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, 2018

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

Indicate by check mark 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 an 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 ☐
	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 (182,622,092 shares) based on the closing price of the registrant's common stock as reported on the Nasdaq Global Select Market on June 30, 2018, which was the last business day of the registrant's most recently completed second fiscal quarter, was $1,139,561,854.

As of February 18, 2019, there were outstanding 241,161,845 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 2019 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, 2018.

THERAPEUTICSMD, INC.
ANNUAL REPORT ON FORM 10-K
Fiscal Year Ended December 31, 2018
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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.

TherapeuticsMD owns or has rights to trademarks, service marks, or trade names that are used in connection with the operation of its business including TherapeuticsMD®, vitaMedMD®, BocaGreenMD® and IMVEXXY®. This Annual Report also contains trademarks and trade names of other companies.

In addition, 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 their information has been obtained from sources believed to be reliable. Although we believe that the industry and market data below is reliable as of the date of this Annual 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 of this Annual Report, 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 healthcare company focused on creating and commercializing innovative products to support the lifespan of women and championing awareness of women's healthcare issues, specifically, for pregnancy prevention, pregnancy, childbirth, nursing, pre-menopause, and menopause. At TherapeuticsMD, we combine entrepreneurial spirit, clinical expertise, and business leadership to develop and commercialize health solutions that enable new standards of care for women. Our solutions range from advanced hormone therapy pharmaceutical products to patient-controlled, long-acting contraceptive. We also manufacture and distribute branded and generic prescription prenatal vitamins under the vitaMedMD® and BocaGreenMD® brands.

With our SYMBODA™ technology, we are developing and commercializing advanced hormone therapy pharmaceutical products to enable delivery of bio-identical hormones through a variety of dosage forms and administration routes. Our track record of commercialization allows us to efficiently leverage and grow our marketing and sales organization to commercialize our recently approved products.

During 2018, the U.S. Food and Drug Administration, or FDA, approval of our drugs has transitioned our company from predominately focused on conducting research and development to one focused on commercializing our drugs. In July 2018, we launched our recently FDA approved product, IMVEXXY® (estradiol vaginal inserts) for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy, or VVA, due to menopause. We are also focused on commercialization activities necessary for launch of BIJUVA™ and ANNOVERA™. BIJUVA™ is our hormone therapy combination of bio-identical 17ß-estradiol and bio-identical progesterone in a single, oral softgel capsule, for the treatment of moderate-to-severe vasomotor symptoms, or VMS, due to menopause in women with a uterus, which was approved by the FDA on October 28, 2018. ANNOVERA™ (segesterone acetate/ethinyl estradiol vaginal system), is the first and only patient-controlled, procedure-free, reversible prescription contraceptive that can prevent unintended pregnancy for up to a full year, which was approved by the FDA on August 10, 2018. On July 30, 2018, we entered into an exclusive license agreement, or the Population Council License Agreement, with the Population Council, Inc., or the Population Council, to commercialize ANNOVERA™ in the U.S. In addition, on July 30, 2018, we entered into a license and supply agreement with Knight Therapeutics Inc., or Knight, pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY® and BIJUVA™ in Canada and Israel.

Our Business Model

At TherapeuticsMD, we combine entrepreneurial spirit, clinical expertise, and business leadership to develop and commercialize health solutions that enable a new standard of care. Our solutions range from advanced hormone therapy pharmaceutical products to patient-controlled, long-acting contraceptive. We also manufacture and distribute branded and generic prescription prenatal vitamins under the vitaMedMD® and BocaGreenMD® brands. Our purposeful and continuous partnership with healthcare professionals and women is at the heart of our strategies for delivering innovative solutions for women at every stage of her life. From pregnancy to after menopause, we believe the only way to truly connect with and understand women and their healthcare professionals is to ask questions.

Healthcare has become increasingly consumer driven. Therefore, 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, payer, pharmacist, and patient through the following means:

- We will offer physicians a comprehensive product line of women's healthcare products, across women's lifecycles.
- Our hormone therapy drugs and drug candidates are designed to use the lowest effective dose.
- Our contraceptive product is the only long acting reversible contraceptive option that is patient-controlled and procedure-free.

- We believe the attributes of our prenatal vitamins will result in greater consumer acceptance and satisfaction than competitive products while offering the highest quality products, such as Quatrefolic®, FOLMAX®, FePlus®, and pur-DHA™. All 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, or HCPs, can offer alternatives to patients that meet the patient's individual nutritional requirements and provide patients a cost that is competitive in the marketplace.

- Improved patient education, a high level of patient compliance, and reduced cost of products all result in lower cost of care for payers and improved outcomes for patients.

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 a portfolio of high-quality product options that can be recommended or prescribed by both the physician and payer is the foundation of providing valuable options to the patient. We are dedicated to enabling healthcare professionals to advance the health of woman by offering new treatment options and giving voice to women's needs and health concerns. We are committed to partnering with women's health advocacy organizations as we create and commercialize solutions to help women transform how they experience reproductive health.

Our sales model focuses on the "4Ps": patient, provider, pharmacist, and payer. We market and sell our products primarily through a dedicated national sales force that calls on HCPs primarily in the OB/GYN market space. In addition, our products allow HCPs to offer an alternative to patients at a co-payment and that provides patients a cost that is competitive in the marketplace. We also believe that our combination of branded and authorized generic lines of prenatal vitamins offers physicians, women, and payers 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 HCPs, pharmacies, and consumers via incoming and outgoing telephone calls, e-mails, and live-chat.

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. As a result, we will leverage our existing infrastructure, including our sales force, to commercialize our VitaMedMD line of prenatal vitamins and our recently approved products: IMVEXXY®, BIJUVA™, and ANNOVERA™. In addition to our focus on direct selling from our sales organization, we have executed a branded multichannel awareness campaign for HCPs leveraging digital, non-personal promotion and journal advertising and have already reached virtually all the active writing HCPs within the VVA category with IMVEXXY® branded messages. Our sales organization is planned for approximately 200 territories that will cover the most important HCPs for our product portfolio. In addition, we may partner with additional licensors or other strategic partners to commercialize our drugs outside of the OB/GYN market or in non-U.S. markets.

As of December 31, 2018, we marketed and sold IMVEXXY®, our first FDA approved product and 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 healthcare, while our BocaGreenMD products provide physicians, women, and payers with a lower wholesale acquisition cost alternative for prenatal vitamins. We intend to leverage our existing relationships and distribution system to introduce our next two products, BIJUVA™ and ANNOVERA™, which will enable us to provide a comprehensive line of women's healthcare products.

Our Growth Strategy

We believe that the relationships our national sales force has developed with OB/GYN's, through our current prescription prenatal vitamin products and newly-approved products such as IMVEXXY®, will continue to grow as these products along with ANNOVERA™ and BIJUVA™ offer new opportunities to serve the needs of their patients at each stage of their life. By delivering our entire portfolio through the same sales channel and demonstrating how these products can help women as different needs emerge throughout their lifetime, we believe we can create efficiencies and synergies to further our growth.

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 prenatal vitamins and IMVEXXY®. 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 to after menopause.

Focus on Hormone Therapy Products. We plan to continue our focus on the development, clinical trials, and commercialization of bio-identical hormone therapy products designed to (1) alleviate the symptoms of, and reduce the health effects resulting from, menopause-related hormone deficiencies, including VMS and VVA, and (2) demonstrate equivalent clinical efficacy at lower doses. We believe there is a large unmet need in this segment of the market.

Deepening focus on other parts of a women's reproductive lifecycle. With the acquisition and forthcoming launch of ANNOVERA™, we are demonstrating our intent to provide effective and innovative products for women at all lifecycle stages.

Penetrate Compounding Market with FDA-approved Products. We believe BIJUVA™ is the only current FDA-approved hormone therapy combination product that is bio-identical to the estradiol and progesterone produced by the ovaries, and will provide a proven alternative to non-FDA approved compounded bio-identical hormone therapy products, and potentially at a lower price to patients since most insurance companies do not provide coverage for non-FDA approved compounded products. We continue to work with independent and community-based pharmacies that currently compound bio-identical hormone therapy products to help introduce patients and prescribers to our FDA-approved hormone therapy products. 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 potentially dispensing our FDA-approved products. As part of the BIO-IGNITE™ program, qualified pharmacies may be eligible to participate in certain purchasing groups and wholesaler programs so that offering BIJUVA™ and IMVEXXY® as appropriate treatment alternatives is economically practical for the pharmacy.

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. In addition, we may partner with additional licensors or other strategic partners to commercialize our drugs outside of the OB/GYN market or in non-U.S. markets. In addition, the proliferation of digital technology has dramatically increased the amount of information available to patients and providers. We believe this makes patient/provider engagement and experience a more important factor for life sciences companies and that providing patients and providers with important information on a real-time basis is a critical piece of serving this market.

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

Geographical Expansion. We currently plan to expand our geographic marketing footprint in the United States and sales team to approximately 200 professionals as we commercialize IMVEXXY®, BIJUVA™ and ANNOVERA™.

Commercialization Model

We plan to commercialize the products in our portfolio through a common model focused on the belief that providing good experiences for both HCPs and patients will drive profitability for TherapeuticsMD. Given that our portfolio focus is exclusively in women's health, each new product launch will allow us to further leverage our existing infrastructure and build out our reputation as the premier women's health organization in the United Sates. Below is more detail on our commercialization model:

- **HCP Education -** Initially, we focus on the high writing and high potential HCPs in each territory to gain a full understanding of their prescribing behavior and practices. This provides us with the information to ensure the selling proposition of each drug is within the context of our understanding of each HCP. Our focus is on driving initial prescriptions of these writers for each new product launch and utilizing the time to also pull through on our portfolio of existing products. Once regular writing is established with the initial group of HCPs, we expand our reach to a larger set of HCPs writing in the category.

  We accomplish educating HCPs primarily with our field sales organization. We have defined a sales force targeting approximately 200 territories, covering approximately 26,000 HCPs which covers approximately 63% of the addressable market. We are deploying a hybrid sales model that combines an internal sales leadership team with a fully dedicated contract sales force to call on our target HCPs. Additionally, we have an inside sales team that covers areas of the U.S. where key HCPs are located but where we do not have defined territories. In addition to the traditional sales organization, we have launched our key account management organization, or KAMs, to engage with our BIO-IGNITE™ partners.

  In addition to our sales organization, we leverage non-personal promotion (multi-channel advertising) to targets and non-targets that drive awareness, education, and action. These efforts allow for pull through of the sales organization efforts and identification of new targets that have interest in writing prescriptions for one or more of our products. We believe this will drive increased prescribing for our products and lift the overall writing universe by keep the menopause categories and our products top of mind in the HCP community.

- **Payer Access** - With the ever-changing payer environment, it is critical to maximize breadth of coverage as quickly as possible to not inhibit patient access to product. We do this while working to negotiate the best possible contracts for us. Many commercial payers employ “new-to-market blocks” for newly launched brands until the payers have the opportunity to make a coverage decision based upon their internal review the product. When a product is not covered, the patient is responsible to pay the full price for the medication, which can significantly limit utilization of the product. As we seek to increase the number of lives covered by commercial payers, it is our objective to continue to seek unrestricted coverage.

- **Supply** - We want to ensure our products are available in all classes of trade and delivery systems. We intend to offer our products through traditional chain wholesalers (Cardinal, McKesson and AmerisourceBergen) and independent retail pharmacies, community compounding pharmacies with our Bio-Ignite program, and mail order. We continue to develop unique opportunities to sell direct to pharmacies to streamline distribution and better control costs.

- **Patient Affordability Programs** - We have affordability and adherence programs in place for the patient so that we can support appropriate use of the product. Our co-pay assistance programs allow all patients to access the product at a reasonable cost.

- **Patient Adherence** - Establishing compliance and adherence programs that make getting on and obtaining prescribed refills easy and convenient for the patient and doctor is a critical lever in our commercial model. Our focus is on minimizing complications in patients filling their first prescription and engaging with them throughout the life of their treatment to ensure patients stay on and use therapy for the appropriate length of time. We believe that the patient engagement programs that we created and piloted around our prescription prenatal vitamin business have the potential to improve patient compliance for all our products. For example, in our prescription prenatal vitamin business, our patient co-pay programs have achieved over 73% utilization in the twelve months ended August 31, 2018 compared to an industry standard of 18%.

- **Consumer Communication** - Once the fundamentals of our commercialization model are established, we will launch consumer communication. Our initial focus will be on those patients who are already predisposed to seek treatment (new to therapy) and those unhappy with their current therapy. Our next focus will be to expand the market by energizing patients who are experiencing bothersome symptoms but who have not been motived to seek treatment. Methods of communication will include online and offline media and span branded and unbranded communication to ensure we drive action from awareness of symptoms to desire to speak to an HCP to acquire a prescription.

Industry and Market

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.

Women’s Healthcare Market

According to the BBC Research report “Pharmaceuticals for Women’s Health: Global markets to 2023,” post-menopausal osteoporosis, pregnancy disorders and management, menopause, endometriosis, and polycystic ovary syndrome (PCOS) are the largest segments within the global market for women’s health therapeutics. The global market for women’s health therapeutics reached nearly $30.5 billion in 2018 and should reach nearly $37.3 billion by 2023, at a compound annual growth rate, or CAGR, of 4.2% for the period of 2018-2023. In addition, the menopause market for women’s health therapeutics reached $5.4 billion in 2018 and should reach $6.7 billion by 2023 at a CAGR of 4.5% through 2023. 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.

Menopause Market

Menopause is the spontaneous and permanent cessation of menstruation, which naturally occurs in most women between the ages of 40 and 58. Hormone therapy is the most effective treatment in the United States and Canada for relief of menopausal symptoms according to the North American Menopause Society, or 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 $5.0 billion on over 30 million prescriptions for the 12 months ended December 31, 2018, of which prescriptions for oral hormone therapy accounted for approximately $2.1 billion in U.S. sales on 20 million prescriptions over the same 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. Several additional studies regarding the benefits and risks of hormone therapy have been conducted over the last decade since the WHI results were first published. 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.

Hormone Therapy Products for Menopause

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 $4.1 billion for the 12 months ended December 31, 2018. 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 for Menopause

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 $4.1 billion, of which $1.9 billion was specifically used for the treatment of VVA, for the 12 months ended December 31, 2018.

Progestin-Only Therapies for Menopause

Progestins include the naturally occurring hormone progesterone and several 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 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 for Menopause

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 $580 million and the sales of estrogens and progesterone on a stand-alone basis were approximately $1.6 million and approximately $746 million, respectively, in the United States for the 12 months ended December 31, 2018. According to national surveys of compounding pharmacists, it is estimated that compounding pharmacies fill $1.3 billion annually in menopausal hormone therapy.

Healthcare and Pharmaceutical Market

According to the EvaluatePharma® World Preview 2018, Outlook to 2024 report, despite the global pharmaceutical industry facing pricing and market access concerns, worldwide prescription drug sales are expected to reach approximately $1.2 trillion by 2024, which would represent a compound annual growth rate of approximately 6.4% between 2018 and 2024. New drug approvals in 2017 increased to 55 (consisting of new molecular entities and biologics), up 104% as compared to the low of 27 approvals in 2016. Following the drop in 2016 approvals, 2017 suggests a return to form in industry research and development productivity. A record of 55 new molecular entities were approved in 2017 with total US sales five years post launch for products approved in 2017 reaching $33.2 billion. There were 56 new drugs (consisting of new molecular entities and biologics) approved by FDA in 2015 and 51 new drugs 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 2017, 2016 and 2015 forecast to be over $33 billion, $13 billion, $28 billion, respectively.

Our Hormone Therapy Drugs

IMVEXXY®

On May 30, 2018, we announced that the FDA had approved the 4 µg and 10 µg doses of IMVEXXY® (estradiol vaginal inserts) for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of VVA, due to menopause. The 4-µg formulation of IMVEXXY® represents the lowest FDA-approved dose of vaginal estradiol available. IMVEXXY® 10-µg became available for commercial distribution in late July 2018 and both doses were commercially available by September 2018.

As part of the FDA's approval of IMVEXXY®, we have committed to conduct a post-approval observational study to evaluate the risk of endometrial cancer in post-menopausal women with a uterus who use a low-dose vaginal estrogen unopposed by a progestogen. The FDA has also asked the sponsors of other vaginal estrogen products to also participate in the observational study. In connection with the observational study, we will be required to provide progress reports to the FDA on an annual basis. The development of this method is underway, and we do not believe that the costs will be material. In addition, the FDA asked for post-approval information with respect to certain characteristics related to the product's specifications, which we submitted to FDA.

IMVEXXY® Commercialization Update

On July 9, 2018, we launched IMVEXXY® 10-µg with our early experience program to a targeted sample of HCPs throughout the U.S. The national launch of the 10-µg dose of IMVEXXY® began in August 2018, and the 4-µg dose of IMVEXXY® launched on September 13, 2018.

Since FDA approval of our NDA for IMVEXXY®, we have been focused on executing our launch plan. The key objectives of our launch plan include: (i) providing broad commercial access at the retail level and with commercial payers, (ii) increasing awareness and appreciation of the clinical and patient features of IMVEXXY® amongst HCPs, (iii) designing and deploying our customer facing model, and (iv) developing our internal capabilities (for example, in the areas of finance, human resources, medical affairs, information technology, data analytics, pharmacovigilance capacity and compliance) to support our commercial-stage company. We have made progress in each of these key strategic areas:

Commercial Access:

- Both the 4-µg and 10-µg doses of IMVEXXY® are broadly available in major pharmacy chains in the U.S., as well as with our BIO-IGNITE™ partners, via our third-party logistics and our distribution partners.

- We have aggressively sought commercial payer coverage as many commercial payers employ “new-to-market blocks” for newly launched brands until the payers make a coverage decision based upon their internal review the product. As we seek to increase the number of lives covered by commercial payers, it is our objective to continue to seek unrestricted coverage that involves affordable access for patients.

- Through December 31, 2018, we achieved unrestricted coverage with 3 of the top 10 commercial payers of VVA products and we continue to sign new agreements with payers to cover IMVEXXY®.

- Beginning at launch, we instituted a patient education and affordability program that allows all eligible patients who enroll to receive IMVEXXY® at an affordable out-of-pocket cost. When a product is not covered, the patient is responsible to pay the full price for the medication, which can significantly limit a patient’s ability to pay and subsequent utilization of the product. With our co-pay assistance program, enrolled patients do not pay more than $35 for a prescription of IMVEXXY®.

Brand Awareness and Adoption:

- In addition to our focus on direct selling from our sales organization, we have executed a branded multichannel awareness campaign for HCPs leveraging digital, non-personal promotion and journal advertising and have already reached most of the active writing HCPs within the VVA category with IMVEXXY® branded messages. The focus of our interactions with HCPs included: (i) introducing IMVEXXY® and highlighting the unmet medical that IMVEXXY® can fulfill for many women, (ii) increasing awareness of the clinical data and patient features of IMVEXXY®, and (iii) familiarizing HCPs with our patient support services for IMVEXXY®. Based on our early sales effectiveness research, more than 90% of HCPs that responded to our surveys indicated that they have prescribed or intend to prescribe IMVEXXY®. As of December 31, 2018, more than 7,000 HCPs had sent an IMVEXXY® prescription to a pharmacy for at least one patient.

Patient Affordability and Adherence Programs:

- We believe the patient affordability and adherence programs that we created and piloted around our prescription prenatal vitamin business have the potential to improve patient compliance for IMVEXXY®, compared to other products in the VVA category. For example, in our prescription prenatal vitamin business, our patient co-pay programs have achieved over 73% utilization in the twelve months ended August 31, 2018 compared to an industry standard of 18%. We launched our patient affordability and adherence program for IMVEXXY® to help patients manage out-of-pocket costs (eligible patients pay no more than $35 per prescription) and improve education regarding VVA and IMVEXXY® with the goal of increasing patient adherence and compliance for an improved treatment experience. As of December 31, 2018, we have seen that 90% of our IMVEXXY® patients have enrolled in the patients saving programs. We expect this level to continue into 2019. We plan to launch print and digital direct-to-consumer marketing for IMVEXXY® in the second half of 2019. As of December 31, 2018, we have approximately 25,000 patients who have received at least one paid prescription filled at a pharmacy.

Customer Model:

- As of December 31, 2018, we had a sales force targeting approximately 150 territories, covering approximately 25,000 HCPs, and deploying a hybrid sales model that combines an internal sales leadership team with a fully dedicated contract sales force to call on our customer universe. Additionally, we have an internal sales team that covers areas of the U.S. where key HCPs are located but where we do not have defined territories and have launched our Key Account Managers (KAMs) to engage with our BIO-IGNITE™ partners.

Infrastructure:

- We continue to develop our internal capabilities and sales force to support the launch of IMVEXXY®. We have launched KAMs to support our BIO-IGNITE™ partners and continue to build our internal capabilities to support both organizations, including compliance professionals and programs and key data support systems that provide real-time data for the sales force and KAMs.

Competition

According to Symphony Health Solutions, the FDA-approved U.S. market for treatment of VVA in menopausal women was approximately $2.0 billion for the 12 months ended December 31, 2018. Approximately $1.7 billion of such sales were by three products currently on the market: PREMARIN® cream (Pfizer), ESTRACE® cream, both brand and generic (Allergan and Mylan) and Vagifem® which is now mostly generic (Yuvafem by Amneal Pharmaceuticals). The two recent launches were Osphena® (Duchesnay USA, Inc**)** and Intrarosa® (Amag Pharmaceuticals), which still have relatively small market share.

BIJUVA™

On October 28, 2018, the FDA approved BIJUVA™ (estradiol and progesterone) capsules, 1 mg/100 mg, the first and only FDA-approved bio-identical hormone therapy combination of estradiol and progesterone in a single, oral capsule for the treatment of moderate-to-severe vasomotor symptoms, or VMS (commonly known as hot flashes or flushes), due to menopause in women with a uterus. The estrogen and progesterone in BIJUVA™ have the same chemical and molecular structure as the hormones that are naturally produced in a woman's body. With the approval of BIJUVA™, the FDA required a post-approval commitment to further develop and validate our in-vitro dissolution method to show how BIJUVA™ is released from the capsule in an in-vitro setting for quality control assessments. The development of this method and validation were completed and submitted to FDA as required in our approval.

