documents Incorporated by Reference

Portions of the registrant's definitive Proxy Statement for its 2018 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10- K where indicated. Such Proxy Statement will be filed with the Securities and Exchange Commission no later than 120 days after the end of the registrant's fiscal year ended December 31, 2017.

THERAPEUTICSMD, INC.
ANNUAL REPORT ON FORM 10-K
Fiscal Year Ended December 31, 2017
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PART I

vitaMedMD®, TherapeuticsMD®, and BocaGreenMD® are registered trademarks of our company. This Annual Report also contains trademarks and trade names of other companies.

This Annual Report includes market and industry data that we obtained from periodic industry publications, third-party studies and surveys, government agency sources, filings of public companies in our industry, and internal company surveys. Industry publications and surveys generally state that the information contained therein has been obtained from sources believed to be reliable. Although we believe the foregoing industry and market data to be reliable at the date of the report, this information could prove to be inaccurate as a result of a variety of matters.

Statement Regarding Forward-Looking Information

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve substantial risks and uncertainties. For example, statements regarding our operations, financial position, business strategy, product development, and other plans and objectives for future operations, and assumptions and predictions about future product development and demand, research and development, marketing, expenses and sales are all forward-looking statements. These statements may be found in the items of this Annual Report entitled "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as in this Annual Report generally. These statements are generally accompanied by words such as "intend," "anticipate," "believe," "estimate," "potential(ly)," "continue," "forecast," "predict," "plan," "may," "will," "could," "would," "should," "expect," or the negative of such terms or other comparable terminology.

We have based these forward-looking statements on our current expectations and projections about future events. We believe that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to us on the date hereof, but we cannot assure you that these assumptions and expectations will prove to have been correct or that we will take any action that we may presently be planning. These forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected or anticipated in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, research and product development uncertainties, regulatory policies and approval requirements, competition from other businesses, market and general economic factors, and the other risks discussed in Item 1A of this Annual Report. This discussion should be read in conjunction with the consolidated financial statements and notes thereto included in this Annual Report.

We have identified some of the important factors that could cause future events to differ from our current expectations and they are described in this Annual Report in the section entitled "Risk Factors" that you should review carefully. Please consider our forward-looking statements in light of those risks as you read this Annual Report. If one or more of these or other risks or uncertainties materialize, or if our underlying assumptions prove to be incorrect, actual results may vary materially from what we project. We do not undertake to update any forward-looking statements or to publicly announce the results of any revisions to any statements to reflect new information or future events or developments.

PART I

Item 1. ***Business***

Overview

Our Company

We are a women's health care company focused on creating and commercializing products targeted exclusively for women. Currently, we are focused on pursuing the regulatory approvals and pre-commercialization activities necessary for commercialization of our advanced hormone therapy pharmaceutical products. Our drug candidates that have completed clinical trials are designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes and vaginal discomfort. We are developing these hormone therapy drug candidates, which contain estradiol and progesterone alone or in combination, with the aim of demonstrating clinical efficacy at lower doses, thereby enabling an enhanced side-effect profile compared with competing products. With our SYMBODA™ technology, we are developing advanced hormone therapy pharmaceutical products to enable delivery of bio-identical hormones through a variety of dosage forms and administration routes. In addition, we manufacture and distribute branded and generic prescription prenatal vitamins.

We have submitted two new drug applications, or NDAs, to the U.S. Food and Drug Administration, or FDA. In December 2017, we submitted our NDA for TX-001HR, our bio-identical hormone therapy combination of 17ß- estradiol and progesterone in a single, oral softgel drug candidate, for the treatment of moderate to severe vasomotor symptoms, or VMS, due to menopause in menopausal women with an intact uterus. In November 2017, we re-submitted our NDA for TX-004HR, our applicator-free vaginal estradiol softgel drug candidate for the treatment of moderate to severe dyspareunia (vaginal pain during sexual intercourse), a symptom of vulvar and vaginal atrophy, or VVA, in menopausal women with vaginal linings that do not receive enough estrogen. The NDA for our TX-004HR drug candidate has a Prescription Drug User Fee Act, or PDUFA, target action date for the completion of the FDA's review of May 29, 2018 and, if approved on that date, the drug candidate could be launched as early as the third quarter of 2018. If the NDA for TX-001HR is accepted by the FDA, it could be approved as soon as the fourth quarter of 2018 and launched in 2019. We intend to leverage and grow our current marketing and sales organization to commercialize our advanced hormone therapy drug candidates in the United States assuming the successful completion of the FDA regulatory process. We believe that our national sales force has developed strong relationships in the OB/GYN market to sell our current prescription prenatal vitamin products and that by delivering additional products through the same sales channel we can leverage our already deployed assets.

Throughout this Annual Report, the terms "we," "us," "our," "TherapeuticsMD," or "our company" refer to TherapeuticsMD, Inc., a Nevada corporation, and unless specified otherwise, include our wholly owned subsidiaries, vitaMedMD, LLC, a Delaware limited liability company, or VitaMed; BocaGreenMD, Inc., a Nevada corporation, or BocaGreen; and VitaCare Prescription Services, Inc., a Florida corporation, or VitaCare.

Hormone Therapy Market

The menopause hormone therapy market includes two major components: an FDA-approved drug market and a non-FDA approved drug market supplied by compounding pharmacies. On November 27, 2013, the Drug Quality and Security Act of 2013, or the DQSA, became law and the FDA was given additional oversight over compounding pharmacies. We believe FDA-approved products are easily measured and monitored, while non-FDA approved hormone therapy drug products, typically referred to as bioidenticals when produced and sold by compounding pharmacies, are not easily measured or monitored. We estimate the sales of non-FDA approved compounded bioidentical hormone therapy combinations of estradiol and progesterone products by compounding pharmacies approximate $1.5 billion per year. According to PHAST™ Prescription from Symphony Health IVD, or Symphony Heath Solutions, the market for FDA-approved hormone therapy products for the treatment of menopause symptoms or prevention of osteoporosis approximated $4.7 billion based on 2017 sales. Our phase 3 clinical trials were intended to establish an indication of the safety and efficacy of our hormone therapy drug candidates at specific dosage levels. We intend our hormone therapy drug candidates, if approved, to provide hormone therapies with well characterized safety and efficacy profiles that can be consistently manufactured to target specifications. This would provide an alternative to the non-FDA approved compounded bioidentical market. This is based on our belief that our drug candidates will offer advantages in terms of demonstrated safety and efficacy, consistency in the hormone dose, lower patient cost as a result of insurance coverage, and improved access as a result of availability from major retail pharmacy chains rather than custom order or formulation by individual compounders.

Pipeline of our Hormone Therapy Drug Candidates

TX-001HR

TX-001HR is our bio-identical hormone therapy combination of 17ß- estradiol and progesterone in a single, oral softgel drug candidate for the treatment of moderate to severe VMS due to menopause, including hot flashes, night sweats and sleep disturbances in menopausal women with an intact uterus. The hormone therapy drug candidate is bioidentical to – or having the same chemical and molecular structure as - the hormones that naturally occur in a woman's body, namely estradiol and progesterone, and is being studied as a continuous-combined regimen, in which the combination of estrogen and progesterone are taken together in one product daily. If approved by the FDA, we believe this would represent the first time a combination product of estradiol and progesterone bioidentical to the estradiol and progesterone produced by the ovaries would be approved for use in a single combined product. According to Symphony Health Solutions, sales of FDA-approved combinations of estrogen and progestins were approximately $588 million and sales of estradiol and progesterone on a stand-alone basis were approximately $952 million and approximately $404 million, respectively, in the United States for the 12 months ended December 31, 2017. In December 2016, we announced positive top-line results from the recently completed REPLENISH Trial, our phase 3 clinical trial of TX-001HR, and on December 28, 2017 we submitted an NDA for TX-001HR with the FDA. Assuming that the NDA is accepted 74 days thereafter and an FDA review period of ten months from the receipt date to the PDUFA date for a non-new molecular entity, the NDA for TX-001HR could be approved by the FDA as soon as the fourth quarter of 2018.

TX-002HR

TX-002HR is a natural progesterone formulation for the treatment of secondary amenorrhea without the potentially allergenic component of peanut oil. The hormone therapy drug candidate is bioidentical to – or having the same chemical and molecular structure as - the hormones that naturally occur in a woman's body. In July 2014, we suspended enrollment and in October 2014 we stopped the SPRY Trial, our phase 3 clinical trial for TX-002HR, to update the phase 3 protocol based on discussions with the FDA. Our Investigational New Drug Application, or IND, related to TX-002HR is currently in inactive status. We have currently suspended further development of this drug candidate to prioritize our leading drug candidates.

TX-003HR

TX-003HR is a natural estradiol formulation. This hormone therapy drug candidate is bioidentical to the hormones that naturally occur in a woman's body. We currently do not have plans to further develop this hormone therapy drug candidate. Our IND related to TX-003HR is currently inactive.

TX-004HR

TX-004HR is our applicator-free vaginal estradiol softgel drug candidate for the treatment of dyspareunia, a symptom of VVA in menopausal women with vaginal linings that do not receive enough estrogen. We believe that our drug candidate will be at least as effective as the traditional treatments for VVA because of an early onset of action with less systemic exposure, and it will have an added advantage of being a simple, easier to use dosage form versus traditional VVA treatments. According to Symphony Health Solutions, sales of FDA-approved products for VVA treatment were approximately $1.8 million in the United States for the 12 months ended December 31, 2017. In December 2015, we announced positive top-line results from the REJOICE Trial, our phase 3 clinical trial of TX-004HR. In November 2017, we re-submitted our NDA for TX-004HR. The NDA has a PDUFA target action date for the completion of the FDA's review of May 29, 2018, and, if approved on that date, the drug candidate could be launched as early as the third quarter of 2018.

Preclinical Development

Based upon leveraging our SYMBODA™ hormone technology, we have four preclinical projects that include development of a progesterone-alone and combination estradiol and progesterone products in a topical cream form, which we refer to as TX-005HR and TX-006HR, respectively, and transdermal patch form, which we refer to as TX-007HR and TX-008HR, respectively. We completed a proof-of-concept preclinical study of TX-005HR in 32 rats. The study used four groups of eight female ovariectomized rats, each of whom were treated with subcutaneous injections of estradiol for eight days. On day four of treatment, they were also dosed with a placebo, subcutaneous injections of progesterone or a similar dose of TX-005HR topical progesterone cream. The results, presented at North American Menopause Society, or NAMS, meeting in October 2015, showed that the progesterone in TX-005HR penetrated the skin and opposed the effect of subcutaneous estradiol on the endometrium. In the fourth quarter of 2016, we submitted an IND application for TX-006HR, our combination estradiol and progesterone drug candidate in a topical cream form, and intend to commence phase 1 clinical trials of this drug candidate as early as 2018. We may in the future engage with a financing partner to advance our topical cream and transdermal patch projects. We have recently conducted rat bioavailability studies on several novel, oral formulations of progesterone. We are currently adapting this formulation for the inclusion of estradiol and have embarked on its development as TX-009HR. In addition to menopausal treatments, we are also evaluating various other indications for our hormone technology, including contraception and premature ovarian failure.

Current Products

As we continue the clinical development of our hormone therapy drug candidates, we continue to manufacture and distribute our prescription product lines, consisting of prenatal vitamins under our vitaMedMD® brand name and authorized generic formulations of some of our prescription prenatal vitamin products under our BocaGreenMD® Prena1 name. All of our prenatal vitamins are gluten-, sugar-, and lactose-free. A prenatal vitamin option that is both vegan and kosher is also available for women with special dietary needs. We believe our product attributes result in greater consumer acceptance and satisfaction than competitive products while offering the highest quality and patented ingredients. As of January 1, 2017, we decided to focus on selling our prescription vitamins and ceased manufacturing and distributing our over-the-counter, or OTC, product lines, except for Iron 21/7 which we ceased manufacturing and distributing in October 2017. The sales of discontinued products have declined steadily over time resulting in immaterial sales.

Industry and Market

Health Care and Pharmaceutical Market

According to the EvaluatePharma® World Preview 2017, Outlook to 2022 report, despite the global pharmaceutical industry facing pricing and market access concerns, worldwide prescription drug sales are expected to reach approximately $1.1 trillion by 2022, which would represent a compound annual growth rate of approximately 6.5% between 2017 and 2022. New drug approvals in 2016 dropped to 27 (consisting of new molecular entities and biologics), down 50%, as compared to the record high of 56 approvals in 2015. A positive drug approval trend was observed in the first months of 2017 with 21 novel drugs already approved as compared to 15 drugs approved up to May 2016, suggesting that the decline in approvals in 2016 was mostly due to timing of approvals rather than more structural dynamics. There were 51 new drugs (consisting of new molecular entities and biologics) approved by FDA in 2014. The value of these drugs continues to be high, and with U.S. five years post-launch sales of the new drugs approved in 2016, 2015 and 2014 forecast to be over $14 billion, $30 billion, $23 billion, respectively.

Women's Health Care Market

According to the BBC Research report "Therapeutics for Women's Health: Technologies and Global Markets," menopause, post-menopause osteoporosis, endometriosis, breast cancer and polycystic ovary syndrome (PCOS) are the most common issues within women's health and the U.S. women's health therapeutics market will grow from nearly $19.5 billion in 2015 to $25.3 billion by 2020, rising at compound annual growth rate of 5.4%. According to the GBI Research (a provider of industry-leading business intelligence solutions on a global basis) report "Women's Health Therapeutic Market through 2018," the women's health therapeutics market is one of the most attractive markets in the global pharmaceutical industry. Hormone therapy, gynecological disorders, and musculoskeletal disorders in women are the prime areas of focus in the women's health therapeutics market.

Hormone Therapy Market

Menopause is the spontaneous and permanent cessation of menstruation, which naturally occurs in most women between the ages of 40 and 58. It is defined as the final menstrual period and is confirmed when a woman has not had her period for 12 consecutive months. Hormone therapy is the most effective treatment in the United States and Canada for relief of menopausal symptoms according to NAMS. These symptoms are caused by the reduced levels of circulating estrogen as ovarian production shuts down. The symptoms include hot flashes, night sweats, sleep disturbances, and vaginal dryness. According to Symphony Health Solutions, prescriptions for FDA-approved hormone therapy products for the treatment of menopause symptoms or prevention of osteoporosis generated total U.S. sales of over $4.7 billion on over 30 million prescriptions for the 12 months ended December 31, 2017, of which prescriptions for oral hormone therapy accounted for approximately $2.0 billion in U.S. sales on 20 million prescriptions over the same time period.

Prescriptions for menopausal hormone therapy in the United States dropped significantly following the Women's Health Initiative, or WHI, study in 2002, which found that subjects using conjugated equine estrogens plus the synthetic progestin medroxyprogesterone acetate had, among other things, a greater incidence of coronary heart disease, breast cancer, stroke, and pulmonary embolism. A number of additional studies regarding the benefits and risks of hormone therapy have been conducted over the last decade since the WHI results were first published. In general, recommendations for hormone therapy use are to be judged on an individual basis, and the FDA recommends that women with moderate to severe menopausal symptoms who want to try menopausal hormone therapy for relief use it for the shortest time needed and at the lowest effective dose.

There were approximately 41.7 million women in the United States between the ages of 45 and 64 in 2010, projected to increase slightly by 2.8% to 42.9 million in 2015 and to approximately 44.3 million in 2040, according to the 2010 National Census population figures. These women are the target market for hormone therapy to treat menopausal related symptoms.

Hormone Therapy Products

Estrogen (with or without a progestin) is the most effective treatment of VMS and VVA due to menopause according to NAMS. According to Symphony Health Solutions, total U.S. sales of FDA-approved oral, transdermal, and suppository estrogen (with and without a progestin) hormone therapy products were approximately $4.0 billion for the 12 months ended December 31, 2017. The three primary hormone therapy products are estrogen, progestin, and combination of estrogen and progestin, which are produced in a variety of forms, including oral tablets or capsules, skin patches, gels, emulsion, or vaginal suppositories and creams.

Estrogen-Only Therapies

Estrogen therapies are used to treat VMS due to menopause that are a direct result of the decline in estrogen levels associated with ovarian shutdown at menopause. Estrogen therapy has been used to manage these symptoms for more than 50 years. Estrogen is a generic term for any substance, natural or synthetic, that exerts biological effects characteristic of estrogenic hormones, such as estradiol, a natural ovarian produced estrogen. Based upon the age demographic for all women receiving prescriptions for estrogen therapy and the average age range during which women experience VMS, we believe that estrogen is primarily used for the treatment of VMS, but also is prescribed for the prevention of osteoporosis.

Estrogen-only therapy, or ET, is used primarily in women who have had a hysterectomy and/or have undergone surgical menopause, as those women do not require a progestin to protect the uterine endometrium. Approximately 433,000 women undergo a hysterectomy each year in the United States according to the United States Centers for Disease Control and Prevention. ET is also used for the treatment of VVA, which has a variety of indications, including dyspareunia (painful intercourse), vaginal dryness, vaginal itching and irritation, painful urination, and other symptoms.

ET is also approved for the prevention of osteoporosis. Multiple studies conducted on various estrogen compositions, including studies published in the Journal of the American Medical Association in 2002, Osteoporosis International in 2000, The Lancet in 2002, Maturitas in 2008, and Climacteric in 2005, suggested efficacy based on increases in bone mineral density. Epidemiological and some fracture prevention studies, such as the study published in the New England Journal of Medicine in 1980, also have suggested a decrease in bone fractures as a result of ET.

According to Symphony Health Solutions, total FDA-approved ET only U.S. sales amounted to $2.8 billion, of which $1.8 billion was specifically used for the treatment of VVA, for the 12 months ended December 31, 2017.

Progestin-Only Therapies

Progestins include the naturally occurring hormone progesterone and a number of synthetic progestin compounds that have progestational activity. These agents are used for a variety of indications and conditions, but most often, progestins are used either alone or in combination with an estrogen for hormonal contraception and to prevent endometrial hyperplasia from unopposed estrogen in hormone therapy. Progestins alone are also used to treat women with secondary amenorrhea in order to create withdrawal bleeding in these women who have not had regular menses. Progestins are also used to treat dysfunctional uterine bleeding and endometriosis. Progesterone has also been used to prevent threatened or recurrent pregnancy loss and for the prevention of preterm birth. Progestins have also been used in fertility treatments. Progestins have also been used as a palliative measure for metastatic endometrial carcinoma and in the treatment of renal and breast carcinoma.

Estrogen/Progestin Combination Products

Progestins are used in combination with estrogen in menopausal women with uteruses to avoid an increase in the incidence of endometrial hyperplasia, which is a condition caused by chronic use of estrogen alone by a woman with a uterus and is associated with an increased incidence of uterine, or endometrial, cancer. Studies have shown that, after one year, the incidence of endometrial hyperplasia is less than 1% in women taking estrogen/progestin combinations, in contrast to up to 20% in women taking estrogen alone. In accordance with FDA recommendations, doctors typically recommend that a menopausal or post-menopausal woman who has a uterus take estrogen plus a progestin, either as a combination drug or as two separate drugs. Symphony Health Solutions estimates that sales of FDA-approved combinations of estrogen and progestins were approximately $588 million and the sales of estradiol and progesterone on a stand-alone basis were approximately $952 million and approximately $404 million, respectively, in the United States for the 12 months ended December 31, 2017.

Limitations of Existing Estrogen/Progestin Therapies

The most commonly prescribed progestin is a synthetic progestin (medroxyprogesterone acetate), which can cause some women to experience painful vaginal bleeding, breast tenderness, and bloating and may reduce cardio-protective benefits potentially associated with estrogen therapy by limiting the estrogen's ability to raise high-density lipoprotein cholesterol, or good cholesterol, and low-density lipoprotein, or bad cholesterol. A widely prescribed naturally occurring progesterone is known as Prometrium® (progesterone USP). The brand is marketed by AbbVie Inc., and generic versions have been available since 2012. Natural progesterone is used in combination with estrogen for hormone therapy; however, we believe there are currently no FDA-approved hormone therapy combination products with natural progesterone.

Prenatal Vitamin Market

According to the Centers for Disease Control and Prevention, there are approximately four million births per year in the U.S. Of women giving birth in the U.S., the U.S. Department of Health and Human Services reports that approximately 73% received early prenatal care in the first trimester, while 6% began prenatal care in the third trimester or did not receive any prenatal care. Most doctors encourage taking a prenatal vitamin as the recommended standard of care. Prenatal vitamins are dietary supplements intended to be taken before and during pregnancy and during postnatal lactation that provide nutrients recognized by various health organizations as helpful for a healthy pregnancy outcome.

There are hundreds of prenatal vitamins available, with both prescription and OTC choices. According to Symphony Health Solutions, during the 12 months ended December 31, 2017, approximately 6.2 million prescriptions for prenatal vitamins were issued in the United States resulting in total sales of approximately $379 million, with sales between branded and generic products split nearly evenly.

Our Business Model

We are a women's health care company focused on creating and commercializing products exclusively for women, including products specifically for pregnancy, childbirth, nursing, pre-menopause, and menopause. We have utilized our current product lines as the foundation of our business platform. If approved and commercialized, our hormone therapy drug candidates will allow us to enter the $4.7 billion market for FDA-approved hormone therapy products for the treatment of menopause symptoms or prevention of osteoporosis, based on 2017 total U.S. sales of the hormone therapy market, according to Symphony Health Solutions.

Our current product line is marketed and sold by a direct national sales force that calls on health care providers in the OB/GYN market space. We market our prescription prenatal vitamins under our vitaMedMD brand name and authorized generic formulations of our prescription prenatal vitamin products under our BocaGreenMD Prena1 brand name. We believe that our vitaMedMD brand name has become a recognized name for high quality women's health care, while our BocaGreenMD products provide physicians, women, and payors with a lower Wholesale Acquisition Cost (WAC) alternative for prenatal vitamins. We intend to leverage our existing relationships and distribution system to introduce our hormone therapy drug candidates, if approved, which we believe will enable us to provide a comprehensive line of women's health care products all under one brand. As of January 1, 2017, we decided to focus on selling our prescription vitamins and ceased manufacturing and distributing our OTC product lines, except for Iron 21/7 which we ceased manufacturing and distributing in October 2017. The sales of discontinued products have declined steadily over time resulting in immaterial sales.

Our sales model focuses on the "4Ps": patient, provider, pharmacist, and payor. We market and sell our current products primarily through a direct national sales force of approximately 50 full-time professionals that calls on health care providers in the OB/GYN market space. In addition, our products allow health care providers to offer an alternative to patients to meet their individual nutritional and financial requirements related to co-payment and cost-of-care considerations and help patients realize cost savings over competing products. We also believe that our combination of branded and authorized generic lines offers physicians, women, and payors cost-effective alternatives for top-quality care. We supply our prescription products to consumers through retail pharmacies nationwide. Our fully staffed customer care center uses current customer relationship management software to respond to health care providers, pharmacies, and consumers via incoming and outgoing telephone calls, e-mails, and live-chat. As of January 1, 2017, we stopped selling our products through our websites directly to consumers.

As health care becomes increasingly consumer driven, patients are seeking more information, control, and convenience, which places additional time and financial pressures on physicians, and as a result, physicians are looking for improved ways to provide better service to their patients. A recent study by IMS Health Inc. concluded that physicians desire fewer but more encompassing relationships with companies that can provide more valuable information, deliver more relevant services, and better respond to specific needs of their practice and patients. Our goal is to meet this challenge by focusing on the opportunities in women's health, specifically the OB/GYN market, to provide a better customer experience for physician, payor, pharmacist, and patient through the following means:

- We believe we will offer physicians a comprehensive product line of women's health care products, including our hormone therapy drug candidates, if approved.
- Our hormone therapy drug candidates are designed to use the lowest effective dose for the shortest duration.
- We believe the attributes of our dietary supplements will result in greater consumer acceptance and satisfaction than competitive products while offering the highest quality products incorporating patented ingredients, such as Quatrefolic®, FOLMAX®, FePlus®, and pur-DHA™. All of our prenatal vitamins are gluten-, sugar-, and lactose-free.
- We strive to improve our existing products and develop new products to generate additional revenue through our existing sales channels.
- We believe health care providers are able to offer alternatives to patients that meet the patient's individual nutritional and financial requirements and help patients realize cost savings over competing products.
- Improved patient education, a high level of patient compliance, and reduced cost of products all result in lower cost of care for payors and improved outcomes for patients.

Our Growth Strategy

We are a women's health care company with a corporate culture designed to foster innovation in the development and commercialization of products that address the needs of patients, pharmacists, payers and providers in the twenty-first century.

We believe that building a culture of innovation around patient needs and opportunities, rather than focusing on specific drugs, will enable us to effectively develop and commercialize our products.

Exclusive Focus on Women's Health Issues . We have steadily developed relationships with many of the largest OB/GYN practices in the country through the sales of our line of prenatal vitamins. We believe that our singular focus on women's health issues will enable us to continue to build long-term relationships with women as they move through their life cycles of family planning through menopause.

Focus on Hormone Therapy Products. We plan to continue our focus on the development, clinical trials, and commercialization of hormone therapy products designed to (1) alleviate the symptoms of, and reduce the health effects resulting from, menopause-related hormone deficiencies, including hot flashes and vaginal dryness, and (2) demonstrate equivalent clinical efficacy at lower doses, enabling an enhanced side effect profile compared with competing products. We believe there is a large unmet need in this segment of the market.

Penetrate Compounding Market with FDA-approved Products. As we are not aware of any current FDA-approved hormone therapy combination products that are bioidentical to – or having the same chemical and molecular structure as - the estradiol and progesterone produced by the ovaries, we believe that our hormone therapy drug candidate for combined estradiol and progesterone, if approved by the FDA, will provide a safer and more effective alternative to non-FDA approved compounded bioidentical hormone therapy products, at a lower price to patients since most insurance companies do not provide coverage for non-FDA approved compounded products. We intend to work with independent and community based pharmacies that currently compound bioidentical hormone therapy products to help them transition their patients to our hormone therapy products, if approved. We launched the BIO-IGNITE™ program, an outreach program to quantify the number of compounded bio-identical estradiol and progesterone prescriptions currently dispensed by the 3,000-3,500 high-volume compounding pharmacies and qualify their interests in dispensing our hormone therapy product candidates, if approved. As part of the BIO-IGNITE™ program, we intend to work with compounding pharmacies to identify the number of compounded estradiol and progesterone prescriptions that are directly substitutable by the two potential doses of TX-001HR, if approved, and to enter into agreements with such pharmacies to dispense our hormone therapy products in lieu of compounding, if approved.

Multi-Channel Marketing Emphasis. We plan to continue our emphasis on large group OB/GYN practices that provide opportunities to reach large patient bases and that are receptive to the data and savings we provide. We believe this will effectively position us for the launch of our hormone therapy products, if approved.

In addition, proliferation of digital technology has dramatically increased the amount of information to available to patients and providers putting more power in their hands. We believe this makes patient/provider engagement and experience a more important lever for life sciences companies and that providing patients and providers with important information whenever and however they want it, on a real-time basis, is a critical piece of serving this market.

Multiple Sales Partners. We plan to continue to pursue multiple sales partners, including large chain pharmacies, independent community pharmacies, mail order and compounding and specialty pharmacies. We believe providing a higher level of customer care through unique programs targeted at each of these sales partners can produce better outcomes and value for the patient, provider and payer.

Geographical Expansion. We currently plan to expand our geographic market and sales team to approximately 150 professionals as we commercialize our TX-001HR and TX-004HR product candidates, if approved.

Sales and Marketing

Although our direct national sales force is similar to that of a traditional pharmaceutical company in that sales representatives call on OB/GYN practices to provide education and sampling, we believe our sales representatives are more customer-centric in their sales approach by offering physicians more than just differences in our products from the competition; they are also able to offer physicians opportunities to assist their patients in obtaining products in a cost-effective manner.

Our national rollout strategy has been to focus first on the largest metropolitan areas in the United States. In order to accelerate the sales ramp-up in a new territory, we employ a national sales/large practice sales effort to identify key practices in new or expanding markets. Concurrent with our provider sales effort, we work with commercial insurance payors for partnerships in which the payor can support the prescription and/or recommendation of our products for the benefit of the patient, physician, and payor, with an end result of providing better outcomes for all three constituents.

At the forefront of our sales approach is the philosophy that the physician should recommend or prescribe products based only on what is best for the patient. In general, a better outcome is achieved by providing patients with the best products and care at the best value. We believe having an assortment of high-quality product options that can be recommended or prescribed by both the physician and payor is the foundation of providing valuable options to the patient.

We believe our sales force has developed strong relationships in the OB/GYN market to sell our current products. We have also established relationships with some of the largest OB/GYN practices in their respective markets. By delivering additional products through the same sales channel, we believe we can leverage our already deployed assets to increase our sales and achieve profitability. We intend to leverage and grow our current marketing and sales organization to commercialize our drug candidates in the United States assuming the successful completion of the FDA regulatory process. In addition, we may partner with licensors or other strategic partners to commercialize our drug candidates outside of the OB/GYN market or in non-U.S. markets.

Online Commerce

A vast majority of our OTC product sales were completed online. As of January 1, 2017, we decided to focus on selling our prescription vitamins and ceased manufacturing and distributing our OTC product lines, except for Iron 21/7 which we ceased manufacturing and distributing in October 2017. The sales of discontinued products have declined steadily over time resulting in immaterial sales. As a result, as of January 1, 2017, we stopped selling our products through our websites directly to consumers.

Sales Concentration

See Note 11 to the consolidated financial statements included in this Annual Report for a discussion of the concentration of sales of our prescription prenatal vitamin products.

Commercialization

We cannot market or promote a new product until a marketing application has been approved by the FDA. On November 29, 2017, we resubmitted the NDA for TX-004HR with the FDA. The FDA has acknowledged that the resubmission is a complete, class 2 response to the complete response letter, or CRL, that we received on May 5, 2017 for TX-004HR. The PDUFA target action date for the completion of the FDA's review of the NDA for TX-004HR is May 29, 2018.

We submitted the NDA for TX-001HR with the FDA on December 28, 2017. Assuming that the NDA is accepted 74 days thereafter and an FDA review period of ten months from the receipt date to the PDUFA date for a non-new molecular entity, the NDA for TX-001HR could be approved by the FDA as soon as the fourth quarter of 2018.

We believe that it will be possible for us to access the United States market through a specialty sales force. Subject to receiving marketing authorization in the United States, we expect to commence commercialization via our then-in-place sales and marketing organization. If approved, we plan to launch TX-004HR in the third quarter of 2018 and TX-001HR in 2019.

Our Current Product Lines

We offer a wide range of products targeted for women's health specifically associated with pregnancy, child birth, nursing, and post-child birth. As we continue the clinical development of our hormone therapy drug candidates, we continue to manufacture and distribute our prescription prenatal vitamins product lines under our vitaMedMD® brand name and authorized generic formulations of some of our prescription prenatal vitamin products under our BocaGreenMD® Prena1 name. As of January 1, 2017, we decided to focus on selling our prescription vitamins and ceased manufacturing and distributing our OTC product lines, except for Iron 21/7 which we ceased manufacturing and distributing in October 2017. The sales of discontinued products have declined steadily over time resulting in immaterial sales.

For the years ended December 31, 2017, 2016, and 2015, approximately 99.9%, 99.8%, and 99.5%, respectively, of our consolidated revenue was generated by our prenatal vitamin products.

In March 2012, we launched our first prescription prenatal vitamin, vitaMedMD Plus Rx, with subsequent launches of our second prescription prenatal vitamin, vitaMedMD One Rx, in April 2012 and our third prescription prenatal vitamin, vitaMedMD RediChew™ Rx, in May 2012. In the fourth quarter of 2012, we launched our BocaGreenMD Prena1 line of prescription prenatal vitamins, which included three prescription prenatal vitamins that were authorized generic formulations of our vitaMedMD-branded prescription prenatal vitamins. In the first quarter of 2014, we introduced a new prescription prenatal vitamin product under our branded vitaMedMD name as vitaPearl and under our authorized generic Prena1 name as Prena1 Pearl, which features a unique, proprietary combination of FOLMAX™, FePlus™, and pur-DHA™. In January 2016, we launched vitaTrue. Our current product line is detailed below.

vitaTrue™

vitaTrue™ is our newest prescription prenatal vitamin and is targeted at health-conscious consumers. *vitaTrue™* is the first and only vegan and kosher prenatal vitamin with 40% more folic acid than the leading prescription prenatal vitamin. *vitaTrue™* contains a complete multivitamin with 16 essential vitamins and minerals and 300 mg of plant based docosahexaenoic acid, or DHA. vitaTrue is fish, gluten, lactose, and sugar free.

vitaPearl™

vitaPearl is our leading prescription prenatal vitamin and is a complete prenatal vitamin in one tiny pearl. *vitaPearl* provides 40% more folic acid than the leading prescription prenatal vitamin. *vitaPearl* delivers 14 key vitamins and minerals plus 200 mg of DHA, providing comprehensive support for a woman and her body whether she is planning a pregnancy, pregnant, or nursing.

vitaMedMD One Rx Prenatal Multivitamin

vitaMedMD One Rx is a prescription product with a single-dose daily multivitamin that provides 14 vitamins and minerals, Quatrefolic®, and 200 mg of plant-based DHA.

vitaMedMD RediChew® Rx Prenatal Multivitamin

vitaMedMD RediChew® Rx is a prescription, easy-to-chew, small, vanilla-flavored chewable tablet containing Folmax®, vitamin D3, vitamin B2, vitamin B6, and vitamin B12. We believe *vitaMedMD RediChew Rx* is an excellent option for women who have difficulty swallowing tablets or softgels, or are experiencing nausea and morning sickness.

BocaGreenMD Prena1 True

BocaGreenMD Prena1 True is an authorized generic of *vitaTrue™*, the first vegan and kosher prenatal vitamin.

BocaGreenMD Prena1 Pearl

BocaGreenMD Prena1 Pearl is an authorized generic of *vitaPearl*, a complete prescription prenatal vitamin in one tiny pearl.

BocaGreenMD Prena1 Chew

BocaGreenMD Prena1 Chew is an authorized generic of *vitaMedMD RediChew Rx*, a prescription, single daily easy-to-chew, vanilla-flavored, chewable tablet.

Products discontinued: *vitaMedMD Plus (Prenatal Women's Multivitamin + DHA™)* , *vitaMedMD One Prenatal Multivitamin, vitaMedMD Plus Rx Prenatal Multivitamin, vitaMedMD Menopause Relief with Lifenol® Plus Bone Support, vitaMedMD Vitamin D3 50,000 IU, and vitaMedMD Iron 21/7.*

Our Hormone Therapy Drug Candidates

We have submitted two NDAs with the FDA for our hormone therapy drug candidates. In December 2017, we submitted the NDA for TX-001HR, our bio-identical hormone therapy combination of 17ß- estradiol and progesterone in a single, oral softgel drug candidate, for the treatment of VMS due to menopause in menopausal women with an intact uterus. In November 2017, we re-submitted our NDA for TX-004HR, our applicator-free vaginal estradiol softgel drug candidate for the treatment of moderate to severe dyspareunia (vaginal pain during sexual intercourse), a symptom of VVA in menopausal women with vaginal linings that do not receive enough estrogen. The NDA for our TX-004HR drug candidate has a PDUFA target action date of May 29, 2018, and if approved on that date, the drug candidate could be launched as early as the third quarter of 2018. If the NDA for our TX-001HR drug candidate is accepted by the FDA, it could be approved as soon as the fourth quarter of 2018 and launched in 2019.

TX-001HR

TX-001HR is our bio-identical hormone therapy combination of 17ß- estradiol and progesterone in a single, oral softgel drug candidate for the treatment of moderate to severe VMS due to menopause, including hot flashes, night sweats and sleep disturbances for menopausal women with an intact uterus. The hormone therapy drug candidate is bioidentical to – or having the same chemical and molecular structure as - the hormones that naturally occur in a woman's body, namely estradiol and progesterone, and is being studied as a continuous-combined regimen, in which the combination of estrogen and progesterone are taken together in one product daily. If approved by the FDA, we believe this would represent the first time a combination product of estradiol and progesterone bioidentical to the estradiol and progesterone produced by the ovaries would be approved for use in a single combined product.

We previously conducted a pharmacokinetics, or PK, study of TX-001HR to demonstrate that our drug candidate is bioequivalent to the reference listed drug based on the criterion that the 90% confidence interval on the test-to-reference ratio is contained entirely within the interval 80% to 125%. The study compared our combined capsule TX-001HR of 2 mg estradiol and 200 mg of progesterone to 2 mg of Estrace® and 200 mg of Prometrium®.

The study compared the mean plasma concentrations for free estradiol between TX-001HR and Estrace® in 62 female test subjects. When the results of a single dose-fed study were compared over 48 hours by the test drug versus reference drug, the ratio was 0.93 with the standard deviation within the subject being 0.409 for an upper 95% confidence bound of -0.089. The maximum plasma concentration levels of free estradiol showed that the drug -versus - reference drug ratio was 0.88 with the standard deviation within the subject being 0.344 for an upper 95% confidence bound of -0.040 over 48 hours.