We believe the substitutable menopausal hormone therapy market for BIJUVA™ consists of three distinct product categories, two of which are FDA-approved products that are easily measured and monitored, and the third of which is typically referred to as "bio-identicals," which are not FDA-approved, not easily measured, and sold through compounding pharmacies. The first category, representing approximately 2.5 million annual prescriptions as of December 31, 2018, is for FDA-approved synthetic hormone combinations, which have been linked to the risks identified in the WHI, and do not represent our target market. The other two categories consist of bio-identical hormone markets that represent our target market. The second category includes approximately 3.9 million prescriptions of FDA-approved separate bio-identical hormone products, like Estrace® and Prometrium®, as of December 31, 2018. This bio-identical hormone regimen has not been studied or FDA-approved to be used together. Instead, these products are often used off-label to provide patients with an FDA-approved bio-identical hormone regimen but require two separate copays as well as issues related to compliance with separate products. We believe that there is no reason healthcare providers and patients would continue to use this combination of two separate products once BIJUVA™ is available. The third and largest category represents at least 10 million prescriptions annually of the unapproved, compounded bio-identical hormones that have not been proven safe and effective, are not covered by insurance, and are substitutable with BIJUVA™.

The approval of BIJUVA™, based on the phase 3 clinical trials established for the first time, a combination of bio-identical estradiol and bio-identical progesterone used in a continuous combined daily fashion with safety and efficacy data to support FDA-approval. Our hormone therapy drugs are characterized by safety and efficacy profiles that can be consistently manufactured to target specifications. This would provide an alternative to the non-FDA approved compounded bio-identical market. We believe that our drugs 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.

BIJUVA™ is planned to launch early in the second quarter of 2019 with a similar model to IMVEXXY®. The key objectives of our launch plan include: (i) broad commercial access at the retail level and with commercial payers, (ii) increasing awareness and appreciation of the clinical and patient features of BIJUVA™ amongst HCPs, (iii) expanding and leveraging our existing customer facing model, and (iv) leverage our internal capabilities (for example, in the areas of finance, human resources, information technology, data analytics and compliance) to support launch of BIJUVA™.

Our focus will first be on key OB/GYN targets, particularly those that have already adopted IMVEXXY®, to deliver the core clinical messages as well as provide information on our patient affordability and adherence programs. In support of BIJUVA™, our field force is expanding to approximately 200 territories. In addition, we will continue to expand our BIO-IGNITE program throughout 2019 with a fuller expansion towards the end of 2019 when the six-month payer block for BIJUVA™ is expected to lift.

We believe that the successful launch of IMVEXXY® will allow us to leverage existing contracts with our third-party logistics partner and our distribution partners. With regards to payer coverage, we anticipate similar timing as experienced with IMVEXXY® as many commercial payers employ "new-to-market blocks" for newly launched brands until they have the opportunity to make a coverage decision based upon their internal review. However, our ability to leverage existing payer contracts by amending to include BIJUVA™ along with our recent experience with the payers may simplify the process.

Symphony Health Solutions estimates that sales of FDA-approved combinations of estrogen and progestins were approximately $580 million and the sales of estrogens and progesterone on a stand-alone basis were approximately $1.6 million and approximately $746 million, respectively, in the United States for the 12 months ended December 31, 2018. According to national surveys of compounding pharmacists, it is estimated that compounding pharmacies fill $1.3 billion annually in menopausal hormone therapy.

Competition

The largest competitors for BIJUVA™ in the FDA-approved market are Pfizer (PREMPRO®) and Premarin, Teva and Mylan (generic estradiol, generic version of Estrace® oral), and Noven (CombiPatch®), with sales of PREMPRO® constituting the largest branded product. None of the current FDA-approved drugs for the treatment of moderate-to-severe VMS due to menopause are bio-identical 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 addressable 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 BIJUVA™ represents the first time a combination product of estradiol and progesterone that is bio-identical to the estradiol and progesterone produced by the ovaries in a single combined product.

ANNOVERA™

On July 30, 2018, we entered into an exclusive license agreement with the Population Council to commercialize in the U.S. ANNOVERA™ (segesterone acetate/ethinyl estradiol vaginal system), the first and only patient-controlled, procedure-free, reversible prescription contraceptive that can prevent pregnancy for up a full year, which was approved by the FDA on August 10, 2018. ANNOVERA™ was classified by the FDA as a "new chemical entity," or NCE, and thus has five years of regulatory exclusivity under the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act.

ANNOVERA™ is a one-year ring-shaped contraceptive vaginal system, or CVS. ANNOVERA™, which is made with a silicone elastomer, contains segesterone acetate, a 19-nor progesterone derivative also known as Nestorone®, or NES, and ethinyl estradiol, or EE. EE is an approved active ingredient in many marketed hormonal products. Segesterone acetate, a new chemical entity, is a potent progestin that is not active orally but is active when administered via non-oral routes such as vaginal rings, implants, and transdermal systems. NES has been evaluated in 51 clinical studies across these delivery systems with more than 26,794 cycles of exposure.

ANNOVERA™ can be inserted and removed by the woman herself without the aid of a healthcare provider and, unlike oral contraceptives, or OCs, ANNOVERA™ does not require daily administration to obtain the contraceptive effect. After 21 days of use, the woman removes ANNOVERA™ for 7 days, thereby providing a regular bleeding pattern (i.e., withdrawal/scheduled bleeding). The same CVS is then re-inserted for additional 21/7-days in/out, for up to a total of 13 cycles (1 year).

ANNOVERA™ releases daily vaginal doses of both active ingredients (NES and EE). The claimed release rate of 150 µg/day NES and 13/day µg EE is supported by the calculated average release rate from an ex vivo analysis of ANNOVERA™ used for 13 cycles and is also supported by data from 13 cycles of in vitro release.

We currently estimate that ANNOVERA™ will be commercially available as early as the third quarter of 2019 with a planned full commercial launch by the first quarter of 2020. We intend to leverage our existing infrastructure, including our sales force, to commercialize ANNOVERA™, together with our recently approved IMVEXXY® and BIJUVA™. ANNOVERA™ will also follow the same commercialization model as IMVEXXY® and BIJUVA™.

Contraception market

Contraception can be defined as the deliberate prevention of pregnancy by interfering with normal process of ovulation, fertilization and implantation through the use of barriers, drugs, medical devices, or surgical techniques. Contraceptive market includes non-hormonal barrier methods, such as the non-hormonal IUD, contraceptive sponge, diaphragm, cervical cap or shield and condoms, and hormonal methods such as oral contraceptives, injections, implants, hormonal IUDs and vaginal ring and transdermal contraceptive products. Contraceptive drugs include pills, topical, and injectables. Hormonal contraceptives can be composed of synthetic estrogens and progestins. Contraceptives containing both estrogen and a progestin are referred to as combination hormonal contraceptives, or CHCs, and contraceptives containing only progestin are referred to as progestin-only, or P-only. There are three synthetic estrogens approved in the United States for use in contraceptive products: EE, mestranol, or ME, and estradiol valerate, or EV. EE has been available for over 40 years and is the estrogen component in nearly all CHCs today. There are 10 different progestins that have been used in contraceptives sold in the United States. The progestin component provides most of the contraceptive effect, while the estrogen component primarily provides cycle control, for example, minimizing bleeding or spotting between cycles. The progestin exerts its contraceptive effect by inhibiting ovulation, or release of an egg from the ovary, and by thickening cervical mucus. Thickening cervical mucus helps to prevent sperm entry into the upper genital tract. The estrogen component, in addition to providing cycle control, makes a small contribution to contraception by decreasing the maturation of the egg in the ovary. The latest data from 2015 to 2017 from the Centers for Disease Control, or CDC, indicate that approximately 65% of women aged 15 to 49 were using some type of contraceptive method. Most women who were not using contraception had reasons for not doing so, such as seeking pregnancy, being pregnant or postpartum, or not being sexually active.

According to Grand View Research: “Contraceptives Market Analysis By Drug (Oral Contraceptive Pills, Injectables, Topical), By Device (Male, Female Condoms, Copper, Hormonal IUD, Vaginal Rings, Subdermal Implants) And Segment Forecasts To 2022,” male and female condoms, vaginal implants, subdermal implants, diaphragms, sponges, and intrauterine devices, or IUDs, are key devices and accounted for the largest share of the contraceptives market in terms of revenue. The IUD segment held one of the largest shares of the contraceptive devices in 2014, owing to the rising demand in the regions of Europe and Asia Pacific. A rising number of gynecologists opting for these contraception devices is expected to drive this segment over the forecast period. Contraceptive pills dominated the overall drugs market in 2014 in terms of revenue, owing to a significantly large consumer base, very high usage and government programs and initiatives to address the unmet needs of the women of the reproductive age. TherapeuticsMD now has presence in both the early and late reproductive years with our portfolio.

The U.S. contraceptive market size is expected to reach at $11.6 billion by 2025 expanding at a CAGR of 5.3% over the forecast period, according to Grand View Research, Inc. Increasing awareness about LARC is expected to augment the product demand, thereby driving the market over the next few years. According to the National Center for Health and Statistics, the use of LARCs in the U.S. has increased nearly five-fold in the last decade among women aged 15 to 44 and, we believe, that this segment of the contraceptive market is attractive given its current growth trajectory. We believe that the increasing awareness about long-acting reversible contraceptive options will grow incremental product demand, thereby driving market growth over the coming years. This is currently led by IUDs. The market leader in the IUD market is Bayer with the following products: Mirena®, Kyleena®, Jaydess® and Skyla®. The remainder of the market is dominated by oral contraceptives, which is represented by one major brand, Lo Loestrin® Fe by Allergan, and a variety of generics led by generic manufacturers such as Teva Pharmaceuticals and Lupin Pharma.

Contraception Competition

The industry for contraceptive products is characterized by intense competition and strong promotion of proprietary products. While we believe that ANNOVERA™ provides us with a competitive advantage, we may face potential competition from many different sources, including large pharmaceutical companies, specialty pharmaceutical and generic drug companies, and medical device companies. We expect that primary competition for ANNOVERA™ will come from oral contraceptives, a vaginal ring contraceptive and LARCs. The vaginal ring contraceptive is represented by NuvaRing, (etonogestrel/ethinyl estradiol vaginal ring), a monthly contraceptive ring marketed by Merck. LARC methods include two types of contraceptives: IUDs and subcutaneous hormone-releasing implants. It has been reported that newer LARC products have recently gained in popularity, potentially due to their lower rates of side effects, greater effectiveness, and broader acceptability among different populations of women.

For patients, we believe that ANNOVERA™ provides a single long-acting reversible birth control product that would not require a procedure for insertion at a doctor’s office, empowering women to be in complete control of their fertility and menstruation with a 21/7 regime. We anticipate that ANNOVERA™ is acceptable for nulliparous women, or women who have never given birth. Further, ANNOVERA™ is softer and more pliable than NuvaRing and, unlike NuvaRing, does not require refrigeration before being prescribed. NuvaRing generated approximately $564 million, $576 million and $515 million in net sales in 2017, 2016 and 2015, respectively, based on approximately 4.3 million, 4.5 million and 4.4 million prescriptions, respectively. We believe that ANNOVERA™ will have significant competitive advantages to NuvaRing and anticipated generic versions of NuvaRing, including the ability to fill a one-year prescription in one pharmacy visit and the lack of a requirement to refrigerate the ring.

ANNOVERA™ Commercialization Strategy

We believe that our existing sales territories cover a majority of the area where the leading monthly contraceptive ring prescribers are located. Our existing HCP targets represent approximately 87% of the current prescription volume of the leading monthly contraceptive ring. We believe, this will allow us to have strong coverage of target HCPs while using our existing sales force to commercialize ANNOVERA™. We intend to add a dedicated marketing team exclusively focused on ANNOVERA™ and believe that much of the marketing plan will focus in the digital space given the target patient demographics.

We believe that the unique characteristics of ANNOVERA™ will assist us in pursuing favorable commercial payer coverage, including only one pharmacy fill fee per year and no office visit or procedure fees. However, obtaining and maintaining favorable reimbursement can be a time-consuming and expensive process, and there is no guarantee that we will be able to negotiate or continue to negotiate reimbursement or pricing terms for our products, including ANNOVERA™, with payers at profitable levels.

In addition, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010, or the ACA, mandates that private health plans provide coverage for women's preventative services, without imposing patient cost-sharing requirements, as recommended by the Health Resources and Services Administration, or HRSA. HRSA Guidelines require private health plans to cover, without cost-sharing, at least one form of contraception, or product, in each of the methods, or classes, identified by the FDA for women in its Birth Control Guide, which currently includes 18 separate classes. For classes with more than one type of treatment, private payers need only provide no-cost coverage for one product in each class and may use reasonable medical management to determine whether and to what extent to cover other products in the class. We believe, that given no other vaginal contraceptive product offers contraceptive benefits for an entire year that it is possible that FDA could determine that ANNOVERA™ constitutes a new class of contraceptive, which could allow for coverage of ANNOVERA™ by private health plans with no out-of-pocket cost for patients. However, it is possible that other FDA-approved products could also be included in such a new class. To the extent ANNOVERA™ is not the only FDA-approved product in a designated class of contraception, private payers may choose not to cover ANNOVERA™ or may require patient cost-sharing obligations.

As part of the Population Council License Agreement, we have agreed to provide significantly reduced pricing to federally designated Title X family planning clinics serving underrepresented women.

The Population Council has previously entered into a supply agreement with Crystal Pharma SAU for the supply of Nestorone®, one of the active pharmaceutical ingredients for ANNOVERA™, and a letter agreement with QPharma AB for the optimization of the commercial manufacturing process for ANNOVERA™. We intend to enter into agreements Crystal Pharma SAU for the supply of Nestorone® and the Population Council has agreed to use commercially reasonable efforts to assist us in doing so. However, Crystal Pharma could decline to enter into similar agreements with us on the terms we anticipate, or at all. We entered into a manufacturing agreement with QPharma for the manufacturing of ANNOVERA™, with an effective date of September 28, 2018.

License Agreement with the Population Council

Under the terms of the Population Council License Agreement, we paid the Population Council a milestone payment of $20 million within 30 days following approval by the FDA of the NDA for ANNOVERA™ and will be required to pay the Population Council an additional $20 million within 30 days following the release of the first commercial batch of ANNOVERA™. The Population Council is also eligible to receive milestone payments and royalties from commercial sales of ANNOVERA™, as detailed below.

We assumed responsibility for marketing expenses related to the commercialization of ANNOVERA™.

We are required to pay the Population Council milestone payments of $40 million upon cumulative net sales of ANNOVERA™ in the U.S. by us and our affiliates and permitted sublicensees of each of $200.0 million, $400.0 million and $1.0 billion.

In addition, we are required to pay the Population Council, on a quarterly basis, step-based royalty payments based on annual net sales of ANNOVERA™ in the U.S. by us and our affiliates and permitted sublicensees as follows:

Annual Net Sales	Royalty Rate
Less than or equal to $50.0 million	5%
Greater than $50.0 million and less than or equal to $150.0 million	10%
Greater than $150.0 million	15%

The annual royalty rate will be reduced to 50% of the initial rate during the six-month period beginning on the date of the first arms-length commercial sale of a generic equivalent of ANNOVERA™ that is launched by a third party in the U.S., and thereafter will be reduced to 20% of the initial rate.

As part of the approval of ANNOVERA™, the FDA has required a post-approval observational study be performed to measure the risk of venous thromboembolism. A protocol submission for the study is due to the FDA in August 2019. We have agreed to perform and pay the costs and expenses associated with this post-approval study, provided that if the costs and expenses associated with such post-approval study exceed $20 million, half of such excess will be offset against royalties or other payments owed by us to the Population Council under the Population Council License Agreement. Given the observational nature of the study, we do not believe that the costs of the study will be material on an annual basis.

Unless earlier terminated, the Population Council License Agreement will remain in effect until the later of the expiration of the last-to-expire of the Population Council's U.S. patents that are licensed to us, or the date following such expiration that follows a continuous period of six months during which we and our affiliates have not made a commercial sale of ANNOVERA™ in the U.S. The Population Council License Agreement may also be terminated for certain breach and bankruptcy-related events and by us on 180 days prior notice to the Population Council.

As part of the Population Council License Agreement, we have the exclusive right to negotiate co-development and U.S. marketing rights for two other investigational vaginal contraceptive systems in development by the Population Council: a three-month contraceptive ring using Nestorone® plus bio-identical estradiol, which is currently in phase 2 clinical trials, and a new one-year contraceptive ring using Nestorone® plus EE, which is designed as a life cycle management product for the CVS that we have licensed.

License Agreement with Knight Therapeutics Inc.

On July 30, 2018, we entered into a license and supply agreement, or the Knight License Agreement, with Knight pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY® and BIJUVA™ in Canada and Israel.

Under the Knight License Agreement, Knight will pay us milestone fees when it receives regulatory approval in Canada for: (i) IMVEXXY®; and (ii) BIJUVA™. Additional milestone fees and royalties are based upon certain aggregate annual sales in Canada and Israel for both IMVEXXY® and BIJUVA™. Knight will be responsible for all regulatory and commercial activities in Canada and Israel related to IMVEXXY® and BIJUVA™.

We may terminate the Knight License Agreement if Knight does not submit all regulatory applications, submissions or registrations required for regulatory approval to use and commercialize IMVEXXY® and BIJUVA™ in Canada within certain specified time periods. Either party may terminate the Knight License Agreement for any material breach by the other party that is not cured within certain specified time periods or if the other party files for bankruptcy or other related matters.

Our Prenatal Vitamin Products

As we commercialize our recently approved hormone therapy drugs, 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. 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 payers with a lower wholesale acquisition cost alternative for prenatal vitamins. 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.

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 vitamin product line is as follows:

- *vitaTrue™*
- *vitaPearl™*
- *vitaMedMD One Rx Prenatal Multivitamin*
- *vitaMedMD RediChew® Rx Prenatal Multivitamin*
- *BocaGreenMD Prena1 True*
- *BocaGreenMD Prena1 Pearl*
- *BocaGreenMD Prena1 Chew*

For the years ended December 31, 2018, 2017, and 2016, approximately 93%, 99.9%, and 99.8%, respectively, of our consolidated revenue was generated by our prenatal vitamin products.

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.

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, 2018, approximately 5.4 million prescriptions for prenatal vitamins were issued in the United States resulting in total sales of approximately $338 million.

Pipeline for Our Hormone Therapy Drug Candidates

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 bio-identical 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 to update the phase 3 protocol based on discussions with the FDA. Our IND related to TX-002HR is currently inactive. 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 suspended further development of this drug candidate to prioritize our leading drugs.

TX-003HR

TX-003HR is a natural estradiol formulation. This hormone therapy drug candidate is bio-identical 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. We have suspended further development of this drug candidate to prioritize our leading drugs.

Preclinical Development

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-00THR and TX-0008HR, 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 dosed with a placebo, subcutaneous injections of progesterone, or a dose of TX-005HR topical progesterone cream. The results, presented at 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. In 2018, we investigated the capability of the estradiol and progesterone in TX-006HR to penetrate human skin. This experiment used donated skin from a postmenopausal woman and showed significant penetration of both active ingredients. We may in the future engage with a financing partner to advance our topical cream and transdermal patch projects. We have also developed and patented novel, oral formulations of progesterone that have shown improved bioavailability in animals. In the fourth quarter of 2018, we submitted an IND for TX-009HR, an estradiol and progesterone containing oral formulation. In addition to menopausal treatments, we are also evaluating various other indications for our hormone technology, including contraception.

Sales Concentration

We sell our prescription prenatal vitamin products and hormone therapy drug products to wholesale distributors and retail pharmacy distributors. See Note 12 to the consolidated financial statements included in this Annual Report for a discussion of the concentration of sales of our products.

Seasonality

The pharmaceutical markets in which we compete are not subject to seasonal sales fluctuation. However, our net revenues for the first quarter of each year can be negatively affected by the annual reset of high-deductible commercial insurance plans.

Manufacturing of Our Products

We have sourced and qualified third-party contract manufacturing organizations, or CMOs, for the commercial supply of our products. 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 IMVEXXY® and BIJUVA™, and QPharma for the supply of ANNOVERA™. Under the terms of the agreements, we are obligated to purchase certain minimum annual amounts of each product. We may terminate the agreement for a particular drug for certain specified reasons. If we are unable to obtain sufficient quantities of drugs 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.

We have a multi-faceted risk management approach to ensure continuous supply from our qualified CMOs for the commercial supply of our 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 drugs and drug candidates. 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 all 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 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. 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 IMVEXXY® and BIJUVA™. In 2018, the Catalent facility that manufactures IMVEXXY® and BIJUVA™ received FDA Form 483 observations from an FDA inspection. For our vitaTrue product, a subcontractor to Lang received FDA Form 483 observations from an FDA inspection during 2018. Neither of these investigations were specific to our products. We have contracted with QPharma to manufacture the commercial supply for ANNOVERA™. Although QPharma 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.

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

We distribute our products through our third-party logistics partner, Cardinal Logistics who ship to national wholesaler distributors such as Cardinal, McKesson, and AmerisourceBergen, regional wholesalers such as Smith Drug, Anda, Value Drug and RDC and alternate distribution partners. 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 HCPs, 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.

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 before 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 products; and
- help HCPs and payers by delivering information on patient compliance and satisfaction.

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

Research and Development

Our product development programs are concentrated in advanced hormone therapy pharmaceutical products. We engage in programs to provide alternatives to the FDA and non-FDA-approved compounded bio-identical 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.

Our research and development expenses were approximately $27.3 million in 2018, $33.9 million in 2017, and $53.9 million in 2016.

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 way 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.

As of December 31, 2018, we had 21 issued domestic or U.S. patents and 24 issued foreign patents, including:

- 11 domestic patents and five foreign patents that relate to BIJUVA™ as well as three domestic patents that relate to non-approved doses of BIJUVA™. These patents establish an important intellectual property foundation for BIJUVA™ and are owned by us. The domestic patents will expire in 2032. The foreign patents will expire no earlier than 2032. In addition, we have pending patent applications relating to BIJUVA™ in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;

- Three foreign patents that relate to our progesterone-only candidate, which are owned by us. The foreign patents will expire no earlier than 2033. In addition, we have pending patent applications with respect to our progesterone-only candidate in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;

- Three domestic patents (two utility and one design) and 12 foreign patents (three utility and nine design) that relate to IMVEXXY®. These patents establish an important intellectual property foundation for IMVEXXY® and are owned by us. The domestic patents will expire in 2032 or 2033. The foreign utility patents will expire no earlier than 2033. The foreign design patents provide protection expiring no earlier than 2025. In certain jurisdictions, the foreign design patents provide protection through at least 2037. In addition, we have pending patent applications related to IMVEXXY® in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, New Zealand, Russia, South Africa, and South Korea;

- One domestic utility patent that relates to our topical-cream candidates, which is owned by us. The domestic patent will expire in 2035. We have pending patent applications with respect to our topical-cream candidates in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;

- One domestic utility patent and four foreign patents that relate to our transdermal-patch candidates, which are owned by us. The domestic utility patent will expire in 2032. The foreign patents will expire no earlier than 2033. We have pending patent applications with respect to our transdermal-patch candidates in the U.S., Australia, Brazil, Canada, Europe, Mexico, Japan, and South Africa;

- One domestic utility patent that relates to our OPERA® information-technology platform, which is owned by us and will expire in 2029; and

- One domestic utility patent that relates to TX-009HR, a progesterone and estradiol product candidate, which is owned by us and will expire in 2037. We have pending patent applications with respect to TX-009HR in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, New Zealand, Russia, South Africa, and South Korea.