The study also compared the mean plasma concentrations for progesterone between TX-001HR and Prometrium® in 62 female test subjects. When the results were compared over 48 hours of the test that the drug-versus-reference drug, the ratio was 1.05 with the standard deviation within the subject being 0.956 for an upper 95% confidence bound of -0.542. The maximum plasma concentration levels of progesterone showed drug versus reference drug ratio as 1.16 with the standard deviation within the subject being 1.179 for an upper 95% confidence bound of -0.785 over 48 hours.

On September 5, 2013, we began enrollment in the REPLENISH Trial, a multicenter, double-blind, placebo-controlled, phase 3 clinical trial of TX-001HR in menopausal women with an intact uterus. The trial was designed to evaluate the efficacy of TX-001HR for the treatment of moderate to severe VMS due to menopause and the endometrial safety of TX-001HR. Patients were assigned to one of five arms, four active and one placebo, and received study medication for 12 months. The primary endpoint for the reduction of endometrial hyperplasia was an incidence of endometrial hyperplasia of less than 1% at 12 months, as determined by endometrial biopsy. The primary endpoint for the treatment of moderate to severe VMS was the mean change of frequency and severity of moderate to severe VMS at weeks four and 12 compared to placebo, as measured by the number and severity of hot flashes. Only subjects experiencing a minimum daily frequency of seven moderate to severe hot flashes at screening were included in the VMS analysis, while all subjects were included in the endometrial hyperplasia analysis. The secondary endpoints included reduction in sleep disturbances and improvement in quality of life measures, night sweats and vaginal dryness, measured at 12 weeks, six months and 12 months. The trial evaluated 1,835 patients between 40 and 65 years old at 111 sites. On December 5, 2016, we announced positive topline data for the REPLENISH Trial.

The REPLENISH Trial evaluated four doses of TX-001HR and placebo; the doses studied were:

- 17ß-estradiol 1 mg/progesterone 100 mg (n = 416)

- 17ß-estradiol 0.5 mg/progesterone 100 mg (n = 423)
- 17ß-estradiol 0.5 mg/progesterone 50 mg (n = 421)
- 17ß-estradiol 0.25 mg/progesterone 50 mg (n = 424)
- Placebo (n = 151)

The REPLENISH Trial results demonstrated:

- TX-001HR estradiol 1 mg/progesterone 100 mg and TX-001HR estradiol 0.5 mg/progesterone 100 mg both achieved all four of the co-primary efficacy endpoints and the primary safety endpoint.
- TX-001HR estradiol 1 mg/progesterone 100 mg and TX-001HR estradiol 0.5 mg/progesterone 100 mg both demonstrated a statistically significant and clinically meaningful reduction from baseline in both the frequency and severity of hot flashes compared to placebo.
- TX-001HR estradiol 0.5 mg/progesterone 50 mg and TX-001HR estradiol 0.25 mg/progesterone 50 mg were not statistically significant at all of the co-primary efficacy endpoints. The estradiol 0.25 mg/progesterone 50 mg dose was included in the clinical trial as a non-effective dose to meet the recommendation of the FDA guidance to identify the lowest effective dose.
- The incidence of consensus endometrial hyperplasia or malignancy was 0 percent across all four TX-001HR doses, meeting the recommendations established by the FDA's draft guidance.

As outlined in the FDA guidance, the co-primary efficacy endpoints in the REPLENISH Trial were the change from baseline in the number and severity of hot flashes at weeks four and 12 as compared to placebo. The primary safety endpoint was the incidence of endometrial hyperplasia with up to 12 months of treatment. General safety was also evaluated.

The results of the REPLENISH Trial are summarized in the table below (p-values of < 0.05 meet FDA guidance and support evidence of efficacy):

Replenish Trial Co-Primary Efficacy Endpoints: Mean Change in Frequency and Severity of Hot Flashes Per Week Versus Placebo at Weeks 4 and 12, VMS-MITT Population					
Estradiol/Progesterone	1 mg/100 mg (n = 141)	0.5 mg/100 mg (n = 149)	0.5 mg/50 mg (n = 147)	0.25 mg/50 mg (n = 154)	Placebo (n = 135)
Frequency					
Week 4 P-value versus placebo	<0.001	0.013	0.141	0.001	—
Week 12 P-value versus placebo	<0.001	<0.001	0.002	<0.001	—
Severity					
Week 4 P-value versus placebo	0.031	0.005	0.401	0.100	—
Week 12 P-value versus placebo	<0.001	<0.001	0.018	0.096	—
Replenish Trial Primary Safety Endpoint: Incidence of Consensus Endometrial Hyperplasia or Malignancy up to 12 months, Endometrial Safety Population₸					
Endometrial Hyperplasia	0% (0/280)	0% (0/303)	0% (0/306)	0% (0/274)	0% (0/92)

MITT = Modified intent to treat

₸Per FDA, consensus hyperplasia refers to the concurrence of two of the three pathologists be accepted as the final diagnosis

We submitted the NDA for TX-001HR with the FDA on December 28, 2017. Assuming that the NDA is accepted 74 days thereafter and an FDA review period of ten months from the receipt date to the PDUFA target action date for a non-new molecular entity, the NDA for TX-001HR could be approved by the FDA as soon as the fourth quarter of 2018.

Symphony Health Solutions estimates that sales of FDA-approved combinations of estrogen and progestins were approximately $588 million and the sales of estradiol and progesterone on a stand-alone basis were approximately $952 million and approximately $404 million, respectively, in the United States for the 12 months ended December 31, 2017.

TX-002HR

TX-002HR is a natural progesterone formulation for the treatment of secondary amenorrhea without the potentially allergenic component of peanut oil. The hormone therapy drug candidate is bioidentical to – or having the same chemical and molecular structure as - the hormones that naturally occur in a woman's body. We believe it will be similarly effective to traditional treatments, but may demonstrate efficacy at lower dosages. In January 2014, we began recruitment of patients in the SPRY Trial, a phase 3 clinical trial designed to measure the safety and effectiveness of TX-002HR in the treatment of secondary amenorrhea. During the first two quarters of 2014, the SPRY Trial encountered enrollment challenges because of Institutional Review Board, or IRB, approved clinical trial protocols and FDA inclusion and exclusion criteria. In July 2014, we suspended enrollment and in October 2014 we stopped the SPRY Trial in order to update the phase 3 protocol based on discussions with the FDA. Our IND related to TX-002HR is currently in inactive status. We are considering updating the phase 3 protocol to, among other things, target only those women with secondary amenorrhea due to polycystic ovarian syndrome and to amend the primary endpoint of the trial. We believe that the updated phase 3 protocol, if proposed by us and approved by the FDA, would allow us to mitigate the enrollment challenges in, and shorten the duration of, the SPRY Trial. However, there can be no assurance that the FDA will approve the updated phase 3 protocol if we propose it. We have currently suspended further development of this drug candidate to prioritize our leading drug candidates.

TX-003HR

TX-003HR is a natural estradiol formulation. This hormone therapy drug candidate is bioidentical to the hormones that naturally occur in a woman's body. We currently do not have plans to further develop this hormone therapy drug candidate. Our IND related to TX-003HR is currently inactive.

TX-004HR

TX-004HR is our applicator-free vaginal estradiol softgel drug candidate for the treatment of moderate to severe dyspareunia, a symptom of VVA in menopausal women with vaginal linings that do not receive enough estrogen. We believe that our drug candidate will be at least as effective as the traditional treatments for VVA because of an early onset of action with less systemic exposure, and it will have an added advantage of being a simple, easier to use dosage form versus traditional VVA treatments. We initiated the REJOICE Trial, a randomized, multicenter, double-blind, placebo-controlled phase 3 clinical trial during the third quarter of 2014 to assess the safety and efficacy of three doses – 25 mcg, 10 mcg and 4 mcg (compared to placebo) – of TX-004HR for the treatment of moderate to severe dyspareunia, or painful intercourse, as a symptom of VVA due to menopause.

On November 10, 2015, the FDA held a scientific workshop on labeling "lower" dose estrogen-alone products for symptoms of VVA to provide an opportunity for the FDA to obtain input from experts on several topics related to the product label of lower dose estrogen-alone products approved solely for the treatment of moderate to severe symptoms of VVA due to menopause. According to the FDA, lower-dose estrogen products means products that contain less than the 0.625 mg of conjugated estrogens used in the WHI study and estradiol products containing 0.0375 mg and below. Discussion topics at the workshop included the relevance of the boxed warnings based on data from the WHI to the lower dose estrogen-alone products; certain members in the scientific/medical community have questioned whether the boxed warnings section in the labeling, which is currently required to be included on all estrogen products, is applicable in whole or in part to these lower-dose estrogen products. The boxed warnings include: (1) an increased risk of endometrial cancer in women with a uterus who uses unopposed estrogens, (2) estrogen therapy with or without progestins should not be used for the prevention of cardiovascular disease or dementia, (3) an increased risk of stroke and deep vein thrombosis (DVT) in women treated with estrogen-alone, (4) an increased risk of probable dementia in postmenopausal women 65 years of age and older treated with estrogen-alone, (5) an increased risk of invasive breast cancer in women treated with estrogen plus progestin, and (6) to use the lowest effective dose for the shortest duration. It is unknown at this time what, if any, changes the FDA may propose with respect to the boxed warnings on lower dose estrogen-alone products for symptoms of VVA or whether such label changes would be applicable to TX-004HR, if approved.

On December 7, 2015, we announced positive top-line results from the REJOICE Trial. The pre-specified four co-primary efficacy endpoints were the changes from baseline to week 12 versus placebo in the percentage of vaginal superficial cells, percentage of vaginal parabasal cells, vaginal pH and severity of participants' self-reported moderate to severe dyspareunia as the most bothersome symptom of VVA. The trial enrolled 764 menopausal women (40 to 75 years old) experiencing moderate to severe dyspareunia at approximately 89 sites across the United States and Canada. Trial participants were randomized to receive either TX-004HR at 25 mcg (n=190), 10 mcg (n=191), or 4 mcg (n=191) doses or placebo (n=192) for a total of 12 weeks, all administered once daily for two weeks and then twice weekly (approximately three to four days apart) for ten weeks.

The following table sets forth the statistical significance of the REJOICE Trial results for the four pre-specified co-primary efficacy endpoints, based on mean changes from baseline to week 12 compared to placebo. Based on our analyses of the REJOICE Trial data, statistical significance of the results for the co-primary endpoint of severity of participants' self-reported moderate to severe dyspareunia as the most bothersome symptom of VVA has improved for all three doses from the results originally reported.

	25 mcg	**10 mcg**	**4 mcg**
Superficial Cells	$P < 0.0001$	$P < 0.0001$	$P < 0.0001$
Parabasal Cells	$P < 0.0001$	$P < 0.0001$	$P < 0.0001$
Vaginal pH	$P < 0.0001$	$P < 0.0001$	$P < 0.0001$
Severity of Dyspareunia	$P < 0.0001$	$P < 0.0001$	$P = 0.0149$

The 25 mcg dose of TX-004HR demonstrated highly statistically significant results at the $p < 0.0001$ level compared to placebo across all four co-primary endpoints. The 10 mcg dose of TX-004HR demonstrated highly statistically significant results at the $p < 0.0001$ level compared to placebo across all four co-primary endpoints. The 4 mcg dose of TX-004HR also demonstrated highly statistically significant results at the $p < 0.0001$ level compared to placebo for the endpoints of vaginal superficial cells, vaginal parabasal cells, and vaginal pH; the change from baseline compared to placebo in the severity of dyspareunia was statistically significant at the $p = 0.0149$ level. The FDA has previously indicated to us that in order to approve the drug based on a single trial, the trial would need to show statistical significance at the 0.01 level or lower for each endpoint, and that a trial that is merely statistically significant at a higher level may not provide sufficient evidence to support an NDA filing or approval of a drug candidate where the NDA relies on a single clinical trial.

Statistical improvement over placebo was also observed for all three doses at the first assessment at week two and sustained through week 12 (see table below).

	25 mcg	**10 mcg**	**4 mcg**
Week 2	P = 0.0105	P = 0.0019	P = 0.026
Week 6	P < 0.0001	P = 0.0009	P = 0.0069
Week 8	P < 0.0001	P < 0.0001	P = 0.0003
Week 12	P < 0.0001	P < 0.0001	P = 0.0149

Vaginal dryness was a prespecified key secondary endpoint. The 25 mcg and 10 mcg doses of TX-004HR demonstrated highly statistically significant results at the $p < 0.0001$ level compared to placebo for the endpoint of vaginal dryness. The 4 mcg dose of TX-004HR demonstrated statistically significant results at the $p = 0.0014$ level compared to placebo (see table below).

	25 mcg	**10 mcg**	**4 mcg**
Severity of Vaginal Dryness	P < 0.0001	P < 0.0001	P = 0.0014

The pharmacokinetic data for all three doses demonstrated negligible to very low systemic absorption of 17 beta estradiol, estrone and estrone conjugated, supporting the previous phase 1 trial data. TX-004HR was well tolerated, and there were no clinically significant differences compared to placebo-treated participants with respect to adverse events. There were no drug-related serious adverse events reported.

We submitted the NDA for TX-004HR with the FDA on July 7, 2016. The FDA determined that the NDA was sufficiently complete to permit a substantive review and accepted the NDA for filing with the PDUFA target action date for the completion of the FDA's review of May 7, 2017. The NDA submission was supported by the complete TX-004HR clinical program, including positive results of the phase 3 REJOICE Trial. The NDA submission included all three doses of TX-004HR (4 mcg, 10 mcg and 25 mcg) that were evaluated in the REJOICE Trial.

On May 5, 2017, we received a CRL from the FDA regarding the NDA for TX-004HR. In the CRL, the only approvability concern raised by the FDA was the lack of long-term safety data for TX-004HR beyond the 12 weeks studied in the phase 3 REJOICE Trial. The CRL did not identify any issues related to the efficacy of TX-004HR and did not identify any approvability issues related to chemistry, manufacturing and controls.

On June 14, 2017, we participated in a Type A Post-Action Meeting with the Division of Bone, Reproductive, and Urologic Products (DBRUP) of the FDA to discuss the CRL. At the meeting, we presented information that we believed could address concerns raised by the FDA in the CRL and positively affect the status of the NDA for TX-004HR. On July 5, 2017, we received the official minutes of the meeting from the FDA, which provided the FDA's response to the information presented at the Type A meeting. Per the FDA's request, we formally submitted the information presented at the Type A meeting for consideration related to the NDA for TX-004HR.

On August 3, 2017, we received a formal General Advice Letter from the FDA stating that an initial review of this information has been completed and requesting that we submit the additional endometrial safety information to the NDA for TX-004HR on or before September 18, 2017. On September 14, 2017, we submitted the additional endometrial safety information that was requested by the FDA in the General Advice Letter to the NDA for TX-004HR. The submission included a comprehensive, systematic review of the medical literature on the use of vaginal estrogen products and the risk of endometrial hyperplasia or cancer, including the safety data from the recently published Women's Health Initiative Observational Study, or WHI Study, of vaginal estrogen use in postmenopausal women and information on the relevance of the first uterine pass effect for low-dose vaginal estrogen products. The WHI Study demonstrated no significant difference in the risk of invasive breast cancer, stroke, colorectal cancer, endometrial cancer and venous thromboembolism in vaginal estrogen users versus non-users. The WHI Study also shows that, among women with an intact uterus, there was a decreased risk of cardiovascular disease, hip fracture and all-cause mortality in vaginal estrogen users versus non-users. The WHI Study evaluated over 4,000 women who used vaginal estrogens for a median duration of two to three years.

On November 3, 2017, we participated in an in-person meeting with DBRUP. At the meeting, DBRUP agreed to the resubmission of the NDA for the 4 mcg and 10 mcg doses of TX-004HR without the need for an additional pre-approval study.

On November 29, 2017, we resubmitted the NDA for the 4 mcg and 10 mcg doses of TX-004HR with the FDA. We have committed to conduct a post-approval observational study. The FDA has acknowledged that the resubmission is a complete, class 2 response to the CRL received on May 5, 2017 for TX-004HR. The PDUFA target action date for the completion of the FDA's review is May 29, 2018. If approved, the 4 mcg formulation of TX-004HR would represent a lower effective dose than the currently available VVA therapies approved by the FDA.

According to Symphony Health Solutions, the total FDA-approved market for VVA treatment was approximately $1.8 billion in U.S. sales for the 12 months ended December 31, 2017.

As of December 31, 2017, we had 18 issued patents, which included 13 utility patents that relate to our combination progesterone and estradiol formulations, three utility patents and one design patent that relate to TX-004HR, which establish an important intellectual property foundation for TX-004HR, one utility patent that relates to a pipeline transdermal patch technology, and one utility patent that relates to our OPERA® information technology platform.

Preclinical Development

Based upon leveraging our SYMBODA™ hormone technology, we have four preclinical projects that include development of a progesterone-alone and combination estradiol and progesterone products in a topical cream form, which we refer to as TX-005HR and TX-006HR, respectively, and transdermal patch form, which we refer to as TX-007HR and TX-008HR, respectively. We completed a proof-of-concept preclinical study of TX-005HR in 32 rats. The study used four groups of eight female ovariectomized rats, each of whom were treated with subcutaneous injections of estradiol for eight days. On day four of treatment, they were also dosed with a placebo, subcutaneous injections of progesterone or a similar dose of TX-005HR topical progesterone cream. The results, presented at North American Menopause Society, or NAMS, meeting in October 2015, showed that the progesterone in TX-005HR penetrated the skin and opposed the effect of subcutaneous estradiol on the endometrium. In the fourth quarter of 2016, we submitted an IND application for TX-006HR, our combination estradiol and progesterone drug candidate in a topical cream form, and intend to commence phase 1 clinical trials of this drug candidate as early as 2018. We may in the future engage with a financing partner to advance our topical cream and transdermal patch projects. We have recently conducted rat bioavailability studies on several novel, oral formulations of progesterone. We are currently adapting this formulation for the inclusion of estradiol and have embarked on its development as TX-009HR. In addition to menopausal treatments, we are also evaluating various other indications for our hormone technology, including contraception and premature ovarian failure.

Competition

Pharmaceutical Industry

The pharmaceutical industry is subject to intense competition and is characterized by extensive research efforts and rapid technological change. Competition in our industry occurs in a variety of areas, including developing and bringing new products to market before others, developing new technologies to improve existing products, developing new products to provide the same benefits as existing products at lower cost, and developing new products to provide benefits superior to those of existing products. Most major pharmaceutical companies, as well as numerous specialty pharmaceutical companies, sell products in the women's health sector of the pharmaceutical industry, which is comprised of products designed for post-pubescent females and is generally considered very fragmented. There are many companies focused on the women's health sector of the pharmaceutical industry that have significantly greater financial and other resources than we do, including generic manufacturers, drug compounding pharmacies, and large pharmaceutical companies. In addition, academic and other research institutions could be engaged in research and development efforts for the indications targeted by our products.

Hormone Therapy Market

The menopause hormone therapy market includes two major components: an FDA-approved drug market and a non-FDA approved drug market supplied by compounding pharmacies. On November 27, 2013, the DQSA became law and the FDA was given additional oversight over compounding pharmacies. In January 2018, the FDA announced the release of its 2018 Compounding Priorities Plan, which lays out how the agency will implement certain key provisions of the DQSA and other provisions of the law relevant to compounders over the course of the coming year. This plan confirms the FDA's renewed commitment to compounding oversight and education outreach to health care professionals, all of which, we believe, will help discourage prescribing of compounded bio-identical hormones and encourage compounding pharmacies to collaborate with us.

We believe, FDA-approved products are easily measured and monitored, while non-FDA approved hormone therapy drug products, typically referred to as "bioidenticals" when produced and sold by compounding pharmacies, are not easily measured or monitored. Our phase 3 clinical trials are intended to establish an indication of the safety and efficacy of our hormone therapy drug candidates at specific dosage levels. We intend our hormone therapy drug candidates, if approved by the FDA, to provide hormone therapies with well characterized safety and efficacy profiles that can be consistently manufactured to target specifications. This would provide an alternative to the non-FDA approved compounded bioidentical market. This aim is based on our belief that our drug candidates will offer advantages in terms of demonstrated safety and efficacy consistency in the hormone dose, lower patient cost due to the increased likelihood of insurance coverage and improved access as a result of availability from major retail pharmacy chains rather than custom order or formulation by individual compounders.

TX-001HR is our combination estradiol and progesterone drug candidate for the treatment of moderate to severe VMS due to menopause. The combination of estradiol and progesterone for the treatment of moderate to severe VMS due to menopause for menopausal women with an intact uterus is comprised of two components: the FDA-approved drug market and the non-FDA-approved compounded drug market. Symphony Health Solutions estimates that sales of FDA-approved combinations of estrogen and progestins were approximately $588 million and the sales of estradiol and progesterone on a stand-alone basis were approximately $952 million and approximately $404 million, respectively, in the United States for the 12 months ended December 31, 2017.

The largest competitors in the FDA-approved market are Pfizer (PREMPRO), Breckenridge (generic estradiol) and Noven (CombiPatch), with sales of PREMPRO constituting a majority of such sales. None of the current FDA-approved drugs for the treatment of moderate to severe VMS due to menopause is bioidentical to both the estradiol and progesterone produced by the ovaries. Based on various reports, including data recently presented at the NAMS Annual Meeting, "Knowledge, Use, and Prescribing of Custom-Compounded Bioidentical Hormones for Menopausal Women: It's Not What You Think," by JoAnn V. Pinkerton, et al., we estimate that U.S. sales of non-FDA-approved compounded combination estradiol and progesterone products approximate $1.5 billion per year. The market for non-FDA-approved compounded hormone therapy products is generally considered very fragmented because the products are prepared and sold by individual compounding pharmacies. We believe that TX-001HR, if approved by the FDA, would represent the first time a combination product of estradiol and progesterone that is bioidentical to – or having the same chemical and molecular structure as - the estradiol and progesterone produced by the ovaries would be approved for use in a single combined product.

TX-004HR is our applicator-free vaginal estradiol softgel drug candidate for the treatment of moderate to severe dyspareunia, a symptom of VVA in menopausal women with vaginal linings that do not receive enough estrogen. According to Symphony Health Solutions, the FDA-approved U.S. market for treatment of VVA in menopausal women was approximately $1.8 billion for the 12 months ended December 31, 2017. Approximately $1.5 billion of such sales were by three products currently on the market: Pfizer (PREMARIN cream), Allergan (ESTRACE cream) and Vagifem and its generics. We believe that TX-004HR, if approved by the FDA, will be at least as effective as the existing treatments for VVA because of an early onset of action with less systemic exposure and it will have an added advantage of being a simple, easier to use dosage form versus traditional VVA treatments. Generics for Vagifem were introduced to the market in 2017, taking significant share from Vagifem only. Generics for Estrace were approved by the FDA and are anticipated to enter the market in 2018. Also, a new product– AMAG (Intrarosa insert) – was approved by the FDA for the treatment of dyspareunia in November 2016 and was licensed for commercialization in early 2017.

Prenatal Vitamin Market

The prenatal vitamin market is highly fragmented, with dozens of companies selling hundreds of competitive products. Prenatal vitamin products are marketed as either OTC products or prescription products, with many companies marketing their products through both channels. According to Symphony Health Solutions, during the 12 months ended December 31, 2017, approximately 6.2 million prescriptions for prenatal vitamins were issued in the United States resulting in total sales of approximately $379 million.

Seasonality

The specialty pharmaceutical industry is not subject to seasonal sales fluctuation.

Products in Development

Our market objective is to develop an entire suite of products that are condition-specific and geared to the women's health sector. Our focus is to introduce products in which we use proprietary or patented molecules or ingredients that will differentiate our products from the competition. We currently have numerous products in development, including our hormone therapy drug candidates as described above.

Manufacturing of Our Products; Availability of and Dependence Upon Suppliers; Raw Materials for Our Products

We have sourced and qualified third-party contract manufacturing organizations, or CMOs, for the commercial supply of our hormone therapy drug candidates that have expertise in the manufacture of soft gel capsules. The regulations for manufacturing of approved drug products are significantly more stringent than the standards for manufacturing supplements or drug product for clinical trials. Our CMOs are responsible for the manufacture of our products in accordance with our specifications and applicable regulatory requirements. We have entered into long-term supply agreements with Catalent Pharma Solutions, LLC, or Catalent, for the commercial supply of our TX-001HR and TX- 004HR hormone therapy drug candidates, if approved. Under the terms of the agreements, we will be obligated to purchase certain minimum annual amounts of each product once we commence commercial sales of such product following regulatory approval of Catalent as a manufacturer of the product. We may terminate the agreement for a particular drug candidate in the event that we cease pursuit of regulatory approval for such drug candidate for certain specified reasons. If we are unable to obtain sufficient quantities of drug candidates or receive raw materials in a timely manner, we could be required to delay our manufacturing and seek alternative manufacturers, which would be costly and time-consuming. The hormone therapy drug candidates used in our recently completed phase 3 clinical trials for TX-001HR and TX-004HR were manufactured by a different CMO.

We have a multi-faceted risk management approach to ensure continuous supply from our qualified CMOs for the commercial supply of our hormone therapy products. This approach includes oversight of the manufacturing processes, regular GMP audits, a review of their business continuity plans, management of finished product inventory and safety stock, and second sourcing as appropriate.

We have also sourced and qualified manufacturers of the active pharmaceutical ingredient, or APIs, to be used in our drug candidates, if approved. We follow a risk management approach for our API manufacturer similar to that followed for the commercial supply of the finished drug product.

We use third-party manufacturers to manufacture and package our vitamin and supplement products, as well as meet applicable contract and regulatory requirements. We currently obtain approximately 100% of our vitaMedMD and BocaGreen products from Lang Pharma Nutrition, or Lang, a full-service, private label and corporate brand manufacturer specializing in premium health benefit driven products, including medical foods, nutritional supplements, beverages, bars, and functional foods in the dietary supplement category. As a result, we are dependent on Lang and its subcontractors for the manufacture of most of our vitamin and supplement products. In addition to manufacturing, Lang also provides a variety of additional services to us, including development processes, prototype development, raw materials sourcing, regulatory review, and packaging production. We believe that Lang maintains multiple supply and purchasing relationships throughout the raw materials marketplace to provide an uninterrupted supply of product to meet our manufacturing requirements.

We have experienced no difficulties in obtaining the vitamin and supplement products we need in the amounts we require and do not anticipate those issues in the future. We believe the terms of our agreements with Lang are competitive with other suppliers and manufacturers. At present, we believe our relationship with Lang is excellent, and we intend to continue to use Lang as our third-party manufacturer for most of our vitamins and supplements. Although we anticipate continuing our relationship with Lang, we believe that we could obtain similar terms with other suppliers to provide the same services in the event our relationship with Lang terminates. Accordingly, we do not believe that such termination would have a material adverse effect on our business.

Quality Control for our Products

Our products are required to be manufactured in accordance with the FDA's current Good Manufacturing Practice, or cGMPs. To approve an NDA, the FDA must assure that the proposed manufacturing facilities for our drug candidates are in compliance with the FDA's cGMP regulations, which may include an FDA Pre-Approval Inspection Process, or PAI. Our third-party suppliers and manufacturers are responsible for continued compliance with cGMP requirements. We have executed Quality Agreements that delineate the responsibilities of each company in the quality assurance process. To comply with these drug commercialization standards, we have personnel with pharmaceutical development, manufacturing, and quality assurance experience who are responsible for the relationships with our suppliers. We have contracted with Catalent, an established manufacturer of softgel drug products, to manufacture the commercial supply for both our TX-001HR and TX-004HR hormone therapy drug candidates. Although Catalent has received FDA Form 483 observations from FDA inspections in the past, we are not aware of any open FDA investigations into its manufacturing processes at the facilities that would be used to manufacture our products, if approved. We anticipate that as part of the PAI of our NDA for TX-004HR (or TX-001HR) the FDA may inspect Catalent's facilities.

The CMO that manufactured the hormone therapy drug candidates used in our recently completed phase 3 clinical trials for TX-001HR and TX-004HR was inspected by the FDA, which issued it a FDA Form 483 listing various observations, some of which pertained to the clinical supply of our TX-001HR and TX-004HR drug candidates. The CMO has submitted its written response to the Form 483 observations to the FDA, which we believe will satisfactorily address the FDA's observations with respect to the clinical supply of our TX-001HR and TX-004HR drug candidates. We do not believe that the observations made by the FDA with respect to the CMO will have a material adverse effect on the FDA's review of our NDA for TX-004HR or the timing of our anticipated submission of an NDA for TX-001HR. We believe the inspection was not conducted as part of the FDA's review of our NDA for TX-004HR. As noted above, we have contracted with a different CMO, Catalent, to provide the commercial supply of our TX-001HR and TX- 004HR hormone therapy drug candidates.

Our quality assurance team establishes controls that are designed to document the manufacturing process and ensure that our contract manufacturers meet product specifications and that our finished products contain the correct ingredients, purity, strength, and composition in compliance with FDA regulations. Our contractors test incoming raw materials and finished goods to ensure they meet or exceed FDA and U.S. Pharmacopeia standards (when applicable), including quantitative and qualitative assay and microbial and heavy metal contamination (as appropriate).

Distribution of our Products

During the third quarter of 2016, we centralized the distribution channel for both our retail pharmacy distributors and wholesale distributors, in order to facilitate sales to a broader population of retail pharmacies. In addition to third-party logistics providers, we use some of the same national and regional distributors as other pharmaceutical companies, including Cardinal, McKesson, AmerisourceBergen, H.D. Smith, and Smith Drug. Wholesaler product inventory is monitored daily and sales out is monitored weekly. National and regional retail pharmacies are also an area of focus to make sure our products are purchased and dispensed properly.

Customer Service

Our goal is 100% customer satisfaction by consistently delivering superior customer experiences before, during, and after the sale. To achieve this goal, we maintain a fully-staffed customer care center that uses current customer relationship management software to respond to health care providers, pharmacies, and consumers. We believe our customer service initiatives allow us to establish and maintain long-term customer relationships and facilitate repeat visits and purchases. We also facilitate repeat customer orders through our auto-ship feature.

Our representatives receive regular training so that they can effectively and efficiently field questions from current and prospective customers and are also trained not to answer questions that should be directed to a customer's physician. Having a quality customer care center allows our representatives to provide an array of valuable data in the areas of sales, market research, quality assurance, lead generation, and customer retention.

Our Return Policy

We sell our prescription products through third-party logistics providers, wholesale distributors, and retail pharmacy distributors, all of whom may return a product within six months prior to and twelve months after the expiration date of the product. Once customers buy a prescription product from the pharmacy, the product may not be returned.

Our Quality Guarantee

We proudly stand behind the quality of our products. We believe our guarantee makes it easy, convenient, and safe for customers to purchase our products. Under our quality guarantee, we:

- ensure the potency and quality of our vitamin products; and
- help health care providers and payors by delivering information on patient compliance and satisfaction.

We value frequent communication with and feedback from our customers in order to continue to improve our offerings and services.

Research and Development

Our product development programs are concentrated in the area of advanced hormone therapy pharmaceutical products. We engage in programs to provide alternatives to the FDA and non-FDA-approved compounded bioidentical market for hormone therapy. Our programs seek to bring new products to market in unique delivery systems or formats that enhance the effectiveness, safety, and reliability of existing hormone therapy alternatives.

We intend for our hormone therapy drug candidates, if approved, to provide an alternative to the non-FDA-approved compounded bioidentical market based on our belief that our drug candidates will offer advantages in terms of proven safety, efficacy, and stability, lower patient cost as a result of insurance coverage, and improved access as a result of availability from major retail pharmacy chains rather than custom order or formulation by individual compounders.

Our research and development expenses were approximately $33.9 million in 2017, $53.9 million in 2016, and $72.0 million in 2015.

Intellectual Property

Our success depends, in part, on our ability to obtain patents, maintain trade secret protection, and operate without infringing the proprietary rights of others. Our intellectual property portfolio is one of the means by which we attempt to protect our competitive position. We rely primarily on a combination of know-how, trade secrets, patents, trademarks, and contractual restrictions to protect our products and to maintain our competitive position. We are diligently seeking ways to protect our intellectual property through various legal mechanisms in relevant jurisdictions.

We also have numerous pending foreign and domestic patent applications. As of December 31, 2017, we had 18 issued domestic, or U.S., patents and 13 issued foreign patents, including:

- 13 domestic and three foreign utility patents that relate to our combination progesterone and estradiol product candidates, which are owned by us. The domestic utility patents will expire in 2032. In addition, we have pending patent applications with respect to our combination progesterone and estradiol product candidates in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;
- three domestic and 10 foreign patents that relate to TX-004HR, our applicator-free vaginal estradiol softgel product candidate. These patents establish an important intellectual property foundation for TX-004HR and are owned by us. These domestic patents will expire in 2033 or 2032. In addition, we have pending patent applications related to our applicator-free vaginal estradiol softgel product candidate in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;
- one domestic utility patent that relates to a pipeline transdermal patch technology, which is owned by us and will expire in 2032. We have pending patent applications with respect to this technology in the U.S., Australia, Brazil, Canada, Europe, Mexico, Japan, and South Africa; and
- one utility patent that relates to our OPERA® information-technology platform, which is owned by us and is a domestic patent that will expire in 2029.

As of December 31, 2017, we had filed 46 nonprovisional and 33 provisional patent applications with the U.S. Patent and Trademark Office, or the USPTO, with respect to our technology or our hormone therapy drug candidates, including issued patents, and 123 international patent applications with respect to our technology or our hormone therapy drug candidates, including Patent Cooperation Treaty (PCT) and national stage filings.

We hold multiple U.S. trademark registrations and have numerous pending trademark applications. Issuance of a federally registered trademark creates a rebuttable presumption of ownership of the mark; however, it is subject to challenge by others claiming first use in the mark in some or all of the areas in which it is used. Federally registered trademarks have a perpetual life so long as they are maintained and renewed on a timely basis and used properly as trademarks, subject to the rights of third parties to seek cancellation of the trademarks if they claim priority or confusion of usage. We believe our patents and trademarks are valuable and provide us certain benefits in marketing our products.

We intend to actively protect our intellectual property with patents, trademarks, trade secrets, or other legal avenues for the protection of intellectual property and to aggressively prosecute, enforce, and defend our patents, trademarks, and proprietary technology. The loss, by expiration or otherwise, of any one patent may have a material effect on our business. Defense and enforcement of our intellectual property rights can be expensive and time consuming, even if the outcome is favorable to us. It is possible that the patents issued or licensed to us will be successfully challenged, that a court may find that we are infringing on validly issued patents of third parties, or that we may have to alter or discontinue the development of our products or pay licensing fees to account for patent rights of third parties.

OPERA is our patented information technology platform used in our business. We believe the deployment of OPERA and the further development and deployment of related technology creates a sustainable competitive advantage in clinical development and product improvement.

As we continue to develop proprietary intellectual property, we will expand our protection by applying for patents on future technologies. As we examine our current product offerings and new product pipeline, we are in the process of modifying and developing new formulations that will enable us to gain patent protection for these products.

While we seek broad coverage under our patent applications, there is always a risk that an alteration to the process may provide sufficient basis for a competitor to avoid infringement claims. In addition, patents expire and we cannot provide any assurance that any patents will be issued from our pending application or that any potentially issued patents will adequately protect our intellectual property.

Government Regulation

In the United States, the FDA regulates pharmaceuticals, dietary supplements, and cosmetics under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. These products are also subject to other federal, state, and local statutes and regulations, including federal and state consumer protection laws, laws protecting the privacy of health-related information, and laws prohibiting unfair and deceptive acts and trade practices.

Pharmaceutical Regulation

The process required by the FDA before a new drug product may be marketed in the United States generally involves the following:

- completion of or reference to extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND application under which the holder may begin conducting human clinical trials, provided that the FDA does not object; the IND must be updated annually;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug candidate for each proposed indication; and
- submission to the FDA of an NDA after completion of all pivotal clinical trials.

An IND application is a request for authorization from the FDA to administer an investigational drug product to humans. We have submitted five INDs for our hormone therapy drug candidates. The INDs for TX-002HR and TX-003HR are currently on inactive status. The INDs for TX-004HR, TX-001HR, and TX-006HR remain active.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices, or cGCPs, which include the requirement that all research subjects provide their informed consent for their participation in the clinical trial. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site's IRB before the trials may be initiated, and the IRB must monitor the study until completed and re-assess and approve the study at least annually. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

Clinical trials are usually conducted in three phases. Phase 1 clinical trials are normally conducted in small groups of healthy volunteers to assess safety, characterize pharmacokinetics, and assist in finding the potential dosing range. After phase 1, the drug is administered to small populations of patients (phase 2) to look for initial signs of efficacy in treating the targeted disease or condition and to continue to assess dosing and safety. Phase 3 clinical trials are usually multi-center, double-blind controlled trials in hundreds or even thousands of subjects at various sites to assess the safety and effectiveness of the drug.

During the course of a clinical trial, we are required to inform the FDA and the IRB about adverse events associated with our drug candidate. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee, or DSMB. This group reviews unblinded data from clinical trials and provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study. We may also suspend or terminate a clinical trial based on evolving business objectives or competitive climates.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug product information is submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things.

Once the NDA submission has been accepted for filing, the FDA's goal is to review standard applications within ten months of filing or 12 months of receipt for a new molecular entity. However, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations.

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities in which the drug product will be formulated and its active pharmaceutical ingredient, or API, will be produced, it may issue an approval letter or, instead, a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

After regulatory approval of a drug product is obtained, we would be required to comply with a number of post-approval requirements. As a holder of an approved NDA, we would be required to report, among other things, certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of our products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to ensure and preserve the long-term stability of the drug product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive, and record keeping requirements. For example, Catalent, the CMO that we have contracted with for the commercial supply of our TX-001HR and TX-004HR hormone therapy drug candidates, if approved, was issued a Form FDA-483 in 2016 with respect to its softgel manufacturing plant that will be used for the manufacture of the commercial supply of TX-001HR and TX- 004HR, if approved. The corrective actions identified in Catalent's response to the Form FDA 483 have been completed and we are not aware of any open FDA investigations into Catalent's manufacturing processes at this facility.

In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our drug candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Our hormone therapy drug candidates may compete with unapproved hormone therapy products supplied by compounding pharmacies. Pharmacy compounding is a practice in which a licensed pharmacist combines, mixes, or alters ingredients in response to a prescription to create a medication tailored to the medical needs of an individual patient. The medications created by the compounding pharmacy are theoretically "new drugs" that would otherwise be subject to the new drug approval requirements of the FDCA.

However, for approximately 50 years, the FDA left regulation of compounding pharmacies to the states. In 1992, in response to various safety concerns, the FDA issued a Compliance Policy Guide, which announced that the "FDA may, in the exercise of its enforcement discretion, initiate federal enforcement actions...when the scope and nature of a pharmacy's activities raises the kinds of concerns normally associated with a manufacturer and...results in significant violations of the new drug, adulteration, or misbranding provisions of the Act." Thereafter, Congress enacted the Food and Drug Administration Modernization Act of 1997, or FDAMA, which sought to clarify FDA's regulatory authority over compounding pharmacies. FDAMA exempted "compounded drugs" from the FDA's standard drug approval requirements as long as the providers of those drugs abide by several restrictions, including that they refrain from advertising or promoting particular compounded drugs. In 2002, though, the Supreme Court declared this provision of FDAMA to be unconstitutional under the First Amendment, effectively re-instating the pre-FDAMA regime. Shortly thereafter, the FDA issued its 2002 Compliance Policy Guide 460.200, which states that the FDA will exercise enforcement discretion to exclude compounded drugs from the new drug approval requirements except where compounding pharmacies act more akin to traditional drug manufacturers.

To further clarify the FDA's jurisdiction, Congress enacted and the President signed into law the DQSA, which among other things, formalized the relationship between the FDA and compounding pharmacies by exempting compounding pharmacy products from the FDA approval requirements and the requirement to label products with adequate directions for use, but not the exemption from cGMP requirements. To qualify for this exemption, a compounding pharmacy must register with the FDA as an "outsourcing facility," subject to FDA inspection and other requirements. The FDA does not exercise the same authority to regulate compounding pharmacies as pharmaceutical manufacturers. For example, compounding pharmacies are not required to report adverse events associated with compounded drugs, while commercial drug manufacturers are subject to stringent regulatory reporting requirements.

505(b)(2) Application

We submitted two NDAs for our hormone therapy drug candidates, TX-004HR and TX-001HR, assuming that the clinical data justify submission, under section 505(b)(2) of the FDCA, or Section 505(b)(2). Section 505(b)(2) permits the filing of an NDA when 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 applicant may rely upon published literature and the FDA's findings of safety and effectiveness based on 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 drug candidate for all or some of the label indications for which a referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

As part of our NDA submission, we intend to certify that all of the patents for approved products referenced in the NDA for each of the hormone therapy drug candidates as listed in the FDA's Orange Book have expired and that we will not be compelled to certify that any patent is invalid, unenforceable, or will not be infringed by the new products. If, in fact, this assessment is incorrect, it can have a serious and significant adverse effect on our ability to obtain FDA approval or market our new products. If we are compelled to certify that a patent is invalid, unenforceable, or not infringed, then the holder of that patent can initiate a patent infringement suit against us and the FDA is precluded from approving our product for 30 months or until a court decision or settlement finding that the patent is invalid, unenforceable or not infringed, whichever is earlier.

Marketing Exclusivity

A Section 505(b)(2) NDA applicant may be eligible for its own regulatory exclusivity period, such as a three-year exclusivity. The first approved Section 505(b)(2) NDA applicant for a particular condition, or change to a marketed product, such as a new extended release formulation for a previously approved product, may be granted three-year Hatch-Waxman exclusivity if one or more clinical studies, other than bioavailability or bioequivalence studies, was essential to the approval of the application and was conducted or sponsored by the applicant. Should this occur, the FDA would be precluded from making effective any other application for the same condition of use or for a change to the marketing product that was granted exclusivity until after that three-year exclusivity period has run. Additional exclusivities may also apply.

Additionally, the Section 505(b)(2) NDA applicant may have relevant patents in the Orange Book, and if it does, it can initiate patent infringement litigation against those applicants that challenge such patents, which could result in a 30-month stay delaying those applicants.

Dietary Supplement Regulation

Our currently marketed products are regulated as dietary supplements. The processing, formulation, safety, manufacturing, packaging, labeling, advertising, and distribution of these products are subject to regulation by one or more federal agencies, including the FDA and the Federal Trade Commission, or the FTC, and by various agencies of the states and localities in which our products are sold.

Generally, our nutritional product formulations are proprietary in that in designing them, we attempt to blend an optimal combination of nutrients that appear to have beneficial impact based upon scientific literature and input from physicians; however, we are generally prohibited from making disease treatment and prevention claims in the promotion of our products that use these formulations.

The Dietary Supplement Health and Education Act of 1994, or DSHEA, amended the FDCA to establish a new framework governing the composition, safety, labeling, manufacturing, and marketing of dietary supplements. Generally, under the FDCA, dietary ingredients that were marketed in the United States prior to October 15, 1994 may be used in dietary supplements without notifying the FDA. "New" dietary ingredients (*i.e.*, dietary ingredients that were "not marketed in the United States before October 15, 1994") must be the subject of a new dietary ingredient notification submitted to the FDA unless the ingredient has been "present in the food supply as an article used for food" without being "chemically altered." A new dietary ingredient notification must provide the FDA evidence of a "history of use or other evidence of safety" establishing that use of the dietary ingredient "will reasonably be expected to be safe." A new dietary ingredient notification must be submitted to the FDA at least 75 days before the initial marketing of the new dietary ingredient. The FDA may determine that a new dietary ingredient notification does not provide an adequate basis to conclude that a dietary ingredient is reasonably expected to be safe. Such a determination could prevent the marketing of such dietary ingredient. The FDA recently issued draft guidance governing the notification of new dietary ingredients. FDA guidance is not mandatory and companies are free to use an alternative approach if the approach satisfies the requirements of applicable laws and regulations. However, FDA guidance is a strong indication of the FDA's "current thinking" on the topic discussed in the guidance, including its position on enforcement. The draft guidance on new dietary ingredients is expected to be significantly revised when published in final form. Moreover, Congress can amend the dietary supplement provisions of the FDCA to impose additional restrictions on labeling and marketing of dietary supplements. Such action would have material adverse impact on our business and growth prospects.

The FDA or other agencies could take actions against products or product ingredients that in its determination present an unreasonable health risk to consumers that would make it illegal for us to sell such products. In addition, the FDA could issue consumer warnings with respect to the products or ingredients in such products. Such actions or warnings could be based on information received through FDCA-mandated reporting of serious adverse events. The FDCA requires that reports of serious adverse events be submitted to the FDA, and based in part on such reports, the FDA has issued public warnings to consumers to stop using certain third party dietary supplement products.

The FDCA permits "statements of nutritional support" to be included in labeling for dietary supplements without premarket approval. Such statements must be submitted to the FDA within 30 days of marketing. Such statements may describe how a particular dietary ingredient affects the structure, function, or general well-being of the body, or the mechanism of action by which a dietary ingredient may affect body structure, function, or well-being, but may not expressly or implicitly represent that a dietary supplement will diagnose, cure, mitigate, treat, or prevent a disease. A company that uses a statement of nutritional support in labeling must possess scientific evidence substantiating that the statement is truthful and not misleading. If the FDA determines that a particular statement of nutritional support is an unacceptable drug claim, conventional food claim, or an unauthorized version of a "health claim," or, if the FDA determines that a particular claim is not adequately supported by existing scientific data or is false or misleading, we would be prevented from using the claim.

In addition, DSHEA provides that so-called "third-party literature," such as a reprint of a peer-reviewed scientific publication linking a particular dietary ingredient with health benefits, may be used "in connection with the sale of a dietary supplement to consumers" without the literature being subject to regulation as labeling. The literature: (1) must not be false or misleading; (2) may not "promote" a particular manufacturer or brand dietary supplement; (3) must present a balanced view of the available scientific information on the subject matter; (4) if displayed in establishment, must be physically separate from the dietary supplements; and (5) should not have appended to it any information by sticker or another method. If the literature fails to satisfy each of these requirements, we may be prevented from disseminating such literature with our products, and any dissemination could subject our product to regulatory action as an illegal drug.

In June 2007, pursuant to the authority granted by the FDCA as amended by DSHEA, the FDA published detailed cGMP regulations that govern the manufacturing, packaging, labeling, and holding operations of dietary supplement manufacturers. The cGMP regulations, among other things, impose significant recordkeeping requirements on manufacturers. The cGMP requirements are in effect for all manufacturers, and the FDA is conducting inspections of dietary supplement manufacturers pursuant to these requirements. The failure of a manufacturing facility to comply with the cGMP regulations renders products manufactured in such facility "adulterated," and subjects such products and the manufacturer to a variety of potential FDA enforcement actions. In addition, under the Food Safety Modernization Act, or FSMA, which was enacted on January 2, 2011, the manufacturing of dietary ingredients contained in dietary supplements are subject to similar or even more burdensome manufacturing requirements, which has the potential to increase the costs of dietary ingredients and subject suppliers of such ingredients to more rigorous inspections and enforcement. The FSMA also requires importers of food, including dietary supplements and dietary ingredients, to conduct verification activities to ensure that the food they might import meets applicable domestic requirements.

The FDA has broad authority to enforce the provisions of federal law applicable to dietary supplements, including powers to issue public Warning Letters or Untitled Letters to a company, publicize information about illegal products, detain products intended for import, require the reporting of serious adverse events, request a recall of illegal or unsafe products from the market, and request that the Department of Justice initiate a seizure action, an injunction action, or a criminal prosecution in the U.S. courts. The FSMA expands the reach and regulatory powers of the FDA with respect to the production and importation of food, including dietary supplements. The expanded reach and regulatory powers include the FDA's ability to order mandatory recalls, administratively detain domestic products, require certification of compliance with domestic requirements for imported foods associated with safety issues and administratively revoke manufacturing facility registrations, effectively enjoining manufacturing of dietary ingredients and dietary supplements without judicial process. The regulation of dietary supplements may increase or become more restrictive in the future.

The FTC exercises jurisdiction over the advertising of dietary supplements and cosmetics. In recent years, the FTC has instituted numerous enforcement actions against dietary supplement companies for making false or misleading advertising claims and for failing to adequately substantiate claims made in advertising. These enforcement actions have often resulted in consent decrees and the payment of civil penalties and/or restitution by the companies involved. The FTC also regulates other aspects of consumer purchases, including promotional offers of savings compared policies, telemarketing, continuity plans, and "free" offers.

We are also subject to regulation under various state, local, and international laws that include provisions governing, among other things, the formulation, manufacturing, packaging, labeling, advertising, and distribution of dietary supplements and drugs. For example, Proposition 65 in the state of California is a list of substances deemed to pose a risk of carcinogenicity or birth defects at or above certain levels. If any such ingredient exceeds the permissible levels in a dietary supplement, cosmetic, or drug, the product may be lawfully sold in California only if accompanied by a prominent warning label alerting consumers that the product contains an ingredient linked to cancer or birth defect risk. Private attorney general actions as well as California attorney general actions may be brought against non-compliant parties and can result in substantial costs and fines.

Other U.S. Health Care Laws and Compliance Requirements

We are also subject to additional health care regulation and enforcement by the federal government and the states in which we conduct our business. Applicable federal and state health care laws and regulations include the following:

- The federal health care anti-kickback statute prohibits, among other things, 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 federal health care programs, such as Medicare and Medicaid.

- The Ethics in Patient Referrals Act of 1989, commonly referred to as the Stark Law, and its corresponding regulations, prohibit physicians from referring patients for designated health services, including outpatient drugs, reimbursed under the Medicare or Medicaid programs to entities with which the physicians or their immediate family members have a financial relationship or an ownership interest, subject to narrow regulatory exceptions, and prohibits those entities from submitting claims to Medicare or Medicaid for payment of items or services provided to a referred beneficiary.

- The federal False Claims Act imposes criminal and civil penalties, and authorizes civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, claims for payment involving federally funded programs that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money with respect to a federal program.

- Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information.

- 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 any mater within the jurisdiction of the federal government, including the delivery of or payment for health care benefits, items, or services.

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private insurers, and some 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.

Efforts to ensure that our business arrangements with third parties comply with applicable health care laws and regulations could be costly. Although we believe that our business practices are structured to be compliant with applicable laws, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other health care laws and regulations. If our past or present operations, including activities conducted by our sales team or agents, are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from third party payor programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians, providers, or entities with whom we do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusion from government funded health care programs.

Many aspects of these laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations that increases the risk of potential violations. In addition, these laws and their interpretations are subject to change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business, and damage our reputation.

In addition, from time to time in the future, we may become subject to additional laws or regulations administered by the FDA, the FTC, or by other federal, state, local, or foreign regulatory authorities, to the repeal of laws or regulations that we generally consider favorable, such as DSHEA, or to more stringent interpretations of current laws or regulations. We are not able to predict the nature of such future laws, regulations, repeals, or interpretations, and we cannot predict what effect additional governmental regulation, if and when it occurs, would have on our business in the future. Such developments could, however, require reformulation of certain products to meet new standards, recalls or discontinuance of certain products not able to be reformulated, additional record-keeping requirements, increased documentation of the properties of certain products, additional or different labeling, additional scientific substantiation, additional personnel, or other new requirements. Any such developments could have a material adverse effect on our business.

The growth and demand for eCommerce could result in more stringent consumer protection laws that impose additional compliance burdens on online retailers. These consumer protection laws could result in substantial compliance costs and could interfere with the conduct of our business. There is currently great uncertainty in many states whether or how existing laws governing issues such as property ownership, sales and other taxes, and libel and personal privacy apply to the Internet and commercial online retailers. These issues may take years to resolve. For example, tax authorities in a number of states, as well as a Congressional advisory commission, are currently reviewing the appropriate tax treatment of companies engaged in online commerce and new state tax regulations may subject us to additional state sales and income taxes. New legislation or regulation, the application of laws and regulations from jurisdictions whose laws do not currently apply to our business, or a change in application of existing laws and regulations to the Internet and commercial online services could result in significant additional taxes on our business. These taxes could have an adverse effect on our results of operations.

Employees

As of December 31, 2017, we had 173 full time employees, six of whom are executive officers. Additionally, from time to time, we hire temporary contract employees. None of our employees are covered by a collective bargaining agreement, and we are unaware of any union organizing efforts. We have never experienced a major work stoppage, strike, or dispute. We consider our relationship with our employees to be good.

Our History

On October 3, 2011, we changed our name to TherapeuticsMD, Inc. On October 4, 2011, we closed a reverse merger with VitaMedMD pursuant to which (1) all outstanding membership units of VitaMed were exchanged for shares of our common stock, (2) all outstanding VitaMed options and warrants were exchanged and converted into options and warrants to purchase shares of our common stock, and (3) VitaMed became our wholly owned subsidiary. As of December 31, 2011, we determined that VitaMed would become the sole focus of our company and services previously performed relative to the licensing agreement discussed in the following paragraph were discontinued.

We were incorporated in Utah in 1907 under the name Croff Mining Company, or Croff. Prior to 2008, Croff's operations consisted entirely of oil and natural gas leases. Due to a spin-off of its operations in December 2007, Croff had no business operations or revenue source and had reduced its operations to a minimal level although it continued to file reports required under the Securities Exchange Act of 1934, or the Exchange Act. As a result of the spin-off, Croff was a "shell company" under the rules of the Securities and Exchange Commission, or the SEC. In July 2009, Croff (i) closed a transaction to acquire America's Minority Health Network, Inc. as a wholly owned subsidiary, (ii) ceased being a shell company, and (iii) experienced a change in control in which the former stockholders of America's Minority Health Network, Inc. acquired control of our company. On June 11, 2010, we closed a transaction to acquire Spectrum Health Network, Inc. as a wholly owned subsidiary. On July 20, 2010, we filed Articles of Conversion and Articles of Incorporation to redomicile in the state of Nevada. On July 31, 2010, we transferred the assets of America's Minority Health Network, Inc. to a secured noteholder in exchange for the satisfaction of certain associated debt. On February 15, 2011, we transferred the assets of Spectrum Health Network, Inc. to a secured noteholder in exchange for the satisfaction of associated debt and in exchange for a licensing agreement under which we subsequently sold subscription services and advertising on the Spectrum Health Network for commissions.

Available Information

We are a Nevada corporation. We maintain our principal executive offices at 6800 Broken Sound Parkway NW, Third Floor, Boca Raton, Florida 33487. Our telephone number is (561) 961-1900. We maintain websites at *www.therapeuticsmd.com*, *www.vitamedmdrx.com*, and *www.bocagreenmd.com*. The information contained on our websites or that can be accessed through our websites is not incorporated by reference into this Annual Report or in any other report or document we file with the SEC.

We file reports with the SEC, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any other filings required by the SEC. Through our website, we make available free of charge our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

The public may read and copy any materials we file with, or furnish to, the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site (*www.sec.gov*) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Item 1A. ***Risk Factors***

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, together with all of the information included in this Annual Report before you decide to purchase shares of our common stock. We believe the risks and uncertainties described below are the most significant we face. Additional risks and uncertainties of which we are unaware, or that we currently deem immaterial, also may become important factors that affect us. If any of the following risks occur, our business, financial condition, or results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business

We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future.

We have incurred recurring net losses, including net losses of approximately $77 million, $90 million, and $85 million for the years ended December 31, 2017, 2016, and 2015, respectively. As of December 31, 2017, we had an accumulated deficit of approximately $387 million. We have generated limited revenue and have funded our operations to date primarily from public and private sales of equity and private sales of debt securities. We may incur substantial additional losses over the next few years as a result of our research, development, clinical trial and commercialization activities. As a result, we may never achieve or maintain profitability, even if we successfully commercialize our hormone therapy drug candidates. If we continue to incur substantial losses and are unable to secure additional financing, we could be forced to discontinue or curtail our business operations, sell assets at unfavorable prices, refinance then-existing debt obligations on terms unfavorable to us, or merge, consolidate, or combine with a company with greater financial resources in a transaction that might be unfavorable to us.

We currently derive all of our revenue from sales of our women's health care products, and our failure to maintain or increase sales of these products could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

In 2017, we derived virtually all of our revenue from sales of women's health care products, including prenatal and women's multi-vitamins and iron supplements. Sales of our vitamin products varied from 2010 through 2017. We cannot assure you that we will be able to sustain such sales or that such sales will grow. In addition to other risks described herein, our ability to maintain or increase existing product sales is subject to a number of risks and uncertainties, including the following:

- the presence of new or existing competing products, including generic copies of our prescription prenatal vitamin products that are not our authorized generic products;
- any supply or distribution problems arising with any of our manufacturing and distribution strategic partners;
- changed or increased regulatory restrictions or regulatory actions by the FDA;
- changes in health care laws and policy, including changes in requirements for rebates, reimbursement, and coverage by federal health care programs;
- the impact or efficacy of any price increases we may implement in the future;
- changes to our labels and labeling, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell our products; and
- acceptance of our products as safe and effective by physicians and patients.

If revenue from sales of our existing prescription prenatal vitamins does not continue or increase, we may be required to reduce our operating expenses or to seek to raise additional funds, which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects, or we may not be able to commercialize our hormone therapy drug candidates or commence or continue clinical trials to seek approval for any other products we may choose to develop in the future.

If our products or drug candidates do not have the effects intended or cause undesirable side effects, our business may suffer.

Although many of the ingredients in our current dietary supplement products are vitamins, minerals, and other substances for which there is a long history of human consumption, they also contain innovative ingredients or combinations of ingredients. While we believe that all of these products and the combinations of ingredients in them are safe when taken as directed, the products could have certain undesirable side effects if not taken as directed or if taken by a consumer who has certain medical conditions, such as the potential effect of high doses of folic acid masking pernicious anemia. In addition, these products may not have the effect intended if they are not taken in accordance with certain instructions, which include certain dietary restrictions. Furthermore, there can be no assurance that any of the products, even when used as directed, will have the effects intended or will not have harmful side effects in an unforeseen way or on an unforeseen cohort. If any of our products or products we develop or commercialize in the future are shown to be harmful or generate negative publicity from perceived harmful effects, our business, financial condition, results of operations, and prospects could be harmed significantly.

Our future success will depend in large part on our ability to commercialize our hormone therapy drug candidates designed to alleviate symptoms of and reduce the health risks resulting from menopause, including VMS and VVA.

Our future success will depend in large part on our ability to successfully develop and commercialize our hormone therapy drug candidates designed to alleviate the symptoms of and reduce the health risks resulting from menopause, including hot flashes and dyspareunia. We have submitted IND applications for six hormone therapy drug candidates, which the FDA has allowed to proceed, and which permit us to conduct clinical testing on these proposed products. In December 2015, we completed a phase 3 clinical trial of our TX-004HR drug candidate and in December 2016 we completed a phase 3 clinical trial for our TX-001HR drug candidate. We have submitted NDAs for both drug candidates. In the fourth quarter of 2016 we submitted an IND application for our TX-006HR drug candidate and intend to commence phase 1 clinical trials of this drug candidate as early as 2018. In July 2014, we suspended enrollment in the phase 3 clinical trial for our TX-002HR drug candidate and in October 2014 we stopped the trial and are considering whether to update the phase 3 protocol based on discussions with the FDA. We have currently suspended further development of this drug candidate to prioritize our leading drug candidates and the IND application for this drug candidate is currently inactive. We have no current plans to conduct clinical trials for our TX-003HR drug candidate and the IND application for this drug candidate is currently inactive. Drug development is a necessarily uncertain undertaking. We may not be able to complete the development of our drug candidates, the results of the clinical trials may not be sufficient to support an NDA for any of our drug candidates, and even if we believe the results of our clinical trials are sufficient to support any NDA that we submit, the FDA may disagree and may not approve our NDA. In addition, even if the FDA approves one or more of our NDAs, it may do so with restrictions on the intended uses that may make commercialization of the product or products financially untenable. The failure to commercialize or obtain necessary approval for any one or more of these products could substantially harm our prospects and our business.

We may not be able to complete the development and commercialization of our hormone therapy drug candidates if we fail to obtain additional financing.

We need substantial amounts of cash to complete the clinical development and commercialization of our hormone therapy drug candidates. Our existing cash may not be sufficient to fund these requirements. In addition, changing circumstances may cause us to consume funds significantly faster than we currently anticipate, and we may need to spend more money than currently expected on these programs. We do not currently have any committed external source of funds. We may attempt to raise additional capital from the issuance of equity or debt securities, collaborations with third parties, licensing of rights to our products, or other means, or a combination of any of the foregoing. Securing additional financing will require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from our day-to-day activities, which may adversely affect our ability to conduct our day-to-day operations. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to take one or more of the following actions:

- significantly delay, scale back, or discontinue our product development and commercialization efforts;
- seek collaborators for our hormone therapy drug candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be the case; and
- license, potentially on unfavorable terms, our rights to our hormone therapy drug candidates that we otherwise would seek to develop or commercialize ourselves.

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. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or proposed products or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing discovery, development, and commercialization efforts, and our ability to generate revenue and achieve or sustain profitability will be substantially harmed.

We have no experience as a company in bringing a drug to regulatory approval.

We have never obtained regulatory approval for, or commercialized, a drug. It is possible that the FDA may refuse to accept the NDA for our TX-001HR drug candidate for substantive review or may conclude, after review of our data, that one or more of our NDAs are insufficient to obtain regulatory approval of any of our hormone therapy drug candidates. We have begun to conduct validation and scale up of the manufacturing processes for TX-001HR, our proposed combination estradiol and progesterone drug candidate, and TX-004HR, our proposed applicator-free vaginal estradiol softgel drug candidate. The FDA may also require that we conduct additional clinical or manufacturing validation studies, which may be costly and time-consuming, and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA required studies, approval of any NDA that we submit may be significantly delayed, possibly for years, or may require us to expend more resources than we have available or can secure. Any delay or inability in obtaining regulatory approvals would delay or prevent us from commercializing our hormone therapy drug candidates, generating revenue from these proposed products, and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any NDA we submit. If any of these outcomes occur, we may be forced to abandon our planned NDAs for one or more of our hormone therapy drug candidates, which would materially adversely affect our business and could potentially cause us to cease operations.

We have completed our phase 3 clinical trials of TX-001HR for the treatment of moderate to severe VMS due to menopause in menopausal women with an intact uterus and TX-004HR for the treatment of moderate to severe dyspareunia in menopausal women with VVA. Although we have discussed our clinical development plans for each drug candidate with the FDA, the agency may ultimately determine that our phase 3 clinical trials for one or both candidates are not sufficient for regulatory approval. If we are required to conduct additional clinical trials or non-clinical studies, our development of TX-001HR or TX-004HR, as applicable, will be more time-consuming and costly than we presently anticipate, which could have a material adverse effect on our business, results of operations and financial condition.

On December 5, 2016, we announced positive top-line results from the REPLENISH Trial, our phase 3 clinical trial to evaluate the safety and efficacy of TX-001HR, an investigational bio-identical hormone therapy combination of 17ß-estradiol and progesterone in a single, oral softgel, for the treatment of moderate to severe VMS due to menopause in menopausal women with an intact uterus. The REPLENISH Trial evaluated four doses of TX-001HR and placebo in 1,835 menopausal women between 40 and 65 years old. The doses studied were: 17ß-estradiol 1 mg/progesterone 100 mg; 17ß-estradiol 0.5 mg/progesterone 100 mg; 17ß-estradiol 0.5 mg/progesterone 50 mg; and 17ß-estradiol 0.25 mg/progesterone 50 mg (n = 424). The REPLENISH Trial results demonstrated that TX-001HR estradiol 1 mg/progesterone 100 mg and TX-001HR estradiol 0.5 mg/progesterone 100 mg both achieved all four of the co-primary efficacy endpoints and the primary safety endpoint and demonstrated a statistically significant and clinically meaningful reduction from baseline in both the frequency and severity of hot flashes compared to placebo. TX-001HR estradiol 0.5 mg/progesterone 50 mg and TX-001HR estradiol 0.25 mg/progesterone 50 mg were not statistically significant at all of the co-primary efficacy endpoints; the estradiol 0.25 mg/progesterone 50 mg dose was included in the clinical trial as a non-effective dose to meet the recommendation of the FDA guidance to identify the lowest effective dose. The incidence of consensus endometrial hyperplasia or malignancy was 0 percent across all four TX-001HR doses, meeting the recommendations established by the FDA's draft guidance. Based on the results of the REPLENISH Trial, we currently intend to seek regulatory approval for the estradiol 1 mg/progesterone 100 mg and estradiol 0.5 mg/progesterone 100 mg doses of TX-001HR for the treatment of moderate to severe VMS due to menopause in menopausal women with an intact uterus in the U.S.

On December 7, 2015, we announced positive top-line results from the REJOICE Trial, our phase 3 clinical trial to evaluate the safety and efficacy of three doses—25 mcg, 10 mcg and 4 mcg (compared to placebo)—of TX-004HR for the treatment of moderate to severe dyspareunia in menopausal women with VVA. Both the 25 mcg dose and the 10 mcg dose of TX-004HR demonstrated highly statistically significant results at the $p < 0.0001$ level compared to placebo across all four co-primary efficacy endpoints. The 4 mcg dose of TX-004HR also demonstrated highly statistically significant results at the $p < 0.0001$ level compared to placebo for the endpoints of vaginal superficial cells, vaginal parabasal cells, and vaginal pH; the change from baseline compared to placebo in the severity of dyspareunia was statistically significant at the $p = 0.0149$ level. As discussed below, where an NDA is supported by a single clinical trial, as is the case with TX-004HR, the FDA has taken the position initially that the results of our trial would have to achieve statistical significance at the 0.01 level or better. Statistical significance at the 0.0149 level may not be sufficient to satisfy this requirement. If the FDA continues to maintain this position, we may have to either conduct an additional trial or eliminate the 4 mcg dose formulation from the TX-004HR NDA. The elimination of this low dose from our product line could adversely affect our sales of TX-004HR, if approved.

We cannot assure you that the FDA will approve all or any doses of TX-001HR or TX-004HR for commercialization. The FDA may not agree with one or more aspects of our clinical trial designs, including the duration of the trials, clinical endpoints, controls, dose ranges, collection of safety data, level of statistical significance, or adequacy of our non-clinical studies.

Our TX-001HR or TX-004HR hormone therapy drug candidates are currently undergoing stability testing. The FDA will review the period of time that our drug candidates are stable, which will dictate the amount of time post-manufacturing that the products may be used by patients, if approved. If our hormone therapy drug candidates fail to remain stable or the period of time that they remain stable is too short, it could limit the commercial viability of our products, which could materially adversely impact our business, results of operations and financial condition.

In addition, prior to approval of an NDA, the FDA may audit one or more of the sites where the applicable phase 3 clinical trial was conducted to ensure the integrity of the data, inspect our clinical records in our corporate offices, and will inspect the facilities of our third party contract manufacturers where the applicable drug candidate will be manufactured commercially, if approved and where the drug was manufactured for clinical trials. If one or more site audits reveals anomalies, or if the manufacturing facilities do not pass inspection, full consideration of the NDA by the FDA could be delayed, or the FDA may require us to undertake further clinical or non-clinical trials or could require our contract manufacturers to improve or change their processes, any of which would delay or prevent commercialization of the applicable drug candidate and could materially adversely impact our business, results of operations and financial condition.

Clinical trials are lengthy and expensive with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical trials are expensive, can take many years to complete and have highly uncertain outcomes. For example, we suspended enrollment in and subsequently stopped the SPRY trial for our progesterone alone drug candidate in order to update the phase 3 protocol based on discussions with the FDA. Failure can occur at any time during the clinical trial process as a result of inadequate performance of a drug, inadequate adherence by patients or investigators to clinical trial protocols, or other factors. New drugs in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through earlier clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials as a result of a lack of efficacy or adverse safety profiles, despite promising results in earlier trials. Our future clinical trials may not be successful or may be more expensive or time-consuming than we currently expect. Prior to approving a new drug, the FDA generally requires that the safety and efficacy of the drug be demonstrated in two adequate and well-controlled clinical trials. In some situations, the FDA approves drugs on the basis of a single well-controlled clinical trial. We believe we may be required to conduct only a single phase 3 clinical trial of each of TX-001HR, our proposed combination estradiol and progesterone drug candidate, TX-002HR, our progesterone alone drug candidate, and TX-004HR, our applicator-free vaginal estradiol softgel drug candidate. However, in connection with our TX-004HR drug candidate, the FDA has previously indicated to us that in order to approve the drug based on a single trial, the trial would need to show statistical significance at the 0.01 level or lower for each endpoint, and that a trial that is merely statistically significant at a higher numerical level may not provide sufficient evidence to support an NDA filing or approval of a drug candidate where the NDA relies on a single clinical trial. If clinical trials for any of our hormone therapy drug candidates fail to demonstrate safety or efficacy to the satisfaction of the FDA, the FDA will not approve that drug and we would not be able to commercialize it, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our dependence upon third parties for the manufacture and supply of our existing women's health care products and our hormone therapy drug candidates may cause delays in, or prevent us from, successfully developing, commercializing, and marketing our products.

We do not currently have, nor do we plan to build, the infrastructure or capability to internally manufacture our existing women's health care products or our hormone therapy drug candidates. We have relied, and will continue to rely, on third parties to manufacture these products in accordance with our specifications and in compliance with applicable regulatory requirements. We have entered into long-term supply agreements with Catalent for the commercial supply of our TX-001HR and TX-004HR hormone therapy drug candidates. Under the terms of the agreements, we will be obligated to purchase certain minimum annual amounts of each product once we commence commercial sales of such product following regulatory approval of Catalent as a manufacturer of the product. We depend on Lang, a full-service, private label and corporate brand manufacturer, to supply approximately 100% of our vitaMedMD and BocaGreen products. We do not have long-term contracts for the commercial supply of our existing women's health care products, however, in certain circumstances, including our failure to satisfy our production forecasts to Lang, we may be obligated to reimburse Lang for the costs of excess raw materials purchased by Lang that it cannot use in another product category that it then sells.

Regulatory requirements could pose barriers to the manufacture of our existing women's health care products and our hormone therapy drug candidates. Our third-party manufacturers are required to comply with cGMP regulations. As a result, the facilities used by any of our current or future manufacturers must be approved by the FDA. Holders of NDAs, or other forms of FDA approvals or clearances, or those distributing a regulated product under their own name, are responsible for manufacturing even though that manufacturing is conducted by a third-party CMO. All of our existing products are, and our hormone therapy drug candidates, if approved, will be manufactured by CMOs. These CMOs are required by the terms of our contracts to manufacture our products in compliance with the applicable regulatory requirements. The CMO that will manufacture our hormone therapy drug candidates, if approved, has previously been inspected by the FDA and received Form 483 observations with respect to its softgel manufacturing plant that will be used for the manufacture of the commercial supply of TX-001HR and TX-004HR, if approved. As part of the PAI of our NDA for TX-004HR, the FDA inspected Catalent's manufacturing facilities that would be used to manufacture the product; we anticipate that as part of the PAI of our NDA for TX-001HR, the FDA may again inspect Catalent's manufacturing facilities that would be used to manufacture that product. If this inspection results in Form 483 observations, the approval of our NDA could be delayed significantly. The CMO that manufactured the hormone therapy drug candidates used in our recently completed phase 3 clinical trials for TX-001HR and TX-004HR was recently inspected by the FDA, which issued it a Form FDA-483 listing various observations, some of which pertained to the clinical supply of our TX-001HR and TX-004HR drug candidates. The CMO has submitted its written response to the Form 483 observations to the FDA, however, neither we nor the CMO has been informed by the FDA as to whether the CMO's response addresses and remediates these observations in a manner satisfactory to the FDA. If this CMO is not able to address and remediate the FDA's observations pertaining to the clinical supply of our TX-001HR and TX-004HR drug candidates in a manner satisfactory to the FDA, it could have a material adverse effect on the FDA's review of our NDA for TX-004HR or the timing of our anticipated submission of an NDA for TX-001HR.

If our manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, they will not be able to secure the applicable approval for their manufacturing facilities. If these facilities are not approved for the commercial manufacture of our existing products or our hormone therapy drug candidates, we may need to find alternative manufacturing facilities, which would result in disruptions of our sales and significant delays of up to several years in obtaining approval for our hormone therapy drug candidates. In addition, our manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. Failure by any of our manufacturers to comply with applicable cGMP regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply, recalls, withdrawals, issuance of safety alerts, and criminal prosecutions, any of which could have a material adverse impact on our business, financial condition, results of operations, and prospects. Finally, we also could experience manufacturing delays if our CMOs give greater priority to the supply of other products over our products and proposed products or otherwise do not satisfactorily perform according to the terms of their agreements with us.

We also do not have long-term contracts for the supply of the API used in our hormone therapy drug candidates. If any supplier of the API or other products used in our hormone therapy drug candidates experiences any significant difficulties in its respective manufacturing processes, does not comply with the terms of an agreement between us, or does not devote sufficient time, energy, and care to providing our manufacturing needs, we could experience significant interruptions in the supply of our hormone therapy drug candidates, which could impair our ability to supply our hormone therapy drug candidates at the levels required for commercialization and prevent or delay their successful commercialization.

Future legislation, or the absence of such legislation, regulations, and policies adopted by the FDA or other regulatory authorities may increase the time and cost required for us to conduct and complete clinical trials for our hormone therapy drug candidates.

The FDA has established regulations, guidelines, and policies to govern the drug development and approval process, as have foreign regulatory authorities. Any change in regulatory requirements resulting from the adoption of new legislation, regulations, or policies may require us to amend existing clinical trial protocols or add new clinical trials to comply with these changes. Such amendments to existing protocols or clinical trial applications or the need for new ones, may significantly and adversely affect the cost, timing, and completion of the clinical trials for our hormone therapy drug candidates.