As of December 31, 2018, we had filed over 107 patent applications with the U.S. Patent and Trademark Office, or the USPTO, with respect to our technology or our hormone-therapy drugs and drug candidates, and over 162 international patent applications with respect to our technology or our hormone-therapy drugs and 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 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 six INDs for our hormone therapy drug candidates, including an IND for TX-009HR in 2018. The INDs for TX-002HR and TX-003HR are currently on inactive status. The INDs for TX-004HR, TX-001HR, TX-006HR, and TX-009HR 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 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 10 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.

Since regulatory approval of some of our drug products has been obtained, we are required to comply with several post-approval requirements. As a holder of an approved NDA, we are 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 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 BIJUVA™ and IMVEXXY® hormone therapy drug products, was issued a Form FDA-483 in 2018 with respect to its softgel manufacturing plant. The observations and associated corrective actions identified in Catalent's response to the Form FDA 483 do not relate specifically to our products. The current status of that Form FDA 483 is No Action Indicated. No Action Indicated status indicates that the FDA is satisfied with Catalent's responses and proposed corrective measures to the observations and that no further regulatory action is needed following Catalent's responses.

After regulatory approval of a drug product is obtained, we would be required to comply with several 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.

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 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 to produce clinical and commercial quantities of our drugs and 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 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 drugs and 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 Drug Quality and Security Act of 2013, 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.

New Drug Applications

We received marketing approval for three NDAs in 2018, two for our hormone therapy drug products, IMVEXXY® and BIJUVA™, and one for our in-licensed contraceptive drug ANNOVERA™. Where permitted, patents for our hormone therapy drug products have been submitted to the Orange Book.

Regulatory Exclusivity

A Section 505(b) NDA applicant may be eligible for its own regulatory exclusivity period, such as a five-year or three-year exclusivity. The first approved Section 505(b) NDA applicant for a drug containing a new chemical entity, or NCE, is entitled to a five-year Hatch-Waxman exclusivity period. During this period, an ANDA or 505(b)(2) application cannot be submitted to FDA until the end of the five-year exclusivity period (or at year four if the product is covered by an Orange Book listed patent). Additional exclusivities may also apply.

The first approved Section 505(b) 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 ANDA or 505(b)(2) 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) 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 FDA's approval of ANDA applications further.

Dietary Supplement Regulation

Our currently marketed prenatal vitamins 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 before 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. Healthcare Laws and Compliance Requirements

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

- The federal healthcare 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 healthcare 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 healthcare 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 healthcare 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 healthcare items or services reimbursed by non-governmental third-party payers, 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 healthcare 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 healthcare 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 payer 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 healthcare 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 several 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, 2018, we had 241 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 VitaMedMD were exchanged for shares of our common stock, (2) all outstanding VitaMedMD options and warrants were exchanged and converted into options and warrants to purchase shares of our common stock, and (3) VitaMedMD became our wholly owned subsidiary. As of December 31, 2011, we determined that VitaMedMD 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 a corporate website at *www.therapeuticsmd.com* as well as various product websites. 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, other filings required by the SEC, and all amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. These reports may also be obtained directly from the SEC's website at *www.sec.gov*.

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 and our other filings with the SEC, 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 $133 million, $77 million, and $90 million for the years ended December 31, 2018, 2017, and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of approximately $519 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 because 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 drugs. 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 2018, we derived most of our revenue from sales of women's health care products, including hormone therapy drugs, prenatal and women's multi-vitamins and iron supplements. Sales of products varied from 2010 through 2018. 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 several risks and uncertainties, including the following:

- the presence of new or existing competing products, including generic copies of our hormone therapy drugs and 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 products does not 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 drugs or commence or continue clinical trials to seek approval for any other products we may choose to develop in the future.

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 commercialization of IMVEXXY®, BIJUVA™ and ANNOVERA™ and the clinical development and commercialization of future 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 may attempt to raise additional capital from the issuance of equity securities, collaborations with third parties, licensing of rights to our products, the issuance of debt securities and the incurrence of debt, to the extent permitted under the Credit Agreement, dated May 1, 2018, as amended, by and among us and our subsidiaries party thereto from time to time, each as a borrower, MidCap Financial Trust, as an agent and as lender, and the additional lenders party thereto from time to time, or the Credit Agreement, 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 management's attention away from our day-to-day activities, which may adversely affect our ability to conduct our day-to-day operations.

We cannot guarantee that future debt or equity 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 commercialization and product development efforts;
- seek collaborators for our hormone therapy drug products and candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be the case; or
- license, potentially on unfavorable terms, our rights to our hormone therapy drug products and candidates that we otherwise would seek to develop or commercialize ourselves.

The Credit Agreement does, and any agreements governing future debt financing, if available, may, 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 are subject to extensive and costly government regulation.

The products we currently market, including IMVEXXY® and our prenatal vitamins, the products that we are currently commercializing, including BIJUVA™ and ANNOVERA™, 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.

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, or AKS, 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, Medicaid, TriCare, and Children's Health Insurance Program. Liability may be established without proving actual knowledge of the statute or specific intent to violate it. In addition, federal law provides that the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA, described below. Violations of the AKS carry potentially significant civil and criminal penalties, including imprisonment, fines, administrative civil monetary penalties, and exclusion from participation in government health care programs.

- 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, or FCA, 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. The FCA prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items, or services. Government enforcement agencies and private whistleblowers have asserted liability under the FCA for, among other things, claims for items or services not provided as claimed, with inaccurate coding or for medically unnecessary items or services, kickbacks, promotion of off-label uses, and misreporting of drug prices to federal agencies.

- Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, or collectively, HIPAA, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program, including private payers, or falsifying, concealing, or covering up a material fact, or making any materially false statements in connection with the delivery of or payment for health care benefits, items, or services. HIPAA also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information. State laws may also govern the privacy and security of health information or other personal information in certain circumstances.

- Federal laws require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government health care programs.

- The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, imposes annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under certain government health care programs for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Numerous state laws may also require disclosure of transfers of value to health care providers, pharmaceutical pricing information and marketing expenditures.

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to interactions between pharmaceutical manufacturers and health care providers, sales or marketing arrangements, and claims involving health care items or services reimbursed by commercial third-party payers, including private health care insurers and health maintenance organizations; further, 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.

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. Many state laws differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts. Moreover, the number and complexity of both federal and state laws continues to increase, and additional governmental resources are being used to enforce these laws and to prosecute companies and individuals who are believed to be violating them. In particular, the ACA includes a number of provisions aimed at strengthening the government's ability to pursue AKS and FCA cases against pharmaceutical manufacturers and other health care entities, including substantially increased funding for health care fraud enforcement activities, enhanced investigative powers, and amendments to the FCA that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim violations. We anticipate that government scrutiny of pharmaceutical sales and marketing practices will continue for the foreseeable future and subject us to the risk of government investigations and enforcement actions. For example, federal enforcement agencies recently have shown interest in pharmaceutical companies' product and patient assistance programs, including manufacturer reimbursement support services and relationships with specialty pharmacies. Some of these investigations have resulted in significant civil and criminal settlements.

Efforts to ensure that our operations, including our business arrangements with third parties, comply with applicable health care laws and regulations could be costly. In connection with the commercial launch of IMVEXXY®, we have grown our compliance program and are in the process of developing a program based on industry best practices and tailored to evolving risks as we launch additional products, identify new distribution channels and target new customer types. As this program has not yet been tested and the requirements in this area are constantly evolving, our program may not eliminate all areas of potential exposure. Although effective compliance programs can help mitigate the risk of investigation, regulatory and enforcement actions, and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state fraud, privacy, security, and reporting laws may prove 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 government health care programs, 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 health care programs. 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, even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, and could result in related shareholder suits, any of which could also have an adverse effect on our business, financial condition and results of operations.

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 the Dietary Supplement Health and Education Act of 1994, 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 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.

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 IMVEXXY®, BIJUVA™ and ANNOVERA™, and our hormone therapy drug candidates or prescription vitamins, will depend on coverage and reimbursement policies and may be affected by health care reform measures. Government health care programs and third-party payers decide which prescription drug products they will pay for and establish reimbursement levels. Payers generally do not cover OTC products, and coverage for prescription vitamins and dietary supplements varies. Many private third-party payers, such as managed care plans, manage access to drug products' coverage partly to control costs to their plans, and may use drug formularies and medical policies to limit their exposure. Factors considered by these payers include product efficacy, cost effectiveness, and safety, as well as the availability of other treatments including generic prescription drugs. Our ability to commercialize IMVEXXY®, BIJUVA™ and ANNOVERA™ successfully depends on coverage and reimbursement levels set by government health care programs and third-party private payers. Obtaining and maintaining favorable reimbursement can be a time-consuming and expensive process, and we may not be able to negotiate or continue to negotiate reimbursement or pricing terms for our products with payers at levels that are profitable to us, or at all.

In both the United States and some foreign jurisdictions, there have been several 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 Medicare Part A and Part B—through which Medicare provides coverage for certain drugs in certain circumstances—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. Because 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 IMVEXXY®, BIJUVA™ and ANNOVERA™, and could significantly harm our business. It was historically unclear whether products approved to treat moderate-to-severe dyspareunia, a symptom of vulvar and vaginal atrophy due to menopause, such as IMVEXXY®, were excluded under Medicare Part D, which resulted in limited Medicare coverage for such products. Recent clarification issued by CMS in May 2018 indicated that drugs, such as IMVEXXY®, that are approved for the treatment of moderate-to-severe dyspareunia (as well as drugs approved for the treatment of moderate-to-severe symptoms of vulvar and vaginal atrophy associated with menopause) are not excluded from Medicare Part D coverage. CMS's clarification, however, is no guarantee that such coverage will be obtained for IMVEXXY®, and obtaining Medicare or other government health care program reimbursement for any new drug products may take up to several years following FDA approval. While the MMA applies only to drug benefits for Medicare beneficiaries, third-party payers 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 third-party payers.

Our ability to commercialize ANNOVERA™ depends on coverage and reimbursement levels set by government health care programs and third-party private payers. The ACA mandates that private health plans provide coverage for women's preventative services, without imposing patient cost-sharing requirements, as recommended by HRSA. HRSA Guidelines require private health plans to cover, with no patient out-of-pocket costs, at least one form of treatment (e.g., one product) in each of the methods (e.g., classes of contraception) identified by the FDA for women in its Birth Control Guide. To the extent ANNOVERA™ is deemed a new class of contraception by the FDA, such a designation could allow for coverage by private health plans with no patient out-of-pocket costs. However, there is no guarantee that such coverage will be obtained, and it is possible that other FDA-approved products could also be included in this new class. Pursuant to HRSA Guidelines, private payers need only provide no-cost coverage for one product in each class, and may use reasonable medical management to determine whether and to what extent to cover other products in the class. To the extent ANNOVERA™ is not the only FDA-approved product in a designated class of contraception, private payers may choose not to cover our one-year vaginal contraceptive system, or may require patient cost-sharing obligations.

To the extent we obtain coverage for our products by state Medicaid programs, we may be required to pay a rebate to each state Medicaid program for any covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program, and to comply with all Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Healthcare Act of 1992. Moreover, federal law requires that any company participating in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B Program, which impose additional requirements. In addition, if our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration or to low income patients of certain hospitals, additional laws and requirements may apply.

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, the scrutiny of pharmaceutical pricing, the ongoing debates on reducing government spending and additional legislative proposals. As discussed more below, the goal of the ACA, as enacted in 2010, was to reduce the cost of health care and substantially change the way health care is financed by both government health care programs and third-party payers. Among other measures, the ACA increased rebates on manufacturers for certain covered drug products reimbursed by state Medicaid programs. While we cannot predict the full effect that the ACA will have on government health care programs' 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.

The availability of generic products at lower prices than branded products may substantially reduce the likelihood of reimbursement for branded products, such as IMVEXXY®, BIJUVA™ and ANNOVERA™.

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.

Future legislation or regulations may adversely affect reimbursement from government health care programs and third-party payers.

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 reduction, triggering the legislation's automatic reduction of several government programs. This includes aggregate reductions to Medicare payments to health care 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 health care providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Under the Trump administration, there have been ongoing efforts to modify or repeal all or certain provisions of the ACA. 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 also unclear what programs, if any, Congress might enact to replace the repealed portions of the ACA. The Trump administration may also take executive action in the absence of legislative action. For example, in October 2017, the President announced that the administration will withhold the cost-sharing subsidies paid to health insurance exchange plans serving low-income enrollees. With respect to IMVEXXY®, BIJUVA™ and ANNOVERA™, and to the extent we ever obtain regulatory approval and commercialization of our other drug candidates, these new laws and policies (as well as proposed legislation, if enacted) may result in additional reductions in Medicare and other health care 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 our drug products and drug candidates may be.

There have also been efforts by government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation. Recently, there has been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals; proposed and enacted legislation generally have focused on increasing transparency around drug costs or limiting drug prices, including drug rebates. For example, in 2017, California enacted a new law, which went into effect on January 1, 2018, to facilitate greater transparency in brand-name and generic drug pricing through the implementation of specific price reporting requirements for pharmaceutical manufacturers. If adequate reimbursement levels are not maintained by government and third-party payers for our products, our ability to sell our products may be limited and/or our ability to establish acceptable pricing levels may be impaired, thereby reducing anticipated revenues and profitability.

Further, if a federal government shutdown were to occur for a prolonged period, federal government payment obligations, including its obligations under Medicaid and Medicare, may be delayed. Similarly, if state government shutdowns were to occur, state payment obligations may be delayed. If the federal or state governments fail to make payments under these programs on a timely basis, our ability to sell our products to government payers may be limited and/or our ability to establish acceptable pricing levels may be impaired, thereby reducing anticipated revenues and profitability.

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 currently plan to build or acquire, the infrastructure or capability to internally manufacture our existing women's health care products, IMVEXXY®, BIJUVA™, or ANNOVERA™, 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 IMVEXXY® and BIJUVA™. Under the terms of the agreements, we are 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 such product. We have also entered into a long-term supply contract with QPharma for ANNOVERA™. Under the terms of the QPharma agreement, we are obligated to purchase certain minimum annual amounts of ANNOVERA™. 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. We intend to enter into agreements with Crystal Pharma SAU for the commercial supply of one of the active pharmaceutical ingredients for ANNOVERA™. However, if we experience delays in finalizing this agreement or are unable to execute this agreement on commercially reasonable terms, we may need to find alternative manufacturing facilities, which would result in disruption in our commercialization of ANNOVERA™.

Regulatory requirements could pose barriers to the manufacture of our existing women's health care products and our hormone therapy drug product and drug candidates. Holders of NDAs, or other forms of FDA approvals or clearances, or those distributing a regulated product under their own name, are ultimately responsible for compliance with manufacturing obligations even if the manufacturing is conducted by a third-party contract manufacturing organization, or CMO. All of our existing products are 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 manufactures IMVEXXY® and BIJUVA™ has previously been inspected by the FDA and received Form 483 observations with respect to its softgel manufacturing plant that is used for the manufacture of the commercial supply of IMVEXXY® and BIJUVA™. QPharma, the CMO that will manufacture ANNOVERA™, has previously been inspected by the FDA and received Form 483 observations on December 15, 2017, with respect to its facility that will be used for the commercial supply of ANNOVERA™.

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, our regulatory submissions may be delayed or disapproved, and our marketed products may be affected. If these facilities are not in compliance for the manufacture of our vitamin products, our hormone therapy drug product and our 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 or other applicable requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, violation letters, 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. We do not currently have alternative manufacturers, and we may not be able to enter into a long-term agreement with alternative manufacturers, or do so on commercially reasonable terms, which could have a material adverse impact on our business. 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 to the delay or other detriment of 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 active pharmaceutical ingredient, or API, used in IMVEXXY®, BIJUVA™ and ANNOVERA™. If any supplier of the API or other products used in our approved products or 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 approved products or hormone therapy drug candidates, which could impair our ability to supply our approved products or hormone therapy drug candidates at the levels required for commercialization and prevent or delay their successful commercialization.

Even after the approval of IMVEXXY®, BIJUVA™ and ANNOVERA™, and even if we obtain regulatory approval for our other hormone therapy drug candidates, we will still face extensive, ongoing regulatory requirements and review, and our products may face future development and regulatory difficulties.

With respect to IMVEXXY®, BIJUVA™ and ANNOVERA™, 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 IMVEXXY®, BIJUVA™ and ANNOVERA™ contains restrictions on use and warnings. The Food and Drug Administration Amendments Act of 2007, or FDAAA, gives the FDA enhanced post-market authority, including the Risk Evaluation and Mitigation Strategy, explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information, and compliance with FDA-approved REMS programs. IMVEXXY®, BIJUVA™ and ANNOVERA™ 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. As part of the FDA's approval of IMVEXXY®, we have committed to conduct a post-approval observational study to evaluate the risk of endometrial cancer in post-menopausal women with a uterus who use a low-dose vaginal estrogen unopposed by a progestogen such as IMVEXXY®. As part of the FDA's approval of ANNOVERA™, the FDA has required a post-approval observational study be performed to measure the risk of venous thromboembolism. 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 certain clinical trial results on a publicly available database.

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 and other regulatory requirements, such as adverse event reporting. If we or a regulatory agency discovers 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, and are subject to review by FDA. If the FDA raises concerns regarding our promotional materials or messages, we may be required to modify or discontinue using them and may be required to provide corrective information. Should we fail to comply with these requirements, we may be subject to significant liability including civil and administrative actions as well as criminal sanctions. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act and its implementing regulations.

Our activities are also potentially subject to federal and state consumer protection and unfair competition laws. If we or our third-party suppliers 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.

Recent government enforcement has targeted pharmaceutical companies for violations of fraud, abuse and other laws.

The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, pharmacies, and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical products, including certain discounts, or engagement of speakers or consultants, may be subject to scrutiny if they do not fit squarely within an exemption or safe harbor. Further, the Trumps administration has taken steps to limit applicability of some of these safe harbors, including those related to discounts and rebates, in regulations proposed in February 2019. Our practices with respect to interactions with health care professionals, including but not limited to consultant relationships, speaker programs, advisory boards, and scientific/educational grant programs, as well as our arrangements with pharmacies, may not in all cases meet all of the criteria for safe harbor protection from AKS liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient assistance programs. In addition, several states have recently enacted legislation requiring pharmaceutical companies to establish marketing and promotional compliance programs or codes of conduct and/or to file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Several states have also adopted laws that prohibit certain marketing-related activities, including the provision of gifts, meals or other items to certain health care providers.

We cannot ensure that our compliance controls, policies and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may violate federal or state fraud and abuse laws or other applicable requirements.

Federal enforcement agencies and private whistleblowers recently have shown interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support, co-pay support, nursing, adherence and educational services, referrals to other providers, donations to independent patient assistance charities, and relationships with specialty pharmacies. Co-pay assistance programs are intended to assist qualified patients with private insurance with any out-of-pocket financial obligations but must exclude any government health care program beneficiaries. Several investigations into patient assistance practices have resulted in significant civil and criminal settlements. We offer co-pay assistance for our vitamin products and IMVEXXY®, including co-pay assistance and free drug sample starter packs for IMVEXXY®, and potentially will do so for BIJUVA™ and ANNOVERA™. If we fail to structure these and other support programs to comply with applicable law, we risk becoming subject to government investigations, and potentially, facing penalties or consequences for violations under fraud and abuse laws. In addition, to the extent we, our subsidiary, VitaCare Prescription Services, or our other contractors or agents receive or obtain individually identifiable health information from patients, health care professionals, pharmacies, or other individuals or entities, although we are not directly subject to HIPAA, we could be subject to criminal penalties if we mishandle individually identifiable health information in a manner that is not authorized or permitted by HIPAA. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. In addition, VitaCare Prescription Services' activities could be subject to regulation and enforcement by the federal government and the states in which VitaCare conducts its business, including as a result of potential increased scrutiny of innovation in hub services.

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.

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 direct sales personnel. New and future hires may not become as productive as expected, and we may be unable to hire enough qualified individuals in the future in the markets in which we do business. If we are unable to hire and develop enough productive sales personnel or are required to hire more sales personnel than we expect 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 IMVEXXY®, BIJUVA™ and ANNOVERA™ may be limited.

Licensing of intellectual property involves complex legal, business and scientific issues, and disputes could jeopardize our rights under such agreements. Additionally, our current licensing agreements contain limitations and restrictions that could limit or adversely affect our ability to develop and commercialize other products in the future.

We are currently and may in the future be a party to license agreements of importance to our business and to our current product and product candidates, and we expect to be subject to additional such agreements in the future. Disputes may arise between us and any of these counterparties regarding intellectual property subject to and each parties' obligations under such agreements, including:

- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product and product candidates, and what activities satisfy those diligence obligations;

- the scope of rights granted under the agreement and other interpretation-related issues;
- our obligations to make milestone, royalty or other payments under those agreements;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement;
- our right to sublicense patent and other rights to third parties;
- the ownership of inventions and know-how arising under the agreement or resulting from the joint creation or use of intellectual property by our licensors and us and our partners;
- our right to transfer or assign the license; and
- the effects of termination.

These or other disputes over our obligations or intellectual property that we have licensed may prevent or impair our ability to maintain our current arrangements on acceptable terms, or may impair the value of the arrangement to us. Any such dispute could have an adverse effect on our business.

If we fail to meet our obligations under a license agreement in a material respect, the respective licensor could have the right to terminate the respective agreement and upon the effective date of such termination, have the right to re-obtain the related technology as well as, potentially, aspects of any intellectual property controlled by us and developed during the period the agreement was in force that relate to the applicable technology. This means that the licensor to each of these agreements could effectively take control of the development and commercialization of the applicable product or product candidate after an uncured, material breach of the agreement by us. This may also be the case if we voluntarily terminate the relevant agreement. Any uncured, material breach under a license agreement could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for the applicable product or product candidates.

In July 2018, we entered into a license agreement with the Population Council to obtain exclusive U.S. rights to commercialize the Population Council's segesterone acetate/ethinyl estradiol one-year vaginal system for human contraceptive indications, which was approved by the FDA in August 2018 and which we intend to commercialize under the name ANNOVERA™. The agreement requires us to commercialize this product and enter into certain manufacturing agreements, make timely milestone and other payments, provide certain information regarding our activities under the agreement, and indemnify the other party with respect to our development and commercialization activities under the terms of the agreements.

In addition, our current licensing agreement with the Population Council contains limitations and restrictions, including limitations that could limit or adversely affect our ability to develop and commercialize this or other product candidates including the following:

- we cannot sublicense the rights licensed to us without the consent of the Population Council;
- neither we nor the Population Council may develop a competitive product (as defined with respect to each party in the agreement) for six years from the date of the agreement;
- currently there are no Orange Book listable patents or patent applications covering this system; and
- the Population Council owns any program improvements, as defined in the agreement.

In addition, if we license international rights to our products to third parties that have the right to manufacture such products outside of the U.S., sales of our products in the U.S. and our rights to receive royalties with respect to our products sold outside the U.S. could be adversely affected if products manufactured outside of the U.S. are reimported and sold in the U.S.

Our level of indebtedness and the terms of the Credit Agreement could adversely affect our operations and limit our ability to plan for or respond to changes in our business. If we are unable to satisfy certain conditions in our Credit Agreement, we will be unable to draw down the remaining the facility and if we are unable to comply with restrictions in the Credit Agreement, the repayment of our existing indebtedness could be accelerated.

Under the Credit Agreement, we have incurred a substantial amount of debt, which could adversely affect our business. In June 2018, we drew down the first tranche of $75.0 million under the Credit Agreement and we currently intend to draw down up to an additional $125.0 million in the aggregate in two additional tranches under the terms of the Credit Agreement, when and if the conditions precedent to such tranches have been met. Our high level of indebtedness could affect our business in the following ways, among other things: make it more difficult for us to satisfy our contractual and commercial commitments; require us to use a substantial portion of our cash flow from operations to pay interest and principal, which would reduce funds available for working capital, capital expenditures and other general corporate purposes; limit our ability to obtain additional financing for working capital, capital expenditures, acquisitions and other investments or general corporate purposes; heighten our vulnerability to downturns in our business, our industry or in the general economy; place us at a disadvantage compared to those of our competitors that may have proportionately less debt; limit management's discretion in operating our business; and limit our flexibility in planning for, or reacting to, changes in our business, the industry in which we operate or the general economy.

We must satisfy certain conditions to be eligible to draw down the second tranche of $75.0 million and the third tranche of $50.0 million. The second tranche may be drawn by us on or before May 31, 2019, provided that we satisfy certain conditions described in the Credit Agreement, including (i) the approval by the FDA of the NDA for BIJUVA™ and (ii) that we have consummated our first commercial sale in the United States of BIJUVA™. The third tranche of $50.0 million may be drawn by us on or before December 31, 2019, provided that we satisfy certain conditions described in the Credit Agreement, including that (i) tranche 2 has been drawn and (ii) we and our subsidiaries party to the Credit Agreement have generated at least $75.0 million of consolidated net revenue attributable to commercial sales of BIJUVA™ and IMVEXXY® during the twelve-month period ending immediately before the funding of tranche 3. If we are unable to satisfy those conditions, we would not be able to draw down the respective tranche of financing and may not be able to obtain alternative financing on commercially reasonable terms or at all.

The Credit Agreement requires us to make certain payments of principal and interest over time and contains several other restrictive covenants. Among other requirements of the Credit Agreement, we and our subsidiaries party to the Credit Agreement must (i) maintain a minimum cash balance of $50.0 million and (ii) achieve certain minimum consolidated net revenue amounts attributable to commercial sales of our products. The Credit Agreement also contains covenants that limit, among other things, the ability of us and our subsidiaries party to the Credit Agreement to (i) incur indebtedness, (ii) incur liens on our property, (iii) pay dividends or make other distributions, (iv) sell our assets, (v) make certain loans or investments, (vi) merge or consolidate, (vii) voluntarily repay or prepay certain permitted indebtedness and (viii) enter into transactions with affiliates, in each case subject to certain exceptions. These and other terms in the Credit Agreement have to be monitored closely for compliance and could restrict our ability to grow our business or enter into transactions that we believe would be beneficial to our business.

Our business may not generate cash flow from operations in the future sufficient to service our debt and support our growth strategies. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, including under our current debt obligations.

If our products 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.

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 to update the phase 3 protocol based on discussions with the FDA. Failure can occur at any time during the clinical trial process because 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. Several 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. Before 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 based on a single well-controlled 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.

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 after 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 after we obtain regulatory approval for 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. For example, as part of the FDA's approval of IMVEXXY®, we have committed to conduct a post-approval observational study to evaluate the risk of endometrial cancer in post-menopausal women with a uterus who use a low-dose vaginal estrogen unopposed by a progestogen such as IMVEXXY®. As part of the FDA's approval of ANNOVERA™, the FDA has required a post-approval observational study be performed to measure the risk of venous thromboembolism. 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 includes 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. 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 other hormone therapy drugs that we may develop, if approved in the future, will depend upon gaining and retaining significant market acceptance of these products among physicians and payers.

Physicians may not prescribe our products 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 payers, 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 payers 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 payers, 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 do not achieve an adequate level of acceptance by physicians and payers, 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 payers on the benefits of our products may require significant resources and may never be successful.

Our products 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 and maintaining adequate pricing through our exclusivities. The dietary supplement and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our products face intense competition, including from major multinational pharmaceutical and dietary supplement companies, established biotechnology companies, specialty pharmaceutical, and generic drug companies. 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. 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. Finally, loss of exclusivity may provide opportunity for competing products, particularly generics, to erode pricing and siphon off our customers.

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

We are presently attempting, through certain partnering relationships, to market certain of our hormone therapy drugs in non-U.S. markets. To market our hormone therapy drugs 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. For these non-U.S. regulatory approvals, we may not obtain them on a timely basis, if at all. Our failure to receive necessary non-U.S. regulatory approvals to commercialize our hormone therapy drugs in a given market could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, by seeking to obtain approval to market our hormone therapy drugs 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. If we obtain approval to market our hormone therapy drugs in one or more non-U.S. markets, we will have additional pharmacovigilance reporting requirements for our products. To the extent that the non-U.S. markets we distribute our products in have different pharmacovigilance reporting requirements than the U.S., there is a risk that the marketing of our drugs in those countries may increase the number of adverse events reported for our products.

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 through commercialization of 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 drugs. 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 and clinical trial liability insurance for our hormone therapy drugs and 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 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.

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. 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 several 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.

Our success is tied to our distribution channels.

We sell our prescription prenatal vitamin products and hormone therapy drug products to wholesale distributors and retail pharmacy distributors. During 2018, four customers each generated more than 10% of our total revenues; revenue generated from these four customers combined accounted for approximately 76% of our total revenue during 2018. 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 enough 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 many 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 enough 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 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, 2018, we had federal net operating loss carryforwards, or NOLs, of approximately $481.4 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. If 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 because 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. Management assessed the valuation allowance analyses with respect to our NOLs as affected by various aspects of the Tax Act and determined that a full valuation allowance continues to be appropriate. 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 considering 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.

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.

If 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 several 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, 2018, we had 241 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 drugs 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 because 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 during 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 regarding patents and other proprietary rights that we hold or license;
- delays in development, testing, clinical trials, and regulatory review may reduce the period 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 drugs 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 before, 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 many 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 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 can 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:

- 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 drugs;
- a decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- 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, 2018, our executive officers, directors, holders of 5% or more of our stock, and their affiliates beneficially owned approximately 69% 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.

In October 2018, we entered into a lease for new corporate offices in Boca Raton, Florida. The lease includes 56,212 rentable square feet, or full premises, of which 7,561 has commenced in 2018 and the remaining 48,651 square feet will commence no earlier than June 1, 2019, or full premises commencement date. The lease will expire 11 years after full premises commencement date, unless terminated earlier in accordance with the terms of the lease. We believe that our current facility is in good working order and that our current facility and new corporate headquarters are capable of supporting our operations for the foreseeable future.

Item 3. Legal Proceedings

We have been informed by the staff, or the Staff, of the Securities and Exchange Commission that the Staff is conducting a formal investigation concerning whether certain of our communications during 2017 regarding TX-004HR may have violated Regulation FD. We are cooperating with the Staff in connection with the investigation. Any determination that our actions violated Regulation FD could result in penalties or other remedies being imposed. While we believe that any such penalties and other remedies would be immaterial from a financial perspective, no assurance can be made about the ultimate outcome of the investigation, and there can be no assurance that any such penalties and remedies would not have a material adverse effect on our business.

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." Before that time, our common stock was quoted on the OTCQB.

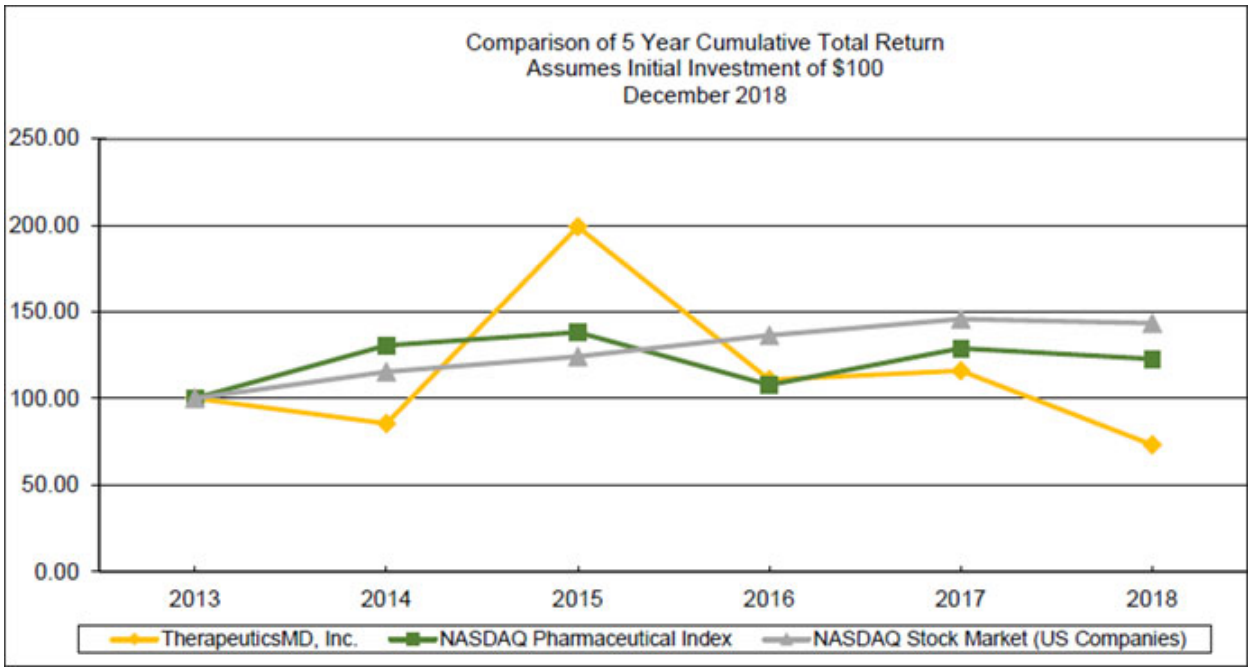
On February 15, 2019, there were approximately 208 record holders and as of February 8, 2019, there were approximately 24,155 beneficial owners of our common stock.

Dividends

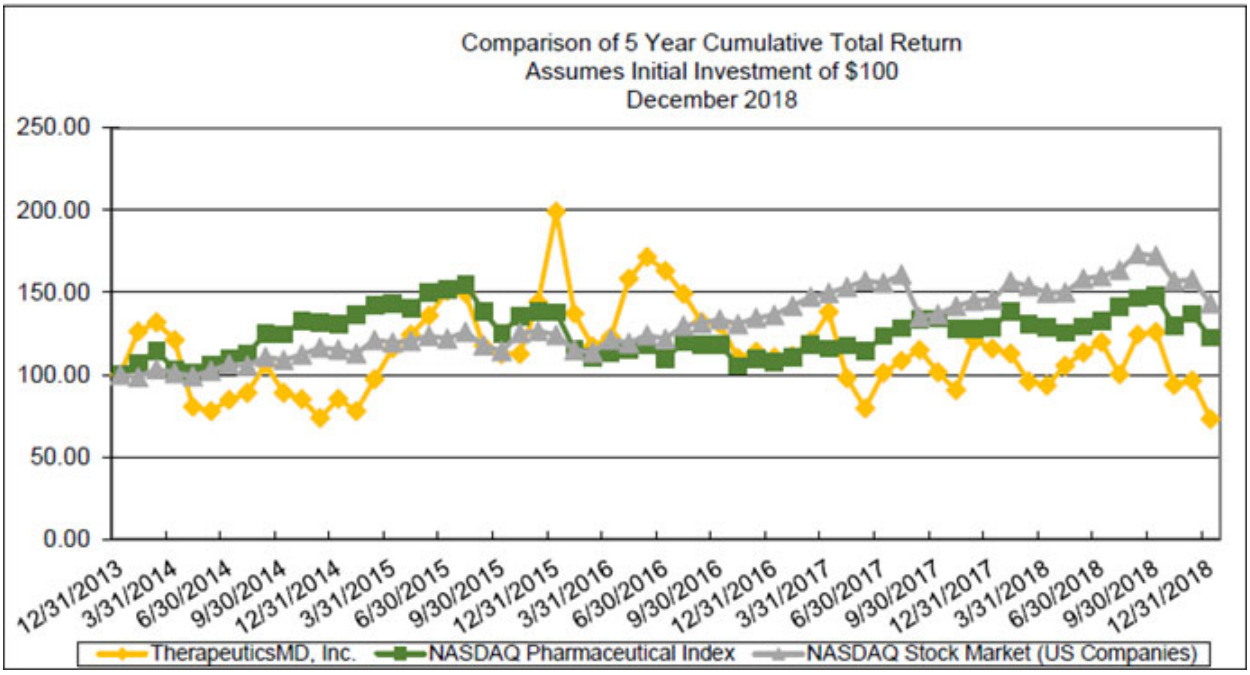
Historically, we have not paid dividends on our common stock, and we currently do not intend to pay any dividends on our common stock in the foreseeable future. We currently plan to retain any earnings to finance the growth of our business rather than to pay cash dividends. Payments of any cash dividends 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. In addition, the Credit Agreement contains covenants that limit our ability to pay dividends or make other distributions on our common stock.

Performance Graph

The following line graph compares cumulative total shareholder return for the five years ended December 31, 2018 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, 2013 and includes reinvestment of dividends. Measurement points are at December 31, 2013 and the last trading day of the fiscal years ended December 31, 2014, 2015, 2016, 2017, and 2018. 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 five years ended December 31, 2018 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, 2013 and includes reinvestment of dividends. Measurement points are December 31, 2013 and the last trading day of the fiscal years ended December 31, 2018, 2017, 2016, 2015, and 2014 and each of the following quarters ended therein. 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, 2018, 2017, and 2016 and the consolidated balance sheet data as of December 31, 2018 and 2017 are derived from our audited consolidated financial statements included in this Annual Report. The consolidated statements of operations for the years ended December 31, 2015 and 2014, and the consolidated balance sheet data as of December 31, 2016, 2015, and 2014, 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,				
	2018	**2017**	**2016**	**2015**	**2014**
Consolidated Statements of Operations Data:					
Revenue, net	$ 16,099	$ 16,778	$ 19,356	$ 20,143	$ 15,026
Cost of goods sold	2,737	2,637	4,185	4,506	3,672
Gross profit	13,362	14,141	15,171	15,637	11,354
Operating expenses:					
Sales, general, and administration	115,989	57,703	51,348	28,721	22,124
Research and development	27,299	33,853	53,943	72,043	43,219
Depreciation and amortization	294	213	133	63	52
Total operating expense	143,582	91,769	105,424	100,827	65,395
Operating loss	(130,220)	(77,628)	(90,253)	(85,190)	(54,041)
Other (expense) income, net	(2,397)	703	378	113	(176)
Net loss	$ (132,617)	$ (76,925)	$ (89,875)	$ (85,077)	$ (54,217)
Net loss per share, basic and diluted	$ (0.59)	$ (0.37)	$ (0.46)	$ (0.49)	$ (0.36)
Weighted average number of common shares outstanding, basic and diluted	225,026	205,523	196,088	173,174	149,727
Consolidated Balance Sheet Data (at end of period)					
Total assets	$ 211,984	$ 143,230	$ 142,472	$ 73,729	$ 59,079
Total liabilities	$ 114,460	$ 13,321	$ 14,983	$ 10,666	$ 10,690
Total stockholders' equity	$ 97,524	$ 129,909	$ 127,489	$ 63,063	$ 48,389
Other Data:					
Capital expenditures (for the period)	$ 1,322	$ 827	$ 1,241	$ 584	$ 617
Working capital (at the end of period)	$ 145,700	$ 126,233	$ 124,428	$ 60,014	$ 45,545

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 healthcare company focused on creating and commercializing innovative products to support the lifespan of women and championing awareness of women's healthcare issues, specifically, for pregnancy prevention, pregnancy, childbirth, nursing, pre-menopause, and menopause. At TherapeuticsMD, we combine entrepreneurial spirit, clinical expertise, and business leadership to develop and commercialize health solutions that enable new standards of care for women. Our solutions range from advanced hormone therapy pharmaceutical products to patient-controlled, long-acting contraceptive. We also manufacture and distribute branded and generic prescription prenatal vitamins under the vitaMedMD® and BocaGreenMD® brands.

With our SYMBODA™ technology, we are developing and commercializing advanced hormone therapy pharmaceutical products to enable delivery of bio-identical hormones through a variety of dosage forms and administration routes. Our track record of commercialization allows us to efficiently leverage and grow our marketing and sales organization to commercialize our recently approved products.

During 2018, the U.S. Food and Drug Administration, or FDA, approval of our drugs has transitioned our company from predominately focused on conducting research and development to one focused on commercializing our drugs. In July 2018, we launched our recently FDA approved product, IMVEXXY® (estradiol vaginal inserts) for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy, or VVA, due to menopause. We are also focused on commercialization activities necessary for launch of BIJUVA™ and ANNOVERA™. BIJUVA™ is our hormone therapy combination of bio-identical 17ß-estradiol and bio-identical progesterone in a single, oral softgel capsule, for the treatment of moderate-to-severe vasomotor symptoms, or VMS, due to menopause in women with a uterus, which was approved by the FDA on October 28, 2018. ANNOVERA™ (segesterone acetate/ethinyl estradiol vaginal system), is the first and only patient-controlled, procedure-free, reversible prescription contraceptive that can prevent unintended pregnancy for up to a full year, which was approved by the FDA on August 10, 2018. On July 30, 2018, we entered into an exclusive license agreement, or the Population Council License Agreement, with the Population Council, Inc., or the Population Council, to commercialize ANNOVERA™ in the U.S. In addition, on July 30, 2018, we entered into a license and supply agreement with Knight Therapeutics Inc., or Knight, pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY® and BIJUVA™ in Canada and Israel.

Product Portfolio

We are focused on activities necessary for commercialization of IMVEXXY®, BIJUVA™ and ANNOVERA™. We continue to manufacture and distribute our prescription product lines, consisting of branded prenatal vitamins under vitaMedMD® and authorized generic formulations of some of our prescription prenatal vitamin products under BocaGreenMD®. 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.

TX-001HR: BIJUVA™

We submitted the New Drug Application, or NDA, for TX-001HR to the FDA on December 28, 2017. On October 28, 2018, the FDA approved BIJUVA™ (estradiol and progesterone) capsules, 1 mg/100 mg, the first and only FDA-approved bio-identical hormone therapy combination of estradiol and progesterone in a single, oral capsule for the treatment of moderate-to-severe VMS due to menopause in women with a uterus. The estrogen and progesterone in BIJUVA™ have the same chemical and molecular structure as the hormones that are naturally produced in a woman's body. With the approval of BIJUVA™, the FDA required a post-approval commitment to further develop and validate our in-vitro dissolution method to show how BIJUVA™ is released from the capsule in an in-vitro setting for quality control assessments. The development of this method and validation were completed and submitted to FDA as required in our approval.

TX-004HR: IMVEXXY®

On May 30, 2018, we announced that the FDA had approved the 4 µg and 10 µg doses of IMVEXXY® (estradiol vaginal inserts) for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of VVA, due to menopause. The 4-µg formulation of IMVEXXY® represents the lowest FDA-approved dose of vaginal estradiol available. IMVEXXY® 10-µg became available for commercial distribution in late July 2018 and both doses were commercially available by September 2018.

As part of the FDA's approval of IMVEXXY®, we have committed to conduct a post-approval observational study to evaluate the risk of endometrial cancer in post-menopausal women with a uterus who use a low-dose vaginal estrogen unopposed by a progestogen. In connection with the observational study, we are required to provide progress reports to the FDA on an annual basis. The development of this method is underway, and we do not believe that the costs will be material. In addition, the FDA asked for post-approval information with respect to certain characteristics related to the product's specifications, which we submitted to FDA in November 2018.

ANNOVERA™

On July 30, 2018, we entered into an exclusive license agreement with the Population Council to commercialize in the U.S. ANNOVERA™ (segesterone acetate/ethinyl estradiol vaginal system), the first and only patient-controlled, procedure-free, reversible prescription contraceptive that can prevent pregnancy for up a full year, which was approved by the FDA on August 10, 2018. ANNOVERA™ was classified by the FDA as a "new chemical entity," or NCE, and thus has five years of regulatory exclusivity under the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act.

ANNOVERA™ is a one-year ring-shaped contraceptive vaginal system, or CVS. ANNOVERA™ is made of silicone elastomer, and contains segesterone acetate, a 19-nor progesterone derivative also known as Nestorone®, or NES, and ethinyl estradiol, or EE. EE is an approved active ingredient in many marketed hormonal products. Segesterone acetate, a new chemical entity is a potent progestin that is not active orally but is active when administered via non-oral routes such as vaginal rings, implants, and transdermal systems. NES has been evaluated in 51 clinical studies across these delivery systems with more than 26,794 cycles of exposure.