In addition, the FDA's policies may change and additional government regulations may be issued that could prevent, limit, or delay regulatory approval of our drug candidates, or impose more stringent product labeling and post-marketing testing and other requirements. For example, in the past the FDA has indicated it would regulate prenatal vitamins containing greater than 0.8 mg of folic acid as a drug under the FDCA. More recently the FDA indicated that there is no specified upper limit on the amount of folic acid permitted in a dietary supplement. If the FDA were to seek to regulate products with higher amounts of folic acid as drugs, it may require us to stop selling certain of our dietary supplement products and otherwise adversely affect our business. If we are slow or unable to adapt to any such changes, our business, prospects, and ability to achieve or sustain profitability could be adversely affected.

Even if we obtain regulatory approval for our hormone therapy drug candidates, we will still face extensive, ongoing regulatory requirements and review, and our products may face future development and regulatory difficulties.

Even if we obtain regulatory approval for one or more of our hormone therapy drug candidates in the United States, the FDA may still impose significant restrictions on a product's indicated uses or marketing or to the conditions for approval, or impose ongoing requirements for potentially costly post-approval studies, including phase 4 clinical trials or post-market surveillance. As a condition to granting marketing approval of a product, the FDA may require a company to conduct additional clinical trials. The results generated in these post-approval clinical trials could result in loss of marketing approval, changes in product labeling, or new or increased concerns about side effects or efficacy of a product. For example, the labeling for our hormone therapy drug candidates, if approved, may include restrictions on use or warnings. The Food and Drug Administration Amendments Act of 2007, or FDAAA, gives the FDA enhanced post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information, and compliance with FDA-approved REMS programs. If approved, our hormone therapy drug candidates will also be subject to ongoing FDA requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record keeping, and reporting of safety and other post-market information. The FDA's exercise of its authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements, and potential restrictions on sales of approved products. Foreign regulatory agencies often have similar authority and may impose comparable costs. Post-marketing studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of our hormone therapy drug candidates once approved, and potentially our other marketed products. Further, the discovery of significant problems with a product similar to one of our products that implicate (or are perceived to implicate) an entire class of products could have an adverse effect on sales of our approved products. Accordingly, new data about our products could negatively affect demand because of real or perceived side effects or uncertainty regarding efficacy and, in some cases, could result in product withdrawal or recall. Furthermore, new data and information, including information about product misuse, may lead government agencies, professional societies, and practice management groups or organizations involved with various diseases to publish guidelines or recommendations related to the use of our products or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of our products.

The holder of an approved NDA also is subject to obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA. Application holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials. Legal requirements have also been enacted to require disclosure of clinical trial results on publicly available databases.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with the FDA's cGMPs regulations. If we or 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, a regulatory agency may impose restrictions on that product, the manufacturing facility, or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, requiring new warnings or other labeling changes to limit use of the drug, requiring that we conduct additional clinical trials, imposing new monitoring requirements, or requiring that we establish a REMS program. Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Sales, marketing, and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, and similar state laws. We would also be required under the Sunshine provision of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act or ACA, to report annually to the Centers for Medicare & Medicaid Services on payments that we make to physicians and teaching hospitals and ownerships interests in the company held by physicians. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Healthcare Act of 1992. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration and to low income patients of certain hospitals, additional laws and requirements apply. Our activities are also potentially subject to federal and state consumer protection and unfair competition laws. If we or our third-party collaborators fail to comply with applicable regulatory requirements, a regulatory agency may take any of the following actions:

- conduct an investigation into our practices and any alleged violation of law;
- issue warning letters or untitled letters asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- require that we suspend or terminate any ongoing clinical trials;

- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall; or
- exclude us from providing our products to those participating in government health care programs, such as Medicare and Medicaid, and refuse to allow us to enter into supply contracts, including government contracts.

The occurrence of any of the foregoing events or penalties may force us to expend significant amounts of time and money and may significantly inhibit our ability to bring to market or continue to market our products and generate revenue. Similar regulations apply in foreign jurisdictions.

The commercial success of our existing products and our hormone therapy drug candidates that we develop, if approved in the future, will depend upon gaining and retaining significant market acceptance of these products among physicians and payors.

Physicians may not prescribe our products, including any of our hormone therapy drug candidates, if approved by the appropriate regulatory authorities for marketing and sale, which would prevent us from generating revenue or becoming profitable. Market acceptance of our products, including our hormone therapy drug candidates, by physicians, patients, and payors, will depend on a number of factors, many of which are beyond our control, including the following:

- the clinical indications for which our hormone therapy drug candidates are approved, if at all;
- acceptance by physicians and payors of each product as a safe and effective treatment;
- the cost of treatment in relation to alternative treatments, including numerous generic drug products;
- the relative convenience and ease of administration of our products in the treatment of the symptoms for which they are intended;
- the availability and efficacy of competitive drugs;
- the effectiveness of our sales force and marketing efforts;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- the availability of coverage and adequate reimbursement by third parties, such as insurance companies and other health care payors, or by government health care programs, including Medicare and Medicaid;
- limitations or warnings contained in a product's FDA-approved labeling; and
- prevalence and severity of adverse side effects.

Even if the medical community accepts that our products are safe and efficacious for their approved indications, physicians may not immediately be receptive to the use or may be slow to adopt our products as an accepted treatment for the symptoms for which they are intended. We cannot assure you that any labeling approved by the FDA will permit us to promote our products as being superior to competing products. If our products, including, in particular our hormone therapy drug candidates, if approved, do not achieve an adequate level of acceptance by physicians and payors, we may not generate sufficient or any revenue from these products and we may not become profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful.

Our products, including our hormone therapy drug candidates if approved, face significant competition from branded and generic products, and our operating results will suffer if we fail to compete effectively.

Development and awareness of our brand will depend largely upon our success in increasing our customer base. The dietary supplement and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our products, including any hormone therapy drug candidates that may be approved, face intense competition, including from major multinational pharmaceutical and dietary supplement companies, established biotechnology companies, specialty pharmaceutical, and generic drug companies. A non-hormonal product, Brisdelle, produced by Noven Pharmaceuticals, was approved by the FDA for treatment of VMS in June 2013. Many of these companies have greater financial and other resources, such as larger research and development staffs and more experienced marketing and manufacturing organizations. As a result, these companies may obtain regulatory approval more rapidly and may be more effective in selling and marketing their products. They also may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the products that we sell or develop obsolete. As a result, our competitors may succeed in commercializing products before we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. If we are unable to economically promote or maintain our brand, our business, results of operations and financial condition could be severely harmed. In addition, our efforts to provide an alternative to the non-FDA-approved compound bioidentical market for estradiol and progesterone products sold by compounding pharmacies may not be successful.

Coverage and reimbursement may not be available for our products, which could make it difficult for us to sell our products profitably, or if available, government mandated rebates may be too high and may adversely affect our profitability.

Market acceptance and sales of our products, including any hormone therapy drug candidates, will depend on coverage and reimbursement policies and may be affected by health care reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which products they will pay for and establish reimbursement levels. Third-party payors generally do not cover OTC products, and coverage for vitamins and dietary supplements varies. We cannot be sure that coverage and reimbursement will be available for our products, including any hormone therapy drug candidates, if approved, or whether the amount of such coverage and reimbursement, if any, will be sufficient to enable us to successfully compete with other products.

Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and certain others by establishing a new Part D to the Medicare program. However, unlike traditional Medicare—which provides coverage for outpatient drugs—coverage under Part D is provided by private insurers operating under contract with CMS. In addition, this legislation provided authority for limiting the number of certain outpatient drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These and future cost-reduction initiatives could decrease the coverage and price that we receive for our products from Medicare, if any, including our hormone therapy drug candidates, if approved, and could significantly harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement under Medicare may result in a similar reduction in payments from private payors.

In March 2010, the Affordable Care Act became law in the United States. The goal of ACA is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. Among other measures, ACA increased rebates on manufacturers for certain covered drug products reimbursed by state Medicaid programs. While we cannot predict the full effect that the Affordable Care Act will have on federal reimbursement policies in general or on our business specifically, the ACA may result in downward pressure on drug reimbursement, which could negatively affect market acceptance of our products. In addition, we cannot predict whether new proposals will be made or adopted, when they may be adopted, or what impact they may have on us if they are adopted. If the ACA or parts of it are repealed, it is unclear what impact that would have on drug reimbursements or coverage and it is equally unclear what programs, if any, Congress might enact to replace the repealed portions of the ACA.

The availability of generic products at lower prices than branded products may also substantially reduce the likelihood of reimbursement for branded products, such as our hormone therapy drug candidates, if approved. We expect to experience pricing pressures in connection with the sale of our products generally due to the trend toward managed health care, the increasing influence of health maintenance organizations, and additional legislative proposals. If we fail to successfully secure and maintain adequate coverage and reimbursement for our products or are significantly delayed in doing so, we could have difficulty achieving market acceptance of our products and our business, financial condition, results of operations, and prospects could be harmed.

Failure to obtain regulatory approval outside the U.S. will prevent us from marketing our drug candidates in non- U.S. markets.

We may attempt to market certain of our drug candidates in non-U.S. markets. In order to market our drug candidates in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals. We have had limited interactions with non-U.S. regulatory authorities, the approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval or clearance. Approval or clearance by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more non-U.S. regulatory authorities does not ensure approval by other regulatory authorities in other countries or by the FDA. The non-U.S. regulatory approval process may include all of the risks associated with obtaining FDA approval or clearance. If we pursue non-U.S. regulatory approvals, we may not obtain them on a timely basis, if at all. If we pursue non-U.S. regulatory approvals, our failure to receive necessary approvals to commercialize our drug candidates in a given market could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, if we seek and obtain approval to market our drug candidates in one or more non-U.S. markets, we will be subject to rules and regulations in those markets relating to our product. In some countries, particularly countries of the European Union, each of which has developed its own rules and regulations, pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of regulatory approval for a drug. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidates to other available products. If reimbursement of our drug candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to generate revenues and achieve or sustain profitability with respect to any given market, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Future legislation or regulations may adversely affect reimbursement from government programs

Legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reductions, triggering the legislation's automatic reduction of several government programs. This includes aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Bipartisan Budget Act of 2015, signed into law on November 2, 2015, increased the rebates that generic drug manufacturers are obligated to pay under the Medicaid program by applying an inflation-based rebate formula to generic drugs that previously only applied to brand name drugs. If we ever obtain regulatory approval and commercialization of any of our drug candidates, these new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations. On December 13, 2016, President Obama signed into law the 21st Century Cures Act, which, among other things, may increase the types of clinical trial designs that would be acceptable to support an NDA. It is unclear, at this time, how these provisions will be implemented or whether they would have any effect on our company.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates may be. If the ACA or parts of it are repealed, it is unclear what impact that would have on drug reimbursements or coverage and it is equally unclear what programs, if any, Congress and the Trump Administration might enact and sign into law to replace the repealed portions of the ACA.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products.

We face an inherent risk of product liability claims as a result of the marketing of our current products and the clinical testing of our hormone therapy drug candidates despite obtaining appropriate informed consents from our clinical trial participants. Additionally, in light of the history of product liability claims related to other hormone replacement therapy products, we will face an even greater risk if we obtain FDA approval and commercialize our hormone therapy drug candidates in the United States or other additional jurisdictions or if we engage in the clinical testing of proposed new products or commercialize any additional products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, failures to warn of dangers inherent in the product, negligence, strict liability, or breaches of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our existing products or hormone therapy drug candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in any of the following:

- the inability to commercialize our products or hormone therapy drug candidates;
- difficulty recruiting subjects for clinical trials or withdrawal of these subjects before a trial is completed;
- labeling, marketing, or promotional restrictions;
- product recalls or withdrawals;

- decreased demand for our products or products that we may develop in the future;
- loss of revenue;
- injury to our reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- exhaustion of any available insurance and our capital resources; and
- a decline in our stock price.

Although we maintain general liability insurance of up to $10 million in the aggregate and clinical trial liability insurance of $10 million in the aggregate for our hormone therapy drug candidates, this insurance may not fully cover potential liabilities. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. In addition, our inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the development and commercial production and sale of our products, which could adversely affect our business, financial condition, results of operations, and prospects.

Our business may be affected by unfavorable publicity or lack of consumer acceptance.

We are highly dependent upon consumer acceptance of the safety and quality of our products, as well as similar products distributed by other companies. Consumer acceptance of a product can be significantly influenced by scientific research or findings, national media attention, and other publicity about product use. A product may be received favorably, resulting in high sales associated with that product that may not be sustainable as consumer preferences change. Future scientific research or publicity could be unfavorable to our industry or any of our particular products and may not be consistent with earlier favorable research or publicity. A future research report or publicity that is perceived by our consumers as less than favorable or that may question earlier favorable research or publicity could have a material adverse effect on our ability to generate revenue. Adverse publicity in the form of published scientific research, statements by regulatory authorities or otherwise, whether or not accurate, that associates consumption of our product or any other similar product with illness or other adverse effects, or that questions the benefits of our product or a similar product, or that claims that such products do not have the effect intended could have a material adverse effect on our business, reputation, financial condition, or results of operations.

If we use hazardous materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical, biological, and radioactive materials. In addition, our operations produce hazardous waste products. Federal, state, and local laws and regulations in the United States govern the use, manufacture, storage, handling, and disposal of hazardous materials. Although we believe that our procedures for use, handling, storing, and disposing of these materials (all of which only occur at third-party sites operated by our contractors) comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. We also cannot predict the impact on our business of new or amended environmental laws or regulations or any changes in the way existing and future laws and regulations are interpreted or enforced. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials, and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources, and we do not carry liability insurance covering the use of hazardous materials. If we fail to comply with applicable requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs, or capital expenditures for control equipment or operational changes necessary to achieve or maintain compliance. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, and may adversely affect our business, financial condition, results of operations, and prospects.

We are subject to extensive and costly government regulation.

The products we currently market, including the vitamins, and the pharmaceutical products we are developing and planning to develop in the future, are subject to extensive and rigorous domestic government regulation, including regulation by the FDA, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, including its Office of Inspector General, the U.S. Department of Justice, the Departments of Defense and Veterans Affairs, to the extent our products are paid for directly or indirectly by those departments, state and local governments, and their respective foreign equivalents. The FDA regulates dietary supplements, cosmetics, and drugs under different regulatory schemes. For example, the FDA regulates the processing, formulation, safety, manufacturing, packaging, labeling, and distribution of dietary supplements and cosmetics under its dietary supplement and cosmetic authority, respectively. The FDA also regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical products under various regulatory provisions. If any drug products we develop are tested or marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding U.S. regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling products. Our failure to comply with these regulations could result in, by way of example, significant fines, criminal and civil liability, product seizures, recalls, withdrawals, withdrawals of approvals, and exclusion and debarment from government programs. Any of these actions, including the inability of our hormone therapy drug candidates to obtain and maintain regulatory approval, could have a materially adverse effect on our business, financial condition, results of operations, and prospects.

We are subject to additional federal and state laws and regulations relating to our business, and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

We are subject to additional health care regulation and enforcement by the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include the following:

- the federal health care program Anti-Kickback Statute, 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 government health care programs such as the Medicare and Medicaid programs;

- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government health care programs that are false or fraudulent;

- federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, the ACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity can now be found guilty of fraud or false claims under ACA without actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including 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 statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare, Medicaid and other government programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations, and financial condition.

The ACA also imposes new reporting requirements on device and pharmaceutical manufacturers to make annual public disclosures of payments to certain health care providers and physician ownership of their stock by health care providers. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value, or ownership or investment interests that are not reported. Manufacturers were required to begin data collection on August 1, 2013 and were required to report such data to CMS by March 31, 2014.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation, and other remuneration to physicians.

The scope and enforcement of these laws is uncertain and subject to change in the current environment of health care reform, especially in light of the lack of applicable precedent and regulations. We cannot predict the impact on our business of any changes in these laws. Federal or state regulatory authorities may 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. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive pharmaceutical industry depends in large part on our ability to attract and retain highly qualified managerial, scientific, and medical personnel. In order to induce valuable employees to remain with us, we have, among other things, provided stock-based compensation that vests over time. The value to employees of stock-based compensation will be significantly affected by movements in our stock price that we cannot control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific, and medical teams may terminate their employment with us on short notice. We do not have employment agreements with a number of our key employees. As a result, most employees are employed on an at-will basis, which means that any of these employees could leave our employment at any time, with or without notice, and may go to work for a competitor. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results, and financial condition. Our success also depends on our ability to continue to attract, retain, and motivate highly skilled scientific and medical personnel.

Any failure to adequately expand a direct sales force will impede our growth.

We expect to be substantially dependent on a direct sales force to attract new business and to manage customer relationships. We plan to expand our direct sales force and believe that there is significant competition for qualified, productive direct sales personnel with advanced sales skills and technical knowledge. Our ability to achieve significant growth in revenue in the future will depend, in large part, on our success in recruiting, training, and retaining sufficient direct sales personnel. New and future hires may not become as productive as expected, and we may be unable to hire sufficient numbers of qualified individuals in the future in the markets in which we do business. If we are unable to hire and develop sufficient numbers of productive sales personnel our business prospects could suffer.

Other pharmaceutical companies with which we compete for qualified personnel may have greater financial and other resources, different risk profiles, and longer histories than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we offer. If we are unable to continue to attract and retain high-quality personnel, our ability to commercialize drug candidates may be limited.

Our success is tied to our distribution channels.

We sell our prescription prenatal vitamin products to wholesale distributors and retail pharmacy distributors. During the year ended December 31, 2017, four customers each generated more than 10% of our total revenues; revenue generated from these four customers combined accounted for approximately 59% of our total revenue during the year ended December 31, 2017. Our business would be harmed if any of these customers refused to distribute our products or refused to purchase our products on commercially favorable terms to us.

A failure to maintain optimal inventory levels to meet commercial demand for our products could harm our reputation and subject us to financial losses.

Our ability to maintain optimal inventory levels to meet commercial demand depends on the performance of third-party contract manufacturers. In some instances, our products have unique ingredients used under license arrangements. If our manufacturers are unsuccessful in obtaining raw materials, if we are unable to manufacture and release inventory on a timely and consistent basis, if we fail to maintain an adequate level of product inventory, if inventory is destroyed or damaged, or if our inventory reaches its expiration date, patients might not have access to our products, our reputation and brands could be harmed, and physicians may be less likely to recommend our products in the future, each of which could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

Delays in clinical trials are common for many reasons, and any such delays could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We may experience delays in future clinical trials for our drug candidates. Clinical trials might not begin on time; may be interrupted, delayed, suspended, or terminated once commenced; might need to be redesigned; might not enroll a sufficient number of patients; or might not be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including the following:

- delays in obtaining regulatory approval to commence a trial;

- imposition of a clinical hold following an inspection of clinical trial operations or trial sites by the FDA or other regulatory authorities;
- imposition of a clinical hold because of safety or efficacy concerns by the DSMB, FDA, or IRB, or us;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required IRB approval at each site;
- delays in identifying, recruiting, and training suitable clinical investigators;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new sites;
- delays in obtaining sufficient supplies of clinical trial materials, including suitable API; or
- delays resulting from negative or equivocal findings of DSMB for a trial.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Any of these delays in completing future clinical trials could increase our costs, slow down our product development and approval process, and jeopardize our ability to commence product sales and generate revenue from our drug candidates subject to the trial.

We may be required to suspend or discontinue clinical trials because of adverse side effects or other safety risks that could preclude approval of our drug candidates.

Clinical trials may be suspended or terminated at any time for a number of reasons. A clinical trial may be suspended or terminated by us, our collaborators, the FDA, or other regulatory authorities because of a failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, presentation of unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using the investigational drug, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or negative or equivocal findings of the DSMB or the IRB for a clinical trial. An IRB may also suspend or terminate our clinical trials for failure to protect patient safety or patient rights. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe the clinical trials are not being conducted in accordance with applicable regulatory requirements or present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate any clinical trial of any proposed product that we develop, the commercial prospects of such proposed product will be harmed and our ability to generate product revenue from any of these proposed products will be delayed or eliminated. Any of these occurrences may harm our business, financial condition, results of operations, and prospects significantly.

We rely on third parties to conduct our research and development activities, including our clinical trials, and we may experience delays in obtaining or may be unsuccessful in obtaining regulatory approval for, or in commercializing, our hormone therapy drug candidates if these third parties do not successfully carry out their contractual duties or meet expected deadlines.

We do not have the resources to independently conduct research and development activities. Therefore, we have relied, and plan to continue to rely, on various third-party CROs to conduct our research and development activities and to recruit patients and monitor and manage data for our on-going clinical programs for our hormone therapy drug candidates, as well as for the execution of clinical studies. Although we control only certain aspects of our CROs' activities, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We cannot assure you that the CROs will conduct the research properly or in a timely manner, or that the results will be reproducible. We and our CROs are required to comply with the FDA's cGCPs, which are regulations and guidelines enforced by the FDA for all of our products in clinical development. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators, and clinical trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable or invalid, and the FDA may require us to perform additional clinical trials before approving our proposed products. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, to evaluate the safety and effectiveness compared to placebo of our hormone therapy drug candidates to a statistically significant degree, our clinical trials will require an adequately large number of test subjects. Any clinical trial that a CRO conducts abroad on our behalf is subject to similar regulation. Accordingly, if our CROs fail to comply with these regulations or recruit a sufficient number of patients, we may be required to repeat clinical trials, which would delay the regulatory approval process.

In addition, we do not employ the personnel of our CROs, and, except for remedies available to us under our agreements with such organizations, we cannot control whether or not they will devote sufficient time and resources to our on-going clinical and pre-clinical programs. Our CROs may also have relationships with other commercial entities, including one or more of our competitors, for which they may also be conducting clinical studies or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised because of the failure to adhere to our clinical protocols or regulatory requirements, or for other reasons, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our hormone therapy drug candidates that we seek to develop. As a result, our financial results and the commercial prospects for our hormone therapy drug candidates that we seek to develop could be harmed, our costs could increase, and our ability to generate revenue could be delayed or end.

We typically engage one or more CROs on a project-by-project basis for each study or trial. While we have developed and plan to maintain our relationships with CROs that we have previously engaged, we also expect to enter into agreements with other CROs to obtain additional resources and expertise in an attempt to accelerate our progress with regard to on-going clinical programs and, specifically, the compilation of clinical trial data for submission with an NDA for each of our hormone therapy drug candidates. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or entering into new relationships with CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially affect our ability to meet our desired clinical development timelines and can increase our costs significantly. Although we try to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, results of operations, or prospects.

Our ability to utilize net operating loss carryforwards may be limited.

As of December 31, 2017, we had federal net operating loss carryforwards, or NOLs, of approximately $338.6 million. Subject to applicable limitations, these NOLs may be used to offset future taxable income, to the extent we generate any taxable income, and thereby reduce our future federal income taxes otherwise payable.

Section 382 of the Internal Revenue Code of 1986, as amended, imposes limitations on a corporation's ability to utilize NOLs if it experiences an ownership change as defined in Section 382. In general terms, an ownership change may result from transactions increasing the ownership of certain stockholders in the stock of a corporation by more than 50 percent over a three-year period. In the event that an ownership change has occurred, or were to occur, utilization of our NOLs would be subject to an annual limitation under Section 382 determined by multiplying the value of our stock at the time of the ownership change by the applicable long-term tax-exempt rate. Any unused annual limitation may be carried over to later years. We may be found to have experienced an ownership change under Section 382 as a result of events in the past or the issuance of shares of our common stock in the future. If so, the use of our NOLs, or a portion thereof, against our future taxable income may be subject to an annual limitation under Section 382.

On December 22, 2017, the U.S. federal government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act, or the Tax Act. The Tax Act makes broad and complex changes to the U.S. federal tax code, including, but not limited to reducing the U.S. federal corporate tax rate from 34 percent to 21 percent and imposing new restrictions on the use of NOLs. The Tax Act reduces the corporate tax rate to 21 percent, effective January 1, 2018. We must assess whether our valuation allowance analyses with respect to our NOLs are affected by various aspects of the Tax Act. Furthermore, the Tax Act limits the NOL carryover deduction in a taxable year to the lesser of the NOL carryforward or 80 percent of the taxpayer's taxable income (before taking into account any deduction on account of such NOLs), which may restrict our ability to offset future taxable income with NOLs and increase our future federal income taxes otherwise payable.

Since we have recorded provisional amounts related to certain portions of the Tax Act, any corresponding determination of the need for or change in a valuation allowance or otherwise is also provisional.

Our business may be impacted by new or changing tax laws or regulations and actions by federal, state, and/or local agencies, or how judicial authorities apply tax laws.

In connection with the products we sell and intend to sell, we calculate, collect, and remit various federal, state, and local taxes, surcharges and regulatory fees ("tax" or "taxes") to numerous federal, state and local governmental authorities. In addition, we incur and pay state and local taxes and fees on purchases of goods and services used in our business.

Tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. In many cases, the application of tax laws (including the recently enacted Tax Act) is uncertain and subject to differing interpretations, especially when evaluated against new technologies and services.

In the event that we have incorrectly described, disclosed, calculated, assessed, or remitted amounts that were due to governmental authorities, we could be subject to additional taxes, fines, penalties, or other adverse actions, which could materially impact our business, results of operations, and financial condition.

Our success depends on how efficiently we respond to changing consumer preferences and demand.

Our success depends, in part, on our ability to anticipate and respond to changing consumer trends and preferences. We may not be able to respond in a timely or commercially appropriate manner to these changes. Our failure to accurately predict these trends could negatively impact our inventory levels, sales, and consumer opinion of us as a source for the latest product. The success of our new product offerings depends upon a number of factors, including our ability to achieve the following:

- accurately anticipate customer needs;
- innovate and develop new products;
- successfully commercialize new products in a timely manner;
- competitively price our products in the market;
- procure and maintain products in sufficient volumes and in a timely manner; and
- differentiate our product offerings from those of our competitors.

If we do not introduce new products, make enhancements to existing products, or maintain the appropriate inventory levels to meet customers' demand in a timely manner, our business, results of operations, and financial condition could be materially and adversely affected.

We may initiate product recalls or withdrawals, or may be subject to regulatory enforcement actions that could negatively affect our business.

We may be subject to product recalls, withdrawals, or seizures if any of the products we formulate, manufacture, or sell are believed to cause injury or illness or if we are alleged to have violated governmental regulations in the manufacture, labeling, promotion, sale, or distribution of any of our products. A recall, withdrawal, or seizure of any of our products could materially and adversely affect consumer confidence in our brands and lead to decreased demand for our products. In addition, a recall, withdrawal, or seizure of any of our products would require significant management attention, would likely result in substantial and unexpected expenditures, and could materially and adversely affect our business, financial condition, and results of operations.

We will need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2017, we had 173 full time employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial, sales and marketing, 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. Also, our management may need to divert a disproportionate amount of its attention away from their day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional drug candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to increase revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our hormone therapy drug candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth in our organization.

We may not be able to maintain effective and efficient information systems or properly safeguard our information systems.

Our operations are dependent on uninterrupted performance of our information systems. Failure to maintain reliable information systems, disruptions in our existing information systems or the implementation of new systems could cause disruptions in our business operations, including violations of patient privacy and confidentiality requirements and other regulatory requirements, increased administrative expenses and other adverse consequences.

In addition, information security risks have generally increased in recent years because of new technologies and the increased activities of perpetrators of cyber-attacks resulting in the theft of protected health, business, or financial information. Despite our layered security controls, experienced computer programmers and hackers may be able to penetrate our information systems and misappropriate or compromise sensitive patient or personnel information or proprietary or confidential information, create system disruptions or cause shutdowns. They also may be able to develop and deploy viruses, worms and other malicious software programs that disable our systems or otherwise exploit any security vulnerabilities. Outside parties may also attempt to fraudulently induce employees to take actions, including the release of confidential or sensitive information or to make fraudulent payments, through illegal electronic spamming, phishing or other tactics.

A failure in or breach of our information systems as a result of cyber-attacks or other tactics could disrupt our business, result in the release or misuse of protected health information, or PHI, confidential or proprietary business information or financial loss, damage our reputation, increase our administrative expenses, and expose us to additional risk of liability to federal or state governments or individuals. Although we believe that we have robust information security procedures and other safeguards in place, as cyber threats continue to evolve, we may be required to expend additional resources to continue to enhance our information security measures or to investigate and remediate any information security vulnerabilities. Our remediation efforts may not be successful and could result in interruptions, delays or cessation of service and loss of existing or potential customers and disruption of our operations. In addition, breaches of our security measures and the unauthorized dissemination of patient healthcare and other sensitive information, proprietary or confidential information about us or other third-parties could expose such persons' private information to the risk of financial or medical identity theft or expose us or such persons to a risk of loss or misuse of this information, result in litigation and potential liability for us, damage our brand and reputation or otherwise harm our business. Any of these disruptions or breaches of security could have a material adverse effect on our business, financial condition, and results of operations.

Our employees and business partners may not appropriately secure and protect confidential information in their possession.

Each of our employees and business partners is responsible for the security of the information in our systems or under our control and to ensure that private and financial information is kept confidential. Should an employee or business partner not follow appropriate security measures, including those related to cyber threats or attacks or other tactics, as well as our privacy and security policies and procedures, the improper release of personal information, including PHI, or confidential business or financial information, or misappropriation of assets could result. The release of such information or misappropriation of assets could have a material adverse effect on our business, financial condition, and results of operations.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state health care fraud and abuse laws and regulations, to report financial information or data accurately, or to disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the health care industry are subject to extensive laws and regulations 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. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, 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 these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Risks Related to our Intellectual Property

Another party could develop hormone therapy products and obtain FDA regulatory exclusivity in the United States before we do, potentially preventing our ability to commercialize our hormone therapy drug candidates and other products in development.

We plan to seek to obtain market exclusivity for our hormone therapy drug candidates and any other drug candidates we develop in the future. To the extent that patent protection is not available or has expired, FDA marketing exclusivity may be the only available form of exclusivity available for these proposed products. Marketing exclusivity can delay the submission or the approval of certain marketing applications. Potentially competitive products may also be seeking marketing exclusivity and may be in various stages of development, including some more advanced than us. We cannot predict with certainty the timing of FDA approval or whether FDA approval will be granted, nor can we predict with certainty the timing of FDA approval for competing products or whether such approval will be granted. It is possible that competing products may obtain FDA approval with marketing exclusivity before we do, which could delay our ability to submit a marketing application or obtain necessary regulatory approvals, result in lost market opportunities with respect to our hormone therapy drug candidates, and materially adversely affect our business, financial condition, and results of operations.

If our efforts to protect the proprietary nature of the intellectual property covering our hormone therapy drug candidates and other products are not adequate, we may not be able to compete effectively in our market.

Our commercial success will depend in part on our ability to obtain additional patents and protect our existing patent positions as well as our ability to maintain adequate protection of other intellectual property for our hormone therapy drug candidates and other products. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. The patent positions of pharmaceutical companies are highly uncertain. The legal principles applicable to patents are in transition due to changing court precedent and legislative action, and we cannot be certain that the historical legal standards surrounding questions of validity will continue to be applied or that current defenses relating to issued patents in these fields will be sufficient in the future. Changes in patent laws in the United States, such as the America Invents Act of 2011, may affect the scope, strength, and enforceability of our patent rights or the nature of proceedings that may be brought by us related to our patent rights. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets.

These risks include the possibility of the following:

- the patent applications that we have filed may fail to result in issued patents in the United States or in foreign countries;
- patents issued or licensed to us or our partners may be challenged or discovered to have been issued on the basis of insufficient, incomplete, or incorrect information, and thus held to be invalid or unenforceable;
- the scope of any patent protection may be too narrow to exclude competitors from developing or designing around these patents;
- we or our licensors were not the first to make the inventions covered by each of our issued patents and pending patent applications;
- we or our licensors may not have been the first inventors to file patent applications for these technologies in the United States or were not the first to file patent applications directed to these technologies abroad;
- we may fail to comply with procedural, documentary, fee payment, and other similar provisions during the patent application process, which can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights;

- future drug candidates may not be patentable;
- others may claim rights or ownership with regard to patents and other proprietary rights that we hold or license;
- delays in development, testing, clinical trials, and regulatory review may reduce the period of time during which we could market our drug candidates under patent protection; and
- we may fail to timely apply for patents on our technologies or products.

While we apply for patents covering our technologies and products, as we deem appropriate, many third parties may already have filed patent applications or have received patents in our areas of product development. These entities' applications, patents, and other intellectual property rights may conflict with patent applications to which we have rights and could prevent us from obtaining patents or could call into question the validity of any of our patents, if issued, or could otherwise adversely affect our ability to develop, manufacture, or commercialize our hormone therapy drug candidates. In addition, if third parties file patent applications in the technologies that also claim technology to which we have rights, we may have to participate in interference, derivation, or other proceedings with the USPTO or foreign patent regulatory authorities to determine our rights in the technologies, which may be time-consuming and expensive. Moreover, issued patents may be challenged in the courts or in post-grant proceedings at the USPTO, or in similar proceedings in foreign countries. These proceedings may result in loss of patent claims or adverse changes to the scope of the claims.

If we, our licensors, or our strategic partners fail to obtain and maintain patent protection for our products, or our proprietary technologies and their uses, companies may be dissuaded from collaborating with us. In such event, our ability to commercialize our hormone therapy drug candidates or future drug candidates, if approved, may be threatened, we could lose our competitive advantage, and the competition we face could increase, all of which could adversely affect our business, financial condition, results of operations, and prospects.

In addition, mechanisms exist in much of the world permitting some form of challenge by generic drug marketers to our patents prior to, or immediately following, the expiration of any regulatory exclusivity, and generic companies are increasingly employing aggressive strategies, such as "at risk" launches to challenge relevant patent rights.

Our business also may rely on unpatented proprietary technology, know-how, and trade secrets. If the confidentiality of this intellectual property is breached, it could adversely impact our business.

If we are sued for infringing intellectual property rights of third parties, litigation will be costly and time consuming and could prevent or delay us from developing or commercializing our drug candidates.

Our commercial success depends, in part, on our not infringing the patents and proprietary rights of other parties and not breaching any collaboration or other agreements we have entered into with regard to our technologies and products. We are aware of numerous third-party U.S. and non-U.S. issued patents and pending applications that exist in the areas of hormone therapy, including compounds, formulations, treatment methods, and synthetic processes, which may be applied towards the synthesis of hormones. Patent applications are confidential when filed and remain confidential until publication, approximately 18 months after initial filing, while some patent applications remain unpublished until issuance. As such, there may be other third-party patents and pending applications of which we are currently unaware with claims directed towards composition of matter, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products or drug candidates. Therefore, we cannot ever know with certainty the nature or existence of every third-party patent filing. We cannot provide assurances that we or our partners will be free to manufacture or market our drug candidates as planned or that we or our licensors' and partners' patents will not be opposed or litigated by third parties. If any third-party patent was held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture, or methods of treatment related to the use or manufacture of any of our drug candidates, the holders of any such patent may be able to block our ability to develop and commercialize the applicable drug candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. There can be no assurances that we will be able to obtain a license to such patent on favorable terms or at all. Failure to obtain such license may have a material adverse effect on our business.

There is a substantial amount of litigation involving intellectual property in the pharmaceutical industry generally. If a third party asserts that we infringe its patents or other proprietary rights, we could face a number of risks that could adversely affect our business, financial condition, results of operations, and prospects, including the following:

- infringement and other intellectual property claims, which would be costly and time-consuming to defend, whether or not we are ultimately successful, which in turn could delay the regulatory approval process, consume our capital, and divert management's attention from our business;

- substantial damages for past infringement, which we may have to pay if a court determines that our products or technologies infringe a competitor's patent or other proprietary rights;

- a court prohibiting us from selling or licensing our technologies or future products unless the third party licenses its patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do;

- if a license is available from a third party, we may have to pay substantial royalties or lump sum payments or grant cross licenses to our patents or other proprietary rights to obtain that license; or

- redesigning our products so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

We are party from time to time to legal proceedings relating to our intellectual property, and third parties in the future may file claims asserting that our technologies, processes, or products infringe on their intellectual property. We cannot predict whether third parties will assert these claims against us or our strategic partners or against the licensors of technology licensed to us, or whether those claims will harm our business. In addition, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. If we or our partners were to face infringement claims or challenges by third parties relating to our drug candidates, an adverse outcome could subject us to significant liabilities to such third parties, and force us or our partners to curtail or cease the development of some or all of our drug candidates, which could adversely affect our business, financial condition, results of operations, and prospects.

We have submitted, and intend to submit, NDAs for our hormone therapy drug candidates, assuming that the clinical data justify submission, under Section 505(b)(2), which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the filing of an NDA when 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. To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications in its Section 505(b)(2) NDA with respect to any patents for the approved product on which the application relies that are listed in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. Specifically, the applicant must certify for each listed patent that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (iv) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification.

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months beginning on the date the patent holder receives notice, or until a court deems the patent unenforceable, invalid or not infringed, whichever is earlier. The court also has the ability to shorten or lengthen the 30 month period if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized. Alternatively, if the NDA or relevant patent holder does not file a patent infringement lawsuit within the specified 45 day period, the FDA may approve the Section 505(b)(2) application at any time.

If we cannot certify that all of the patents listed in the Orange Book for the approved products referenced in the NDAs for each of our hormone therapy drug candidates have expired, we will be compelled to include a Paragraph IV certification in the NDA for such drug candidate. Our inability to certify that all of the patents listed in the FDA's Orange Book for approved products referenced in the NDAs for each of our hormone therapy drug candidates could have significant adverse effects on the timing for obtaining approval of our hormone therapy drug candidates.

We may be required to file lawsuits or take other actions to protect or enforce our patents or the patents of our licensors, which could be expensive and time-consuming.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.

In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents, or those of our licensors, do not cover the technology in question or on other grounds. An adverse result in any litigation or defense proceedings could put one or more of our patents, or those of our licensors, at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications, or those of our licensors, at risk of not issuing. Moreover, we may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries in which the laws may not protect those rights as fully as in the United States or in those countries in which we do not file national phase patent applications. 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. In addition, if securities analysts or investors perceive public announcements of the results of hearings, motions, or other interim proceedings or developments to be negative, the price of our common stock could be adversely affected. The occurrence of any of the above could adversely affect our business, financial condition, results of operations, and prospects.

If we are unable to protect the confidentiality of certain information, the value of our products and technology could be materially adversely affected.

We also rely on trade secrets, know-how, and continuing technological advancement to develop and maintain our competitive position. To protect this competitive position, we regularly enter into confidentiality and proprietary information agreements with third parties, including employees, independent contractors, suppliers, and collaborators. We cannot, however, ensure that these protective arrangements will be honored by third parties, and we may not have adequate remedies if these arrangements are breached. In addition, enforcement of claims that a third party has illegally obtained and is using trade secrets, know-how, or technological advancements is expensive, time-consuming, and uncertain. Non-U.S. courts are sometimes less willing than U.S. courts to protect this information. Moreover, our trade secrets, know-how, and technological advancements may otherwise become known or be independently developed by competitors in a manner providing us with no practical recourse against the competing parties. If any such events were to occur, they could adversely affect our business, financial condition, results of operations, and prospects.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers or of other third parties with whom we have obligations of confidentiality.

As is common in the pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Such claims may lead to material costs for us, or an inability to protect or use valuable intellectual property rights, which could adversely affect our business, financial condition, results of operations, and prospects.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and you could lose all or part of your investment.

The trading price of our common stock on Nasdaq is likely to be volatile. This volatility may prevent you from being able to sell your shares at or above the price you paid for your shares. Our stock price could be subject to wide fluctuations in response to a variety of factors, which include the following:

- any delay in filing our NDAs for our hormone therapy drug candidates and any adverse development or perceived adverse development with respect to the FDA's review of the NDAs, including the FDA's issuance of a "refusal to file" letter or a request for additional information;
- changes in laws or regulations applicable to our products or proposed products, including clinical trial requirements for approvals;
- unanticipated serious safety concerns related to the use of our hormone therapy drug candidates;
- a decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- any delay of our phase 3 clinical trials for our hormone therapy drug candidates;

- adverse results or delays in clinical trials;
- the inability to obtain adequate clinical supply for our hormone therapy drug candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- the introduction of new products or technologies offered by us or our competitors;
- the effectiveness of our or our potential strategic partners' commercialization efforts;
- developments concerning our sources of manufacturing supply and any commercialization strategic partners;
- the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- the inability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- the failure to meet or exceed the estimates and projections of the investment community;
- the overall performance of the U.S. equity markets and general political and economic conditions;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- additions or departures of key scientific or management personnel;
- adverse market reaction to any indebtedness we may incur or securities we may issue in the future;
- sales of our common stock by us or our stockholders in the future;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- the trading volume of our common stock;
- increases in our common stock available for sale upon expiration of lock-up agreements;
- effects of natural or man-made catastrophic events or other business interruptions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general and the stock of biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2017, our executive officers, directors, holders of 5% or more of our stock, and their affiliates beneficially owned approximately 73% of our common stock on an as converted basis. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

If we fail to maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required annually to deliver a report that assesses the effectiveness of our internal control over financial reporting and our independent registered public accounting firm is required annually to deliver an attestation report on the effectiveness of our internal control over financial reporting. If we are unable to maintain effective internal control over financial reporting or if our independent auditors are unwilling or unable to provide us with an attestation report on the effectiveness of internal control over financial reporting for future periods as required by Section 404 of the Sarbanes-Oxley Act, we may not be able to produce accurate financial statements, and investors may therefore lose confidence in our operating results, our stock price could decline and we may be subject to litigation or regulatory enforcement actions.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which might cause our stock price and trading volume to decline.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain any future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will be limited to the value of their stock.

Some provisions of our charter documents and Nevada law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our articles of incorporation and bylaws, as well as certain provisions of Nevada law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if an acquisition would benefit our stockholders, and could also make it more difficult to remove our current management. These provisions in our articles of incorporation and bylaws include the following:

- authorizing the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt;
- prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates; and

- advance notice provisions in connection with stockholder proposals that may prevent or hinder any attempt by our stockholders to bring business to be considered by our stockholders at a meeting or replace our board of directors.

In addition, we are subject to Nevada's Combination with Interested Stockholders statute (Nevada Revised Statute Sections 78.411 - 78.444), which prohibits an "interested stockholder" from entering into a "combination" with a company, unless certain conditions are met. An "interested stockholder" is a person who, together with affiliates and associates, beneficially owns (or within the prior two years, did beneficially own) 10% or more of the corporation's capital stock entitled to vote.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate headquarters is located in Boca Raton, Florida, where we lease 33,124 square feet of office space pursuant to a non-cancelable operating lease that commenced on July 1, 2013 and was subsequently amended on February 18, 2015, April 26, 2016 and October 4, 2016 to lease additional administrative space. The lease expires on October 31, 2021. The primary functions performed at this location are executive, administrative, accounting, treasury, marketing, and human resources. We believe that our current facility is in good working order and is capable of supporting our operations for the foreseeable future.

Item 3. Legal Proceedings

From time to time, we are involved in litigation and proceedings in the ordinary course of our business. We are not currently involved in any legal proceeding that we believe would have a material effect on our business or financial condition.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information on Common Stock

Since October 9, 2017, our common stock has been listed on the Nasdaq Global Select Market of the Nasdaq Stock Market LLC under the symbol "TXMD." From April 23, 2013 to October 6, 2017, our common stock was listed on the NYSE American under the symbol "TXMD." Prior to that time, our common stock was quoted on the OTCQB. The following table sets forth for the periods indicated the high and low sales prices of our common stock on the NYSE American or Nasdaq, as applicable.

	High	Low
2017		
Fourth Quarter	$ 6.97	$ 4.34
Third Quarter	$ 7.01	$ 4.54
Second Quarter	$ 8.30	$ 3.50
First Quarter	$ 7.32	$ 5.38
2016		
Fourth Quarter	$ 7.48	$ 4.39
Third Quarter	$ 8.72	$ 6.18
Second Quarter	$ 9.29	$ 6.20
First Quarter	$ 10.17	$ 5.69

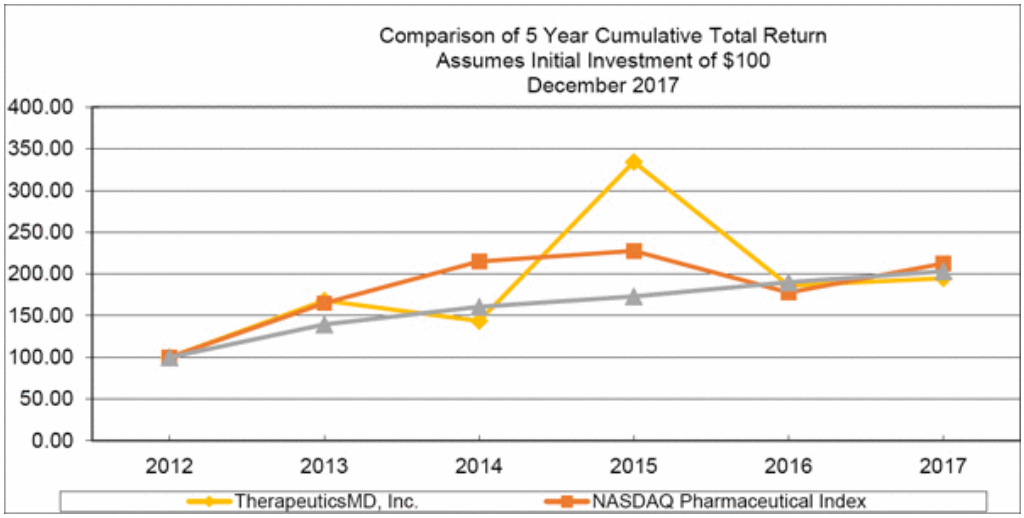
On February 20, 2018, there were approximately 208 record holders and as of February 9, 2018, there were approximately 20,119 beneficial owners of our common stock.

Dividends

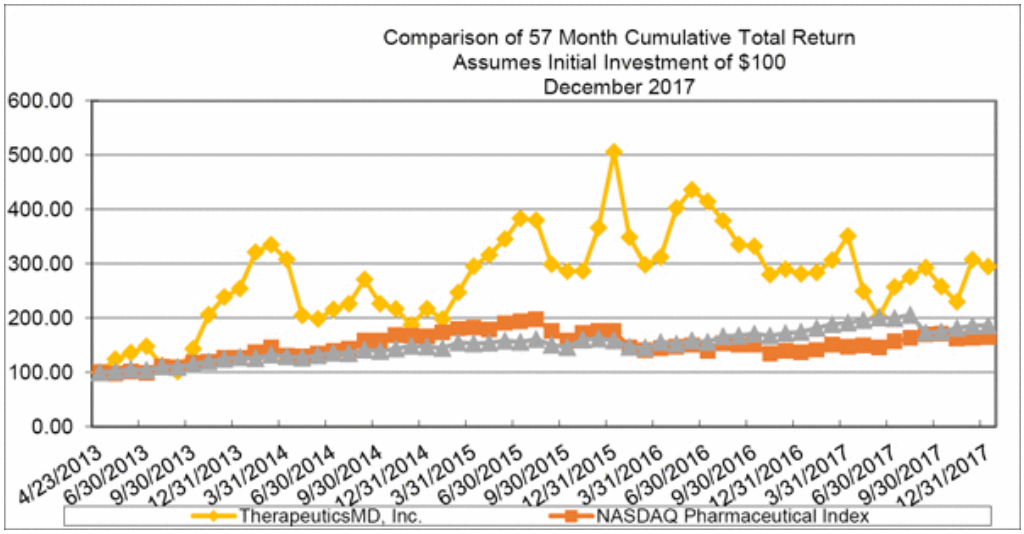
Historically, we have not paid dividends on our common stock, and we currently do not intend to pay any dividends on our common stock in the foreseeable future. We currently plan to retain any earnings to finance the growth of our business rather than to pay cash dividends. Payments of any cash dividends in the future will depend on our financial condition, results of operations, and capital requirements as well as other factors deemed relevant by our board of directors.

Performance Graph

The following line graph compares cumulative total shareholder return for the five years ended December 31, 2017 for (i) our common stock; (ii) Nasdaq Pharmaceutical Index; and (iii) Nasdaq Stock Market (U.S. companies). The graph assumes $100 invested on December 31, 2012 and includes reinvestment of dividends. Measurement points are at the last trading day of the fiscal years ended December 31, 2012, 2013, 2014, 2015, 2016 and 2017. The stock price performance on the following graph is not necessarily indicative of future stock price performance.



The following line graph compares cumulative total shareholder return for the period beginning when our common stock became listed on the NYSE American exchange (April 23, 2013) and ended December 31, 2017 for (i) our common stock; (ii) Nasdaq Pharmaceutical Index; and (iii) Nasdaq Stock Market (U.S. companies). The graph assumes $100 invested on April 23, 2013 and includes reinvestment of dividends. Measurement points are April 23, 2013 and the last trading day of the fiscal years ended December 31, 2017, 2016, 2015, 2014 and 2013 and each of the following quarters ended therein beginning with the quarter ended June 30, 2013. The stock price performance on the following graph is not necessarily indicative of future stock price performance.



The performance graphs shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section. The performance graphs will not be deemed incorporated by reference into any filing of our company under the Exchange Act or the Securities Act.

Item 6. Selected Financial Data

The following table sets forth selected consolidated financial and other data as of and for the periods indicated. You should read the following information together with the more detailed information contained in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this Annual Report. The consolidated statements of operations for the years ended December 31, 2017, 2016, and 2015 and the consolidated balance sheet data as of December 31, 2017 and 2016 are derived from our audited consolidated financial statements included in this Annual Report. The consolidated statements of operations for the years ended December 31, 2014 and 2013, and the consolidated balance sheet data as of December 31, 2015, 2014, and 2013, are derived from our audited consolidated financial statements not included in this Annual Report.

THERAPEUTICSMD, INC. AND SUBSIDIARIES
(in thousands, except per share data)

	Year Ended December 31,				
	2017	**2016**	**2015**	**2014**	**2013**
Consolidated Statements of Operations Data:					
Revenue, net	$ 16,778	$ 19,356	$ 20,143	$ 15,026	$ 8,776
Cost of goods sold	2,637	4,185	4,506	3,672	1,960
Gross profit	14,141	15,171	15,637	11,354	6,816
Operating expenses:					
Sales, general, and administration	57,703	51,348	28,721	22,124	19,015
Research and development	33,853	53,943	72,043	43,219	13,551
Depreciation and amortization	213	133	63	52	58
Total operating expense	91,769	105,424	100,827	65,395	32,624
Operating loss	(77,628)	(90,253)	(85,190)	(54,041)	(25,808)
Other income (expense), net	703	378	113	(176)	(2,611)
Net loss	$ (76,925)	$ (89,875)	$ (85,077)	$ (54,217)	$ (28,419)
Net loss per share, basic and diluted	$ (0.37)	$ (0.46)	$ (0.49)	$ (0.36)	$ (0.22)
Weighted average number of common shares outstanding, basic and diluted	205,523	196,088	173,174	149,727	127,570
Consolidated Balance Sheet Data (at end of period)					
Total assets	$ 143,230	$ 142,472	$ 73,729	$ 59,079	$ 62,016
Total liabilities	$ 13,321	$ 14,983	$ 10,666	$ 10,690	$ 7,318
Total stockholders' equity	$ 129,909	$ 127,489	$ 63,063	$ 48,389	$ 54,698
Other Data:					
Capital expenditures (for the period)	$ 827	$ 1,241	$ 584	$ 617	$ 480
Working capital (at the end of period)	$ 126,233	$ 124,428	$ 60,014	$ 45,545	$ 52,085

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

You should read the following discussion and analysis in conjunction with the information set forth under "Selected Financial Data" and our consolidated financial statements and the notes to those financial statements included elsewhere in this Annual Report. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. See "Statement Regarding Forward-Looking Information." Our actual results may differ materially from those contained in or implied by any forward-looking statements as a result of various factors, including, but not limited to, the risks and uncertainties described under "Risk Factors" elsewhere in this Annual Report.

Company Overview

We are a women's health care company focused on creating and commercializing products targeted exclusively for women. Currently, we are focused on pursuing the regulatory approvals and pre-commercialization activities necessary for commercialization of our advanced hormone therapy pharmaceutical products. Our drug candidates that have completed clinical trials are designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, and vaginal discomfort. We are developing these hormone therapy drug candidates, which contain estradiol and progesterone alone or in combination, with the aim of demonstrating clinical efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products. With our SYMBODA™ technology, we are developing advanced hormone therapy pharmaceutical products to enable delivery of bio-identical hormones through a variety of dosage forms and administration routes. In addition, we manufacture and distribute branded and generic prescription prenatal vitamins.

Research and Development – Overview

We have submitted two new drug applications, or NDAs, with the U.S. Food and Drug Administration, or FDA, for our hormone therapy drug candidates. In December 2017, we submitted the NDA for TX-001HR, our bio-identical hormone therapy combination of 17ß- estradiol and progesterone in a single, oral softgel drug candidate, for the treatment of vasomotor symptoms, or VMS, due to menopause in menopausal women with an intact uterus. In November 2017, we re-submitted our NDA for TX-004HR, our applicator-free vaginal estradiol softgel drug candidate for the treatment of moderate to severe dyspareunia (vaginal pain during sexual intercourse), a symptom of vulvar and vaginal atrophy, or VVA, in menopausal women with vaginal linings that do not receive enough estrogen. The NDA for our TX-004HR drug candidate has a Prescription Drug User Fee Act, or PDUFA, target action date for the completion of the FDA's review of May 29, 2018, and if approved on that date, the drug candidate could be launched as early as the third quarter of 2018. If the NDA for our TX-001HR drug candidate is accepted by the FDA, it could be approved as soon as the fourth quarter of 2018 and launched in 2019.

TX-001HR

TX-001HR is our bio-identical hormone therapy combination of 17ß- estradiol and progesterone in a single, oral softgel drug candidate for the treatment of moderate to severe VMS due to menopause, including hot flashes, night sweats and sleep disturbances in menopausal women with an intact uterus. The hormone therapy drug candidate is bioidentical to, or having the same chemical and molecular structure as, the hormones that naturally occur in a woman's body, namely estradiol and progesterone, and is being studied as a continuous-combined regimen, in which the combination of estrogen and progesterone are taken together in one product daily. If approved by the FDA, we believe this would represent the first time a combination product of estradiol and progesterone bioidentical to the estradiol and progesterone produced by the ovaries would be approved for use in a single combined product.

We previously conducted a pharmacokinetics, or PK, study of TX-001HR to demonstrate that our drug candidate is bioequivalent to the reference listed drug based on the criterion that the 90% confidence interval on the test-to-reference ratio is contained entirely within the interval 80% to 125%. The study compared our combined capsule TX-001HR of 2 mg estradiol and 200 mg of progesterone to 2 mg of Estrace® and 200 mg of Prometrium®.

The study compared the mean plasma concentrations for free estradiol between TX-001HR and Estrace® in 62 female test subjects. When the results of a single dose-fed study were compared over 48 hours by the test drug versus reference drug, the ratio was 0.93 with the standard deviation within the subject being 0.409 for an upper 95% confidence bound of -0.089. The maximum plasma concentration levels of free estradiol showed that the drug -versus - reference drug ratio was 0.88 with the standard deviation within the subject being 0.344 for an upper 95% confidence bound of -0.040 over 48 hours.

The study also compared the mean plasma concentrations for progesterone between TX-001HR and Prometrium® in 62 female test subjects. When the results were compared over 48 hours of the test that the drug-versus-reference drug, the ratio was 1.05 with the standard deviation within the subject being 0.956 for an upper 95% confidence bound of -0.542. The maximum plasma concentration levels of progesterone showed drug versus reference drug ratio as 1.16 with the standard deviation within the subject being 1.179 for an upper 95% confidence bound of -0.785 over 48 hours.

On September 5, 2013, we began enrollment in the REPLENISH Trial, a multicenter, double-blind, placebo-controlled, phase 3 clinical trial of TX-001HR in menopausal women with an intact uterus. The trial was designed to evaluate the efficacy of TX-001HR for the treatment of moderate to severe VMS due to menopause and the endometrial safety of TX-001HR. Patients were assigned to one of five arms, four active and one placebo, and received study medication for 12 months. The primary endpoint for the reduction of endometrial hyperplasia was an incidence of endometrial hyperplasia of less than 1% at 12 months, as determined by endometrial biopsy. The primary endpoint for the treatment of moderate to severe VMS was the mean change of frequency and severity of moderate to severe VMS at weeks four and 12 compared to placebo, as measured by the number and severity of hot flashes. Only subjects experiencing a minimum daily frequency of seven moderate to severe hot flashes at screening were included in the VMS analysis, while all subjects were included in the endometrial hyperplasia analysis. The secondary endpoints included reduction in sleep disturbances and improvement in quality of life measures, night sweats and vaginal dryness, measured at 12 weeks, six months and 12 months. The trial evaluated 1,835 patients between 40 and 65 years old at 111 sites. On December 5, 2016, we announced positive topline data for the REPLENISH Trial.

The REPLENISH Trial evaluated four doses of TX-001HR and placebo; the doses studied were:

- 17ß-estradiol 1 mg/progesterone 100 mg (n = 416)
- 17ß-estradiol 0.5 mg/progesterone 100 mg (n = 423)
- 17ß-estradiol 0.5 mg/progesterone 50 mg (n = 421)
- 17ß-estradiol 0.25 mg/progesterone 50 mg (n = 424)
- Placebo (n = 151)

The REPLENISH Trial results demonstrated:

● TX-001HR estradiol 1 mg/progesterone 100 mg and TX-001HR estradiol 0.5 mg/progesterone 100 mg both achieved all four of the co-primary efficacy endpoints and the primary safety endpoint.

● TX-001HR estradiol 1 mg/progesterone 100 mg and TX-001HR estradiol 0.5 mg/progesterone 100 mg both demonstrated a statistically significant and clinically meaningful reduction from baseline in both the frequency and severity of hot flashes compared to placebo.

● TX-001HR estradiol 0.5 mg/progesterone 50 mg and TX-001HR estradiol 0.25 mg/progesterone 50 mg were not statistically significant at all of the co-primary efficacy endpoints. The estradiol 0.25 mg/progesterone 50 mg dose was included in the clinical trial as a non-effective dose to meet the recommendation of the FDA guidance to identify the lowest effective dose.

● The incidence of consensus endometrial hyperplasia or malignancy was 0 percent across all four TX-001HR doses, meeting the recommendations established by the FDA's draft guidance.

As outlined in the FDA guidance, the co-primary efficacy endpoints in the REPLENISH Trial were the change from baseline in the number and severity of hot flashes at weeks four and 12 as compared to placebo. The primary safety endpoint was the incidence of endometrial hyperplasia with up to 12 months of treatment. General safety was also evaluated.

The results of the REPLENISH Trial are summarized in the table below (p-values of < 0.05 meet FDA guidance and support evidence of efficacy):

Replenish Trial Co-Primary Efficacy Endpoints: Mean Change in Frequency and Severity of Hot Flashes Per Week Versus Placebo at Weeks 4 and 12, VMS-MITT Population					
Estradiol/Progesterone	1 mg/100 mg (n = 141)	0.5 mg/100 mg (n = 149)	0.5 mg/50 mg (n = 147)	0.25 mg/50 mg (n = 154)	Placebo (n = 135)
Frequency					
Week 4 P-value versus placebo	<0.001	0.013	0.141	0.001	—
Week 12 P-value versus placebo	<0.001	<0.001	0.002	<0.001	—
Severity					
Week 4 P-value versus placebo	0.031	0.005	0.401	0.100	—
Week 12 P-value versus placebo	<0.001	<0.001	0.018	0.096	—
Replenish Trial Primary Safety Endpoint: Incidence of Consensus Endometrial Hyperplasia or Malignancy up to 12 months, Endometrial Safety Population₸					
Endometrial Hyperplasia	0% (0/280)	0% (0/303)	0% (0/306)	0% (0/274)	0% (0/92)

MITT = Modified intent to treat

₸Per FDA, consensus hyperplasia refers to the concurrence of two of the three pathologists be accepted as the final diagnosis

We submitted the NDA for TX-001HR with the FDA on December 28, 2017. Assuming that the NDA is accepted 74 days thereafter and an FDA review period of ten months from the receipt date to the PDUFA target action date for a non-new molecular entity, the NDA for TX-001HR could be approved by the FDA as soon as the fourth quarter of 2018.

TX-002HR

TX-002HR is a natural progesterone formulation for the treatment of secondary amenorrhea without the potentially allergenic component of peanut oil. The hormone therapy drug candidate is bioidentical to – or having the same chemical and molecular structure as - the hormones that naturally occur in a woman's body. We believe it will be similarly effective to traditional treatments, but may demonstrate efficacy at lower dosages. In January 2014, we began recruitment of patients in the SPRY Trial, a phase 3 clinical trial designed to measure the safety and effectiveness of TX-002HR in the treatment of secondary amenorrhea. During the first two quarters of 2014, the SPRY Trial encountered enrollment challenges because of Institutional Review Board, or IRB, approved clinical trial protocols and FDA inclusion and exclusion criteria. In July 2014, we suspended enrollment and in October 2014 we stopped the SPRY Trial in order to update the phase 3 protocol based on discussions with the FDA. Our IND related to TX-002HR is currently in inactive status. We are considering updating the phase 3 protocol to, among other things, target only those women with secondary amenorrhea due to polycystic ovarian syndrome and to amend the primary endpoint of the trial. We believe that the updated phase 3 protocol, if proposed by us and approved by the FDA, would allow us to mitigate the enrollment challenges in, and shorten the duration of, the SPRY Trial. However, there can be no assurance that the FDA will approve the updated phase 3 protocol if we propose it. We have currently suspended further development of this drug candidate to prioritize our leading drug candidates.

TX-003HR

TX-003HR is a natural estradiol formulation. This hormone therapy drug candidate is bioidentical to the hormones that naturally occur in a woman's body. We currently do not have plans to further develop this hormone therapy drug candidate. Our IND related to TX-003HR is currently inactive.

TX-004HR

TX-004HR is our applicator free vaginal estradiol softgel drug candidate for the treatment of moderate to severe dyspareunia, a symptom of VVA in menopausal women with vaginal linings that do not receive enough estrogen. We believe that our drug candidate will be at least as effective as the traditional treatments for VVA because of an early onset of action with less systemic exposure, and it will have an added advantage of being a more simple, easier to use dosage form versus traditional VVA treatments. We initiated the REJOICE Trial, a randomized, multicenter, double-blind, placebo-controlled phase 3 clinical trial during the third quarter of 2014 to assess the safety and efficacy of three doses – 25 mcg, 10 mcg and 4 mcg (compared to placebo) – of TX-004HR for the treatment of moderate to severe dyspareunia, or painful intercourse, as a symptom of VVA due to menopause.

On November 10, 2015, the FDA held a scientific workshop on labeling "lower" dose estrogen-alone products for symptoms of VVA to provide an opportunity for the FDA to obtain input from experts on several topics related to the product label of lower dose estrogen-alone products approved solely for the treatment of moderate to severe symptoms of VVA due to menopause. According to the FDA, lower-dose estrogen products means products that contain less than the 0.625 mg of conjugated estrogens used in the WHI study and estradiol products containing 0.0375 mg and below. Discussion topics at the workshop included the relevance of the boxed warnings based on data from the WHI to the lower dose estrogen-alone products; certain members in the scientific/medical community have questioned whether the boxed warnings section in the labeling, which is currently required to be included on all estrogen products, is applicable in whole or in part to these lower-dose estrogen products. The boxed warnings include: (1) an increased risk of endometrial cancer in women with a uterus who uses unopposed estrogens, (2) estrogen therapy with or without progestins should not be used for the prevention of cardiovascular disease or dementia, (3) an increased risk of stroke and deep vein thrombosis (DVT) in women treated with estrogen-alone, (4) an increased risk of probable dementia in post-menopausal women 65 years of age and older treated with estrogen-alone, (5) an increased risk of invasive breast cancer in women treated with estrogen plus progestin, and (6) to use the lowest effective dose for the shortest duration. It is unknown at this time what, if any, changes the FDA may propose with respect to the boxed warnings on lower dose estrogen-alone products for symptoms of VVA or whether such label changes would be applicable to TX-004HR, if approved.

On December 7, 2015, we announced positive top-line results from the REJOICE Trial. The pre-specified four co-primary efficacy endpoints were the changes from baseline to week 12 versus placebo in the percentage of vaginal superficial cells, percentage of vaginal parabasal cells, vaginal pH and severity of participants' self-reported moderate to severe dyspareunia as the most bothersome symptom of VVA. The trial enrolled 764 menopausal women (40 to 75 years old) experiencing moderate to severe dyspareunia at approximately 89 sites across the United States and Canada. Trial participants were randomized to receive either TX-004HR at 25 mcg (n=190), 10 mcg (n=191), or 4 mcg (n=191) doses or placebo (n=192) for a total of 12 weeks, all administered once daily for two weeks and then twice weekly (approximately three to four days apart) for ten weeks.

The following table sets forth the statistical significance of the REJOICE Trial results for the four pre-specified co-primary efficacy endpoints, based on mean changes from baseline to week 12 compared to placebo. Based on our analyses of the REJOICE Trial data, statistical significance of the results for the co-primary endpoint of severity of participants' self-reported moderate to severe dyspareunia as the most bothersome symptom of VVA has improved for all three doses from the results originally reported.

	25 mcg	10 mcg	4 mcg
Superficial Cells	P < 0.0001	P < 0.0001	P < 0.0001
Parabasal Cells	P < 0.0001	P < 0.0001	P < 0.0001
Vaginal pH	P < 0.0001	P < 0.0001	P < 0.0001
Severity of Dyspareunia	P < 0.0001	P < 0.0001	P = 0.0149

The 25 mcg dose of TX-004HR demonstrated highly statistically significant results at the $p < 0.0001$ level compared to placebo across all four co-primary endpoints. The 10 mcg dose of TX-004HR demonstrated highly statistically significant results at the $p < 0.0001$ level compared to placebo across all four co-primary endpoints. The 4 mcg dose of TX-004HR also demonstrated highly statistically significant results at the $p < 0.0001$ level compared to placebo for the endpoints of vaginal superficial cells, vaginal parabasal cells, and vaginal pH; the change from baseline compared to placebo in the severity of dyspareunia was statistically significant at the $p = 0.0149$ level. The FDA has previously indicated to us that in order to approve the drug based on a single trial, the trial would need to show statistical significance at the 0.01 level or lower for each endpoint, and that a trial that is merely statistically significant at a higher level may not provide sufficient evidence to support an NDA filing or approval of a drug candidate where the NDA relies on a single clinical trial.

Statistical improvement over placebo was also observed for all three doses at the first assessment at week two and sustained through week 12 (see table below).

	25 mcg	10 mcg	4 mcg
Week 2	P = 0.0105	P = 0.0019	P = 0.026
Week 6	P < 0.0001	P = 0.0009	P = 0.0069
Week 8	P < 0.0001	P < 0.0001	P = 0.0003
Week 12	P < 0.0001	P < 0.0001	P = 0.0149

Vaginal dryness was a prespecified key secondary endpoint. The 25 mcg and 10 mcg doses of TX-004HR demonstrated highly statistically significant results at the $p < 0.0001$ level compared to placebo for the endpoint of vaginal dryness. The 4 mcg dose of TX-004HR demonstrated statistically significant results at the $p = 0.0014$ level compared to placebo (see table below).

	25 mcg	10 mcg	4 mcg
Severity of Vaginal Dryness	P < 0.0001	P < 0.0001	P = 0.0014

The pharmacokinetic data for all three doses demonstrated negligible to very low systemic absorption of 17 beta estradiol, estrone and estrone conjugated, supporting the previous phase 1 trial data. TX-004HR was well tolerated, and there were no clinically significant differences compared to placebo-treated participants with respect to adverse events. There were no drug-related serious adverse events reported.

We submitted the NDA for TX-004HR with the FDA on July 7, 2016. The FDA determined that the NDA was sufficiently complete to permit a substantive review and accepted the NDA for filing with the PDUFA target action date for the completion of the FDA's review of May 7, 2017. The NDA submission was supported by the complete TX-004HR clinical program, including positive results of the phase 3 REJOICE Trial. The NDA submission included all three doses of TX-004HR (4 mcg, 10 mcg and 25 mcg) that were evaluated in the REJOICE Trial.

On May 5, 2017, we received a CRL from the FDA regarding the NDA for TX-004HR. In the CRL, the only approvability concern raised by the FDA was the lack of long-term safety data for TX-004HR beyond the 12 weeks studied in the phase 3 REJOICE Trial. The CRL did not identify any issues related to the efficacy of TX-004HR and did not identify any approvability issues related to chemistry, manufacturing and controls.

On June 14, 2017, we participated in a Type A Post-Action Meeting with the Division of Bone, Reproductive, and Urologic Products (DBRUP) of the FDA to discuss the CRL. At the meeting, we presented information that we believed could address concerns raised by the FDA in the CRL. On July 5, 2017, we received the official minutes of the meeting from the FDA, which provided the FDA's response to the information presented at the Type A meeting. Per the FDA's request, we formally submitted the information presented at the Type A meeting for consideration related to the NDA for TX-004HR.

On August 3, 2017, we received a formal General Advice Letter from the FDA stating that an initial review of this information has been completed and requesting that we submit the additional endometrial safety information to the NDA for TX-004HR on or before September 18, 2017. On September 14, 2017, we submitted the additional endometrial safety information that was requested by the FDA in the General Advice Letter to the NDA for TX-004HR. The submission included a comprehensive, systematic review of the medical literature on the use of vaginal estrogen products and the risk of endometrial hyperplasia or cancer, including the safety data from the recently published Women's Health Initiative Observational Study, or WHI Study, of vaginal estrogen use in post-menopausal women and information on the relevance of the first uterine pass effect for low-dose vaginal estrogen products. The WHI Study demonstrated no significant difference in the risk of invasive breast cancer, stroke, colorectal cancer, endometrial cancer and venous thromboembolism in vaginal estrogen users versus non-users. The WHI Study also shows that, among women with an intact uterus, there was a decreased risk of cardiovascular disease, hip fracture and all-cause mortality in vaginal estrogen users versus non-users. The WHI Study evaluated over 4,000 women who used vaginal estrogens for a median duration of two to three years.

On November 3, 2017, we participated in an in-person meeting with DBRUP. At the meeting, DBRUP agreed to the resubmission of the NDA for the 4 mcg and 10 mcg doses of TX-004HR without the need for an additional pre-approval study.

On November 29, 2017, we resubmitted the NDA for the 4 mcg and 10 mcg doses of TX-004HR with the FDA. We have committed to conduct a post-approval observational study. The FDA has acknowledged that the resubmission is a complete, class 2 response to the CRL received on May 5, 2017 for TX-004HR. The PDUFA target action date for the completion of the FDA's review is May 29, 2018. If approved, the 4 mcg formulation of TX-004HR would represent a lower effective dose than the currently available VVA therapies approved by the FDA.

Research and Development Expenses

A significant portion of our operating expenses to date have been incurred in research and development activities. Research and development expenses relate primarily to the discovery and development of our drug products. Our business model is dependent upon our company continuing to conduct a significant amount of research and development. "Other research and development" costs in the table below consist of products costs incurred prior to IND approval from the FDA as well as other clinical and regulatory consulting costs. Our research and development expenses consist primarily of expenses incurred under agreements with contract research organizations, or CROs, investigative sites, and consultants that conduct our clinical trials and a substantial portion of our preclinical studies; employee-related expenses, which include salaries and benefits, and non-cash share-based compensation; the cost of developing our chemistry, manufacturing and controls capabilities, and acquiring clinical trial materials; and costs associated with other research activities and regulatory approvals.

We make payments to the CROs based on agreed upon terms that may include payments in advance of a study starting date. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Advance payments to be expensed in future research and development activities were $0, $228,933 and $1,138,073, at December 31, 2017, 2016 and December 31, 2015, respectively.

The following table indicates our research and development expense by project for the periods indicated:

	Years Ended December 31,		
	2017	2016	2015
	(000s)		
TX-001HR	$ 19,381	$ 31,857	$ 33,227
TX-002HR	—	—	23
TX-004HR	8,043	9,248	19,574
Other research and development	6,429	12,838	19,219
Total research and development	$ 33,853	$ 53,943	$ 72,043

Research and development expenditures will continue to be incurred as we continue development of our drug candidates and advance the development of our proprietary pipeline of novel drug candidates. We expect to incur ongoing research and development costs as we develop our drug pipeline, continue stability testing and validation on our drug candidates, prepare regulatory submissions and work with regulatory authorities on existing submissions.

During the year ended December 31, 2017 and since the project's inception in February 2013, we have incurred approximately $19,381,000 and $115,397,000, respectively, in research and development costs with respect to TX-001HR, our combination estradiol and progesterone drug candidate.

During the year ended December 31, 2017 and since the project's inception in April 2013, we have incurred approximately $0 and $2,525,000, respectively, in research and development costs with respect to TX-002HR, our progesterone only drug candidate.

During the year ended December 31, 2017 and since the project's inception in August 2014, we have incurred approximately $8,043,000 and $40,849,000, respectively, in research and development costs with respect to TX-004HR, our vaginal estradiol softgel drug candidate.

The costs of clinical trials may vary significantly over the life of a project owing to factors that include, but are not limited to, the following: per patient trial costs; the number of patients that participate in the trials; the number of sites included in the trials; the length of time each patient is enrolled in the trial; the number of doses that patients receive; the drop-out or discontinuation rates of patients; the amount of time required to recruit patients for the trial; the duration of patient follow-up; and the efficacy and safety profile of the drug candidate. We base our expenses related to clinical trials on estimates that are based on our experience and estimates from CROs and other third parties. Research and development expenditures for the drug candidates will continue after the trial completes for on-going stability and laboratory testing, regulatory submission and response work.