ANNOVERA™ can be inserted and removed by the woman herself without the aid of a healthcare provider and, unlike oral contraceptives, or OCs, ANNOVERA™ does not require daily administration to obtain the contraceptive effect. After 21 days of use, the woman removes ANNOVERA™ for 7 days, thereby providing a regular bleeding pattern (i.e., withdrawal/scheduled bleeding). The same CVS is then re-inserted for additional 21/7-days in/out, for up to a total of 13 cycles (1 year).

ANNOVERA™ releases daily vaginal doses of both active ingredients (NES and EE). The claimed release rate of 150 µg/day NES and 13/day µg EE is supported by the calculated average release rate from an ex vivo analysis of ANNOVERA™ used for 13 cycles and is also supported by data from 13 cycles of in vitro release.

We assumed responsibility for marketing expenses related to the commercialization of ANNOVERA™.

The Population Council License Agreement includes exclusive rights for us to negotiate co-development of two other investigational vaginal contraceptive systems in development by the Population Council.

Under the terms of the Population Council License Agreement, we paid the Population Council a milestone payment of $20 million within 30 days following approval by the FDA of the NDA for ANNOVERA™ and will be required to pay the Population Council an additional $20 million within 30 days following the release of the first commercial batch of ANNOVERA™. The Population Council is also eligible to receive milestone payments and royalties from commercial sales of ANNOVERA™, as detailed below. We are required to pay the Population Council milestone payments of $40 million upon cumulative net sales of ANNOVERA™ in the U.S. by us and our affiliates and permitted sublicensees of each of $200.0 million, $400.0 million and $1.0 billion.

In addition, we are required to pay the Population Council, on a quarterly basis, step-based royalty payments based on annual net sales of ANNOVERA™ in the U.S. by us and our affiliates and permitted sublicensees as follows:

Annual Net Sales	Royalty Rate
Less than or equal to $50.0 million	5%
Greater than $50.0 million and less than or equal to $150.0 million	10%
Greater than $150.0 million	15%

The annual royalty rate will be reduced to 50% of the initial rate during the six-month period beginning on the date of the first arms-length commercial sale of a generic equivalent of ANNOVERA™ that is launched by a third party in the U.S., and thereafter will be reduced to 20% of the initial rate.

As part of the approval of ANNOVERA™, the FDA has required a post-approval observational study be performed to measure the risk of venous thromboembolism. A protocol submission for the study is due to the FDA in August 2019. We have agreed to perform and pay the costs and expenses associated with this post-approval study, provided that if the costs and expenses associated with such post-approval study exceed $20 million, half of such excess will offset against royalties or other payments owed by us to the Population Council under the Population Council License Agreement. Given the observational nature of the study, we do not believe that the costs of the study will be material on an annual basis.

Unless earlier terminated, the Population Council License Agreement will remain in effect until the later of the expiration of the last-to-expire of the Population Council's U.S. patents that are licensed to us, or the date following such expiration that follows a continuous period of six months during which we and our affiliates have not made a commercial sale of ANNOVERA™ in the U.S. The Population Council License Agreement may also be terminated for certain breach and bankruptcy-related events and by us on 180 days prior notice to the Population Council.

As part of the Population Council License Agreement, we have the exclusive right to negotiate co-development and U.S. marketing rights for two other investigational vaginal contraceptive systems in development by the Population Council: a three-month contraceptive ring using Nestorone® plus bio-identical estradiol, which is currently in phase 2 clinical trials, and a new one-year contraceptive ring using Nestorone® plus EE, which is designed as a life cycle management product for the one-year vaginal CVS that we have licensed.

Pipeline for Our Hormone Therapy Drug Candidates

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 bio-identical 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 inactive. We have suspended further development of this drug candidate to prioritize our leading drugs.

TX-003HR

TX-003HR is a natural estradiol formulation. This hormone therapy drug candidate is bio-identical 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.

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 candidates. Our business model is dependent upon our company continuing to conduct research and development. 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 costs associated with other research activities and regulatory approvals. Other research and development costs listed below consist of costs incurred with respect to drug candidates that have not received IND application approval from the FDA.

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, $0 and $228,933, at December 31, 2018, 2017, and 2016, respectively.

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

	Years Ended December 31,		
	2018	2017	2016
	(000s)		
TX-001HR (BIJUVA™)	$ 11,790	$ 19,381	$ 31,857
TX-002HR	—	—	—
TX-004HR (IMVEXXY®)	4,890	8,043	9,248
Other research and development	10,619	6,429	12,838
Total research and development	$ 27,299	$ 33,853	$ 53,943

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, 2018 and since the project's inception in February 2013, we have incurred approximately $11,790,000 and $127,187,000, respectively, in research and development costs with respect to BIJUVA™.

During the year ended December 31, 2018 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.

During the year ended December 31, 2018 and since the project's inception in August 2014, we have incurred approximately $4,890,000 and $45,739,000, respectively, in research and development costs with respect to IMVEXXY®.

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, 2018, 2017, and 2016:

Year ended December 31, 2018 compared with year ended December 31, 2017

	Years Ended December 31,		
	2018	2017	Change
	(000s)		
Revenue	$ 16,099	$ 16,778	$ (679)
Cost of goods sold	2,737	2,637	100
Operating expenses	143,582	91,769	51,813
Operating loss	(130,220)	(77,628)	(52,592)
Other (expense) income	(2,397)	703	(3,100)
Net loss	$ (132,617)	$ (76,925)	$ (55,692)

Revenue

Revenue is recorded net of sales discounts, chargebacks, wholesaler fees, customer rebates, coupons and estimated returns. Revenue for the year ended December 31, 2018 decreased by approximately $679,000, or 4%, to approximately $16,099,000, compared with approximately $16,778,000 for the year ended December 31, 2017. Revenues, net decreased primarily due to a decrease in prenatal vitamin sales of approximately $1,737,000 partially offset by sales of IMVEXXY® of approximately $1,058,000. The revenue decrease related to our prenatal vitamins was primarily affected by lower number of units sold and higher utilization of coupons offered to customers during the year ended December 31, 2018 as compared to the prior year. We launched sales of IMVEXXY® in the third quarter of 2018. During this launch period, revenues, net related to our newly approved drug were greatly affected by the co-pay assistance program that we introduced to launch IMVEXXY®, which allowed patients to access the product at a reasonable cost regardless of insurance coverage. We expect our revenues, net related to IMVEXXY® to improve as commercial payer coverage for IMVEXXY® increases.

Cost of Goods Sold

Cost of goods sold increased by approximately $100,000, or 4%, to approximately $2,737,000 for the year ended December 31, 2018, compared with approximately $2,637,000 for the year ended December 31, 2017 primarily related to product costs attributable to IMVEXXY®, partially offset by lower royalty fees attributable to prenatal vitamins, and lower shipping costs. Our gross margin was 83% for the year ended December 31, 2018 as compared to 84% for the year ended December 31, 2017. The decrease in gross margin percentage was primarily attributable to higher utilization of coupons/co-pay assistance offered in 2018 as compared with 2017.

Operating Expenses

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

	Years Ended December 31,	
	2018	2017
Sales and marketing costs, excluding human resource costs	43%	22%
Human resource related costs	25%	27%
Product research and development costs	19%	37%
Professional fees and consulting costs	5%	6%
Other operating expenses	8%	8%

Operating expenses increased by approximately $51,813,000, or 56%, to approximately $143,582,000 for the year ended December 31, 2018, compared with approximately $91,769,000 for the year ended December 31, 2017, as a result of the following items:

	Years Ended December 31,		
	2018	2017	Change
	(000s)		
Sales and marketing, excluding human resource costs	$ 61,845	$ 19,614	$ 42,231
Human resource related costs	35,003	24,720	10,283
Research and development costs	27,299	33,853	(6,554)
Professional and consulting costs	7,661	5,859	1,802
Other operating expenses	11,774	7,723	4,051
Total operating expenses	$ 143,582	$ 91,769	$ 51,813

Sales and marketing costs increased by approximately $42,231,000, or 215%, to approximately $61,845,000 for the year ended December 31, 2018, compared with approximately $19,614,000 for the year ended December 31, 2017, primarily as a result of increased expenses associated with sales and marketing efforts to support launch and commercialization of IMVEXXY® and BIJUVA™, including costs related to outsourced sales personnel and their related expenses, physician education and product samples, advertising and travel expenses related to product commercialization. We expect sales and marketing expenses to continue to increase as we continue the launch of BIJUVA™, prepare for the launch of ANNOVERA™ and continue to support our growing business and commercialization of our products.

Human resource related costs, including salaries and benefits increased by approximately $10,283,000, or 42%, to approximately $35,003,000 for the year ended December 31, 2018, compared with approximately $24,720,000 for the year ended December 31, 2017, primarily as a result of an increase of approximately $7,975,000 in personnel costs in sales, marketing and regulatory areas to support commercialization of our new drugs and an increase in non-cash compensation expense included in this category of approximately $2,308,000 related to employee stock option amortization during 2018 as compared to 2017.

Research and development costs decreased by approximately $6,554,000, or 19%, to approximately $27,299,000 for the year ended December 31, 2018, compared with approximately $33,853,000 for the year ended December 31, 2017, primarily as a result of the completion of the REPLENISH Trial for BIJUVA™ and FDA approval of IMVEXXY® and BIJUVA™, partially offset by scale-up and manufacturing activities for BIJUVA™ before FDA approval as well as increased pre-clinical work to support our product pipeline. Research and development costs in 2017 included approximately $2,400,000 in NDA submission fees related to BIJUVA™ and a write-off of approximately $1,000,000 of prepaid manufacturing costs. Research and developments costs during the year ended December 31, 2018 included the following research and development projects:

During the year ended December 31, 2018 and since the project's inception in February 2013, we have incurred approximately $11,790,000 and $127,187,000, respectively, in research and development costs with respect to BIJUVA™.

During the year ended December 31, 2018 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, 2018 and since the project's inception in August 2014, we have incurred approximately $4,890,000 and $45,739,000, respectively, in research and development costs with respect to IMVEXXY®.

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 Drugs," "Item 1. Business — Pipeline for Our Hormone Therapy Drug Candidates" 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.

Professional and consulting costs increased by approximately $1,802,000, or 31%, for the year ended December 31, 2018, to approximately $7,661,000 compared with approximately $5,859,000 for the year December 31, 2017, primarily as a result of increased legal, consulting and recruiting fees.

All other costs increased by approximately $4,051,000, or 52%, to approximately $11,774,000 for the year ended December 31, 2018, compared with approximately $7,723,000 for the year ended December 31, 2017, as a result of increased information technology, travel, allowance for bad debt expense, insurance and other office expenses primarily to support commercialization of our new drugs.

Operating Loss

As a result of the foregoing, our operating loss increased approximately $52,592,000, or 68%, to approximately $130,220,000 for the year ended December 31, 2018, compared with approximately $77,628,000 for the year ended December 31, 2017, primarily as a result of increased personnel costs, sales and marketing expenses to support commercialization of IMVEXXY® and BIJUVA™, including costs related to outsourced sales personnel and their related expenses, professional fees and other operating expenses, as well a decrease in revenue, partially offset by a decrease in research and development costs.

We anticipate that we will continue to have operating losses for the near future until we successfully commercialize IMVEXXY®, BIJUVA™ and ANNOVERA™, although there is no assurance that any commercialization of IMVEXXY® and BIJUVA™ and ANNOVERA™ will be successful.

Other (Expense) Income

Other non-operating income changed by approximately $3,100,000, or 441%, to an expense of approximately $2,397,000 for the year ended December 31, 2018 compared with an income of approximately $703,000 for 2017, primarily as a result of increased interest expense related to our term loan that we obtained in 2018 partially offset by increased interest income in 2018 as compared to 2017.

Net Loss

Because of the net effects of the foregoing, net loss increased approximately $55,692,000, or 72%, to approximately $132,617,000 for the year ended December 31, 2018, compared with approximately $76,925,000 for the year ended December 31, 2017. Net loss per share of common stock, basic and diluted, was ($0.59) for the year ended December 31, 2018, compared with ($0.37) per share of common stock for the year ended December 31, 2017.

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 margin 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, because 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 because of a decrease in costs related to our phase 3 clinical trials of BIJUVA™ and IMVEXXY®, partially offset by scale-up and manufacturing activities for our phase 3 clinical trials of BIJUVA™ and IMVEXXY® and costs related to regulatory submission related to BIJUVA™. Research and development costs in 2017 included approximately a $2,400,000 in NDA submission fees related to BIJUVA™ 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 BIJUVA™.

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.

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 IMVEXXY®.

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," "Item 1. Business — Pipeline for Our Hormone Therapy Drug Candidates" 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 IMVEXXY®, 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 drugs are brought to market, although there is no assurance that our hormone therapy drugs 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 because of increased interest income.

Net Loss

Because 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.

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, 2018, we received approximately $293,344,000 in net proceeds from the issuance of shares of our common stock. As of December 31, 2018, we had a cash balance of approximately $161,613,000, 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 August 1, 2018, we entered into an underwriting agreement with Goldman Sachs & Co. LLC, as representative of the underwriters, relating to an underwritten public offering of 12,745,098 shares of our common stock at a price to the public of $5.10 per share. We granted the underwriters an option, exercisable for a period of 30 days, to purchase up to 1,911,764 additional shares of common stock. On August 2, 2018, the underwriters exercised the option in full. The net proceeds from the offering, including the exercise of the option to purchase additional shares, were approximately $69,908,000, after deducting the underwriting discount and offering expenses payable by us. The offering closed on August 6, 2018 and we issued 14,656,862 shares of our common stock. In connection with the Knight License Agreement, Knight entered into a subscription agreement with us, pursuant to which Knight purchased 3,921,568 shares of our common stock concurrently with the closing of the underwritten public offering of common stock at a price of $5.10, for proceeds of $20,000,000.

On May 1, 2018, we entered into a Credit Agreement, by and among us and our subsidiaries party thereto from time to time, each as a borrower, MidCap Financial Trust, as an agent and as lender, and the additional lenders party thereto from time to time, which provides a secured term loan facility in an aggregate principal amount of up to $200,000,000, or the Term Loan. Under the terms of the Credit Agreement, the Term Loan will be made in three separate tranches, each, a Tranche, with each Tranche to be made available to us, at our option, upon our achievement of certain milestones. The first Tranche of $75,000,000, or Tranche 1, was drawn by us on June 7, 2018, following approval by FDA of the NDA for IMVEXXY®. We intend to use the proceeds from the first draw down to support the commercial launch of IMVEXXY®. The second Tranche of $75,000,000, or Tranche 2, may be drawn by us on or before May 31, 2019, provided that we satisfy certain conditions described in the Credit Agreement, including (i) that Tranche 1 has been drawn, (ii) the approval by the FDA of the NDA for BIJUVA™ and (iii) we have consummated our first commercial sale in the United States of BIJUVA™. The third Tranche of $50,000,000, or Tranche 3, may be drawn by us on or before December 31, 2019, provided that we satisfy certain conditions described in the Credit Agreement, including that (i) Tranche 2 has been drawn and (ii) we have generated at least $75,000,000 of consolidated net revenue attributable to commercial sales of IMVEXXY® and BIJUVA™ during the twelve-month period ending immediately before the funding of Tranche 3.

Our net days sales outstanding, or net DSO, is calculated by dividing gross accounts receivable less the reserve for doubtful accounts, chargebacks and payment discounts divided by the average daily net revenues during the fourth quarter of 2018. We also disclose gross DSO, which includes the calculation of gross accounts receivable divided by the average daily gross revenues to distributors during the fourth quarter of 2018. For the quarter ended December 31, 2018, our gross DSO was 77 days compared to 68 days for the quarter ended December 31, 2017 and our net DSO was 200 days for the quarter ended December 31, 2018 compared to 97 days for the quarter ended December 31, 2017. The increase in our gross DSO as of December 31, 2018 was primarily related to extended terms given to our customers in connection with the launch of IMVEXXY®. Our net DSO was affected by extended terms and increased coupons and discounts given to our customers in connection with the launch of IMVEXXY®. We anticipate that our DSO will fluctuate in the future based upon a variety of factors, including longer payment terms associated with the launch of IMVEXXY®, BIJUVA™ and ANNOVERA™ and changes in the healthcare industry.

We believe that our existing cash and availability under the Term Loan 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 IMVEXXY®, BIJUVA™ or ANNOVERA™ is delayed, our existing cash and availability under the Term Loan, if we are able to access such funds, may be insufficient to satisfy our liquidity requirements until we are able to commercialize IMVEXXY®, BIJUVA™ and ANNOVERA™ and we may not be able to access funds under the Term Loan. If our available cash is insufficient to satisfy our liquidity requirements, we may curtail our sales, marketing and other commercialization and pre-commercialization efforts and we may seek to sell additional equity or debt securities. Our ability to sell debt securities or obtain additional debt financing is restricted pursuant to the Credit Agreement. To the extent that we raise additional capital through the sale of equity or convertible debt securities, to the extent permitted under the Credit Agreement, 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, certain of which are restricted under the Credit Agreement, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or proposed products, if permitted under the Credit Agreement. 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 launch and commercialization of our hormone therapy and contraceptive drugs. 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,		
	2018	2017	2016
Net cash flows used in operating activities	$ (106,811,781)	$ (76,155,614)	$ (69,142,333)
Net cash flows used in investing activities	$ (21,497,857)	$ (827,108)	$ (1,255,456)
Net cash flows provided by financing activities	$ 162,787,087	$ 72,584,249	$ 137,225,535

Operating Activities

The principal use of cash in operating activities for the year ended December 31, 2018 was to fund our current expenses primarily related to supporting commercialization activities for IMVEXXY®, BIJUVA™ and ANNOVERA™, sales, marketing, scale-up and manufacturing activities and clinical development, adjusted for non-cash items. The increase of approximately $30,656,000 in cash used in operating activities for the year ended December 31, 2018 in comparison to the year ended December 31, 2017 was due primarily to an increase in our net loss and non-cash compensation expense coupled with changes in the components of working capital.

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 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.

Investing Activities

During the year ended December 31, 2018, we paid $20,000,000 to the Population Council, upon FDA approval of ANNOVERA™, based on the Population Council License Agreement. In addition, an increase in spending on patents and trademarks resulted in an increase in cash used in investing activities for the year ended December 31, 2018 compared with the same period in 2017.

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.

Financing Activities

Financing activities represent the principal source of our cash flow. Our financing activities for the year ended December 31, 2018 provided net cash of approximately $162,787,000. The cash provided by financing activities during the year ended December 31, 2018 included approximately $89,908,000 in proceeds from the sale of our common stock, approximately $1,666,000 in proceeds from the exercise of options as well as funding from our Term Loan of approximately $75,000,000 offset by payment of financing fees of approximately $3,787,000.

On August 1, 2018, we entered into an underwriting agreement with Goldman Sachs & Co. LLC, as representative of the underwriters, relating to an underwritten public offering of 14,656,862 shares of our common stock at a price to the public of $5.10 per share. The net proceeds from the offering, including the exercise of the option to purchase additional shares, were approximately $69,908,000, after deducting the underwriting discount and offering expenses payable by us. The offering closed on August 6, 2018 and we issued 14,656,862 shares of our common stock. In connection with the Knight License Agreement, Knight entered into a subscription agreement with us, pursuant to which Knight purchased 3,921,568 shares of our common stock concurrently with the closing of the underwritten public offering of common stock at a price of $5.10, for proceeds of $20,000,000.

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.

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 606, Revenue Recognition. In accordance with ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which we expect to be entitled to receive in exchange for these goods or services. The provisions of ASC 606 include a five-step process by which we determine revenue recognition, depicting the transfer of goods or services to customers in amounts reflecting the payment to which we expect to be entitled in exchange for those goods or services. ASC 606 requires us to apply the following steps: (1) identify the contract with the customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when, or as, we satisfy the performance obligation.

Our products consist primarily of prescription vitamins and IMVEXXY®, which we began selling during the third quarter of 2018. We sell our name brand and generic prescription products primarily through wholesale distributors, and retail pharmacy distributors. We have one performance obligation related to prescription products sold through wholesale distributors, which is to transfer promised goods to a customer, and two performance obligations related to products sold through retail pharmacy distributors, which are to: (1) transfer promised goods and (2) provide customer service for an immaterial fee. We treat shipping as a fulfillment activity rather than as a separate obligation. We recognize prescription revenue only when we satisfy performance obligations by transferring a promised good or service to a customer. A good or service is considered to be transferred when the customer receives the goods or service or obtains control. Control refers to the customer’s ability to direct the use of, and obtain substantially all of the remaining benefits from, an asset. All of our performance obligations, and associated revenue, are transferred to customers at a point in time. Based on our contracts, we invoice customers once our performance obligations have been satisfied, at which point payment is unconditional. We disclose receivables from contracts with customers separately in the statement of financial position. Payment for goods or services sold by us is typically due between 30 and 60 days after an invoice is sent to the customer.

The transaction price of a contract is the amount of consideration which we expect to be entitled to in exchange for transferring promised goods or services to a customer. Prescription products are sold at fixed wholesale acquisition cost determined based on our list price. However, the total transaction price is variable as it is calculated net of estimated product returns, chargebacks, rebates, coupons, discounts and wholesaler fees. These estimates are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). To determine the transaction price, we estimate the amount of variable consideration at the outset of the contract either utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract or each variable consideration. The estimated amount of variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. In determining amounts of variable consideration to include in a contract's transaction price, we rely on our historical experience and other evidence that supports our qualitative assessment of whether revenue would be subject to a significant reversal. We consider all the facts and circumstances associated with both the risk of a revenue reversal arising from an uncertain future event and the magnitude of the reversal if that uncertain event were to occur. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our original estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such changes in estimates become known.

Research and Development Expenses. Research and development, or R&D, expenses include internal R&D activities, services of external 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. 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 to 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. Before 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. Before 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, 2018 and 2017, 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. Our U.S. federal and state tax returns since 2011, which was the first year we generated net operating losses, remain open to examination.

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. As the result of our initial analysis of the impact of the Tax Act, we recorded a provisional amount of net tax expense of $46.7 million in 2017 related to the remeasurement of our deferred tax balances and other effects. We completed our accounting for the income tax effects of the Tax Act in 2018, and no material adjustments were required to the provisional amounts initially recorded.

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 August 2018, the FASB issued Accounting Standards Update, or ASU, 2018-13, which eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. The FASB developed the amendments to Accounting Standards Codification, or ASC, 820 as part of its broader disclosure framework project, which aims to improve the effectiveness of disclosures in the notes to financial statements by focusing on requirements that clearly communicate the most important information to users of the financial statements. The new guidance is effective for all entities for fiscal years beginning after December 15, 2019 and for interim periods within those fiscal years. An entity is permitted to early adopt either the entire standard or only the provisions that eliminate or modify requirements. We are currently evaluating the effect of this guidance on our disclosures.

In June 2018, the FASB issued ASU 2018-07 to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance expands the scope of ASC 718 to include share-based payments granted to nonemployees in exchange for goods or services used or consumed in an entity's own operations and supersedes the guidance in ASC 505-50. The guidance is effective for public business entities in annual periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted, including in an interim period for which financial statements have not been issued, but not before an entity adopts ASC 606. We do not expect that the adoption of this standard will have a material effect on our consolidated financial statements and disclosures.

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. In July 2018, the FASB amended the new leases standard and issued ASU 2018-11, Leases, (Topic 842): Targeted Improvements to give entities another option for transition and to provide lessors with a practical expedient. We plan to adopt ASU 2016-02 on January 1, 2019 utilizing the alternative transition method allowed for under ASU 2018-11. While we are still finalizing the quantitative and qualitative impact of adopting this new standard and the subsequent amendments, the most significant impact is expected to be the recognition of a right of use asset and lease liability on our statement of financial position related to the operating leases for our new and existing office space. We elected the optional transition method of recognizing a cumulative-effect adjustment to the opening balance of retained earnings on January 1, 2019. Therefore, comparative financial information will not be adjusted and will continue to be reported under ASC 840. We also elected the transition relief package of practical expedients and as a result we will not assess 1) whether existing or expired contracts contain leases, 2) lease classification for any existing or expired leases, and 3) whether lease origination costs qualified as initial direct costs. We elected the short-term lease practical expedient by establishing an accounting policy to exclude leases with a term of 12 months or less. We will not separate lease components from non-lease components for our specified asset classes. Based on our preliminary calculations, we currently expect to recognize right-of-use asset and corresponding lease liability between $4 million to $5 million on our Consolidated Balance Sheet based on the present value of future minimum lease payments under operating leases in effect on January 1, 2019. Additionally, the adoption of the new standard will result in increased disclosure requirements in our quarterly and annual filings.

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 adopted this standard under the modified retrospective method to all contracts not completed as of January 1, 2018 and the adoption did not have a material effect on our financial statements however we expanded our disclosures related to contracts with customers.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants and the SEC did not, and are not expected to, have a material effect on our results of operations or financial position.

Off-Balance Sheet Arrangements

As of December 31, 2018, 2017, and 2016, 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 drugs or drug candidates, use of such drugs or 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 sometimes 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, 2018, 2017, and 2016.

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, 2018, 2017, and 2016, our business and operations have not been materially affected by inflation.

Contractual Obligations

A summary of contractual obligations as of December 31, 2018 is as follows:

		Payments Due By Period		
	Total	Less than 1 Year	1-3 Years	4-5 Years
Operating lease obligations[1]	$ 9,609,015	$ 1,142,404	$ 4,820,336	$ 3,646,275
Debt payments[2]	75,000,000	—	41,666,667	33,333,333
Interest payment[3]	21,699,957	7,760,888	11,764,925	2,174,144
Purchase commitments[4]	2,565,538	286,901	1,112,578	1,166,059
Total	$ 108,874,510	$ 9,190,193	$ 59,364,506	$ 40,319,811

(1) Operating lease obligations represent our current lease and the full premises relating to our new lease that we signed in the fourth quarter of 2018.
(2) Principal on each tranche of our debt is payable in 36 equal monthly installments beginning May 1, 2020 until paid in full on May 1, 2023. However, if we generate at least $95,000,000 of consolidated net revenue attributable to commercial sales of BIJUVA™ and IMVEXXY® by December 31, 2019, we may extend the interest-only period by an additional 12 months to May 1, 2021.
(3) Interest calculation is based on interest rates in place on December 31, 2018.
(4) Includes Catalent purchase commitments described below. The amounts presented here represent our estimates of the minimum required payments under the agreement with Catalent.

Intellectual Property Licenses

We have license agreements with third parties that provide for minimum royalty, license, and exclusivity payments to be paid by us for access to certain technologies. In addition, we pay royalties as a percent of revenue as described in Note 6, Intangible Assets, to these consolidated financial statements.

Purchase commitments

We have a manufacturing and supply agreement whereby we are required to purchase from Catalent a minimum of number of softgels during the first contract year and a higher number or softgels after the first contract year. If the minimum order quantities of specific products are not met, we are required to pay Catalent 50% of the difference between the total amount we would have paid to Catalent if the minimum requirement had been fulfilled and the sum of all purchases of our products from Catalent during the contract year.

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 $161,613,000 as of December 31, 2018 . 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.

We are also subject to market risk in connection with borrowings under our Term Loan. Amounts borrowed under our Term Loan bear interest at a rate equal to the sum of (i) one-month LIBOR (subject to a LIBOR floor of 1.50%) plus (ii) 7.75% per annum. At December 31, 2018, the outstanding principal balance on our Term Loan, net of issuance costs, was approximately $73,381,000. Considering the total outstanding balance of approximately $75,000,000, as of December 31, 2018, a 1.0% change in interest rates would result in an impact to income before income taxes of approximately $750,000 per year.

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, 2018, 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 because 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, 2018. 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, 2018.

The effectiveness of our internal control over financial reporting as of December 31, 2018 has been audited by Grant Thornton LLP, an independent registered public accounting firm, as stated in their Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting as of December 31, 2018, 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, 2018, 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, 2018, 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, 2018, and our report dated February 27, 2019 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 27, 2019

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 2019 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 2019 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 2019 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 2019 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 2019 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**	May 1, 2018	Credit and Security Agreement, by and among TherapeuticsMD, Inc., as borrower, its subsidiaries party thereto from time to time, each as a borrower, MidCap Financial Trust, as agent and as lender, and the additional lenders party thereto from time to time(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(21)
10.14	May 16, 2013	Lease between the Company and 6800 Broken Sound LLC(21)
10.15	February 18, 2015	First Amendment to Lease between the Company and 6800 Broken Sound, LLC(22)
10.16	April 26, 2016	Second Amendment to Lease between the Company and 6800 Broken Sound, LLC(23)
10.17	October 4, 2016	Third Amendment to Lease between the Company and 6800 Broken Sound, LLC(24)
10.18	May 9, 2018	Fourth Amendment to Lease between the Company and 6800 Broken Sound, LLC(17)
10.19**	April 20, 2016	Softgel Commercial Supply Agreement, by and between TherapeuticsMD, Inc. and Catalent Pharma Solutions, LLC(17)
10.20***†	June 24, 2016	Softgel Commercial Supply Agreement, by and between TherapeuticsMD, Inc. and Catalent Pharma Solutions, LLC
10.21**	July 30, 2018	Population Council License Agreement, by and between TherapeuticsMD, Inc. and The Population Council, Inc.(25)
10.22	July 30, 2018	Amendment No. 1 to the Credit and Security Agreement, by and among TherapeuticsMD, Inc., as borrower, its subsidiaries party thereto from time to time, each as a borrower, MidCap Financial Trust, as agent and as lender, and the additional lenders party thereto from time to time(25)

10.23*	December 17, 2015	Employment Agreement between the Company and Brian Bernick(8)
10.24*	December 17, 2015	Employment Agreement between the Company and Michael Donegan(8)
10.25*	December 17, 2015	Employment Agreement between the Company and Mitchel Krassan(8)
21.1†	February 27, 2019	Subsidiaries of the Company
23.1†	February 27, 2019	Consent of Grant Thornton, LLP
31.1†	February 27, 2019	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 27, 2019	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 27, 2019	Certification pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2†	February 27, 2019	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.

** Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission.

*** Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

† 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 10-Q for quarter ended June 30, 2018 filed with the Commission on July 30, 2018 and incorporated herein by reference (SEC File No. 001-00100).

(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).
(25) Filed as an exhibit to Form 10-Q for quarter ended September 30, 2018 filed with the Commission on November 8, 2018 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 27, 2019

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 27, 2019
/s/ John C.K. Milligan, IV John C.K. Milligan, IV	President, Secretary, Director	February 27, 2019
/s/ Daniel A. Cartwright Daniel A. Cartwright	Chief Financial Officer, Treasurer (Principal Financial and Accounting Officer)	February 27, 2019
/s/ Tommy G. Thompson Tommy G. Thompson	Chairman	February 27, 2019
/s/ Brian Bernick Brian Bernick	Director	February 27, 2019
/s/ Jane F. Barlow Jane F. Barlow	Director	February 27, 2019
/s/ J. Martin Carroll J. Martin Carroll	Director	February 27, 2019
/s/ Cooper C. Collins Cooper C. Collins	Director	February 27, 2019
/s/ Robert V. LaPenta, Jr. Robert V. LaPenta, Jr	Director	February 27, 2019
/s/ Jules Musing Jules Musing	Director	February 27, 2019
/s/ Angus C. Russell Angus C. Russell	Director	February 27, 2019
/s/ Nicholas Segal Nicholas Segal	Director	February 27, 2019

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, 2018 and 2017, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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, 2018, 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 27, 2019 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 27, 2019

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2018	2017
ASSETS		
Current Assets:		
Cash	$ 161,613,077	$ 127,135,628
Accounts receivable, net of allowance for doubtful accounts of $596,602 and $380,580, respectively	11,063,821	4,328,802
Inventory	3,267,670	1,485,358
Other current assets	10,834,693	6,604,284
Total current assets	186,779,261	139,554,072
Fixed assets, net	472,683	437,055
Other Assets:		
License rights	20,000,000	—
Intangible assets, net	4,092,679	3,099,747
Other assets	324,855	—
Security deposit	314,446	139,036
Total other assets	24,731,980	3,238,783
Total assets	$ 211,983,924	$ 143,229,910
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 22,743,841	$ 4,097,600
Accrued expenses and other current liabilities	18,334,948	9,223,595
Total current liabilities	41,078,789	13,321,195
Long-Term Liabilities:		
Long-term debt	73,381,014	—
Total liabilities	114,459,803	13,321,195
Commitments and Contingencies - See Note 13		
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: 240,462,439 and 216,429,642 issued and outstanding, respectively	240,463	216,430
Additional paid-in capital	616,559,938	516,351,405
Accumulated deficit	(519,276,280)	(386,659,120)
Total stockholders' equity	97,524,121	129,908,715
Total liabilities and stockholders' equity	$ 211,983,924	$ 143,229,910

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2018	2017	2016
Revenues, net	$ 16,099,460	$ 16,777,713	$ 19,356,450
Cost of goods sold	2,737,652	2,636,943	4,185,708
Gross profit	13,361,808	14,140,770	15,170,742
Operating expenses:			
Sales, general, and administrative	115,988,954	57,703,370	51,348,414
Research and development	27,299,138	33,852,993	53,943,477
Depreciation and amortization	293,886	213,117	132,451
Total operating expenses	143,581,978	91,769,480	105,424,342
Operating loss	(130,220,170)	(77,628,710)	(90,253,600)
Other (expense) income			
Miscellaneous income	2,280,844	695,631	367,317
Interest expense	(4,677,834)	—	—
Accreted interest	—	7,699	10,824
Total other (expense) income	(2,396,990)	703,330	378,141
Loss before income taxes	(132,617,160)	(76,925,380)	(89,875,459)
Provision for income taxes	—	—	—
Net loss	$ (132,617,160)	$ (76,925,380)	$ (89,875,459)
Loss per share, basic and diluted:			
Net loss per share, basic and diluted	$ (0.59)	$ (0.37)	$ (0.46)
Weighted average number of common shares outstanding, basic and diluted	225,026,300	205,523,288	196,088,196

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, 2018, 2017 AND 2016

	Common Stock		Additional Paid in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance, January 1, 2016	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 options, net	722,744	723	1,372,277	—	1,373,000
Shares issued for exercise of warrants, 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
Shares issued in offerings, net of cost	18,578,430	18,578	89,889,219		89,907,797
Shares issued for exercise of options, net	5,454,367	5,455	1,660,753		1,666,208
Share-based compensation			8,658,561		8,658,561
Net loss	—	—	—	(132,617,160)	(132,617,160)
Balance, December 31, 2018	240,462,439	$ 240,463	$ 616,559,938	$ (519,276,280)	$ 97,524,121

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,		
	2018	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (132,617,160)	$ (76,925,380)	$ (89,875,459)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of fixed assets	181,412	141,601	77,906
Amortization of intangible assets	112,474	71,516	54,545
Provision for doubtful accounts	216,022	4,206	2,524,909
Share-based compensation	8,661,967	6,889,323	17,411,021
Amortization of deferred financing costs	269,859	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(6,951,041)	167,691	(3,975,893)
Inventory	(1,782,312)	(409,037)	(386,168)
Other current assets	(2,332,335)	(4,434,130)	709,907
Other assets	(324,855)	—	—
Accounts payable	18,646,241	(3,260,914)	4,232,340
Accrued expenses and other current liabilities	9,107,947	1,599,510	84,559
Net cash used in operating activities	(106,811,781)	(76,155,614)	(69,142,333)
CASH FLOWS FROM INVESTING ACTIVITIES			
Payment for intellectual property license	(20,000,000)	—	—
Patent costs	(1,105,407)	(765,291)	(845,266)
Purchase of fixed assets	(217,040)	(61,817)	(396,154)
Payment of security deposit	(175,410)	—	(14,036)
Net cash used in investing activities	(21,497,857)	(827,108)	(1,255,456)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from sale of common stock, net of costs	89,907,797	68,572,635	134,863,475
Proceeds from term loan	75,000,000	—	—
Payment of deferred financing fees	(3,786,918)	—	—
Proceeds from exercise of options	1,666,208	212,615	989,060
Proceeds from exercise of warrants	—	3,798,999	1,373,000
Net cash provided by financing activities	162,787,087	72,584,249	137,225,535
Increase (decrease) in cash	34,477,449	(4,398,473)	66,827,746
Cash, beginning of period	127,135,628	131,534,101	64,706,355
Cash, end of period	$ 161,613,077	$ 127,135,628	$ 131,534,101
Supplemental disclosure of cash flow information			
Interest paid	$ 1,890,166	$ —	$ —

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 healthcare company focused on creating and commercializing innovative products to support the lifespan of women and championing awareness of women's healthcare issues, specifically, for pregnancy prevention, pregnancy, childbirth, nursing, pre-menopause, and menopause. At TherapeuticsMD, we combine entrepreneurial spirit, clinical expertise, and business leadership to develop and commercialize health solutions that enable new standards of care for women. Our solutions range from advanced hormone therapy pharmaceutical products to patient-controlled, long-acting contraceptive. We also manufacture and distribute branded and generic prescription prenatal vitamins under the vitaMedMD® and BocaGreenMD® brands.

With our SYMBODA™ technology, we are developing and commercializing advanced hormone therapy pharmaceutical products to enable delivery of bio-identical hormones through a variety of dosage forms and administration routes. Our track record of commercialization allows us to efficiently leverage and grow our marketing and sales organization to commercialize our recently approved products.

During 2018, U.S. Food and Drug Administration, or FDA, approval of our drugs has transitioned our company from predominately focused on conducting research and development to one focused on commercializing our drugs. In July 2018, we launched our recently FDA approved product, IMVEXXY® (estradiol vaginal inserts) for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy, or VVA, due to menopause. We are also focused on commercialization activities necessary for launch of BIJUVA™ and ANNOVERA™. BIJUVA™ is our hormone therapy combination of bio-identical 17ß-estradiol and bio-identical progesterone in a single, oral softgel capsule, for the treatment of moderate-to-severe vasomotor symptoms, or VMS, due to menopause in women with a uterus, which was approved by the FDA on October 28, 2018. ANNOVERA™ (segesterone acetate/ethinyl estradiol vaginal system), is the first and only patient-controlled, procedure-free, reversible prescription contraceptive that can prevent unintended pregnancy for up to a full year, which was approved by the FDA on August 10, 2018. On July 30, 2018, we entered into a license and supply agreement with Knight Therapeutics Inc., or Knight, pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY® and BIJUVA™ in Canada and Israel. In addition, on July 30, 2018, we entered into an exclusive license agreement, or the Council License Agreement, with the Population Council, Inc., or the Population Council, to commercialize ANNOVERA™ in the U.S.

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, or 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, 2018, three different customers represented 42%, 24% and 13% of our gross accounts receivable. At December 31, 2017, four different customers represented 27%, 23%, 22% and 11% of our gross accounts receivable.

Inventories

Inventories represent hormone therapy drugs, 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, 2018, we had 21 issued domestic, or U.S., patents and 24 issued foreign 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, 2018, 2017, and 2016.

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, 2018, 2017, and 2016.

Fair Value of Financial Instruments

Our financial instruments consist primarily of cash, accounts receivable, accounts payable, accrued expenses and long term debt. 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, 2018 and 2017, 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, 2018, 2017, and 2016.

The carrying amount for the long term debt as of December 31, 2018 (as discussed in Note 8) approximates fair value based on market activity for other debt instruments with similar characteristics and comparable risk (Level 2).

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, 2018 and 2017, we had no tax positions relating to open tax returns that were considered to be uncertain.

Our U.S. federal and state tax returns since 2011, which was the first year we generated net operating losses, remain open to examination.

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: 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 to employees 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 adopted ASC 606 on January 1, 2018 using the modified retrospective method for all contracts not completed as of the date of adoption. ASC 606 states that a contract is considered “completed” if all (or substantially all) of the revenue was recognized in accordance with revenue guidance that was in effect before the date of initial application. Because all (or substantially all) of the revenue related to sales of our products has been recognized under ASC 605 prior to the date of initial application of the new standard, the contracts are considered completed under ASC 606. Based on our evaluation of ASC 606, we concluded that a cumulative adjustment was not necessary upon implementation of ASC 606 on January 1, 2018.

In accordance with ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which we expect to be entitled to receive in exchange for these goods or services. The provisions of ASC 606 include a five-step process by which we determine revenue recognition, depicting the transfer of goods or services to customers in amounts reflecting the payment to which we expect to be entitled in exchange for those goods or services. ASC 606 requires us to apply the following steps: (1) identify the contract with the customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when, or as, we satisfy the performance obligation.

Prescription Products

Our products consist primarily of prescription vitamins and our recently approved product IMVEXXY®, which we began selling during the third quarter of 2018. We sell our name brand and generic prescription products primarily through wholesale distributors and retail pharmacy distributors. We have one performance obligation related to prescription products sold through wholesale distributors, which is to transfer promised goods to a customer and two performance obligations related to products sold through retail pharmacy distributors, which are to: (1) transfer promised goods and (2) provide customer service for an immaterial fee. We treat shipping as a fulfillment activity rather than as a separate obligation. We recognize prescription revenue only when we satisfy performance obligations by transferring a promised good or service to a customer. A good or service is considered to be transferred when the customer receives the goods or service or obtains control. Control refers to the customer’s ability to direct the use of, and obtain substantially all of the remaining benefits from, an asset. All of our performance obligations, and associated revenue, are transferred to customers at a point in time. Based on our contracts, we invoice customers once our performance obligations have been satisfied, at which point payment is unconditional. We disclose receivables from contracts with customers separately in the statement of financial position. Payment for goods or services sold by us is typically due between 30 and 60 days after an invoice is sent to the customer.

The transaction price of a contract is the amount of consideration which we expect to be entitled to in exchange for transferring promised goods or services to a customer. Prescription products are sold at fixed wholesale acquisition cost, or WAC, determined based on our list price. However, the total transaction price is variable as it is calculated net of estimated product returns, chargebacks, rebates, coupons, discounts and wholesaler fees. These estimates are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). In order to determine the transaction price, we estimate the amount of variable consideration at the outset of the contract either utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract or each variable consideration. The estimated amount of variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. In determining amounts of variable consideration to include in a contract's transaction price, we rely on our historical experience and other evidence that supports our qualitative assessment of whether revenue would be subject to a significant reversal. We consider all the facts and circumstances associated with both the risk of a revenue reversal arising from an uncertain future event and the magnitude of the reversal if that uncertain event were to occur. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our original estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such changes in estimates become known.

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. We do not allow product returns for prescription products that have been dispensed to a patient. We estimate the amount of our product sales that may be returned by our customers and record this estimate as a reduction of revenue in the period the related product revenue is recognized. Where historical rates of return exist, we use history as a basis to establish a returns reserve for products shipped to wholesalers. For our newly launched products, for which the right of return exists but for which we currently do not have history of product returns, we estimate returns based on available industry data, our own sales information and our visibility into the inventory remaining in the distribution channel. At the end of each reporting period, we may decide to constrain revenue for product returns based on information from various sources, including channel inventory levels and dating and sell-through data, the expiration dates of products currently being shipped, price changes of competitive products and any introductions of generic products. We recognize the amount of expected returns as a refund liability, representing the obligation to return the customer's consideration. Since our returns primarily consist of expired and short dated products that will not be resold, we do not record a return asset for the right to recover the goods returned by the customer at the time of the initial sale (when recognition of revenue is deferred due to the anticipated return). Return estimates are recorded in the accrued expenses and other current liabilities on the consolidated balance sheet.

We offer various rebate and discount 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. Estimates relating to these rebates and coupons are deducted from gross product revenues at the time the revenues are recognized. We record distributor fees based on amounts stated in contracts. Rebate and coupon estimates and distributor fees are recorded in accrued expenses and other current liabilities on the consolidated balance sheet. We estimate chargebacks based on number of units sold during the period taking into account prices stated in contracts and our historical experience. Estimates related to distributors fees, rebates, coupons and returns are disclosed in Note 7. We provide invoice discounts to our customers for prompt payment. Estimates relating to invoice discounts and chargebacks are deducted from gross product revenues at the time the revenues are recognized.

As part of the commercial launch for IMVEXXY® during the third quarter of 2018, we introduced a co-pay assistance program where enrolled patients do not pay more than $35 for up to 12 IMVEXXY® prescription fills. This allows patients to access the product at a reasonable cost regardless of insurance coverage. We reimburse pharmacies for this discount through third-party vendors. We consider these payments as consideration paid to the customer and reflect such payments as a reduction of the transaction price as we do not receive a distinct good or service related to these payments. The variable consideration is estimated based on contract prices, the estimated percentage of patients that will utilize the copay assistance, the average assistance paid, the estimated levels of inventory in the distribution channel and the current level of prescriptions covered by patients' insurance. Payers may change coverage levels for IMVEXXY® positively or negatively, at any time up to the time that we have formally contracted coverage with the payer. As such, the net transaction price of IMVEXXY® is susceptible to such changes in coverage levels, which are outside the influence of the Company. As a result, we constrain revenue recognized for IMVEXXY® to an amount that will not result in a significant revenue reversal in future periods. Our ability to estimate the net transaction price for IMVEXXY® is constrained by our estimates of the amount to be paid for the co-pay assistance program for IMVEXXY® which is directly related to the level of prescriptions paid for by insurance. As such, we record an accrual to reduce gross sales for the estimated co-pay and other patient assistance based on currently available third-party data and our internal analyses. We re-evaluate any constraint each reporting period.