Results of Operations

Comparison of Years Ended December 31, 2017, 2016, and 2015:

Year ended December 31, 2017 compared with year ended December 31, 2016

	Years Ended December 31,		
	2017	2016	Change
	(000s)		
Revenue	$ 16,778	$ 19,356	$ (2,578)
Cost of goods sold	2,637	4,185	(1,548)
Operating expenses	91,769	105,424	(13,655)
Operating loss	(77,628)	(90,253)	12,625
Other income	703	378	325
Net loss	$ (76,925)	$ (89,875)	$ 12,950

Revenue

Revenue is recorded net of sales discounts, chargebacks, wholesaler fees, customer rebates, coupons and estimated returns. Revenue for the year ended December 31, 2017 decreased by approximately $2,578,000, or 13%, to approximately $16,778,000, compared with approximately $19,356,000 for the year ended December 31, 2016. This decrease was attributable to a decrease in the average net revenue per unit of our products, primarily related to higher coupons in 2017 due to implementation of a new point of sale coupon system, partially offset by a slight increase in the number of units sold.

Cost of Goods Sold

Cost of goods sold decreased by approximately $1,548,000, or 37%, to approximately $2,637,000 for the year ended December 31, 2017, compared with approximately $4,185,000 for the year ended December 31, 2016 primarily related to lower distribution costs. Our gross margins was 84% for the year ended December 31, 2017 as compared to 78% for the year ended December 31, 2016. The increase in gross margin percentage was primarily attributable to the centralization of the distribution channel for both our retail pharmacy distributors and wholesale distributors which, among other things, lowered the cost to package, prepare and deliver our products to customers.

Operating Expenses

Our principal operating costs included the following items as a percentage of total operating expenses.

	Years Ended December 31,	
	2017	2016
Human resource related costs	27%	23%
Sales and marketing costs, excluding human resource costs	22%	12%
Product research and development costs	37%	51%
Professional fees and consulting costs	6%	5%
Other operating expenses	8%	9%

Operating expenses decreased by approximately $13,655,000, or 13%, to approximately $91,769,000 for the year ended December 31, 2017, compared with approximately $105,424,000 for the year ended December 31, 2016, as a result of the following items:

	Years Ended December 31,		
	2017	2016	Change
	(000s)		
Research and development costs	$ 33,853	$ 53,943	$ (20,090)
Human resource related costs	24,720	24,599	121
Sales and marketing, excluding human resource costs	19,614	12,753	6,861
Professional and consulting costs	5,859	5,301	558
Other operating expenses	7,723	8,828	(1,105)
Total operating expenses	$ 91,769	$ 105,424	$ (13,655)

Research and development costs for the year ended December 31, 2017 decreased by approximately $20,090,000, or 37%, to approximately $33,853,000, primarily as a result of a decrease in costs related to our phase 3 clinical trials of TX-001HR and TX-004HR, partially offset by scale-up and manufacturing activities for our phase 3 clinical trials of TX-001HR and TX-004HR and costs related to regulatory submission related to TX-001HR. Research and development costs in 2017 included approximately a $2,400,000 in NDA submission fees related to TX-001HR and a write-off of approximately $1,000,000 of prepaid manufacturing costs. Research and developments costs during the year ended December 31, 2017 included the following research and development projects:

During the year ended December 31, 2017 and since the project's inception in February 2013, we have incurred approximately $19,381,000 and $115,397,000, respectively, in research and development costs with respect to TX-001HR, our combination estradiol and progesterone drug candidate.

During the year ended December 31, 2017 and since the project's inception in April 2013, we have incurred approximately $0 and 2,525,000, respectively, in research and development costs with respect to TX-002HR, our progesterone only drug candidate.

During the year ended December 31, 2017 and since the project's inception in August 2014, we have incurred approximately $8,043,000 and $40,849,000, respectively, in research and development costs with respect to TX-004HR, our vaginal estradiol softgel drug candidate.

For a discussion of the nature of efforts and steps necessary to complete these projects, see "Item 1. Business — Research and Development." For a discussion of the risks and uncertainties associated with completing development of our products, see "Item 1A. Risk Factors — Risks Related to Our Business." For a discussion of the extent and nature of additional resources that we may need to obtain if our current liquidity is not expected to be sufficient to complete these projects, see "— Liquidity and Capital Resources." For a discussion as to whether a future milestone such as completion of a development phase, date of filing an NDA with a regulatory agency or approval from a regulatory agency can be reliably determined, see "Item 1. Business — Our Hormone Therapy Drug Candidates," "Item 1. Business — Products in Development" and "Item 1. Business — Pharmaceutical Regulation." Future milestones, including NDA submission dates, are not easily determinable as such milestones are dependent on various factors related to our clinical trials, including the timing of ongoing patient recruitment efforts to find eligible subjects for the applicable trials.

Human resource related costs, including salaries and benefits, increased by approximately $121,000, or 0.5%, to approximately $24,720,000 for the year ended December 31, 2017, compared with approximately $24,599,000 for the year ended December 31, 2016, primarily as a result of an increase of approximately $5,750,000 in personnel costs in sales, marketing and regulatory areas to support commercialization of our hormone therapy drug candidates, partially offset by a decrease in non-cash compensation expense included in this category of approximately $5,629,000 related to employee stock option amortization during 2017 as compared to 2016.

Sales and marketing costs increased by approximately $6,861,000, or 54%, to approximately $19,614,000 for the year ended December 31, 2017, compared with approximately $12,753,000 for the year ended December 31, 2016, primarily as a result of increased expenses in the first half of 2017 associated with sales and marketing efforts to support commercialization of our hormone therapy drug candidates, which were curtailed in the third quarter of 2017 due to the status of the NDA for TX-004HR, higher costs related to outsourced sales personnel and their related expenses which started in the fourth quarter of 2016, together with an increase in employee incentives.

Professional and consulting costs increased by approximately $558,000, or 11%, for the year ended December 31, 2017, to approximately $5,859,000 compared with approximately $5,301,000 for the year December 31, 2016, primarily as a result of result of increased legal and other professional expenses, partially offset by a decrease in consulting and accounting expenses.

All other costs decreased by approximately $1,105,000, or 13%, to approximately $7,723,000 for the year ended December 31, 2017, compared with approximately $8,828,000 for the year ended December 31, 2016, primarily as a result of a decrease in write-off of accounts receivable balances of approximately $2,200,000, which occurred in 2016, partially offset by an increase in rent, information technology, insurance, and other office expenses in 2017.

Operating Loss

As a result of the foregoing, our operating loss decreased approximately $12,625,000, or 14%, to approximately $77,628,000 for the year ended December 31, 2017, compared with approximately $90,253,000 for the year ended December 31, 2016, primarily as a result of decreased research and development expenses, non-cash compensation expense and other expenses, partially offset by increased sales and marketing expenses associated with sales and marketing efforts to support commercialization of our hormone therapy drug candidates and higher personnel costs.

As a result of the continued development of our hormone therapy drug candidates, we anticipate that we will continue to have operating losses for the near future until our hormone therapy drug candidates are approved by the FDA and brought to market, although there is no assurance that we will attain such approvals or that any marketing of our hormone therapy drug candidates, if approved, will be successful.

Other Income

Other non-operating income increased by approximately $325,000, or 86%, to approximately $703,000 for the year ended December 31, 2017 compared with approximately $378,000 for the comparable period in 2016, primarily as a result of increased interest income.

Net Loss

As a result of the net effects of the foregoing, net loss decreased approximately $12,950,000, or 14%, to approximately $76,925,000 for the year ended December 31, 2017, compared with approximately $89,875,000 for the year ended December 31, 2016. Net loss per share of common stock, basic and diluted, was ($0.37) for the year ended December 31, 2017, compared with ($0.46) per share of common stock for the year ended December 31, 2016.

Year ended December 31, 2016 compared with year ended December 31, 2015

	Years Ended December 31,		
	2016	2015	Change
	(000s)		
Revenue	$ 19,356	$ 20,143	$ (787)
Cost of goods sold	4,185	4,506	(321)
Operating expenses	105,424	100,827	4,597
Operating loss	(90,253)	(85,190)	(5,063)
Other income	378	113	265
Net loss	$ (89,875)	$ (85,077)	$ (4,798)

Revenue

Revenue is recorded net of sales discounts, chargebacks, wholesaler fees, customer rebates, coupons and estimated returns. Revenue for the year ended December 31, 2016 decreased by approximately $787,000, or 4%, to approximately $19,356,000, compared with approximately $20,143,000 for the year ended December 31, 2015. This decrease was primarily attributable to a decrease in the average net revenue per unit of our products primarily related to higher estimates related to discounts and returns in 2016, and the reversal of the deferred revenue balance in the first quarter of 2015 related to products sold through wholesale distributors until the right of return no longer existed, partially offset by an increase in the number of units sold.

Cost of Goods Sold

Cost of goods sold decreased by approximately $321,000, or 7%, to approximately $4,185,000 for the year ended December 31, 2016, compared with approximately $4,506,000 for the year ended December 31, 2015 primarily related to lower distribution costs and more favorable product mix of our products sold, partially offset by the reversal of the deferred balance in the first quarter of 2015 related to products sold through wholesale distributors until the right of return no longer existed. Our gross margins of 78% for the year ended December 31, 2016 remained unchanged from the year ended December 31, 2015.

Operating Expenses

Our principal operating costs included the following items as a percentage of total operating expenses.

	Years Ended December 31,	
	2016	2015
Human resource related costs	23%	15%
Sales and marketing costs, excluding human resource costs	12%	6%
Product research and development costs	51%	71%
Professional fees and consulting costs	5%	4%
Other operating expenses	9%	4%

Operating expenses increased by approximately $4,597,000, or 5%, to approximately $105,424,000 for the year ended December 31, 2016, compared with approximately $100,827,000 for year ended December 31, 2015, as a result of the following items:

	Years Ended December 31,		
	2016	2015	Change
	(000s)		
Research and development costs	$ 53,943	$ 72,043	$ (18,100)
Human resource related costs	24,599	14,966	9,633
Sales and marketing, excluding human resource costs	12,753	5,920	6,833
Professional and consulting costs	5,301	3,649	1,652
Other operating expenses	8,828	4,249	4,579
Total operating expenses	$ 105,424	$ 100,827	$ 4,597

Research and development costs for the year ended December 31, 2016 decreased by approximately $18,100,000, or 25%, to approximately $53,943,000, primarily as a result of a decrease in costs related to our phase 3 clinical trials of TX-001HR and TX-004HR, partially offset by scale-up and manufacturing activities for our phase 3 clinical trials of TX-001HR and TX-004HR and costs related to regulatory submission related to TX-004HR. Research and developments costs during the year ended December 31, 2016 included the following research and development projects:

During the year ended December 31, 2016 and since the project's inception in February 2013, we have incurred approximately $31,857,000 and $96,016,000, respectively, in research and development costs with respect to TX-001HR, our combination estradiol and progesterone drug candidate.

During the year ended December 31, 2016 and since the project's inception in April 2013, we have incurred approximately $0 and $2,525,000, respectively, in research and development costs with respect to TX-002HR, our progesterone only drug candidate.

During the year ended December 31, 2016 and since the project's inception in August 2014, we have incurred approximately $9,248,000 and $32,806,000, respectively, in research and development costs with respect to TX-004HR, our vaginal estradiol softgel drug candidate.

For a discussion of the nature of efforts and steps necessary to complete these projects, see "Item 1. Business — Research and Development." For a discussion of the risks and uncertainties associated with completing development of our products, see "Item 1A. Risk Factors — Risks Related to Our Business." For a discussion of the extent and nature of additional resources that we may need to obtain if our current liquidity is not expected to be sufficient to complete these projects, see "— Liquidity and Capital Resources." For a discussion as to whether a future milestone such as completion of a development phase, date of filing an NDA with a regulatory agency or approval from a regulatory agency can be reliably determined, see "Item 1. Business — Our Hormone Therapy Drug Candidates," "Item 1. Business — Products in Development" and "Item 1. Business — Pharmaceutical Regulation." Future milestones, including NDA submission dates, are not easily determinable as such milestones are dependent on various factors related to our clinical trials, including the timing of ongoing patient recruitment efforts to find eligible subjects for the applicable trials.

Human resource related costs, including salaries and benefits, increased by approximately $9,633,000, or 64%, to approximately $24,599,000 for the year ended December 31, 2016, compared with approximately $14,966,000 for the year ended December 31, 2015, primarily as a result of an increase of approximately $3,492,000 in personnel costs in sales, marketing and regulatory areas to support commercialization of our hormone therapy drug candidates and an increase in non-cash compensation expense included in this category of approximately $6,141,000 related to employee stock option amortization during 2016 as compared to 2015.

Sales and marketing costs increased approximately $6,833,000 for the year ended December 31, 2016, or 115%, to approximately $12,753,000, compared with approximately $5,920,000 for the year ended December 31, 2015, primarily as a result of increased expenses associated with sales and marketing efforts to support commercialization of our hormone therapy drug candidates coupled with an increase in employee incentives.

Professional and consulting costs increased approximately $1,652,000 for the year ended December 31, 2016, or 45%, to approximately $5,301,000 compared with approximately $3,649,000 for the year December 31, 2015, primarily as a result of increased legal, consulting, accounting expenses.

All other costs increased approximately $4,579,000, or 108%, to approximately $8,828,000 for the year ended December 31, 2016, compared with approximately $4,249,000 for the year ended December 31, 2015, primarily as a result of a write-off of accounts receivable balances of approximately $2,200,000, increased insurance, rent, information technology and other office expenses.

Operating Loss

As a result of the foregoing, our operating loss increased approximately $5,063,000, or 6%, to approximately $90,253,000 for the year ended December 31, 2016, compared with approximately $85,190,000 for the year ended December 31, 2015, primarily as a result of increased personnel costs, sales and marketing expenses to support commercialization of our hormone therapy drug candidates, coupled with a write-off of accounts receivable balances mentioned above and an increase in non-cash compensation expense, professional fees and other operating expenses as well a decrease in revenue, partially offset by a decrease in research and development costs.

As a result of the continued development of our hormone therapy drug candidates, we anticipate that we will continue to have operating losses for the near future until our hormone therapy drug candidates are approved by the FDA and brought to market, although there is no assurance that we will attain such approvals or that any marketing of our hormone therapy drug candidates, if approved, will be successful.

Other Income

Other non-operating income increased by approximately $265,000, or 235%, to approximately $378,000 for the year ended December 31, 2016 compared with approximately $113,000 for the comparable period in 2015, primarily as a result of increased interest income.

Net Loss

As a result of the net effects of the foregoing, net loss increased approximately $4,798,000, or 6%, to approximately $89,875,000 for the year ended December 31, 2016, compared with approximately $85,077,000 for the year ended December 31, 2015. Net loss per share of common stock, basic and diluted, was ($0.46) for the year ended December 31, 2016, compared with ($0.49) per share of common stock for the year ended December 31, 2015.

Liquidity and Capital Resources

We have funded our operations primarily through public offerings of our common stock and private placements of equity and debt securities. For the three-year period ending December 31, 2017, we received approximately $294,811,000 in net proceeds from the issuance of shares of our common stock. As of December 31, 2017, we had a cash balance of approximately $127,136,000, however, changing circumstances may cause us to consume funds significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control.

On September 25, 2017, we entered into an underwriting agreement with J.P. Morgan Securities LLC relating to an underwritten public offering of 12,400,000 shares of our common stock at a price of $5.55 per share. The net proceeds to us from the offering were approximately $68,573,000, after deducting estimated offering expenses payable by us. The offering closed on September 28, 2017 and we issued 12,400,000 shares of our common stock. We intend to use a majority of the net proceeds from this offering to fund pre-commercialization and commercialization activities for our TX-004HR and TX-001HR drug candidates. We currently intend to fund the next phase of our pre-commercialization and commercialization expenses for our TX-004HR and TX-001HR drug candidates through debt financing and are currently engaged in discussions to secure debt financing commitments. If we are successful in obtaining these commitments, we currently anticipate we would begin to draw on them following approval of either TX-004HR or TX-001HR.

For the fiscal year ended December 31, 2017, our days sales outstanding, or DSO, was 97 days compared to 92 days for the year ended December 31, 2016. The increase in our DSO as of December 31, 2017 was partially related to implementation of a new point of sale coupon system which lowered our revenues, as well as to the timing of payments received from our customers subsequent to December 31, 2017. We anticipate that our DSO will fluctuate in the future based upon a variety of factors, including longer payment terms associated with the centralization of the distribution channel for both our retail pharmacy distributors and wholesale distributors, as compared to the terms previously provided to our retail pharmacy distributors, changes in the healthcare industry and specific terms that may be extended in connection with the launch of our hormone therapy drug candidates, if approved.

We believe that our existing cash will allow us to fund our operating plan through at least the next 12 months from the date of this Annual Report. However, if the commercialization of our hormone therapy drug candidates is delayed, our existing cash may be insufficient to satisfy our liquidity requirements until we are able to commercialize our hormone therapy drug candidates. If our available cash is insufficient to satisfy our liquidity requirements, we may curtail our sales, marketing and other pre-commercialization efforts and we may seek to sell additional equity or debt securities or obtain a credit facility. 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. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our existing shareholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing shareholders. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or proposed products. Additionally, we may have to grant licenses on terms that may not be favorable to us.

We need substantial amounts of cash to complete the clinical development of and commercialize of our hormone therapy drug candidates. The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

Summary of (Uses) and Sources of Cash

	Year Ended December 31,		
	2017	2016	2015
Net cash flows used in operating activities	$ (76,155,614)	$ (69,142,333)	$ (79,044,199)
Net cash flows used in investing activities	$ (827,108)	$ (1,255,456)	$ (584,361)
Net cash flows provided by financing activities	$ 72,584,249	$ 137,225,535	$ 92,973,228

Operating Activities

The principal use of cash in operating activities for the year ended December 31, 2017 was to fund our current expenses primarily related to supporting clinical development, scale-up and manufacturing activities and future commercial activities, adjusted for non-cash items. The increase of approximately $7,013,000 in cash used in operating activities for the year ended December 31, 2017 in comparison to the year ended December 31, 2016 was primarily due to changes in the components of working capital and lower non-cash compensation expense, as well as a decrease in net loss.

The decrease of approximately $9,902,000 in cash used in operating activities for the year ended December 31, 2016 in comparison to the year ended December 31, 2015 was due primarily to an increase in our net loss adjusted for non-cash compensation expense and changes in the components of working capital.

Investing Activities

The decrease of approximately $428,000 in cash used in investing activities for the year ended December 31, 2017 compared with the year ended December 31, 2016 was primarily due to a decrease in patent costs and costs relating to the purchase of fixed assets.

The increase of approximately $671,000 in cash used in investing activities for the year ended December 31, 2016 compared with the year ended December 31, 2015 was primarily due to an increase in patent costs and the increase in costs relating to the purchase of fixed assets.

Financing Activities

Financing activities represent the principal source of our cash flow. Our financing activities for the year ended December 31, 2017 provided net cash of approximately $72,584,000. The cash provided by financing activities during the year ended December 31, 2017 included approximately $68,573,000 in proceeds from sale of our common stock and approximately $4,011,000 in proceeds from the exercise of options and warrants.

On September 25, 2017, we entered into an underwriting agreement with J.P. Morgan Securities LLC relating to an underwritten public offering of 12,400,000 shares of our common stock at a price of $5.55 per share. The net proceeds to us from the offering were approximately $68,573,000, after deducting estimated offering expenses payable by us. The offering closed on September 28, 2017 and we issued 12,400,000 shares of our common stock.

Our financing activities for the year ended December 31, 2016 provided net cash of approximately $137,226,000. The cash provided by financing activities during the year ended December 31, 2016 included approximately $134,864,000 in proceeds from sale of our common stock and approximately $2,362,000 in proceeds from the exercise of options and warrants.

On January 6, 2016, we entered into an underwriting agreement with Goldman, Sachs & Co. and Cowen and Company, LLC, as the representatives of the several underwriters, or Underwriters, relating to an underwritten public offering of 15,151,515 shares of our common stock at a public offering price of $8.25 per share. Under the terms of the underwriting agreement, we granted the Underwriters a 30-day option to purchase up to an aggregate of 2,272,727 additional shares of common stock, which option was exercised in full. The net proceeds to us from the offering were approximately $134,864,000, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. The offering closed on January 12, 2016 and we issued 17,424,242 shares of our common stock.

Our financing activities for the year ended December 31, 2015 provided net cash of approximately $92,973,000. The cash provided by financing activities included approximately $91,375,000 in proceeds from sale of our common stock and approximately $1,598,000 in proceeds from the exercise of options and warrants.

On July 9, 2015, we entered into an underwriting agreement with Stifel, Nicolaus & Company, Incorporated and Guggenheim Securities, LLC, as the representatives of the several underwriters, or the Stifel Underwriters, relating to an underwritten public offering of 3,846,154 shares of our common stock at a public offering price of $7.80 per share. Under the terms of the underwriting agreement, we granted the Stifel Underwriters a 30-day option to purchase up to an aggregate of 576,923 additional shares of our common stock, which option was exercised in full. The net proceeds to us from the offering were approximately $32,257,000, after deducting underwriting discounts and commissions and other estimated offering expense payable by us. The offering closed on July 15, 2015 and we issued 4,423,077 shares of our common stock.

On February 10, 2015, we entered into an underwriting agreement, or the Cowen Agreement, with Cowen and Company, LLC, as the representative of the several underwriters, or the Cowen Underwriters, relating to an underwritten public offering of 13,580,246 shares of our common stock, at a public offering price of $4.05 per share. Under the terms of the Cowen Agreement, we granted the Cowen Underwriters a 30-day option to purchase up to an aggregate of 2,037,036 additional shares of our common stock, which option was exercised in full. The net proceeds to us from the offering were approximately $59,118,000, after deducting underwriting discounts and commissions and other estimated offering expense payable by us. The offering closed February 17, 2015 and we issued 15,617,282 shares of our common stock.

Critical Accounting Policies and New Accounting Pronouncements

Critical Accounting Policies

The preparation of financial statements in accordance with accounting principles generally accepted in the United States, or GAAP, requires us to make estimates and assumptions that affect reported amounts and related disclosures in the financial statements. We consider an accounting estimate to be critical if:

- it requires assumptions to be made that were uncertain at the time the estimate was made, and
- changes in the estimate or different estimates that could have been selected could have a material impact on our results of operations or financial condition.

We base our estimates and judgments on our experience, our current knowledge, our beliefs of what could occur in the future, our observation of trends in the industry, information provided by our customers, and information available from other sources. Actual results may differ from these estimates under different assumptions or conditions. We have identified the following accounting policies and estimates as those that we believe are most critical to our financial condition and results of operations and that require our most subjective and complex judgments in estimating the effect of inherent uncertainties: share-based compensation expense and income taxes.

Revenue Recognition. We recognize revenue on arrangements in accordance with ASC 605, *Revenue Recognition*. We recognize revenue only when the price is fixed or determinable, persuasive evidence of an arrangement exists, the service is performed, and collectability is reasonably assured.

Prescription Products

We sell our name brand and generic prescription products primarily through wholesale distributors and retail pharmacy distributors. We recognize revenue from prescription product sales, net of sales discounts, chargebacks, wholesaler fees, customer rebates, coupons and estimated returns.

Revenue related to prescription products sold through wholesale distributors is recognized when the prescription products are shipped to the distributors and the control of the products passes to each distributor. We accept returns of unsalable prescription products sold through wholesale distributors within a return period of six months prior to and up to 12 months following product expiration. Our prescription products currently have a shelf life of 24 months from the date of manufacture.

Prior to September 1, 2016, we recognized revenue related to prescription products sold through retail pharmacy distributors when the product was dispensed by the retail pharmacy distributor, at which point all revenue and discounts related to such product were known or determinable and there was no right of return with respect to such product. On September 1, 2016, we centralized the distribution channel for both our retail pharmacy distributors and wholesale distributors, in order to facilitate sales to a broader population of retail pharmacies and mitigate exposure to any one retail pharmacy. Beginning on September 1, 2016, all of our prescription products are distributed under the wholesale distributor model described above.

We offer various rebate programs in an effort to maintain a competitive position in the marketplace and to promote sales and customer loyalty. We estimate the allowance for consumer rebates and coupons that we have offered based on our experience and industry averages, which is reviewed, and adjusted if necessary, on a quarterly basis. We record distributor fees based on amounts stated in contracts and estimate chargebacks based on the number of units sold each period.

Research and Development Expenses. Research and development, or R&D, expenses include internal R&D activities, services of external contract research organizations, or CROs, costs of their clinical research sites, manufacturing, scale-up and validation costs, and other activities. Internal R&D activity expenses include laboratory supplies, salaries, benefits, and non-cash share-based compensation expenses. Advance payments to be expensed in future research and development activities are capitalized, and were $0 and $228,933 at December 31, 2017 and 2016, respectively, all of which was included in other current assets on the accompanying consolidated balance sheets. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include regulatory consulting and legal fees and costs. The activities undertaken by our regulatory consultants that were classified as R&D expenses include assisting, consulting with, and advising our in-house staff with respect to various FDA submission processes, clinical trial processes, and scientific writing matters, including preparing protocols and FDA submissions. Legal activities that were classified as R&D expenses include professional research and advice regarding R&D, patents and regulatory matters. These consulting and legal expenses were direct costs associated with preparing, reviewing, and undertaking work for our clinical trials and investigative drugs. We charge internal R&D activities and other activity expenses to operations as incurred. We make payments to CROs based on agreed-upon terms, which may include payments in advance of a study starting date. We expense nonrefundable advance payments for goods and services that will be used in future R&D activities when the activity has been performed or when the goods have been received rather than when the payment is made. We review and accrue CRO expenses and clinical trial study expenses based on services performed and rely on estimates of those costs applicable to the completion stage of a study as provided by CROs. Estimated accrued CRO costs are subject to revisions as such studies progress to completion. We charge revisions expense in the period in which the facts that give rise to the revision become known.

Share-Based Compensation. We measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees are required to provide services. Share-based compensation arrangements may include options, restricted stock, restricted stock units, performance-based awards, and share appreciation rights. We amortize such compensation amounts, if any, over the respective service periods of the award. We use the Black-Scholes-Merton option pricing model, or the Black-Scholes Model, an acceptable model in accordance with ASC 718, *Compensation-Stock Compensation*, to value options. Option valuation models require the input of assumptions, including the expected life of the stock-based awards, the estimated stock price volatility, the risk-free interest rate, and the expected dividend yield. The risk-free interest rate assumption is based upon observed interest rates on zero coupon U.S. Treasury bonds whose maturity period is appropriate for the term of the instrument. Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the term of the award. Prior to January 1, 2017, the expected volatility of share options was estimated based on a historical volatility analysis of peer entities whose stock prices were publicly available that were similar to our company with respect to industry, stage of life cycle, market capitalization, and financial leverage. On January 1, 2017, we began using our own stock price in our volatility calculation along with two other peer entities whose stock prices were publicly available that were similar to our company. Our calculation of estimated volatility is based on historical stock prices over a period equal to the expected term of the awards. The average expected life of warrants is based on the contractual terms of the awards. The average expected life of options is based on the contractual terms of the stock option using the simplified method. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends. Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, estimates of expected life of the share-based award, stock price volatility and risk-free interest rates. The assumptions used in calculating the fair value of share-based awards represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our share-based compensation expense could be materially different in the future.

Equity instruments ("instruments") issued to non-employees are recorded on the basis of the fair value of the instruments, as required by ASC 505, *Equity - Based Payments to Non-Employees*, or ASC 505. ASC 505 defines the measurement date and recognition period for such instruments. In general, the measurement date is when either (a) a performance commitment, as defined, is reached or (b) the earlier of (i) the non-employee performance is complete or (ii) the instruments are vested. The estimated expense is recognized each period based on the current fair value of the award. As a result, the amount of expense related to awards to non-employees can fluctuate significantly during the period from the date of the grant through the final measurement date. The measured value related to the instruments is recognized over a period based on the facts and circumstances of each particular grant as defined in ASC 505. We recognize the compensation expense for all share-based compensation granted based on the grant date fair value estimated in accordance with ASC 718. We generally recognize the compensation expense on a straight-line basis over the employee's requisite service period. We adopted ASU 2016-09, effective January 1, 2017, electing to account for forfeitures when they occur. Prior to that, we estimated the forfeiture rate based on our historical experience of forfeitures.

Income Taxes. We account for income taxes under the asset and liability method. We recognize deferred tax assets and liabilities for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. We measure deferred tax assets and liabilities using enacted tax rates expected to apply to taxable income in the years in which the related temporary differences are expected to be recovered or settled. We recognize the effect on deferred tax assets and liabilities of a change in tax rates when the rate change is enacted. Valuation allowances are recorded to reduce deferred tax assets to the amount that will more likely than not be realized.

In accordance with ASC 740, *Income Taxes*, we recognize the effect of uncertain income tax positions only if the positions are more likely than not of being sustained in an audit, based on the technical merits of the position. We measure recognized uncertain income tax positions using the largest amount that has a likelihood of being realized that is greater than 50%. Changes in recognition or measurement are reflected in the period in which those changes in judgment occur. We recognize both interest and penalties related to uncertain tax positions as part of the income tax provision. At December 31, 2017 and 2016, we had no tax positions relating to open tax returns that were considered to be uncertain. Our tax returns are subject to review by the Internal Revenue Service three years after they are filed. Currently, years filed after 2013 are subject to review.

The determination of our provision for income taxes requires significant judgment, the use of estimates, and the interpretation and application of complex tax laws. In the ordinary course of our business, there are transactions and calculations for which the ultimate tax determination is uncertain. In spite of our belief that we have appropriate support for all the positions taken on our tax returns, we acknowledge that certain positions may be successfully challenged by the taxing authorities. We determine the tax benefits more likely than not to be recognized with respect to uncertain tax positions. Although we believe our recorded tax assets and liabilities are reasonable, tax laws and regulations are subject to interpretation and inherent uncertainty; therefore, our assessments can involve both a series of complex judgments about future events and rely on estimates and assumptions. Although we believe these estimates and assumptions are reasonable, the final determination could be materially different than that which is reflected in our provision for income taxes and recorded tax assets and liabilities.

On December 22, 2017, the U.S. federal government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act, or the Tax Act. The Tax Act makes broad and complex changes to the U.S. federal tax code, including, but not limited to reducing the U.S. federal corporate tax rate from 34 percent to 21 percent, effective January 1, 2018. Consequently, we have recorded a decrease related to deferred tax assets and deferred tax liabilities of approximately $49,500,000 and approximately $2,800,000, respectively, with a corresponding net adjustment to the valuation allowance of approximately $46,700,000 for the year ended December 31, 2017. The Tax Act modifies Section 162(m) of the Internal Revenue Code of 1986, as amended, or the IRC, by (1) expanding which employees are considered covered employees by including the chief financial officer, (2) providing that if an individual is a covered employee for a taxable year beginning after December 31, 2016, the individual remains a covered employee for all future years, and (3) removing the exceptions for compensation stemming from contracts entered into on or before November 2, 2017, unless such contracts were materially modified on or after the date. Compensation agreements entered into and share-based payment awards granted after this date will be subject to the revised terms of IRC Section 162(m). In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act* (SAB 118), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. Since the Tax Act was passed late in the fourth quarter of 2017, and ongoing guidance and accounting interpretation are expected over the next 12 months, we consider the accounting for share-based compensation arrangements under the Tax Act to be incomplete due to the forthcoming guidance and our ongoing analysis of final year-end data and tax positions. We must assess whether our valuation allowance analyses are affected by various aspects of the Tax Act. Since, as discussed herein, we have recorded provisional amounts related to certain portions of the Tax Act, any corresponding determination of the need for or change in a valuation allowance is also provisional.

Segment Reporting. We are managed and operated as one business, which is focused on creating and commercializing products targeted exclusively for women. Our business operations are managed by a single management team that reports to the President of our Company. We do not operate separate lines of business with respect to any of our products and we do not prepare discrete financial information with respect to separate products. All product sales are derived from sales in the United States. Accordingly, we view our business as one reportable operating segment.

New Accounting Pronouncements . In May 2017, the Financial Accounting Standards Board, or FASB, issued an Accounting Standards Update, or ASU, 2017-09 that clarifies when changes to the terms or conditions of a share-based payment award must be accounted for as modifications. The new guidance will reduce diversity in practice and result in fewer changes to the terms of an award being accounted for as modifications. The new guidance will allow companies to make certain changes to awards without accounting for them as modifications. This guidance does not change the accounting for modifications. The guidance will be applied prospectively to awards modified on or after the adoption date and is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including in an interim period. We adopted this guidance and it did not have an impact on our consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230). ASU 2016-15 is intended to reduce the diversity in practice regarding how certain transactions are classified within the statement of cash flows. ASU 2016-15 is effective for public business entities for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted with retrospective application. We adopted this guidance and it did not have an impact on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation – Stock Compensation: Improvements to Employee Share-Based Payment Accounting. This guidance simplifies several aspects of the accounting for employee share-based payment transactions for both public and nonpublic entities, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The guidance is effective for public business entities for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. We adopted ASU 2016-09 effective January 1, 2017, electing to account for forfeitures when they occur. The impact from adoption of the provisions related to forfeiture rates was reflected in our consolidated financial statements on a modified retrospective basis, resulting in an adjustment of approximately $31,000 to retained earnings. The impact from adoption of the provisions related to excess tax benefits or deficiencies in the provision for income taxes rather than paid-in capital was adopted on a modified retrospective basis. Since we have a full valuation allowance on our net deferred tax assets, an amount equal to the cumulative adjustment made to retained earnings to recognize the previously unrecognized net operating losses from prior periods was made to the valuation allowance through retained earnings for the first quarter financial statements. Adoption of all other changes did not have an impact on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases. This guidance requires lessees to record most leases on their balance sheets but recognize expenses on their income statements in a manner similar to current accounting. The guidance also eliminates current real estate-specific provisions for all entities. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. The standard is effective for public business entities for annual periods beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted for all entities. We are in the process of analyzing the quantitative impact of this guidance on our results of operations and financial position. While we are continuing to assess all potential impacts of the standard, we currently believe the impact of this standard will be primarily related to the accounting for our operating lease.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under previous guidance. This may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In July 2015, the FASB approved the proposal to defer the effective date of ASU 2014-09 standard by one year. Early adoption is permitted after December 15, 2016, and the standard is effective for public entities for annual reporting periods beginning after December 15, 2017 and interim periods therein. In 2016, the FASB issued final amendments to clarify the implementation guidance for principal versus agent considerations (ASU 2016-08), accounting for licenses of intellectual property and identifying performance obligations (ASU 2016-10), narrow-scope improvements and practical expedients (ASU 2016-12) and technical corrections and improvements to topic 606 (ASU 2016-20) in its new revenue standard. We have performed a review of the requirements of the new revenue standard and are monitoring the activity of the FASB and the transition resource group as it relates to specific interpretive guidance. We have reviewed customer contracts and applied the five-step model of the new standard to our contracts as well as compared the results to our current accounting practices. We are currently in the process of drafting disclosures required by the new standard. At this point of our analysis, we do not believe that the adoption of this standard will have a material effect on our financial statements but will potentially expand our disclosures related to contracts with customers.

Off-Balance Sheet Arrangements

As of December 31, 2017, 2016, and 2015, we had no off-balance sheet arrangements that have had or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

In the ordinary course of business, we enter into agreements with third parties that include indemnification provisions, which, in our judgment, are normal and customary for companies in our industry sector. These agreements are typically with business partners, clinical sites, and suppliers. Pursuant to these agreements, we generally agree to indemnify, hold harmless, and reimburse indemnified parties for losses suffered or incurred by the indemnified parties with respect to our drug candidates, use of such drug candidates, or other actions taken or omitted by us. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. We have not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of liabilities relating to these provisions is minimal. Accordingly, we have no liabilities recorded for these provisions as of December 31, 2017, 2016, and 2015.

In the normal course of business, we may be confronted with issues or events that may result in a contingent liability. These generally relate to lawsuits, claims, environmental actions or the actions of various regulatory agencies. We consult with counsel and other appropriate experts to assess the claim. If, in our opinion, we have incurred a probable loss as set forth by GAAP, an estimate is made of the loss and the appropriate accounting entries are reflected in our financial statements.

Effects of Inflation

For each of the fiscal years ended December 31, 2017, 2016, and 2015, our business and operations have not been materially affected by inflation.

Contractual Obligations

A summary of contractual obligations as of December 31, 2017 is as follows:

		Payments Due By Period		
	Total	Less than 1 Year	1-3 Years	4-5 Years
Operating Lease Obligations	$ 4,101,506	$ 951,194	$ 2,207,185	$ 943,127

Legal Proceedings

From time to time, we are involved in litigation and proceedings in the ordinary course of business. We are not currently involved in any legal proceeding that we believe would have a material effect on our consolidated financial condition, results of operations, or cash flows.

Employment Agreements

We have entered into employment agreements with certain of our executives that provide for compensation and certain other benefits. Under certain circumstances, including a change in control, some of these agreements provide for severance or other payments, if those circumstances occur during the term of the employment agreement.