OTC Products

Our over the counter, or OTC, and prescription prenatal vitamin products are generally variations of the same product with slight modifications in formulation and marketing. 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 in October 2017. We generated OTC revenue from product sales primarily to retail consumers. We recognized revenue from product sales upon shipment, when the rights of ownership and risk of loss have passed to the consumer. We included outbound shipping and handling fees, if any, in revenues, net, and bill them upon shipment. We included shipping expenses in cost of goods sold. A majority of our OTC customers paid for our products with credit cards, and we usually received the cash settlement in two to three banking days. Credit card sales minimized accounts receivable balances relative to OTC sales. We provided an unconditional 30-day money-back return policy under which we accept product returns from our retail and eCommerce OTC customers. We recognized revenue from OTC sales, net of estimated returns and sales discounts.

Disaggregation of revenue

The following table provides information about disaggregated revenue by product mix for the years ended December 31, 2018, 2017, and 2016:

	For the Years Ended December 31,		
	2018	2017	2016
Prescription vitamins	$ 15,041,259	$ 16,744,831	$ 18,854,984
IMVEXXY®	1,058,201	—	—
OTC products	—	32,882	501,466
Net revenue	$ 16,099,460	$ 16,777,713	$ 19,356,450

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 $1,682,746, $448,288, and $752,611 during the years ended December 31, 2018, 2017, and 2016, 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. 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 to 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, warrants and restricted stock awards 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,		
	2018	2017	2016
Stock options	20,872,824	23,365,225	21,767,854
Warrants	3,007,571	3,115,905	12,060,071
Restricted stock awards	1,040,000	—	—
	24,920,395	26,481,130	33,827,925

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. We have 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 August 2018, the FASB issued Accounting Standards Update, or ASU, 2018-13 which eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. The FASB developed the amendments to ASC 820 as part of its broader disclosure framework project, which aims to improve the effectiveness of disclosures in the notes to financial statements by focusing on requirements that clearly communicate the most important information to users of the financial statements. The new guidance is effective for all entities for fiscal years beginning after December 15, 2019 and for interim periods within those fiscal years. An entity is permitted to early adopt either the entire standard or only the provisions that eliminate or modify requirements. We are currently evaluating the effect of this guidance on our disclosures.

In June 2018, the FASB issued ASU 2018-07 to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance expands the scope of ASC 718 to include share-based payments granted to nonemployees in exchange for goods or services used or consumed in an entity's own operations and supersedes the guidance in ASC 505-50. The guidance is effective for public business entities in annual periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted, including in an interim period for which financial statements have not been issued, but not before an entity adopts ASC 606. We do not expect that the adoption of this standard will have a material effect on our consolidated financial statements and disclosures.

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. In July 2018, the FASB amended the new leases standard and issued ASU 2018-11, Leases, (Topic 842): Targeted Improvements to give entities another option for transition and to provide lessors with a practical expedient. We plan to adopt ASU 2016-02 on January 1, 2019 utilizing the alternative transition method allowed for under ASU 2018-11. While we are still finalizing the quantitative and qualitative impact of adopting this new standard and the subsequent amendments, the most significant impact is expected to be the recognition of a right of use asset and lease liability on our statement of financial position related to the operating leases for our new and existing office space. We elected the optional transition method of recognizing a cumulative-effect adjustment to the opening balance of retained earnings on January 1, 2019. Therefore, comparative financial information will not be adjusted and will continue to be reported under ASC 840. We also elected the transition relief package of practical expedients and as a result we will not assess 1) whether existing or expired contracts contain leases, 2) lease classification for any existing or expired leases, and 3) whether lease origination costs qualified as initial direct costs. We elected the short-term lease practical expedient by establishing an accounting policy to exclude leases with a term of 12 months or less. We will not separate lease components from non-lease components for our specified asset classes. Based on our preliminary calculations, we currently expect to recognize right-of-use asset and corresponding lease liability between $4 million to $5 million on our Consolidated Balance Sheet based on the present value of future minimum lease payments under operating leases in effect on January 1, 2019. Additionally, the adoption of the new standard will result in increased disclosure requirements in our quarterly and annual filings.

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 adopted this standard under the modified retrospective method to all contracts not completed as of January 1, 2018 and the adoption did not have a material effect on our financial statements but we expanded our disclosures related to contracts with customers.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants and the SEC did not, and are not expected to, have a material effect on our results of operations or financial position.

NOTE 3 – INVENTORY

Inventory consists of the following:

	December 31,	
	2018	2017
Finished products	$ 2,908,958	$ 1,485,358
Work in process	339,312	—
Raw materials	19,400	—
TOTAL INVENTORY	$ 3,267,670	$ 1,485,358

NOTE 4 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	December 31,	
	2018	2017
Prepaid sales and marketing costs	$ 5,148,789	$ 5,335,936
Debt financing fees (Note 8)	1,898,074	—
Prepaid insurance	790,465	680,243
Other prepaid costs	2,997,365	588,105
TOTAL OTHER CURRENT ASSETS	10,834,693	$ 6,604,284

NOTE 5 – FIXED ASSETS, NET

Fixed assets, net consist of the following:

	December 31,	
	2018	2017
Accounting system	$ 301,096	$ 301,096
Equipment	490,576	273,536
Furniture and fixtures	116,542	116,542
Computer hardware	80,211	80,211
Leasehold improvements	37,888	37,888
TOTAL FIXED ASSETS	1,026,313	809,273
Accumulated depreciation	(553,630)	(372,218)
TOTAL FIXED ASSETS, NET	$ 472,683	$ 437,055

Depreciation expense for the years ended December 31, 2018, 2017, and 2016 was $181,412, $141,601, and $77,906, 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, 2018 and 2017:

	December 31, 2018			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizable intangible assets:				
OPERA® software patent	$ 31,951	$ (10,484)	$ 21,467	10.75
Development costs of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	2,234,129	(282,485)	1,951,644	14
Hormone therapy drug candidate patents (pending)	1,855,279	—	1,855,279	n/a
Non-amortizable intangible assets:				
Multiple trademarks	264,289	—	264,289	indefinite
TOTAL	$ 4,477,391	$ (384,712)	$ 4,092,679	

	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	

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, 2018 and 2017, there was no impairment recognized related to intangible assets.

As of December 31, 2018, we had 21 issued domestic or U.S. patents and 24 issued foreign patents, including:

- 11 domestic patents and five foreign patents that relate to BIJUVA™ as well as 3 domestic patents that relate to non-approved doses of BIJUVA™. These patents establish an important intellectual property foundation for BIJUVA™ and are owned by us. The domestic patents will expire in 2032. The foreign patents will expire no earlier than 2032. In addition, we have pending patent applications relating to BIJUVA™ in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;

- Three foreign patents that relate to our progesterone-only candidate, which are owned by us. The foreign patent will expire no earlier than 2033. In addition, we have pending patent applications with respect to our progesterone-only candidate in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;

- Three domestic patents (two utility and one design) and 12 foreign patents (three utility and nine design) that relate to IMVEXXY®. These patents establish an important intellectual property foundation for IMVEXXY® and are owned by us. These domestic patents will expire in 2032 or 2033. The foreign utility patents will expire no earlier than 2033. The foreign design patents provide protection expiring no earlier than 2025. In certain jurisdictions, the foreign design patents provide protection through at least 2037. In addition, we have pending patent applications related to IMVEXXY® in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, New Zealand, Russia, South Africa, and South Korea;

- One domestic utility patent that relates to our topical-cream candidates, which is owned by us. The domestic patent will expire in 2035. We have pending patent applications with respect to our topical-cream candidates in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;

- One domestic utility patent and four foreign patents that relate to our transdermal-patch candidates, which are owned by us. The domestic utility patent will expire in 2032. The foreign patents will expire no earlier than 2033. We have pending patent applications with respect to our transdermal-patch candidates in the U.S., Australia, Brazil, Canada, Europe, Mexico, Japan, and South Africa;

- One domestic utility patent that relates to our OPERA® information-technology platform, which is owned by us and will expire in 2029; and

- One domestic utility patent that relates to TX-009HR, a progesterone and estradiol product candidate, which is owned by us and will expire in 2037. We have pending patent applications with respect to TX-009HR in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, New Zealand, Russia, South Africa, and South Korea.

Amortization expense was $112,474, $71,516, and $54,545 for the years ended December 31, 2018, 2017, and 2016, 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
2019	$	139,410
2020	$	139,410
2021	$	139,410
2022	$	139,410
2023	$	139,410
Thereafter	$	1,276,061

License Agreement with the Population Council

On July 30, 2018, we entered into the Council License Agreement to commercialize in the U.S. ANNOVERA™. We currently estimate that ANNOVERA™ will be commercially available as early as the third quarter of 2019 with a planned full commercial launch by the first quarter of 2020.

Under the terms of the Council License Agreement, we paid the Population Council a milestone payment of $20,000,000 within 30 days following approval by the FDA of the NDA for ANNOVERA™ and will be required to pay the Population Council $20,000,000 within 30 days following the release of the first commercial batch of ANNOVERA™. The Population Council is also eligible to receive milestone payments and royalties from commercial sales of ANNOVERA™. We will assume responsibility for marketing expenses related to the commercialization of ANNOVERA™. The milestone payment of $20,000,000 upon the FDA's approval of ANNOVERA™ in the third quarter of 2018 was recorded as a finite-lived intangible asset in the consolidated balance sheet and will be amortized on a straight-line basis once it becomes available for use which is expected to be upon release of first commercial batch of ANNOVERA™. In addition, we are required to pay the Population Council, on a quarterly basis, step-based royalty payments based on annual net sales of ANNOVERA™ in the U.S. by the Company and its affiliates and permitted licensees as follows: (i) if annual net sales are less than or equal to $50,000,000, a royalty of 5% of net sales; (ii) for annual net sales greater than $50,000,000 and less than or equal to $150,000,000, a royalty of 10% of such net sales; and (iii) for net sales greater than $150,000,000, a royalty of 15% of such net sales. The annual royalty rate will be reduced to 50% of the initial rate during the six-month period beginning on the date of the first arms-length commercial sale of a generic equivalent of the one-year vaginal contraceptive system that is launched by a third party in the U.S., and thereafter will be reduced to 20% of the initial rate. The Population Council has agreed to perform and pay the costs and expenses associated with four post-approval studies required by the FDA for ANNOVERA™ and we have agreed to perform and pay the costs and expenses associated with a post approval study required by the FDA to measure risk for venous thromboembolism, provided that if the costs and expenses associated with such post-approval study exceed $20,000,000, half of such excess will be offset against royalties or other payments owed by us to the Population Council under the Council License Agreement. We and the Population Council have agreed to form a joint product committee responsible for overseeing activities under the Council License Agreement. We will be responsible for all aspects of promotion, product positioning, pricing, education programs, publications, sales messages and any additional desired clinical studies for the one-year vaginal contraceptive system, subject to oversight and decisions made by the joint product committee. The Council License Agreement includes exclusive rights for us to negotiate co-development of two other investigational vaginal contraceptive systems in development by the Population Council.

We assess our intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. If impairment indicators are present or changes in circumstance suggest that impairment may exist, we perform a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, we would determine the fair value of the intangible asset and recognize an impairment loss if the carrying value of the intangible asset exceeds its fair value. We also evaluate the remaining useful life of intangible assets subject to amortization on a periodic basis to determine whether events and circumstances would indicate impairment or warrant a revision to the remaining useful life. If the estimate of an intangible asset's remaining useful life is changed, we will amortize the remaining carrying value of the intangible asset prospectively over the revised remaining useful life.

License Agreement with Knight Therapeutics Inc.

On July 30, 2018, we entered into a license and supply agreement, or the Knight License Agreement, with Knight pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY® and BIJUVA™ in Canada and Israel. Pursuant to the terms of the Knight License Agreement, Knight will pay us a milestone fee upon first regulatory approval in Canada of each of IMVEXXY® and BIJUVA™, sales milestone fees based upon certain aggregate annual sales in Canada and Israel of each of IMVEXXY® and BIJUVA™ and royalties based on aggregate annual sales of each of IMVEXXY® and BIJUVA™ in Canada and Israel. Knight will be responsible for all regulatory and commercial activities in Canada and Israel related to IMVEXXY® and BIJUVA™. We may terminate the Knight License Agreement if Knight does not submit all regulatory applications, submissions and/or registrations required for regulatory approval to use and commercialize IMVEXXY® and BIJUVA™ in Canada and Israel within certain specified time periods. We also may terminate the Knight License Agreement if Knight challenges our patents. Either party may terminate the Knight License Agreement for any material breach by the other party that is not cured within certain specified time periods or if the other party files for bankruptcy or other related matters. In connection with the Knight License Agreement, Knight entered into a subscription agreement with us, pursuant to which Knight purchased 3,921,568 of shares of our Common Stock concurrently with the closing of the underwritten public offering of Common Stock at a price of $5.10, for proceeds of $20,000,000, on August 6, 2018.

NOTE 7– ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of the following:

	December 31,	
	2018	2017
Accrued payroll, bonuses and commission costs	$ 6,854,002	$ 4,240,379
Allowance for coupons and returns	5,294,120	1,432,846
Accrued sales and marketing costs	2,288,028	420,162
Accrued compensated absences	1,178,110	945,457
Allowance for wholesale distributor fees	792,891	172,973
Accrued legal and accounting expense	385,824	600,350
Accrued research and development	388,675	366,933
Accrued rent	365,155	327,099
Accrued rebates	412,570	76,917
Accrued royalties	—	114,480
Other accrued expenses	375,573	525,999
TOTAL	$ 18,334,948	$ 9,223,595

NOTE 8 – DEBT

On May 1, 2018, we entered into a Credit and Security Agreement, or the Credit Agreement, with MidCap Financial Trust, or MidCap, as agent, or Agent, and as lender, and the additional lenders party thereto from time to time (together with MidCap as a lender, the Lenders).

On July 30, 2018, we entered into Amendment No. 1 to the Credit Agreement in order to permit our entry into the Council License Agreement. Pursuant to the amendment, we were required to receive aggregate net cash proceeds of at least $75,000,000 from the issuance of our equity securities within thirty days of entering into the Council License Agreement, which we did in connection with the August 2018 underwritten public offering.

The Credit Agreement provides a secured term loan facility in an aggregate principal amount of up to $200,000,000, or the Term Loan. Under the terms of the Credit Agreement, the Term Loan will be made in three separate tranches, with each tranche to be made available to us, at our option, upon our achievement of certain milestones. The first tranche of $75,000,000, or Tranche 1, was drawn by us on June 7, 2018, following approval by the FDA of the NDA for IMVEXXY®. The second tranche of $75,000,000, or Tranche 2, may be drawn by us on or before May 31, 2019, provided that we satisfy certain conditions described in the Credit Agreement, including (i) that Tranche 1 has been drawn, (ii) the approval by the FDA of the NDA for BIJUVA™ and (iii) we have consummated our first commercial sale in the United States of BIJUVA™. The third tranche of $50,000,000, or Tranche 3, may be drawn by us on or before December 31, 2019, provided that we satisfy certain conditions described in the Credit Agreement, including that (i) Tranche 2 has been drawn and (ii) we have generated at least $75,000,000 of consolidated net revenue attributable to commercial sales of BIJUVA™ and IMVEXXY® during the twelve-month period ending immediately prior to the funding of Tranche 3.

Amounts borrowed under the Term Loan bear interest at a rate equal to the sum of (i) one-month LIBOR (subject to a LIBOR floor of 1.50%) plus (ii) 7.75% per annum. Interest on amounts borrowed under the Term Loan is due and payable monthly in arrears. Principal on each Tranche is payable in 36 equal monthly installments beginning May 1, 2020 until paid in full on May 1, 2023, or the Maturity Date. However, if we generate at least $95,000,000 of consolidated net revenue attributable to commercial sales of BIJUVA™ and IMVEXXY® by December 31, 2019, we may extend the interest-only period by an additional 12 months to May 1, 2021. Interest expense related to this Term Loan for the year ended December 31, 2018 was $4,407,975.

The Term Loan may be prepaid, in whole or in part, subject to a prepayment fee on the amount being prepaid (or required to be prepaid, if such amount is greater) of (i) 4.0% for the first year following the Tranche 1 funding date, (ii) 3.0% for the second year following the Tranche 1 funding date and (iii) 2.0% thereafter. Upon repayment of the Term Loan at the Maturity Date or prepayment on any earlier date, we will be required to pay a termination payment based on the principal amount paid or prepaid. In connection with the execution of the Credit Agreement, we paid the Agent, for the benefit of all Lenders, an origination fee equal to 1.00% of the maximum potential amount of the Term Loan. We are also required to pay the Agent an annual administration fee of 0.25% based on the amounts borrowed under the Term Loan, in addition to other fees and expenses.

Our obligations under the Credit Agreement are secured, subject to customary permitted liens and other agreed upon exceptions, by a first priority perfected security interest in all of our existing and after-acquired assets. Our obligations under the Credit Agreement are guaranteed by each of our future direct and indirect subsidiaries (other than certain non-U.S. subsidiaries of ours and certain U.S. subsidiaries substantially all of whose assets consist of equity interests in non-U.S. subsidiaries, subject to certain exceptions). The Credit Agreement contains customary restrictions and covenants. Among other requirements, we must (i) maintain a minimum cash balance of $50,000,000 and (ii) achieve certain minimum consolidated net revenue amounts attributable to commercial sales of our products. As of December 31, 2018, we were in compliance with the covenants under the Credit Agreement.

The Credit Agreement also contains customary covenants that limit, among other things, our ability to (i) incur indebtedness, (ii) incur liens on our property, (iii) pay dividends or make other distributions, (iv) sell our assets, (v) make certain loans or investments, (vi) merge or consolidate, (vii) voluntarily repay or prepay certain permitted indebtedness and (viii) enter into transactions with affiliates, in each case subject to certain exceptions. The Credit Agreement contains customary representations and warranties and events of default relating to, among other things, payment defaults, breaches of covenants, the occurrence of any fact, event or circumstance that could reasonably be expected to result in a Material Adverse Effect (as defined in the Credit Agreement), delisting of our common stock, par value $0.001 per share, or Common Stock, bankruptcy and insolvency, cross defaults with certain material indebtedness and certain material contracts, judgments and inaccuracies of representations and warranties. Upon or after an event of default, the agent and the Lenders may declare all or a portion of our obligations under the Credit Agreement to be immediately due and payable and exercise other rights and remedies provided for under the Credit Agreement.

As of December 31, 2018, we had $75,000,000 in borrowings outstanding under the Term Loan, which are classified as long-term debt in the accompanying consolidated financial statements. We incurred $3,786,918 in debt issuance costs related to the Term Loan. Debt financing fees related to the entire Term Loan have been allocated pro rata between the funded and unfunded portions of each tranche. Allocated debt financing fees related to Tranche 1 of $1,888,844 have been reclassified to debt discount and are accreted to interest expense using the effective interest method. Debt financing fees associated with unfunded tranches are deferred as assets until Tranche 2 and Tranche 3 milestones have been met. As of December 31, 2018, deferred financing fees related to Tranche 2 and Tranche 3 are included in other current assets in the accompanying consolidated financial statements. During the year ended December 31, 2018, we amortized $269,859, of debt issuance costs related to Tranche 1 as interest expense in our accompanying consolidated financial statements. The overall effective interest rate was approximately 11% as of December 31, 2018. As of December 31, 2018, the carrying value of debt consists of the following:

	December 31, 2018
Term Loan	$ 75,000,000
Debt discount and financing fees	(1,618,986)
TOTAL LONG-TERM DEBT	$ 73,381,014

NOTE 9 – STOCKHOLDERS' EQUITY

Preferred Stock

At December 31, 2018, 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, 2018, we had 350,000,000 shares of Common Stock authorized for issuance, of which 240,462,439 shares of our Common Stock were issued and outstanding.

On August 1, 2018, we entered into an underwriting agreement with Goldman Sachs & Co. LLC, as representative of the underwriters, relating to an underwritten public offering of 12,745,098 shares of our Common Stock at a price of $5.10 per share. We granted the underwriters an option, exercisable for a period of 30 days, to purchase up to 1,911,764 additional shares of Common Stock. On August 2, 2018, the underwriters exercised the option in full. The net proceeds from the offering, including the exercise of the option to purchase additional shares, were approximately $69,908,000, after deducting the underwriting discount and offering expenses payable by us. The offering closed on August 6, 2018.

In connection with the Knight License Agreement, on August 6, 2018, Knight entered into a subscription agreement with us, pursuant to which Knight purchased 3,921,568 of shares of our Common Stock concurrently with the closing of the underwritten public offering of Common Stock at a price of $5.10, for proceeds of $20,000,000.

Issuances During 2018

During the year ended December 31, 2018, certain individuals exercised stock options to purchase 5,444,526 shares of Common Stock for $1,666,208 in cash. Also, during the year ended December 31, 2018, stock options to purchase 10,000 shares of Common Stock were exercised pursuant to the options' cashless exercise provisions, wherein 9,841 shares of Common Stock were issued.

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 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 the 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 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.

Warrants to Purchase Common Stock

As of December 31, 2018, we had warrants outstanding to purchase an aggregate of 3,007,571 shares of Common Stock with a weighted-average contractual remaining life of approximately 1.6 years, and exercise prices ranging from $0.24 to $8.20 per share, resulting in a weighted average exercise price of $2.78 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, 2018, we granted warrants to purchase 175,000 shares of Common Stock to outside consultants at an exercise price of $5.16 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 62.1%; risk free rate of 2.36%; and dividend yield of 0%. The grant date fair value of the warrants was $2.79 per share. The warrants vest ratably over a 12-month period and have an expiration date of March 15, 2023.

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. We recorded share-based compensation expense related to warrants previously issued of $494,136, $313,271 and $936,974 for the years ended December 31, 2018, 2017 and 2016, respectively, in the accompanying consolidated financial statements. At December 31, 2018, total unrecognized estimated compensation expense related to unvested warrants was approximately $106,000 which is expected to be recognized over weighted-average period of 0.2 years.