Seasonality

The specialty pharmaceutical industry component of women's health is not subject to seasonal sales fluctuation.

Item 7A. ***Quantitative and Qualitative Disclosures about Market Risk***

We had a cash balance of approximately $127,136,000 as of December 31, 2017 . We hold certain portions of our cash balances in overnight money market placements all of which are fully available to us to support our cash flow requirements. The primary objective of our investment policy is to preserve principal and maintain proper liquidity to meet operating needs . Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment . Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates . To minimize this risk, we intend to maintain a portfolio that may include cash, cash equivalents and investment securities available-for-sale in a variety of securities which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates . Due to the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

Item 8. ***Financial Statements and Supplementary Data***

Reference is made to the financial statements, the notes thereto, and the reports thereon, commencing on page F-1 of this Annual Report, which financial statements, notes, and reports are incorporated herein by reference.

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

None.

Item 9A. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in reports filed under the Exchange Act is recorded, processed, summarized and reported within the specified time periods, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) or 15d-15(e)) as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2017, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is (i) recorded, processed, summarized, and reported within the time periods specified in the SEC rules and forms, and (ii) is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls 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. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, misstatements, errors, and instances of fraud, if any, within our company have been or will be prevented or detected. Further, internal controls may become inadequate as a result of changes in conditions, or through the deterioration of the degree of compliance with policies or procedures.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined under Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2017. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework (2013). Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of its internal control over financial reporting. Based on management's assessment, we believe that our internal controls over financial reporting were effective as of December 31, 2017.

The effectiveness of our internal control over financial reporting as of December 31, 2017 has been audited by Grant Thornton LLP, an independent registered public accounting firm, as stated in their Report of Independent Registered Certified Public Accounting Firm on Internal Control Over Financial Reporting as of December 31, 2017, which appears below.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
TherapeuticsMD, Inc.

Opinion on internal control over financial reporting

We have audited the internal control over financial reporting of TherapeuticsMD, Inc. (a Nevada corporation) and subsidiaries (the "Company") as of December 31, 2017, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated financial statements of the Company as of and for the year ended December 31, 2017, and our report dated February 23, 2018 expressed an unqualified opinion on those financial statements.

Basis for opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and limitations of internal control over financial reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ GRANT THORNTON LLP

Fort Lauderdale, Florida

February 23, 2018

Item 9B. ***Other Information***

None.

PART III

Item 10. ***Directors, Executive Officers, and Corporate Governance***

The information required by this Item relating to our directors and corporate governance is incorporated herein by reference to the definitive Proxy Statement to be filed pursuant to Regulation 14A of the Exchange Act for our 2018 Annual Meeting of Stockholders.

Item 11. ***Executive Compensation***

The information required by this Item is incorporated herein by reference to the definitive Proxy Statement to be filed pursuant to Regulation 14A of the Exchange Act for our 2018 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference to the definitive Proxy Statement to be filed pursuant to Regulation 14A of the Exchange Act for our 2018 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference to the definitive Proxy Statements to be filed pursuant to Regulation 14A of the Exchange Act for our 2018 Annual Meeting of Stockholders.

Item 14. ***Principal Accounting Fees and Services***

The information required by this Item is incorporated herein by reference to the definitive Proxy Statement to be filed pursuant to Regulation 14A of the Exchange Act for our 2018 Annual Meeting of Stockholders.

PART IV

Item 15. ***Exhibits, Financial Statement Schedules***

(a) **Financial Statements and Financial Statements Schedules**

(1) Financial Statements are listed in the Index to Consolidated Financial Statements on page F-1 of this Annual Report.

(2) No financial statement schedules are included because such schedules are not applicable, are not required, or because required information is included in the consolidated financial statements or notes thereto.

(b) **Exhibits**

Exhibit	Date	Description
2.1	July 6, 2009	Agreement and Plan of Reorganization among Croff Enterprises, Inc., AMHN Acquisition Corp., America's Minority Health Network, Inc., and the Major Shareholders(1)
2.2	June 11, 2010	Agreement and Plan of Reorganization among AMHN, Inc., SHN Acquisition Corp., Spectrum Health Network, Inc., and the Sole Shareholder of Spectrum Health Network, Inc.(2)
2.3	October 25, 2007	Croff Enterprises, Inc. Plan of Corporate Division and Reorganization(3)
2.4	July 18, 2011	Agreement and Plan of Merger among VitaMedMD, LLC, AMHN, Inc., and VitaMed Acquisition, LLC(4)
3.1	July 20, 2010	Articles of Conversion of AMHN, Inc. filed in the State of Nevada(5)
3.2	July 20, 2010	Articles of Incorporation of AMHN, Inc. filed in the State of Nevada(5)
3.3	n/a	Composite Amended and Restated Articles of Incorporation of the Company, as amended(6)
3.4	n/a	Bylaws of AMHN, Inc.(7)
3.5	December 17, 2015	First Amendment to Bylaws of the Company(8)
4.1	n/a	Form of Certificate of Common Stock(9)
10.1	n/a	Form of Common Stock Purchase Warrant (10)
10.2*	n/a	Form of Non-Qualified Stock Option Agreement (10)
10.3*	n/a	Amended and Restated 2012 Stock Incentive Plan(11)
10.4*	n/a	2009 Long Term Incentive Compensation Plan, as amended(12)
10.5	October 23, 2011	Common Stock Purchase Warrant to Lang Naturals, Inc.(13)
10.6	February 24, 2012	Form of Common Stock Purchase Warrant(14)
10.7	April 17, 2012	Master Services Agreement between the Company and Sancilio and Company, Inc.(15)
10.8	May 17, 2012	Consulting Agreement between the Company and Sancilio and Company, Inc.(16)
10.9	September 26, 2012	Form of Securities Purchase Agreement (17)
10.10*	November 8, 2012	Form of Employment Agreement(18)
10.11	January 31, 2013	Common Stock Purchase Warrant, issued to Plato & Associates, LLC(19)
10.12	May 7, 2013	Consulting Agreement between the Company and Sancilio and Company, Inc. (20)
10.13*	May 8, 2013	Agreement to Forfeit Non-Qualified Stock Options between the Company and Robert G. Finizio(22)
10.14	May 16, 2013	Lease between the Company and 6800 Broken Sound LLC(23)
10.15	February 18, 2015	First Amendment to Lease between the Company and 6800 Broken Sound, LLC(24)
10.16	April 26, 2016	Second Amendment to Lease between the Company and 6800 Broken Sound, LLC(25)
10.17	October 4, 2016	Third Amendment to Lease between the Company and 6800 Broken Sound, LLC(26)
10.18*	December 17, 2015	Employment Agreement between the Company and Brian Bernick(8)
10.19*	December 17, 2015	Employment Agreement between the Company and Michael Donegan(8)
10.20*	December 17, 2015	Employment Agreement between the Company and Mitchel Krassan(8)
21.1†	February 23, 2018	Subsidiaries of the Company
23.1†	February 23, 2018	Consent of Grant Thornton, LLP

Exhibit	Date	Description
31.1†	February 23, 2018	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities Exchange Act of 1934, as amended
31.2†	February 23, 2018	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities Exchange Act of 1934, as amended
32.1†	February 23, 2018	Certification pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2†	February 23, 2018	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS†	n/a	XBRL Instance Document
101.SCH†	n/a	XBRL Taxonomy Extension Schema Document
101.CAL†	n/a	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF†	n/a	XBRL Taxonomy Extension Definition Linkbase Instance Document
101.LAB†	n/a	XBRL Taxonomy Extension Label Linkbase Instance Document
101.PRE†	n/a	XBRL Taxonomy Extension Presentation Linkbase Instance Document

* Indicates a contract with management or compensatory plan or arrangement.

† Filed herewith.

(1) Filed as an exhibit to Form 8-K filed with the Commission on July 10, 2009 and incorporated herein by reference (SEC File No. 000-16731).

(2) Filed as an exhibit to Form 8-K filed with the Commission on June 14, 2010 and incorporated herein by reference (SEC File No. 000-16731).

(3) Filed as an exhibit to Form 10-K for the year ended December 31, 2007 filed with the Commission on May 1, 2008 and incorporated herein by reference (SEC File No. 000-16731).

(4) Filed as an exhibit to Form 8-K filed with the Commission on July 21, 2011 and incorporated herein by reference (SEC File No. 000-16731).

(5) Filed as an exhibit to Form 10-Q for quarter ended June 30, 2010 filed with the Commission on August 3, 2010 and incorporated herein by reference (SEC File No. 000-16731).

(6) Filed as an exhibit to Form 10-Q for quarter ended June 30, 2015 filed with the Commission on August 7, 2015 and incorporated herein by reference (SEC File No. 001-00100).

(7) Filed as an exhibit to Definitive 14C Information Statement filed with the Commission on June 29, 2010 and incorporated herein by reference (SEC File No. 000-16731).

(8) Filed as an exhibit to Form 8-K filed with the Commission on December 22, 2015 and incorporated herein by reference (SEC File No. 001-00100).

(9) Filed as an exhibit to Form S-3 filed with the Commission on January 25, 2013 and incorporated hereby by reference (SEC File No. 333-186189).

(10) Filed as an exhibit to Form 8-K filed with the Commission on October 11, 2011 and incorporated herein by reference (SEC File No. 000-16731).

(11) Filed as an exhibit to Form 8-K filed with the Commission on August 22, 2013 and incorporated herein by reference (SEC File No. 001-00100).

(12) Filed as an exhibit to Registration Statement on Form S-8 filed with the Commission on October 15, 2013 and incorporated herein by reference (SEC File No. 333-191730).

(13) Filed as an exhibit to Form 8-K filed with the Commission on October 24, 2011 and incorporated herein by reference (SEC File No. 000-16731).

(14) Filed as an exhibit to Form 8-K filed with the Commission on February 24, 2012 and incorporated herein by reference (SEC File No. 000-16731).

(15) Filed as an exhibit to Form 10-Q for quarter ended June 30, 2012 filed with the Commission on August 9, 2012 and incorporated herein by reference (SEC File No. 000-16731).

(16) Filed as an exhibit to Form 10-K for the year ended December 31, 2015, filed with the Commission on February 26, 2016 and incorporated herein by reference (SEC File No. 001-00100).

(17) Filed as an exhibit to Form 8-K filed with the Commission on October 2, 2012 and incorporated herein by reference (SEC File No. 000-16731).

(18) Filed as an exhibit to Form 10-Q for quarter ended September 30, 2012 filed with the Commission on November 13, 2012 and incorporated herein by reference (SEC File No. 000-16731).

(19) Filed as an exhibit to Form 8-K filed with the Commission on February 6, 2013 and incorporated herein by reference (SEC File No. 000-16731).

(20) Filed as an exhibit to Form 10-Q for quarter ended March 31, 2013 filed with the Commission on May 10, 2013 and incorporated herein by reference (SEC File No. 001-00100).

(21) Filed as an exhibit to Form 10-Q for quarter ended June 30, 2013 filed with the Commission on August 7, 2013 and incorporated herein by reference (SEC File No. 001-00100).
(22) Filed as an exhibit to Form 10-K for the year ended December 31, 2014 filed with the Commission on March 12, 2015 and incorporated herein by reference (SEC File No. 001-00100).
(23) Filed as an exhibit to Form 10-Q for quarter ended March 31, 2016 filed with the Commission on May 5, 2016 and incorporated herein by reference (SEC File No. 001-00100).
(24) Filed as an exhibit to Form 10-Q for quarter ended September 30, 2016 filed with the Commission on November 5, 2016 and incorporated herein by reference (SEC File No. 001-00100).

Item 16. Form 10-K Summary

None.

SIGNATURES

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

Date: February 23, 2018

THERAPEUTICSMD, INC.

/s/ Robert G. Finizio
Robert G. Finizio
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 and in the capacities and on the date indicated.

Signature	Capacity	Date
/s/ Robert G. Finizio Robert G. Finizio	Chief Executive Officer, Director (Principal Executive Officer)	February 23, 2018
/s/ John C.K. Milligan, IV John C.K. Milligan, IV	President, Secretary, Director	February 23, 2018
/s/ Daniel A. Cartwright Daniel A. Cartwright	Chief Financial Officer, Treasurer (Principal Financial and Accounting Officer)	February 23, 2018
/s/ Tommy G. Thompson Tommy G. Thompson	Chairman	February 23, 2018
/s/ Brian Bernick Brian Bernick	Director	February 23, 2018
/s/ J. Martin Carroll J. Martin Carroll	Director	February 23, 2018
/s/ Cooper C. Collins Cooper C. Collins	Director	February 23, 2018
/s/ Robert V. LaPenta, Jr. Robert V. LaPenta, Jr	Director	February 23, 2018
/s/ Jules Musing Jules Musing	Director	February 23, 2018
/s/ Angus C. Russell Angus C. Russell	Director	February 23, 2018
/s/ Nicholas Segal Nicholas Segal	Director	February 23, 2018

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
TherapeuticsMD, Inc.

Opinion on the financial statements
We have audited the accompanying consolidated balance sheets of TherapeuticsMD, Inc. (a Nevada corporation) and subsidiaries (the "Company") as of December 31, 2017 and 2016, the related consolidated 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 as of 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 accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated February 23, 2018 expressed an unqualified opinion.

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 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. 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 supporting 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/ GRANT THORNTON LLP

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

Fort Lauderdale, Florida
February 23, 2018

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2017	2016
ASSETS		
Current Assets:		
Cash	$ 127,135,628	$ 131,534,101
Accounts receivable, net of allowance for doubtful accounts of $380,580 and $376,374, respectively	4,328,802	4,500,699
Inventory	1,485,358	1,076,321
Other current assets	6,604,284	2,299,052
Total current assets	139,554,072	139,410,173
Fixed assets, net	437,055	516,839
Other Assets:		
Intangible assets, net	3,099,747	2,405,972
Security deposit	139,036	139,036
Total other assets	3,238,783	2,545,008
Total assets	$ 143,229,910	$ 142,472,020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 4,097,600	$ 7,358,514
Other current liabilities	9,223,595	7,624,085
Total current liabilities	13,321,195	14,982,599
Commitments and Contingencies - See Note 12		
Stockholders' Equity:		
Preferred stock - par value $0.001; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock - par value $0.001; 350,000,000 shares authorized: 216,429,642 and 196,688,222 issued and outstanding, respectively	216,430	196,688
Additional paid-in capital	516,351,405	436,995,052
Accumulated deficit	(386,659,120)	(309,702,319)
Total stockholders' equity	129,908,715	127,489,421
Total liabilities and stockholders' equity	$ 143,229,910	$ 142,472,020

The accompanying footnotes are an integral part of these consolidated financial statements.

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2017	2016	2015
Revenues, net	$ 16,777,713	$ 19,356,450	$ 20,142,898
Cost of goods sold	2,636,943	4,185,708	4,506,673
Gross profit	14,140,770	15,170,742	15,636,225
Operating expenses:			
Sales, general, and administrative	57,703,370	51,348,414	28,721,236
Research and development	33,852,993	53,943,477	72,042,774
Depreciation and amortization	213,117	132,451	62,400
Total operating expenses	91,769,480	105,424,342	100,826,410
Operating loss	(77,628,710)	(90,253,600)	(85,190,185)
Other income			
Miscellaneous income	695,631	367,317	95,719
Accreted interest	7,699	10,824	17,442
Total other income	703,330	378,141	113,161
Loss before income taxes	(76,925,380)	(89,875,459)	(85,077,024)
Provision for income taxes	—	—	—
Net loss	$ (76,925,380)	$ (89,875,459)	$ (85,077,024)
Loss per share, basic and diluted:			
Net loss per share, basic and diluted	$ (0.37)	$ (0.46)	$ (0.49)
Weighted average number of common shares outstanding, basic and diluted	205,523,288	196,088,196	173,174,229

The accompanying footnotes are an integral part of these consolidated financial statements.

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2017, 2016 AND 2015

	Common Stock		Additional Paid in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance, January 1, 2015	156,097,019	$ 156,097	$ 182,982,846	$ (134,749,836)	$ 48,389,107
Shares issued in offerings, net of cost	20,040,359	20,040	91,354,609	—	91,374,649
Shares issued for exercise of options, net	612,981	613	1,231,966	—	1,232,579
Shares issued for exercise of warrants, net	1,177,682	1,178	364,822	—	366,000
Share-based compensation	—	—	6,777,835	—	6,777,835
Net loss	—	—	—	(85,077,024)	(85,077,024)
Balance, December 31, 2015	177,928,041	177,928	282,712,078	(219,826,860)	63,063,146
Shares issued in offerings, net of cost	17,424,242	17,424	134,846,051	—	134,863,475
Shares issued for exercise of warrants, net	722,744	723	1,372,277	—	1,373,000
Shares issued for exercise of options, net	613,195	613	988,447	—	989,060
Share-based compensation	—	—	17,076,199	—	17,076,199
Net loss	—	—	—	(89,875,459)	(89,875,459)
Balance, December 31, 2016	196,688,222	196,688	436,995,052	(309,702,319)	127,489,421
Shares issued in offerings, net of cost	12,400,000	12,400	68,560,235	—	68,572,635
Shares issued for exercise of warrants, net	7,238,874	7,239	3,791,760	—	3,798,999
Shares issued for exercise of options, net	102,546	103	212,512	—	212,615
Share-based compensation	—	—	6,760,425	—	6,760,425
Adoption of ASU 2016-09	—	—	31,421	(31,421)	—
Net loss	—	—	—	(76,925,380)	(76,925,380)
Balance, December 31, 2017	216,429,642	$ 216,430	$ 516,351,405	$ (386,659,120)	$ 129,908,715

The accompanying footnotes are an integral part of these consolidated financial statements.

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December, 31,		
	2017	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (76,925,380)	$ (89,875,459)	$ (85,077,024)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	141,601	77,906	29,959
Amortization of intangible assets	71,516	54,545	32,441
Provision for doubtful accounts	4,206	2,524,909	22,157
Share-based compensation	6,889,323	17,411,021	7,189,699
Changes in operating assets and liabilities:			
Accounts receivable	167,691	(3,975,893)	(917,656)
Inventory	(409,037)	(386,168)	491,960
Other current assets	(4,434,130)	709,907	(773,532)
Other assets	—	—	(17,442)
Accounts payable	(3,260,914)	4,232,340	(3,200,955)
Deferred revenue	—	—	(522,613)
Other current liabilities	1,599,510	84,559	3,698,887
Net cash used in operating activities	(76,155,614)	(69,142,333)	(79,044,119)
CASH FLOWS FROM INVESTING ACTIVITIES			
Patent costs	(765,291)	(845,266)	(419,104)
Purchase of fixed assets	(61,817)	(396,154)	(165,257)
Payment of security deposit	—	(14,036)	—
Net cash used in investing activities	(827,108)	(1,255,456)	(584,361)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from sale of common stock, net of costs	68,572,635	134,863,475	91,374,649
Proceeds from exercise of options	212,615	989,060	1,232,579
Proceeds from exercise of warrants	3,798,999	1,373,000	366,000
Net cash provided by financing activities	72,584,249	137,225,535	92,973,228
(Decrease) increase in cash	(4,398,473)	66,827,746	13,344,748
Cash, beginning of period	131,534,101	64,706,355	51,361,607
Cash, end of period	$ 127,135,628	$ 131,534,101	$ 64,706,355

The accompanying footnotes are an integral part of these consolidated financial statements.

NOTE 1 – THE COMPANY

TherapeuticsMD, Inc., a Nevada corporation, or TherapeuticsMD or the Company, has three wholly owned subsidiaries, vitaMedMD, LLC, a Delaware limited liability company, or VitaMed; BocaGreenMD, Inc., a Nevada corporation, or BocaGreen; and VitaCare Prescription Services, Inc., a Florida corporation, or VitaCare. Unless the context otherwise requires, TherapeuticsMD, VitaMed, BocaGreen, and VitaCare collectively are sometimes referred to as "our company," "we," "our," or "us."

Nature of Business

We are a women's health care company focused on creating and commercializing products targeted exclusively for women. Currently, we are focused on pursuing the regulatory approvals and pre-commercialization activities necessary for commercialization of our advanced hormone therapy pharmaceutical products. Our drug candidates that have completed clinical trials are designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis and vaginal discomfort. We are developing these hormone therapy drug candidates, which contain estradiol and progesterone alone or in combination, with the aim of demonstrating clinical efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products. With our SYMBODA™ technology, we are developing advanced hormone therapy pharmaceutical products to enable delivery of bio-identical hormones through a variety of dosage forms and administration routes. In addition, we manufacture and distribute branded and generic prescription prenatal vitamins, as well as over-the-counter, or OTC, iron supplements, which we ceased manufacturing in October 2017.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of our company and our wholly owned subsidiaries, VitaMed, BocaGreen and VitaCare. All intercompany balances and transactions have been eliminated in consolidation.

Cash

We maintain cash at financial institutions that at times may exceed the Federal Deposit Insurance Corporation (the "FDIC") insured limits of $250,000 per bank. We have never experienced any losses related to these funds.

Trade Accounts Receivable and Allowance for Doubtful Accounts

Trade accounts receivable are customer obligations due under normal trade terms. We review accounts receivable for uncollectible accounts and credit card charge-backs and provide an allowance for doubtful accounts, which is based upon a review of outstanding receivables, historical collection information, and existing economic conditions. We consider trade accounts receivable past due for more than 90 days to be delinquent. We write off delinquent receivables against our allowance for doubtful accounts based on individual credit evaluations, the results of collection efforts, and specific circumstances of customers. We record recoveries of accounts previously written off when received as an increase in the allowance for doubtful accounts. To the extent data we use to calculate these estimates does not accurately reflect bad debts, adjustments to these reserves may be required. At December 31, 2017, four different customers represented 27%, 23%, 22% and 11%, respectively, of our gross accounts receivable. At December 31, 2016, two different customers represented 28% and 20%, respectively, of our gross accounts receivable.

During the third quarter of 2016, we wrote-off accounts receivable balances of approximately $2,200,000 related to two retail pharmacy distributors. Both pharmacies are relatively small owner-managed pharmacies and share a similar amount of collection risk. Among the factors that contributed to our decision to write-off these balances were our inability to collect the outstanding balances and the lack of a continuing communication and business relationship with these parties following the centralization of the distribution channel for both our retail pharmacy distributors and wholesale distributors, effective September 1, 2016.

Inventories

Inventories represent packaged vitamins, nutritional products and supplements and raw materials, which are valued at the lower of cost or net realizable value using the average-cost method. We review our inventory for excess or obsolete inventory and write-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. Obsolescence may occur due to product expiring or product improvements rendering previous versions obsolete.

Pre-Launch Inventory

Inventory costs associated with product candidates that have not yet received regulatory approval are capitalized if we believe there is probable future commercial use and future economic benefit. If the probability of future commercial use and future economic benefit cannot be reasonably determined, then pre-launch inventory costs associated with such product candidates are expensed as research and development expenses during the period the costs are incurred. We have not capitalized any pre-launch inventory to date.

Fixed Assets

We state fixed assets at cost, net of accumulated depreciation. We charge maintenance costs, which do not significantly extend the useful lives of the respective assets, and repair costs to operating expenses as incurred. We compute depreciation using the straight-line method over the estimated useful lives of the related assets, which range from three to seven years. Leasehold improvements are depreciated over the shorter of their useful life or the term of the lease.

We capitalize software and software development costs incurred to create and acquire computer software for internal use, principally related to software coding and application development. We begin to capitalize software development costs when both the preliminary project stage is completed and it is probable that the software will be used as intended. Capitalized software costs include only external direct costs and services utilized in developing or obtaining computer software. Capitalized software costs are amortized on a straight-line basis when placed into service over the estimated useful life, generally five to seven years.

Intangible Assets

We have adopted the provisions of Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, 350, *Intangibles - Goodwill and Other*, or ASC 350. Capitalized patent costs, net of accumulated amortization, include outside legal costs incurred for patent applications. In accordance with ASC 350, once a patent is granted, we amortize the capitalized patent costs over the remaining life of the patent using the straight-line method. If the patent is not granted, we write-off any capitalized patent costs at that time. As of December 31, 2017, we had 18 issued patents (See Note 6). We capitalize external costs, consisting primarily of legal costs, related to securing our trademarks. Trademarks are perpetual and are not amortized. We review intangible assets for impairment annually or when events or circumstances indicate that their carrying amount may not be recoverable.

Impairment of Long-Lived Assets

We review the carrying values of fixed assets and long-lived intangible assets to be held and used for impairment whenever events or changes in circumstances indicate that their carrying values may not be recoverable. Such events or circumstances may include, among others, the following:

- significant declines in an asset's market price;
- significant deterioration in an asset's physical condition;
- significant changes in the nature or extent of an asset's use or operation;
- significant adverse changes in the business climate that could impact an asset's value, including adverse actions or assessments by regulators;
- accumulation of costs significantly in excess of original expectations related to the acquisition or construction of an asset;
- current-period operating or cash flow losses combined with a history of such losses or a forecast that demonstrates continuing losses associated with an asset's use; and
- expectations that it is more likely than not that an asset will be sold or otherwise disposed of significantly before the end of its previously estimated useful life.

If impairment indicators are present, we determine whether an impairment loss should be recognized by testing the applicable asset or asset group's carrying value for recoverability. This test requires long-lived assets to be grouped at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities, the determination of which requires judgment. We estimate the undiscounted future cash flows expected to be generated from the use and eventual disposal of the assets and compare that estimate to the respective carrying values in order to determine if such carrying values are recoverable. This assessment requires the exercise of judgment in assessing the future use of and projected value to be derived from the eventual disposal of the assets to be held and used. In our assessments, we also consider changes in asset utilization, including, if applicable, the temporary idling of capacity and the expected timing for placing this capacity back into production. If the carrying value of the assets is not recoverable, then we record a loss for the difference between the assets' fair value and respective carrying values. We determine the fair value of the assets using an "income approach" based upon a forecast of all the expected discounted future net cash flows associated with the subject assets. Some of the more significant estimates and assumptions include market size and growth, market share, projected selling prices, manufacturing cost, and discount rate. We base estimates upon historical experience, our commercial relationships, market conditions, and available external information about future trends. We believe our current assumptions and estimates are reasonable and appropriate. Unanticipated events and changes in market conditions, however, could affect such estimates, resulting in the need for an impairment charge in future periods. There was no impairment of long-lived assets to be held and used during the years ended December 31, 2017, 2016, and 2015.

We perform impairment tests for intangible assets with indefinite useful lives annually, or more frequently if events occur or circumstances change that would more likely than not reduce the fair value of an intangible asset below its carrying value. The impairment test for assets with indefinite lives consists of a comparison of the fair value of the asset with its carrying amount. If the carrying amount of an intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. There was no impairment of indefinite lived intangible assets during the years ended December 31, 2017, 2016, and 2015.

Fair Value of Financial Instruments

Our financial instruments consist primarily of cash, accounts receivable, accounts payable and accrued expenses. The carrying amount of cash, accounts receivable, accounts payable and accrued expenses approximates their fair value because of the short-term maturity of such instruments, which are considered Level 1 assets under the fair value hierarchy.

We categorize our assets and liabilities that are valued at fair value on a recurring basis into a three-level fair value hierarchy as defined by ASC 820, *Fair Value Measurements.* The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets and liabilities (Level 1) and lowest priority to unobservable inputs (Level 3). Assets and liabilities recorded in the consolidated balance sheet at fair value are categorized based on a hierarchy of inputs, as follows:

Level 1	unadjusted quoted prices in active markets for identical assets or liabilities;
Level 2	quoted prices for similar assets or liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument; and
Level 3	unobservable inputs for the asset or liability.

At December 31, 2017 and 2016, we had no assets or liabilities that were valued at fair value on a recurring basis.

The fair value of indefinite-lived assets is measured on a non-recurring basis using significant unobservable inputs (Level 3) in connection with any required impairment test. There was no impairment of intangible assets during the years ended December 31, 2017, 2016, and 2015.

Income Taxes

We account for income taxes under the asset and liability method. We recognize deferred tax assets and liabilities for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. We measure deferred tax assets and liabilities using enacted tax rates expected to apply to taxable income in the years in which the related temporary differences are expected to be recovered or settled. We recognize the effect on deferred tax assets and liabilities of a change in tax rates when the rate change is enacted. Valuation allowances are recorded to reduce deferred tax assets to the amount that will more likely than not be realized.

In accordance with ASC 740, *Income Taxes*, we recognize the effect of uncertain income tax positions only if the positions are more likely than not of being sustained in an audit, based on the technical merits of the position. We measure recognized uncertain income tax positions using the largest amount that has a likelihood of being realized that is greater than 50%. Changes in recognition or measurement are reflected in the period in which those changes in judgment occur.

We recognize both interest and penalties related to uncertain tax positions as part of the income tax provision. At December 31, 2017 and 2016, we had no tax positions relating to open tax returns that were considered to be uncertain.

Our tax returns are subject to review by the Internal Revenue Service three years after they are filed. Currently, years filed after 2013 are subject to review.

Share-Based Compensation

We measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees are required to provide services. Share-based compensation arrangements include options, restricted stock, restricted stock units, performance-based awards, share appreciation rights, and employee share purchase plans. We amortize such compensation amounts, if any, over the respective service periods of the award. We use the Black-Scholes-Merton option pricing model, or the Black-Scholes Model, an acceptable model in accordance with ASC 718, *Compensation-Stock Compensation*, to value options. Option valuation models require the input of assumptions, including the expected life of the stock-based awards, the estimated stock price volatility, the risk-free interest rate, and the expected dividend yield. The risk-free interest rate assumption is based upon observed interest rates on zero coupon U.S. Treasury bonds whose maturity period is appropriate for the term of the instrument. Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the term of the award. Prior to January 1, 2017, the expected volatility of share options was estimated based on a historical volatility analysis of peer entities whose stock prices were publicly available that were similar to the Company with respect to industry, stage of life cycle, market capitalization, and financial leverage. On January 1, 2017, we began using our own stock price in our volatility calculation along with the other peer entities whose stock prices were publicly available that were similar to our company. Our calculation of estimated volatility is based on historical stock prices over a period equal to the expected term of the awards. The average expected life is based on the contractual terms of the stock option using the simplified method. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends. Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, including forfeiture rates, estimates of expected life of the share-based award, stock price volatility and risk-free interest rates. The assumptions used in calculating the fair value of share-based awards represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our share-based compensation expense could be materially different in the future.

Equity instruments ("instruments") issued to non-employees are recorded on the basis of the fair value of the instruments, as required by ASC 505, *Equity - Based Payments to Non-Employees*, or ASC 505. ASC 505 defines the measurement date and recognition period for such instruments. In general, the measurement date is when either (a) a performance commitment, as defined, is reached or (b) the earlier of (i) the non-employee performance is complete or (ii) the instruments are vested. The estimated expense is recognized each period based on the current fair value of the award. As a result, the amount of expense related to awards to non-employees can fluctuate significantly during the period from the date of the grant through the final measurement date. The measured value related to the instruments is recognized over a period based on the facts and circumstances of each particular grant as defined in ASC 505.

We recognize the compensation expense for all share-based compensation granted, net of estimated forfeitures, based on the grant date fair value estimated in accordance with ASC 718. We generally recognize the compensation expense on a straight-line basis over the employee's requisite service period. We estimate the forfeiture rate based on our historical experience of forfeitures. If our actual forfeiture rate is materially different from our estimate, share-based compensation expense could be significantly different from what we have recorded in the current period.

Revenue Recognition

We recognize revenue on arrangements in accordance with ASC 605, *Revenue Recognition*. We recognize revenue only when the price is fixed or determinable, persuasive evidence of an arrangement exists, the service is performed, and collectability is reasonably assured.

Our OTC and prescription prenatal vitamin products are generally variations of the same product with slight modifications in formulation and marketing. The primary difference between our OTC and prescription prenatal vitamin products is the source of payment. Purchasers of our OTC prenatal vitamin products pay for the product directly while purchasers of our prescription prenatal vitamin products pay for the product primarily via third-party payers. Both OTC and prescription prenatal vitamin products share the same marketing support team utilizing similar marketing techniques. As of January 1, 2017, we ceased manufacturing and distributing our OTC product lines, except for Iron 21/7, which we ceased manufacturing in October 2017. The revenue that is generated by us from major customers is all generated from sales of our prescription prenatal vitamin products, which is disclosed in Note 11. There are no major customers for our OTC prenatal vitamin or other products.

Over-the-Counter Products

We generate OTC revenue from product sales primarily to retail consumers. We recognize revenue from product sales upon shipment, when the rights of ownership and risk of loss have passed to the consumer. We include outbound shipping and handling fees, if any, in revenues, net, and bill them upon shipment. We include shipping expenses in cost of goods sold. A majority of our OTC customers pay for our products with credit cards, and we usually receive the cash settlement in two to three banking days. Credit card sales minimize accounts receivable balances relative to OTC sales (Iron 21/7). We provide an unconditional 30-day money-back return policy under which we accept product returns from our retail and eCommerce OTC customers. We recognize revenue from OTC sales, net of estimated returns and sales discounts. As of January 1, 2017, we ceased manufacturing and distributing our OTC product lines, except for Iron 21/7, which we ceased manufacturing in October 2017.

Prescription Products

We sell our name brand and generic prescription products primarily through wholesale distributors and retail pharmacy distributors. We recognize revenue from prescription product sales, net of sales discounts, chargebacks, wholesaler fees, customer rebates, coupons and estimated returns.

Revenue related to prescription products sold through wholesale distributors is recognized when the prescription products are shipped to the distributors and the control of the products passes to each distributor. We accept returns of unsalable prescription products sold through wholesale distributors within a return period of six months prior to and up to 12 months following product expiration. Our prescription products currently have a shelf life of 24 months from the date of manufacture.

Prior to September 1, 2016, we recognized revenue related to prescription products sold through retail pharmacy distributors when the product was dispensed by the retail pharmacy distributor, at which point all revenue and discounts related to such product were known or determinable and there was no right of return with respect to such product. On September 1, 2016, we centralized the distribution channel for both our retail pharmacy distributors and wholesale distributors, in order to facilitate sales to a broader population of retail pharmacies and mitigate exposure to any one retail pharmacy. Beginning on September 1, 2016, all of our prescription products are distributed under the wholesale distributor model described above.

We offer various rebate programs in an effort to maintain a competitive position in the marketplace and to promote sales and customer loyalty. We estimate the allowance for consumer rebates and coupons that we have offered based on our experience and industry averages, which is reviewed, and adjusted if necessary, on a quarterly basis. We record distributor fees based on amounts stated in contracts and estimate chargebacks based on the number of units sold each period.

Segment Reporting

We are managed and operated as one business, which is focused on creating and commercializing products targeted exclusively for women. Our business operations are managed by a single management team that reports to the President of our company. We do not operate separate lines of business with respect to any of our products and we do not prepare discrete financial information with respect to separate products. All product sales are derived from sales in the United States. Accordingly, we view our business as one reportable operating segment.

Shipping and Handling Costs

We expense all shipping and handling costs as incurred. We include these costs in cost of goods sold on the accompanying consolidated financial statements.

Advertising Costs

We expense advertising costs when incurred. Advertising costs were $448,288, $752,611, and $792,574 during the years ended December 31, 2017, 2016, and 2015, respectively.

Research and Development Expenses

Research and development, or R&D, expenses include internal R&D activities, services of external contract research organizations, or CROs, costs of their clinical research sites, manufacturing, scale-up and validation costs, and other activities. Internal R&D activity expenses include laboratory supplies, salaries, benefits, and non-cash share-based compensation expenses. Advance payments to be expensed in future research and development activities are capitalized, and were $0 and $228,933 at December 31, 2017 and 2016, respectively, all of which was included in other current assets on the accompanying consolidated balance sheets. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include regulatory consulting and legal fees and costs. The activities undertaken by our regulatory consultants that were classified as R&D expenses include assisting, consulting with, and advising our in-house staff with respect to various U.S. Food and Drug Administration, or the FDA, submission processes, clinical trial processes, and scientific writing matters, including preparing protocols and FDA submissions. Legal activities that were classified as R&D expenses include professional research and advice regarding R&D, patents and regulatory matters. These consulting and legal expenses were direct costs associated with preparing, reviewing, and undertaking work for our clinical trials and investigative drugs. We charge internal R&D activities and other activity expenses to operations as incurred. We make payments to CROs based on agreed-upon terms, which may include payments in advance of a study starting date. We expense nonrefundable advance payments for goods and services that will be used in future R&D activities when the activity has been performed or when the goods have been received rather than when the payment is made. We review and accrue CRO expenses and clinical trial study expenses based on services performed and rely on estimates of those costs applicable to the completion stage of a study as provided by CROs. Estimated accrued CRO costs are subject to revisions as such studies progress to completion. We charge revisions expense in the period in which the facts that give rise to the revision become known.

Earnings Per Share

We calculate earnings per share, or EPS, in accordance with ASC 260, *Earnings Per Share*, which requires the computation and disclosure of two EPS amounts: basic and diluted. We compute basic EPS based on the weighted-average number of shares of common stock, par value $0.001 per share, or Common Stock, outstanding during the period. We compute diluted EPS based on the weighted-average number of shares of our Common Stock outstanding plus all potentially dilutive shares of our Common Stock outstanding during the period. Such potentially dilutive shares of our Common Stock consist of options and warrants and were excluded from the calculation of diluted earnings per share because their effect would have been anti-dilutive due to the net loss reported by us. The table below presents potentially dilutive securities that could affect our calculation of diluted net loss per share allocable to common stockholders for the periods presented.

	As of December 31,		
	2017	2016	2015
Stock options	23,365,225	21,767,854	20,725,325
Warrants	3,115,905	12,060,071	12,722,431
	26,481,130	33,827,925	33,447,756

Concentration of Credit Risk and other Risks and Uncertainties

Financial instruments that potentially expose us to concentrations of credit risk consist primarily of cash and trade accounts receivable. Cash is on deposit with financial institutions in the United States and these deposits generally exceed the amount of insurance provided by the FDIC. The Company has not experienced any historical losses on its deposits of cash.

Concentration of credit risk with respect to our trade accounts receivable from our customers is primarily limited to drug wholesalers and retail pharmacy distributors. Credit is extended to our customers based on an evaluation of a customer's financial condition, and collateral is not required.

Use of Estimates

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of these financial statements requires us to make significant estimates and judgments that affect the reported amounts of assets, liabilities, revenue, expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates, including those related to contingencies, on an ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ, at times in material amounts, from these estimates under different assumptions or conditions.

Recently Issued Accounting Pronouncements

In May 2017, the FASB issued ASU 2017-09, which clarifies when changes to the terms or conditions of a share-based payment award must be accounted for as modifications. The new guidance will reduce diversity in practice and result in fewer changes to the terms of an award being accounted for as modifications. The new guidance will allow companies to make certain changes to awards without accounting for them as modifications. This guidance does not change the accounting for modifications. The guidance will be applied prospectively to awards modified on or after the adoption date and is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including in an interim period. We adopted this guidance and it did not have an impact on our consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230). ASU 2016-15 is intended to reduce the diversity in practice regarding how certain transactions are classified within the statement of cash flows. ASU 2016-15 is effective for public business entities for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted with retrospective application. We adopted this guidance and it did not have an impact on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation – Stock Compensation: Improvements to Employee Share-Based Payment Accounting. This guidance simplifies several aspects of the accounting for employee share-based payment transactions for both public and nonpublic entities, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The guidance is effective for public business entities for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. We adopted ASU 2016-09 effective January 1, 2017, electing to account for forfeitures when they occur. The impact from adoption of the provisions related to forfeiture rates was reflected in our consolidated financial statements on a modified retrospective basis, resulting in an adjustment of approximately $31,000 to retained earnings. The impact from adoption of the provisions related to excess tax benefits or deficiencies in the provision for income taxes rather than paid-in capital was adopted on a modified retrospective basis. Since we have a full valuation allowance on our net deferred tax assets, an amount equal to the cumulative adjustment made to retained earnings to recognize the previously unrecognized net operating losses from prior periods was made to the valuation allowance through retained earnings for the first quarter financial statements. Adoption of all other changes did not have an impact on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases. This guidance requires lessees to record most leases on their balance sheets but recognize expenses on their income statements in a manner similar to current accounting. The guidance also eliminates current real estate-specific provisions for all entities. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. The standard is effective for public business entities for annual periods beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted for all entities. We are in the process of analyzing the quantitative impact of this guidance on our results of operations and financial position. While we are continuing to assess all potential impacts of the standard, we currently believe the impact of this standard will be primarily related to the accounting for our operating lease.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under previous guidance. This may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In July 2015, the FASB approved the proposal to defer the effective date of ASU 2014-09 standard by one year. Early adoption is permitted after December 15, 2016, and the standard is effective for public entities for annual reporting periods beginning after December 15, 2017 and interim periods therein. In 2016, the FASB issued final amendments to clarify the implementation guidance for principal versus agent considerations (ASU 2016-08), accounting for licenses of intellectual property and identifying performance obligations (ASU 2016-10), narrow-scope improvements and practical expedients (ASU 2016-12) and technical corrections and improvements to topic 606 (ASU 2016-20) in its new revenue standard. We have performed a review of the requirements of the new revenue standard and are monitoring the activity of the FASB and the transition resource group as it relates to specific interpretive guidance. We have reviewed customer contracts and applied the five-step model of the new standard to our contracts as well as compared the results to our current accounting practices. We are currently in the process of drafting disclosures required by the new standard. At this point of our analysis, we do not believe that the adoption of this standard will have a material effect on our financial statements but will potentially expand our disclosures related to contracts with customers.

NOTE 3 – INVENTORY

Inventory consists of the following:

	December 31,	
	2017	2016
Finished product	$ 1,485,358	$ 1,062,285
Raw material	—	14,036
TOTAL INVENTORY	$ 1,485,358	$ 1,076,321

NOTE 4 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	December 31,	
	2017	2016
Prepaid sales and marketing costs	$ 5,335,936	$ —
Prepaid insurance	680,243	628,039
Prepaid manufacturing costs	—	991,809
Prepaid consulting	—	128,898
Other prepaid costs	523,694	405,960
Prepaid vendor deposits	64,411	44,311
Prepaid research and development costs	—	100,035
TOTAL OTHER CURRENT ASSETS	$ 6,604,284	$ 2,299,052

NOTE 5 – FIXED ASSETS, NET

Fixed assets, net consist of the following:

	December 31,	
	2017	2016
Accounting system	$ 301,096	$ 301,096
Equipment	273,536	215,182
Computer hardware	80,211	80,211
Furniture and fixtures	116,542	113,079
Leasehold improvements	37,888	37,888
TOTAL	809,273	747,456
Accumulated depreciation	(372,218)	(230,617)
TOTAL FIXED ASSETS, NET	$ 437,055	$ 516,839

Depreciation expense for the years ended December 31, 2017, 2016, and 2015 was $141,601, $77,906, and $29,959, respectively.

NOTE 6 – INTANGIBLE ASSETS, NET

The following table sets forth the gross carrying amount, accumulated amortization and net carrying amount of our intangible assets as of December 31, 2017 and 2016:

	December 31, 2017			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizable intangible assets:				
OPERA® software patent	$ 31,951	$ (8,487)	$ 23,464	11.75
Development costs of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	1,293,614	(171,911)	1,121,703	15
Hormone therapy drug candidate patents (pending)	1,721,305	—	1,721,305	n/a
Non-amortizable intangible assets:				
Multiple trademarks	233,275	—	233,275	indefinite
TOTAL	$ 3,371,888	$ (272,141)	$ 3,099,747	

	December 31, 2016			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizable intangible assets:				
OPERA® software patent	$ 31,951	$ (6,490)	$ 25,461	12.75
Development costs of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	1,093,452	(102,393)	991,059	16
Hormone therapy drug candidate patents (pending)	1,203,987	—	1,203,987	n/a
Non-amortizable intangible assets:				
Multiple trademarks for vitamins/supplements	185,465	—	185,465	indefinite
Total	$ 2,606,598	$ (200,626)	$ 2,405,972	

We capitalize external costs, consisting primarily of legal costs, related to securing our patents and trademarks. Once a patent is granted, we amortize the approved hormone therapy drug candidate patents using the straight-line method over the estimated useful life of approximately 20 years, which is the life of intellectual property patents. If the patent is not granted, we write-off any capitalized patent costs at that time. Trademarks are perpetual and are not amortized. During the years ended December 31, 2017 and 2016, there was no impairment recognized related to intangible assets.

We have numerous pending foreign and domestic patent applications. As of December 31, 2017, we had 18 issued domestic, or U.S., patents and 13 issued foreign patents, including:

- 13 domestic and three foreign utility patents that relate to our combination progesterone and estradiol product candidates, which are owned by us. The domestic utility patents will expire in 2032. In addition, we have pending patent applications with respect to our combination progesterone and estradiol product candidates in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;
- three domestic and 10 foreign patents that relate to TX-004HR, our applicator-free vaginal estradiol softgel product candidate. These patents establish an important intellectual property foundation for TX-004HR and are owned by us. These domestic patents will expire in 2033 or 2032. In addition, we have pending patent applications related to our applicator-free vaginal estradiol softgel product candidate in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;
- one domestic utility patent that relates to a pipeline transdermal patch technology, which is owned by us and will expire in 2032. We have pending patent applications with respect to this technology in the U.S., Australia, Brazil, Canada, Europe, Mexico, Japan, and South Africa; and
- one utility patent that relates to our OPERA® information-technology platform, which is owned by us and is a domestic patent that will expire in 2029.

Amortization expense was $71,516, $54,545, and $32,441 for the years ended December 31, 2017, 2016, and 2015, respectively. Estimated amortization expense, based on current patent cost being amortized, for the next five years is as follows:

Year Ending December 31,	Estimated Amortization
2018	$ 76,777
2019	$ 76,777
2020	$ 76,777
2021	$ 76,777
2022	$ 76,777
Thereafter	$ 761,282

NOTE 7– OTHER CURRENT LIABILITIES

Other current liabilities consist of the following:

	December 31,	
	2017	2016
Accrued clinical trial costs	$ 366,933	$ 1,281,080
Accrued payroll, bonuses and commission costs	4,240,379	3,531,440
Accrued compensated absences	945,457	665,561
Accrued legal and accounting expense	600,350	176,518
Accrued sales and marketing costs	420,162	665,773
Other accrued expenses	602,916	224,865
Allowance for wholesale distributor fees	172,973	76,510
Accrued royalties	114,480	26,507
Allowance for coupons and returns	1,432,846	794,816
Accrued rent	327,099	181,015
TOTAL OTHER CURRENT LIABILITIES	$ 9,223,595	$ 7,624,085

NOTE 8 – STOCKHOLDERS' EQUITY

Preferred Stock

At December 31, 2017, we had 10,000,000 shares of preferred stock, par value $0.001, authorized for issuance, of which no shares of preferred stock were issued or outstanding.

Common Stock

At December 31, 2017, we had 350,000,000 shares of Common Stock authorized for issuance, of which 216,429,642 shares of our Common Stock were issued and outstanding.

Issuances During 2017

On September 25, 2017, we entered into an underwriting agreement with J.P. Morgan Securities LLC relating to an underwritten public offering of 12,400,000 shares of our Common Stock at a price of $5.55 per share. The net proceeds to us from the offering were approximately $68,573,000, after deducting estimated offering expenses payable by us. The offering closed on September 28, 2017 and we issued 12,400,000 shares of Common Stock.

During the year ended December 31, 2017, certain individuals exercised stock options to purchase 102,546 shares of Common Stock for $212,615 in cash.

Issuances During 2016

On January 6, 2016, we entered into an underwriting agreement with Goldman Sachs & Co. and Cowen and Company, LLC, as the representatives of the several underwriters, or the Underwriters, relating to an underwritten public offering of 15,151,515 shares of our Common Stock at a public offering price of $8.25 per share. Under the terms of the underwriting agreement, we granted the Underwriters a 30-day option to purchase up to an aggregate of 2,272,727 additional shares of Common Stock, which option was exercised in full. The net proceeds to us from the offering were approximately $134,864,000, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. The offering closed on January 12, 2016 and we issued 17,424,242 shares of our Common Stock.

During the year ended December 31, 2016, certain individuals exercised stock options to purchase 525,362 shares of Common Stock for $989,060 in cash. Also during the same period, stock options to purchase 127,109 shares of Common Stock were exercised pursuant to the options' cashless exercise provisions, wherein 87,833 shares of Common Stock were issued.

Issuances During 2015

On July 9, 2015, we entered into an underwriting agreement with Stifel, Nicolaus & Company, Incorporated and Guggenheim Securities, LLC, as the representatives of the several underwriters, or the Stifel Underwriters, relating to an underwritten public offering of 3,846,154 shares of Common Stock at a public offering price of $7.80 per share. Under the terms of the underwriting agreement, we granted the Stifel Underwriters a 30-day option to purchase up to an aggregate of 576,923 additional shares of Common Stock, which option was exercised in full. The net proceeds to us from the offering were approximately $32,257,000, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. The offering closed on July 15, 2015 and we issued 4,423,077 shares of our Common Stock.

On February 10, 2015, we entered into an underwriting agreement, or the Cowen Agreement, with Cowen and Company, LLC, as the representative of the several underwriters, or the Cowen Underwriters, relating to an underwritten public offering of 13,580,246 shares of Common Stock, at a public offering price of $4.05 per share. Under the terms of the Cowen Agreement, we granted the Cowen Underwriters a 30-day option to purchase up to an aggregate of 2,037,036 additional shares of Common Stock, which option was exercised in full. The net proceeds from the offering were approximately $59,118,000, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. The offering closed on February 17, 2015 and we issued 15,617,282 shares of our Common Stock.

During the year ended December 31, 2015, certain individuals exercised stock options to purchase 612,867 shares of Common Stock for $1,232,579 in cash. Also during the same period, stock options to purchase 417 shares of Common Stock were exercised pursuant to the options' cashless exercise provisions, wherein 114 shares of Common Stock were issued.

Warrants to Purchase Common Stock

As of December 31, 2017, we had warrants outstanding to purchase an aggregate of 3,115,905 shares of our Common Stock with a weighted-average contractual remaining life of 1.8 years, and exercise prices ranging from $0.24 to $8.20 per share, resulting in a weighted average exercise price of $2.58 per share.

The valuation methodology used to determine the fair value of our warrants is the Black-Scholes Model. The Black-Scholes Model requires the use of a number of assumptions, including volatility of the stock price, the risk-free interest rate, dividend yield and the term of the warrant.

During the year ended December 31, 2017, we granted warrants to purchase 125,000 shares of Common Stock to outside consultants at an exercise price of $6.83 per share. The fair value for these warrants was determined by using the Black-Scholes Model on the date of the grant using a term of five years; volatility of 63.24%; risk free rate of 1.47%; and dividend yield of 0%. The grant date fair value of the warrants was $3.67 per share. The warrants vest ratably over a 12-month period and have an expiration date of March 15, 2022.

During the year ended December 31, 2016, we granted warrants to purchase 245,000 shares of Common Stock to outside consultants at the weighted average price of $7.90 per share. These warrants vest and have expiration dates as follows: warrants to purchase 75,000 shares of Common Stock vested on April 21, 2016 and have an expiration date of April 21, 2021, warrants to purchase 50,000 shares of Common Stock vest ratably over a 24-month period and have an expiration date of April 21, 2021, and warrants to purchase 120,000 shares of Common Stock vest ratable over a 12-month period and have an expiration date of January 21, 2021.

During the year ended December 31, 2015, we granted warrants to purchase 50,000 shares of Common Stock to an outside consultant at an exercise price of $6.35 vesting ratably over a 12-month period, with an expiration date of April 6, 2020. We recorded share-based compensation expense related to warrants previously issued of $313,271, $936,974 and $139,142 for the years ended December 31, 2017, 2016, and 2015, respectively, in the accompanying consolidated financial statements. At December 31, 2017, total unrecognized estimated compensation expense related to the unvested portion of these warrants was approximately $128,000 which is expected to be recognized over a weighted-average period of 0.2 years.

Summary of our Warrant activity during the year ended December 31, 2017:

	Number of Shares Under Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2016	12,060,071	$ 2.08	1.0	$ 45,063,867
Granted	125,000	$ 6.83		
Exercised	(9,066,666)	$ 1.98		$ 48,535,969
Expired	(2,500)	$ 2.64		
Cancelled/Forfeited	—	$ —		
Balance at December 31, 2017	3,115,905	$ 2.58	1.8	$ 11,348,273
Vested and Exercisable at December 31, 2017	2,792,983	$ 2.64	0.8	$ 1,141,836
Unvested at December 31, 2017	322,922	$ 2.57	2.0	$ 10,206,436

The aggregate intrinsic value of warrants exercised during 2016 and 2015, was $3,988,343 and $7,282,404, respectively. The weighted average fair value per share of warrants issued and the assumptions used in the Black-Scholes Model during the years ended December 31, 2017, 2016 and 2015 are set forth in the table below.

	2017	2016	2015
Weighted average exercise price	$ 6.83	$ 7.90	$ 6.35
Weighted average grant date fair value	$ 3.67	$ 4.78	$ 3.27
Risk-free interest rate	1.47%	1.04-1.28%	1.02%
Volatility	63.24%	74.10-74.15%	60.59%
Term (in years)	5	5	5
Dividend yield	0.00%	0.00%	0.00%

The risk-free interest rate assumption is based upon observed interest rates on zero coupon U.S. Treasury bonds whose maturity period is appropriate for the term of the instrument. Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the term of the instrument. The estimated volatility is an average of the historical volatility of the stock prices of our peer entities whose stock prices were publicly available. Our calculation of estimated volatility is based on historical stock prices over a period equal to the term of the instrument as we have insufficient historical information regarding our stock options to provide a basis for estimate. The expected volatility of warrants was estimated based on a historical volatility analysis of peers that were similar to the Company with respect to industry, stage of life cycle, market capitalization, and financial leverage.

In May 2013, we entered into a consulting agreement with Sancilio and Company, Inc., or SCI, to develop drug platforms to be used in our hormone replacement drug candidates. These services include support of our efforts to successfully obtain U.S. Food and Drug Administration, or the FDA, approval for our drug candidates, including a vaginal capsule for the treatment of vulvar and vaginal atrophy, or VVA. In connection with the agreement, SCI agreed to forfeit its rights to receive warrants to purchase 833,000 shares of our Common Stock that were to be granted pursuant to the terms of a prior consulting agreement dated May 17, 2012. As consideration under the agreement, we agreed to issue to SCI a warrant to purchase 850,000 shares of our Common Stock at $2.01 per share that has vested or will vest, as applicable, as follows:

1. 283,333 shares were earned on May 11, 2013 upon acceptance of an Investigational New Drug application by the FDA for an estradiol-based drug candidate in a softgel vaginal capsule for the treatment of VVA; however, pursuant to the terms of the consulting agreement, the shares did not vest until June 30, 2013. The fair value of $405,066 for the shares vested on June 30, 2013 was determined by using the Black-Scholes Model on the date of vesting using a term of 5 years; a volatility of 45.89%; risk free rate of 1.12%; and a dividend yield of 0%. We recorded the entire $405,066 as non-cash compensation as of June 30, 2013. These shares were exercised in 2017 and are included in the warrant exercise details below;

2. 283,333 shares vested on June 30, 2013. The fair value of $462,196 for these shares was determined by using the Black-Scholes Model on the date of vesting using a term of 5 years; a volatility of 45.84%; risk free rate of 1.41%; and a dividend yield of 0%. During the years ended December 31, 2017, 2016, and 2015, we recorded $0, $77,026, and $154,068, respectively, as non-cash compensation in the accompanying consolidated financial statements related to this warrant. As of December 31, 2017 this warrant was fully amortized. These shares were exercised in 2017 and are included in the warrant exercise details below; and

3. 283,334 shares will vest upon the receipt by us, prior to the warrant expiration date of April 30,2018, of any final FDA approval of a drug candidate that SCI helped us design. It is anticipated that receipt of such an approval may occur in the near future.

In May 2012, we issued warrants to purchase an aggregate of 1,300,000 shares of Common Stock to SCI for services to be rendered over approximately five years beginning in May 2012. The warrants vested upon issuance. Services provided are to include (a) services in support of our drug development efforts, including services in support our ongoing and future drug development and commercialization efforts, regulatory approval efforts, third-party investment and financing efforts, marketing efforts, chemistry, manufacturing and controls efforts, drug launch and post-approval activities, and other intellectual property and know-how transfer associated therewith; (b) services in support of our efforts to successfully obtain new drug approval; and (c) other consulting services as mutually agreed upon from time to time in relation to new drug development opportunities. The warrants were valued at $1,532,228 on the date of the issuance using an exercise price of $2.57; a term of five years; a volatility of 44.71%; risk free rate of 0.74%; and a dividend yield of 0%. During the years ended December 31, 2017, 2016, and 2015, we recorded $128,898, $257,796, and $257,796, respectively as non-cash compensation with respect to these warrants in the accompanying consolidated financial statements. As of December 31, 2017, the SCI warrants issued in 2013 and 2012 were fully amortized. This warrant was fully exercised, of which 800,000 shares were exercised in 2017 and 500,000 shares were exercised in 2016.

Warrant exercises

During the year ended December 31, 2017, certain individuals exercised warrants to purchase 2,476,666 shares of Common Stock for $3,798,999 in cash. In addition, during the year ended December 31, 2017, certain individuals exercised warrants to purchase 6,590,000 shares of Common Stock pursuant to the warrants' cashless exercise provisions, wherein 4,762,208 shares of Common Stock were issued.

During the year ended December 31, 2016, certain individuals exercised warrants to purchase 722,744 shares of Common Stock for $1,373,000 in cash.

During the year ended December 31, 2015, certain individuals and an entity exercised warrants to purchase 1,255,485 shares of Common Stock as follows: (i) 945,485 shares of Common Stock were issued for $366,000 in cash and (ii) warrants to purchase 310,000 shares of Common Stock were exercised pursuant to the warrants' cashless exercise provisions, wherein 232,197 shares of Common Stock were issued.

Options to Purchase Common Stock of the Company

In 2009, we adopted the 2009 Long Term Incentive Compensation Plan, or the 2009 Plan, to provide financial incentives to employees, directors, advisers, and consultants of our company who are able to contribute towards the creation of or who have created stockholder value by providing them stock options and other stock and cash incentives, or the Awards. The Awards available under the 2009 Plan consist of stock options, stock appreciation rights, restricted stock, restricted stock units, performance stock, performance units, and other stock or cash awards as described in the 2009 Plan. There are 25,000,000 shares authorized for issuance thereunder. Generally, the options vest annually over four years or as determined by our board of directors, upon each option grant. Options may be exercised by paying the price for shares or on a cashless exercise basis after they have vested and prior to the specified expiration date provided and applicable exercise conditions are met, if any. The expiration date is generally ten years from the date the option is issued. As of December 31, 2017, there were non-qualified stock options to purchase 18,575,084 shares of Common Stock outstanding under the 2009 Plan. As of December 31, 2017, there were 2,173,878 shares available to be issued under 2009 Plan.

In 2012, we adopted the 2012 Stock Incentive Plan, or the 2012 Plan, a non-qualified plan that was amended in August 2013. The 2012 Plan was designed to serve as an incentive for retaining qualified and competent key employees, officers, directors, and certain consultants and advisors of our company. The Awards available under the 2012 Plan consist of stock options, stock appreciation rights, restricted stock, restricted stock units, performance stock, performance units, and other stock or cash awards as described in the 2012 Plan. Generally, the options vest annually over four years or as determined by our board of directors, upon each option grant. Options may be exercised by paying the price for shares or on a cashless exercise basis after they have vested and prior to the specified expiration date provided and applicable exercise conditions are met, if any. The expiration date is generally ten years from the date the option is issued. There are 10,000,000 shares of Common Stock authorized for issuance thereunder. As of December 31, 2017, there were non-qualified stock options to purchase 4,790,141 shares of Common Stock outstanding under the 2012 Plan. As of December 31, 2017, there were 5,128,333 shares available to be issued under 2012 Plan.

The valuation methodology used to determine the fair value of stock options is the Black-Scholes Model. The Black-Scholes Model requires the use of a number of assumptions including volatility of the stock price, the risk-free interest rate, and the expected life of the stock options. The ranges of assumptions used in the Black-Scholes Model during the years ended December 31, 2017, 2016, and 2015 are set forth in the table below.

	2017	2016	2015
Weighted average exercise price	$ 6.60	$ 6.22	$ 8.14
Weighted average grant date fair value	$ 3.82	$ 3.94	$ 4.45
Risk-free interest rate	1.84-2.05%	1.13-1.90%	1.47-1.67%
Volatility	61.56-64.25%	70.26-73.34%	58.78-62.94%
Term (in years)	5.5-6.25	5.5-6.25	5.27-6.25
Dividend yield	0.00%	0.00%	0.00%

The risk-free interest rate assumption is based upon observed interest rates on zero coupon U.S. Treasury bonds whose maturity period is appropriate for the expected term. Estimated volatility is a measure of the amount by which the price of our Common Stock is expected to fluctuate each year during the term of an award. Our estimated volatility is an average of the historical volatility of the stock prices of our peer entities whose stock prices were publicly available. Our calculation of estimated volatility is based on historical stock prices over a period equal to the term of the awards as we have insufficient historical information regarding our stock options to provide a basis for estimate. The expected volatility of share options was estimated based on a historical volatility analysis of peers that were similar to us with respect to industry, stage of life cycle, market capitalization, and financial leverage. The average expected life is based on the contractual terms of the stock option using the simplified method. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends. Future stock-based compensation may significantly differ based on changes in the fair value of our Common Stock and our estimates of expected volatility and the other relevant assumptions.

A summary of activity under the 2009 and 2012 Plans and related information during the year ended December 31, 2017 is as follows:

	Number of Shares Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2016	21,767,854	$ 3.56	5.8	$ 60,495,730
Granted	2,271,500	$ 6.60		
Exercised	(102,546)	$ 2.07		$ 452,287
Expired	(108,375)	$ 7.64		
Cancelled/Forfeited	(463,208)	$ 6.28		
Balance at December 31, 2017	23,365,225	$ 3.78	5.13	$ 64,664,821
Vested and Exercisable at December 31, 2017	19,770,142	$ 3.27	4.47	$ 63,895,512
Unvested at December 31, 2017	3,595,083	$ 6.60	8.79	$ 769,309

At December 31, 2017, our outstanding options had exercise prices ranging from $0.10 to $8.92 per share. The aggregate intrinsic value of options exercised during 2016 and 2015, was $3,828,358 and $3,186,371, respectively. Share-based compensation expense related to options recognized in our results of operations for the years ended December 31, 2017, 2016, and 2015 was approximately $6,447,154, $16,139,225, and $6,621,658, respectively, and it is based on awards vested. At December 31, 2017, total unrecognized estimated compensation expense related to unvested options was approximately $10,596,000, which may be adjusted for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 2.1 years. No tax benefit was realized due to a continued pattern of operating losses.

NOTE 9 – INCOME TAXES

For financial reporting purposes, income before taxes includes the following components:

	2017	2016	2015
United States	$ (76,925,380)	$ (89,875,459)	$ (85,077,024)
Total	$ (76,925,380)	$ (89,875,459)	$ (85,077,024)

For the years ended December 31, 2017, 2016, and 2015, there was no provision for income taxes, current or deferred. At December 31, 2017, we had a federal net operating loss carry forward of approximately $338,613,987 available to offset future taxable income through 2037. The federal carryforwards will begin to expire in 2031.

A reconciliation between taxes computed at the federal statutory rate and the consolidated effective tax rate is as follows:

	2017	2016	2015
Federal statutory tax rate	34.0%	34.0%	34.0%
State tax rate, net of federal tax benefit	5.0%	5.4%	4.73%
Adjustment in valuation allowances	22.6%	(40.3)%	(38.97)%
Federal income tax rate change	(60.8)%	—%	—%
Permanent and other differences	(0.8)%	0.9%	0.24%
(Provision) benefit for income taxes	—%	—%	—%

Deferred income taxes result from temporary differences between the amount of assets and liabilities recognized for financial reporting and tax purposes. The components of the net deferred income tax asset as of December 31, 2017, 2016, and 2015 are as follows:

	2017	2016	2015
Deferred Income Tax Assets:			
Net operating losses	$ 99,596,321	$ 111,730,450	$ 79,499,633
R&D Credit	186,347	186,347	186,347
Total deferred income tax asset	99,782,668	111,916,797	79,685,980
Valuation allowance	(99,782,668)	(111,916,797)	(79,685,980)
Deferred income tax assets, net	$ —	$ —	$ —

We believe that it is more likely than not that we will not generate sufficient future taxable income to realize the tax benefits related to the deferred tax assets on the Company's Balance Sheet and as such, a valuation allowance has been established against the deferred tax assets for the period ended December 31, 2017.

Unrecognized Tax Benefits

As of the period ended December 31, 2017, we have no unrecognized tax benefits.

On December 22, 2017, the U.S. federal government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act, or the Tax Act. The Tax Act makes broad and complex changes to the U.S. federal tax code, including, but not limited to reducing the U.S. federal corporate tax rate from 34 percent to 21 percent, effective January 1, 2018. Consequently, we have recorded a decrease related to deferred tax assets and deferred tax liabilities of approximately $49,500,000 and approximately $2,800,000, respectively, with a corresponding net adjustment to the valuation allowance of approximately $46,700,000 for the year ended December 31, 2017.

The Tax Act modifies Section 162(m) of the Internal Revenue Code of 1986, as amended, or the IRC, by (1) expanding which employees are considered covered employees by including the chief financial officer, (2) providing that if an individual is a covered employee for a taxable year beginning after December 31, 2016, the individual remains a covered employee for all future years, and (3) removing the exceptions for compensation stemming from contracts entered into on or before November 2, 2017, unless such contracts were materially modified on or after the date. Compensation agreements entered into and share-based payment awards granted after this date will be subject to the revised terms of IRC Section 162(m). In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act* (SAB 118), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. Since the Tax Act was passed late in the fourth quarter of 2017, and ongoing guidance and accounting interpretation are expected over the next 12 months, we consider the accounting for share-based compensation arrangements under the Tax Act to be incomplete due to the forthcoming guidance and our ongoing analysis of final year-end data and tax positions.

We must assess whether our valuation allowance analyses are affected by various aspects of the Tax Act. Since, as discussed herein, we have recorded provisional amounts related to certain portions of the Tax Act, any corresponding determination of the need for or change in a valuation allowance is also provisional.

NOTE 10 – RELATED PARTIES

In July 2015, J. Martin Carroll, a director of our company, was appointed to the board of directors of Catalent, Inc. From time to time, we have entered into agreements with Catalent, Inc. and its affiliates, or Catalent, in the normal course of business. Agreements with Catalent have been reviewed by independent directors of our company or a committee consisting of independent directors of our company since July 2015. During the years ended December 31, 2017, 2016 and 2015, we were billed by Catalent approximately $3,646,000, $3,647,000 and $1,266,000, respectively, for manufacturing activities related to our clinical trials, scale-up, registration batches, stability and validation testing. As of December 31, 2017 and December 31, 2016, there were amounts due to Catalent of approximately $523,000 and $57,000, respectively.

NOTE 11 - BUSINESS CONCENTRATIONS

We purchase our products from several suppliers with approximately 100%, 98%, and 60% of our purchases supplied by one vendor for the years ended December 31, 2017, 2016 and 2015, respectively.

We sell our prescription prenatal vitamin products to wholesale distributors, specialty pharmacies, specialty distributors, and chain drug stores that generally sell products to retail pharmacies, hospitals, and other institutional customers. During the years ended December 31, 2017, 2016 and 2015; four, three, and two customers each, respectively, generated more than 10% of our revenues. Revenue generated from four major customers combined accounted for approximately 59% of our revenue during the year ended December 31, 2017. Revenue generated from three major customers combined accounted for approximately 41% of our revenue during the year ended December 31, 2016. Revenue generated from two major customers combined accounted for approximately 67% of our recognized revenue during the year ended December 31, 2015.

During the year ended December 31, 2017, AmerisourceBergen generated approximately $2,667,000 of our revenue; McKesson Corporation generated approximately $1,959,000 of our revenue; Cardinal Health generated approximately $2,559,000 of our revenue and Pharmacy Innovations PA generated approximately $2,715,000 of our revenue. During the year ended December 31, 2016, Woodstock Pharmaceutical and Compounding generated approximately $2,247,000 of our revenue; Medical Center Pharmacy generated approximately $3,700,000 of our revenue and Pharmacy Innovations PA generated approximately $2,040,000 of our revenue. During the year ended December 31, 2015, Woodstock Pharmaceutical and Compounding generated approximately $8,848,000 of our revenue and Due West Pharmacy generated approximately $4,843,000 of our revenue.

As a result of developments in the pharmaceutical industry that negatively affected independent pharmacies, including such pharmacies' reliance on third party payors, in 2016, we identified that payment periods for our retail pharmacy distributors were becoming longer than in prior years. As a result, during the third quarter of 2016, we centralized the distribution channel for both our retail pharmacy distributors and wholesale distributors, in order to facilitate sales to a broader population of retail pharmacies and minimize business risk exposure to any one retail pharmacy. During the third quarter of 2016, we entered into new distribution agreements with our retail pharmacy distributors to effectuate this centralization which were effective September 1, 2016.

NOTE 12 – COMMITMENTS AND CONTINGENCIES

Operating Lease

We lease administrative office space in Boca Raton, Florida pursuant to a non-cancelable operating lease that commenced on July 1, 2013 and originally provided for a 63-month term. On February 18, 2015, we entered into an agreement with the same lessors to lease additional administrative office space in the same location, pursuant to an addendum to such lease. In addition, on April 26, 2016, we entered into an agreement with the same lessors to lease additional administrative office space in the same location. This agreement was effective beginning May 1, 2016 and extended the original expiration of the lease term to October 31, 2021. On October 4, 2016, we entered into an agreement with the same lessors to lease additional administrative office space in the same location, pursuant to an addendum to such lease. This addendum is effective beginning November 1, 2016.

The rental expense related to our current lease during the years ended December 31, 2017, 2016 and 2015 was $1,029,205, $709,483, and $446,099, respectively.

As of December 31, 2017, future minimum rental payments on non-cancelable operating leases are as follows:

Years Ending December 31,		
2018	$	951,194
2019		1,094,116
2020		1,113,069
2021		943,127
2022		—
Total minimum lease payments	$	4,101,506

Legal Proceedings

From time to time, we are involved in litigation and proceedings in the ordinary course of business. We are not currently involved in any legal proceeding that we believe would have a material effect on our consolidated financial condition, results of operations, or cash flows.

Off-Balance Sheet Arrangements

As of December 31, 2017, 2016, and 2015, we had no off-balance sheet arrangements that have had or are reasonably likely to have current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

Employment Agreements

We have entered into employment agreements with certain of our executives that provide for compensation and certain other benefits. Under certain circumstances, including a change in control, some of these agreements provide for severance or other payments, if those circumstances occur during the term of the employment agreement.

NOTE 13 – SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

Summarized quarterly financial data for fiscal years 2017 and 2016 is as follows:

	2017 Quarters			
(In thousands, except per share)	1st	2nd	3rd	4th
Revenues	$ 3,985	$ 4,250	$ 4,418	$ 4,125
Gross profit	$ 3,326	$ 3,568	$ 3,717	$ 3,530
Net loss	$ (21,156)	$ (19,677)	$ (14,665)	$ (21,427)
Loss per common share, basic and diluted	$ (0.11)	$ (0.10)	$ (0.07)	$ (0.10)

	2016 Quarters			
(In thousands, except per share)	1st	2nd	3rd	4th
Revenues	$ 4,930	$ 4,403	$ 5,536	$ 4,487
Gross profit	$ 3,822	$ 3,273	$ 4,298	$ 3,778
Net loss	$ (20,929)	$ (21,094)	$ (25,016)	$ (22,836)
Loss per common share, basic and diluted	$ (0.11)	$ (0.11)	$ (0.13)	$ (0.12)

Exhibit 21.1

Subsidiaries of the Company

Name	State or Jurisdiction of Incorporation or Organization
VitaMedMD, LLC	Delaware
BocagreenMD, Inc.	Nevada
VitaCare Prescription Services, Inc.	Florida

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our reports dated February 23, 2018, with respect to the consolidated financial statements and internal control over financial reporting included in the Annual Report of TherapeuticsMD, Inc. (a Nevada Corporation) on Form 10-K for the year ended December 31, 2017. We consent to the incorporation by reference of said reports in the Registration Statements of TherapeuticsMD, Inc. on Forms S-3 (File No. 333-207837, File No. 333-185156, and File No. 333-201171) and on Form S-8 (File No. 333-191730).

/s/ GRANT THORNTON LLP

Fort Lauderdale, Florida

February 23, 2018

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Robert G. Finizio, certify that:

(1) I have reviewed this annual report on Form 10-K of TherapeuticsMD, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

February 23, 2018

/s/ Robert G. Finizio
Robert G. Finizio
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Daniel A. Cartwright, certify that:

(1) I have reviewed this annual report on Form 10-K of TherapeuticsMD, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

February 23, 2018

/s/ Daniel A. Cartwright
Daniel A. Cartwright
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

SECTION 1350 CERTIFICATION OF CHIEF EXECUTIVE OFFICER

In connection with the annual report of TherapeuticsMD, Inc. (the "Company") on Form 10-K for the year ended December 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert G. Finizio, Chief Executive Officer of the Company, certify, to my best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a) or 78o(d)); and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

February 23, 2018

/s/ Robert G. Finizio
Robert G. Finizio
Chief Executive Officer
(Principal Executive Officer)

A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

SECTION 1350 CERTIFICATION OF CHIEF FINANCIAL OFFICER

In connection with the annual report of TherapeuticsMD, Inc. (the "Company") on Form 10-K for the year ended December 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Daniel A. Cartwright, Chief Financial Officer of the Company, certify to my best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a) or 78o(d)); and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

February 23, 2018

/s/ Daniel A. Cartwright
Daniel A. Cartwright
Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.