Summary of our Warrant activity during the year ended December 31, 2018:

	Number of Shares Under Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2017	3,115,905	$ 2.58	1.8	$ 11,348,273
Granted	175,000	$ 5.16		
Exercised	—			
Expired	(283,334)	$ 2.01		
Cancelled/Forfeited	—			
Balance at December 31, 2018	3,007,571	$ 2.78	1.58	$ 4,826,403
Vested and Exercisable at December 31, 2018	2,963,818	$ 2.75	1.54	$ 4,826,403
Unvested at December 31, 2018	43,753	$ 5.16	4.21	$ 0

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, 2018, 2017, and 2016 are set forth in the table below.

	2018	2017	2016
Weighted average exercise price	$ 5.16	$ 6.83	$ 7.90
Weighted average grant date fair value	$ 2.79	$ 3.67	$ 4.78
Risk-free interest rate	2.36%	1.47%	1.04-1.28%
Volatility	62.12%	63.24%	74.10-74.15%
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 the stock price is expected to fluctuate each year during the term of the instrument. Our calculation of estimated volatility is based on historical stock prices over a period equal to the term of the instrument. The expected volatility of warrants was estimated based on a historical volatility analysis of our Company as well as 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 FDA approval for our drug candidates, including a vaginal capsule for the treatment of 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 five 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 five 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, $0, and $77,026, 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 were going to 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. Since the receipt of such approval did not occur before warrant’s expiration date, the warrant expired on April 30, 2018.

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, 2018, 2017, and 2016, we recorded $0, $128,898, 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, 2018, no warrants were exercised.

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, which included SCI warrants issued in 2012 and 2013. 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, of which 500,000 shares related to SCI warrant issued in 2012.

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, 2018, there were non-qualified stock options to purchase 14,594,350 shares of Common Stock outstanding under the 2009 Plan. As of December 31, 2018, there were 866,912 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, 2018, there were non-qualified stock options to purchase 6,278,474 shares of Common Stock outstanding and 1,040,000 restricted stock units outstanding under the 2009 Plan. As of December 31, 2018, there were 2,433,333 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, 2018, 2017, and 2016 are set forth in the table below.

	2018	2017	2016
Weighted average exercise price	$ 5.45	$ 6.60	$ 6.22
Weighted average grant date fair value	$ 3.24	$ 3.82	$ 3.94
Risk-free interest rate	2.38-2.89%	1.84-2.05%	1.13-1.90%
Volatility	59.45-64.04%	61.56-64.25%	70.26-73.34%
Term (in years)	5.1-6.25	5.5-6.25	5.5-6.25
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 stock price is expected to fluctuate each year during the term of an award. Our calculation of estimated volatility is based on historical stock prices over a period equal to the term of the awards. The expected volatility of share options was estimated based on a historical volatility analysis of our Company as well as 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, 2018 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, 2017	23,365,225	$ 3.78	5.13	$ 64,664,821
Granted	3,264,500	$ 5.45		
Exercised	(5,454,526)	$ 0.31		$ 27,534,623
Expired	(25,000)	$ 7.76		
Cancelled/Forfeited	(277,375)	$ 5.47		
Balance at December 31, 2018	20,872,824	$ 4.93	5.94	$ 12,239,876
Vested and Exercisable at December 31, 2018	16,068,991	$ 4.61	5.09	$ 12,239,876
Unvested at December 31, 2018	4,803,833	$ 5.99	8.8	$ 0

At December 31, 2018, our outstanding options had exercise prices ranging from $0.10 to $8.92 per share. Share-based compensation expense related to options recognized in our results of operations for the years ended December 31, 2018, 2017, and 2016 was approximately $8,091,294, $6,447,154, and $16,139,225, respectively, and it is based on awards vested. At December 31, 2018, total unrecognized estimated compensation expense related to unvested options was approximately $12,175,000, which may be adjusted for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 2.01 years. No tax benefit was realized due to a continued pattern of operating losses.

Restricted Stock

Restricted stock awards granted under our 2009 and 2012 Plans entitle the holder to receive, at the end of vesting period, a specified number of shares of our Common Stock. Share-based compensation expense is measured by the market value of our Common Stock on the day of the grant. The shares vest ratably over the period specified in the grant. There is no partial vesting and any unvested portion is forfeited.

On December 13, 2018, we granted 1,040,000 restricted stock units to certain executive employees which will vest at the end of the third year. The grant date fair value was $4.06 per unit. During the year ended December 31, 2018, we recorded $73,132 in share-based compensation expense related to restricted stock units. At December 31, 2018, total unrecognized estimated compensation expense related to unvested restricted stock units was approximately $4,149,000, which may be adjusted for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 2.95 years. At December 31, 2018, 1,040,000 restricted stock awards remained outstanding.

Cash-Settled Stock Appreciation Rights (SARs)

On July 1, 2018, we issued cash-settled SARs to certain consultants and employees. The SARs plan year begins on July 1 and ends on or immediately following June 30, 2019. SARs are granted with a grant price equal to the market value of a share of our Common Stock on the date of grant. Cash-settled SARs provide for the cash payment of the excess of the fair market value of our Common Stock on June 30, 2019 over the grant price. Cash-settled SARs have no effect on dilutive shares or shares outstanding as any appreciation of our Common Stock over the grant price is paid in cash and not in Common Stock.

Cash settled SARs are recorded in our consolidated balance sheets as a liability until the date of exercise. The fair value of each SAR award is estimated using the Black-Scholes valuation model. In accordance with ASC Topic 718, “Stock Compensation,” the fair value of each SAR award is recalculated at the end of each reporting period and the liability and expense adjusted based on the new fair value and the percent vested. At December 31, 2018, we had 103,000 SARs outstanding and the liability related to SAR calculation was $3,406. The assumptions used to determine the fair value of the cash settled SAR awards at December 31, 2018 were life of 6 months, 49.7% volatility, 2.7% risk-free rate, and zero annual dividends. As of December 31, 2018, the fair value of SARs outstanding was $0.07 per award.

NOTE 10 – INCOME TAXES

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

	2018	2017	2016
United States	(132,617,160)	(76,925,380)	(89,875,459)
Total	(132,617,160)	(76,925,380)	(89,875,459)

For the years ended December 31, 2018, 2017, and 2016, there was no provision for income taxes, current or deferred. At December 31, 2018, we had a federal net operating loss carry forward of approximately $481,365,550. Approximately $338,668,076 of the federal net operating loss carry forward can be carried forward for 20 years and will begin to expire in 2031. The remaining $142,697,474 can be carried forward indefinitely.

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

	2018	2017	2016
Federal statutory tax rate	21.0%	34.0%	34.0%
State tax rate, net of federal tax benefit	5.2%	5.0%	5.4%
Adjustment in valuation allowances	(31.2)%	22.6%	(40.3)%
Excess stock benefit	5.3%	0.0%	0.0%
Federal income tax rate change	0.0%	(60.8)%	—%
Permanent and other differences	(0.3)%	(0.8)%	0.9%
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, 2018, 2017, and 2016 are as follows:

	2018	2017	2016
Deferred Income Tax Assets:			
Net operating losses	$ 140,891,764	$ 99,596,321	$ 111,730,450
R&D Credit	186,347	186,347	186,347
Total deferred income tax asset	141,078,111	99,782,668	111,916,797
Valuation allowance	(141,078,111)	(99,782,668)	(111,916,797)
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 our balance sheet and as such, a valuation allowance has been established against the deferred tax assets for the period ended December 31, 2018.

Unrecognized Tax Benefits

As of the period ended December 31, 2018, 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. As the result of our initial analysis of the impact of the Tax Act, we recorded a provisional amount of net tax expense of $46.7 million in 2017 related to the remeasurement of our deferred tax balances and other effects. We completed our accounting for the income tax effects of the Tax Act in 2018, and no material adjustments were required to the provisional amounts initially recorded.

NOTE 11 – 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, 2018, 2017 and 2016 we were billed by Catalent approximately $4,111,000, $3,646,000 and $3,647,000, respectively, for inventory related to our products, manufacturing activities related to our clinical trials, scale-up, registration batches, stability and validation testing. As of December 31, 2018 and 2017, there were amounts due to Catalent of approximately $88,000 and $523,000, respectively. In addition, we have minimum purchase requirements in place with Catalent as disclosed in Note 13, Commitments and Contingencies.

NOTE 12 - BUSINESS CONCENTRATIONS

We purchase our prescription products from several suppliers with approximately 43%, 33% and 24% of our purchases were supplied by three vendors each, respectively, during the year ended December 31, 2018, and 100% and 98% of our purchases were supplied by one vendor each for the years ended December 31, 2017 and 2016, respectively.

We sell our prescription 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, 2018, 2017 and 2016, four, four and three customers each, respectively, accounted for more than 10% of our total net revenues. Net revenue from the four customers combined accounted for approximately 76% of our net recognized revenue for the year ended December 31, 2018 and approximately 59% of our recognized revenue for the year ended December 31, 2017. Net revenue from three customers combined accounted for approximately 41% of our net revenue during the year ended December 31, 2016.

During the year ended December 31, 2018, McKesson Corporation accounted for approximately $1,610,000 of our revenue, Pillpack, Inc. accounted for approximately $5,075,000 of our revenue, AmerisourceBergen accounted for approximately $3,246,000 of our revenue and Cardinal Health accounted for approximately $2,308,000 of our revenue. During the year ended December 31, 2017, AmerisourceBergen accounted for approximately $2,667,000 of our revenue; McKesson Corporation accounted for approximately $1,959,000 of our revenue; Cardinal Health accounted for approximately $2,559,000 of our revenue and Pharmacy Innovations PA accounted for approximately $2,715,000 of our revenue. During the year ended December 31, 2016, Woodstock Pharmaceutical and Compounding accounted for approximately $2,247,000 of our revenue; Medical Center Pharmacy accounted for approximately $3,700,000 of our revenue and Pharmacy Innovations PA accounted for approximately $2,040,000 of our revenue.

NOTE 13 – COMMITMENTS AND CONTINGENCIES

Operating Leases

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. As of December 31, 2018, future minimum rental payments on non-cancelable operating leases are as follows:

Years Ending December 31,		
2019	$	1,094,116
2020		1,113,069
2021		943,127
Thereafter		—
Total minimum lease payments	$	3,150,312

In October 2018, we entered into a lease for new corporate offices in Boca Raton, Florida. The lease includes 56,212 rentable square feet, or full premises, of which lease on 7,561 square feet has commenced in 2018 and the lease on the remaining 48,651 square feet will commence no earlier than June 1, 2019, or full premises commencement date. The lease will expire 11 years after full premises commencement date, unless terminated earlier in accordance with the terms of the lease. We have the option to extend the term of the lease for two additional consecutive periods of five years. The term of the lease includes escalating rent and free rent periods. We are also responsible for certain other operating costs under the lease, including electricity and utility expenses. In addition, we will be entitled to reimbursement from the landlord of up to $1,800,000 for tenant improvements. As of December 31, 2018, future minimum rental payments on full premises related to the new operating leases are as follows, of which approximately $2.7 million relates to the lease on the suite that has commenced in 2018:

Years Ending December 31,	
2019	$ 48,288
2020	984,756
2021	1,779,384
2022	1,808,312
2023	1,837,963
Thereafter	12,390,298
Total minimum lease payments	$ 18,849,001

The rental expense during the years ended December 31, 2018, 2017 and 2016 was approximately $1,068,275, $1,029,205 and $709,483, respectively.

Intellectual Property Licenses

We have license agreements with third parties that provide for minimum royalty, license, and exclusivity payments to be paid by us for access to certain technologies. In addition, we pay royalties as a percent of revenue as described in Note 6, Intangible Assets, to these consolidated financial statements.

Purchase Commitments

We have a manufacturing and supply agreement whereby we are required to purchase from Catalent a minimum of number of softgels during the first contract year and a higher number or softgels after the first contract year. If the minimum order quantities of specific products are not met, we are required to pay Catalent 50% of the difference between the total amount we would have paid to Catalent if the minimum requirement had been fulfilled and the sum of all purchases of our products from Catalent during the contract year. At December 31, 2018, we had minimum purchase obligations related to this agreement of approximately $2,600,000 over the next five years. This amount represents our estimate of the minimum required payments under the agreement.

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, 2018, 2017, and 2016, we had no off-balance sheet arrangements that have had or are reasonably likely to have current or future effects 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 14 – SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

Summarized quarterly financial data for fiscal years 2018 and 2017 is as follows:

	2018 Quarter			
(In thousands, except per share)	1st	2nd	3rd	4th
Revenues	$ 3,773	$ 3,763	$ 3,474	$ 5,089
Gross profit	$ 3,139	$ 3,309	$ 2,775	$ 4,139
Net loss	$ (24,402)	$ (33,219)	$ (35,605)	$ (39,391)
Loss per common share, basic and diluted	$ (0.11)	$ (0.15)	$ (0.16)	$ (0.17)

	2017 Quarter			
(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)

Exhibit 10.20

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HEREWITH OMITS THE INFORMATION SUBJECT TO THE CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED AS [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

EXECUTION VERSION

SOFTGEL COMMERCIAL SUPPLY AGREEMENT
(Estradiol and Progesterone softgel capsules)

This Softgel Commercial Supply Agreement ("**Agreement**") is made as of this 24th day of June, 2016 ("**Effective Date**"), by and between TherapeuticsMD, Inc., a Nevada corporation, with a place of business at 6800 Broken Sound Parkway NW, Third Floor, Boca Raton, Florida 33487 ("**Client**"), and Catalent Pharma Solutions, LLC, a Delaware limited liability company, having a place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873 ("**Catalent**").

RECITALS

A. Client is a company that develops, markets and sells pharmaceutical products;

B. Catalent is a leading provider of advanced technologies, and development, manufacturing and packaging services for pharmaceutical, biotechnology and consumer healthcare companies;

C. Client and Catalent have entered into the Master Development and Clinical Supply Agreement dated as of December 4, 2015 and amended on April 20, 2016 (as amended, the "**Development Agreement**"); and

D. Client desires to engage Catalent to provide certain services to Client in connection with the processing of Client's Product, and Catalent desires to provide such services, all pursuant to the terms and conditions set forth in this Agreement.

THEREFORE, in consideration of the mutual covenants, terms and conditions set forth below, the parties agree as follows:

ARTICLE 1
DEFINITIONS

The following terms have the following meanings in this Agreement:

1.1 "**Acknowledgement**" has the meaning set forth in Section 4.3.

1.2 "**Affiliate(s)**" means, with respect to Client or any third party, any corporation, firm, partnership or other entity that controls, is controlled by or is under common control with such entity; and with respect to Catalent, Catalent Pharma Solutions, Inc. and any corporation, firm, partnership or other entity controlled by it. For the purposes of this definition, "**control**" means the ownership of at least 50% of the voting share capital of an entity or any other comparable equity or ownership interest or possession of the right to control the management and policies of such entity.

1.3 "**Agreement**" has the meaning set forth in the introductory paragraph, and includes all its Attachments and other appendices agreed to by the parties (all of which are incorporated herein by reference) and any amendments to any of the foregoing made as provided herein or therein.

1.4 "**API**" means the generic compounds Estradiol and Progesterone, as further described in the Specifications that have been released by Client and provided to Catalent, along with a certificate of analysis, as provided in this Agreement.

1.5 "**Applicable Laws**" means, with respect to Client, all laws, ordinances, rules and regulations of each jurisdiction in which API or Product is produced, marketed, distributed, used or sold; and with respect to Catalent, all laws, treaties, or ordinances, rules, regulations, cGMP, guidances, interpretations, authorizations, judgments, directives, injunctions, or orders of any court of any international, national, regional, local, or other governmental body, agency, authority, or court, or arbitrator, that has jurisdiction over the location where Catalent performs services under this Agreement (and applicable cGMP), including, but not limited to, the Federal Food, Drug and Cosmetic Act and Good Laboratory Practices, in each of the foregoing cases as in effect from time-to-time.

1.6 "**Batch**" means a defined quantity of Product that has been or is being Processed in accordance with the Specifications.

1.7 "**Catalent**" has the meaning set forth in the introductory paragraph, or any successor or permitted assign. Catalent shall have the right to cause any of its Affiliates, upon prior written notice to and approval from Client, to perform any of its obligations hereunder, and Client upon its prior approval of the use of the Affiliate, shall accept such performance as if it were performance by Catalent, but Catalent shall remain jointly and severally liable for the performance by any of its Affiliates under this Agreement.

1.8 "**Catalent Defective Processing**" has the meaning set forth in Section 5.2.

1.9 "**Catalent Indemnitees**" has the meaning set forth in Section 13.2.

1.10 "**Catalent IP**" has the meaning set forth in the Development Agreement.

1.11 "**cGMP**" means current Good Manufacturing Practices promulgated by the Regulatory Authorities in the jurisdictions included in Applicable Laws (as applicable to Client and Catalent respectively). In the United States, this includes 21 C.F.R. Parts 210 and 211, as amended together with pertinent guidelines and guidance documents; in the European Union, this includes 2003/94/EEC Directive (as supplemented by Volume 4 of EudraLex published by the European Commission), as amended, if and as implemented in the relevant constituent country, together with pertinent guidelines and guidance documents, in Japan (this includes the guidelines of good manufacturing control and quality control based on the requirements of the Pharmaceutical Affairs law of Japan as implemented in April of 2005), and in Canada (including the Food and Drugs Act, pertinent rules and regulations promulgated by Health Canada including Part C, Division 2 of the Food and Drugs Regulations and the Good Manufacturing Practices (GMP) Guidelines – 2009 Edition, Version 2).

1.12 "**Client**" has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.13 "**Client Indemnitees**" has the meaning set forth in Section 13.1.

1.14 "**Client IP**" has the meaning set forth in the Development Agreement.

1.15 "**Client-supplied Materials**" means any materials to be supplied by or on behalf of Client to Catalent for Processing, as provided in Attachment A, including API and reference standards.

1.16 "**Commencement Date**" means the date of first commercial sale by Client following approval by a Regulatory Authority of Catalent as a manufacturer of the Product. Client shall notify Catalent in writing promptly following such first commercial sale.

1.17 "**Confidential Information**" has the meaning set forth in Section 10.1.

1.18 "**Contract Year**" means each consecutive 12 month period beginning on the Commencement Date or anniversary thereof, as applicable.

1.19 "**Defective Product**" has the meaning set forth in Section 5.2.

1.20 "**Development Agreement**" has the meaning set forth in Recital C.

1.21 "**Development Batch**" has the meaning set forth in the Development Agreement.

1.22 "**Discloser**" has the meaning set forth in Section 10.1.

1.23 "**Effective Date**" has the meaning set forth in the introductory paragraph.

1.24 "**Exception Notice**" has the meaning set forth in Section 5.2.

1.25 "**Facility**" means Catalent's facility located in St. Petersburg, Florida or Morrisville, North Carolina; or such other facility as agreed by the parties in writing.

1.26 "**Firm Commitment**" has the meaning set forth in Section 4.2.

1.27 "**Generic Product"** has the meaning set forth in Section 11.5.

1.28 "**Invention**" has the meaning set forth in Article 11.

1.29 "**Losses**" has the meaning set forth in Section 13.1.

1.30 "**Marks**" means trademarks, trade names, service marks, logos and symbols.

1.31 "**Minimum Requirement**" has the meaning set forth in Section 4.1.

1.32 "**Process**" or "**Processing**" means the compounding, filling, encapsulating, producing, testing and bulk packaging (but not secondary or retail packaging) of Client-supplied Materials and Raw Materials into Product by Catalent, in accordance with the Specifications and under the terms of this Agreement.

1.33 "**Processing Date**" means the day on which the first step of physical Processing is scheduled to occur, as identified in an Acknowledgement.

1.34 "**Process Know-How**" means all know-how provided by Client to Catalent and, subject to the exclusions in the next sentence, certain know-how to the extent it relates to the processing, manufacture, quality control, formulation, filling, finishing, testing and packaging of a Product, whether in bulk or final form, and regardless of container, including, without limitation, analytical tests methods for in-process and final Product, copies of manufacturing records, formulation recipes, designs and drawings (limited to ink print design, and capsule color, shape, and design), and formulae, used in the delivery of Processing for a Product to the extent it is in the possession, or under the control, of Catalent, its Affiliates and their respective subcontractors; "Process Know-How" does not include any of the following: (i) Catalent IP, and (ii) the proprietary process information contained in the drug master file, including without limitation, the gelatin master batch record, the gelatin conversion section of the master batch record, the encapsulation set up page, and processing aids (lubricants and wash solution).

1.35 "**Process Know-How Transfer**" means the commercially reasonable efforts of the parties undertaken pursuant to the Process Know-How Transfer Plan to transfer copies of all Process Know-How (together with relevant books and records) and the "Standards" (defined below) in Catalent's possession, to Client as set forth in greater detail in the Process Know-How Transfer Plan. Catalent shall only be obligated to use its commercially reasonable efforts in the implementation of the Process Know-How Transfer Plan, and in no case shall Catalent personnel visit the site of Client or any third party manufacturer of softgels, as the case may be. For the avoidance of doubt, the foregoing prohibition shall not be construed as a basis for Catalent refusing to assist in the transfer of analytical methods to an independent laboratory, including a visit by Catalent personnel to such site to assist in method transfer, if, and only as, reasonably necessary, and at Client's cost and expense. As used herein "Standards" means data, information, or samples of validated or Catalent manufactured or partially manufactured Product or other indicia measured at various points during Processing, to the extent Catalent possesses such data, information, or samples. "Standards" does not include any of the following: (i) Catalent IP, and (ii) the proprietary process information contained in the drug master file, including without limitation, the gelatin master batch record, the gelatin conversion section of the master batch record, the encapsulation set up page, and processing aids (lubricants and wash solution).

1.36 "**Process Know-How Transfer Plan**" means that plan addressing orderly Process Know-How Transfer, to be prepared in writing and reasonably agreed to by the parties within the sixty (60) day period following notice from Client to Catalent of its intention to commence Process Know-How Transfer.

1.37 "**Product**" means the bulk pharmaceutical product containing the API, as more specifically described in the Specifications.

1.38 "**Product Maintenance Services**" has the meaning set forth in Section 2.2.

1.39 "**Purchase Order**" has the meaning set forth in Section 4.3.

1.40 "**Quality Agreement**" has the meaning set forth in Section 9.6.

1.41 "**Raw Materials**" means all raw materials, supplies, components and packaging necessary to manufacture and ship Product in accordance with the Specifications, but excluding Client-supplied Materials.

1.42 "**Recall**" has the meaning set forth in Section 9.5.

1.43 "**Recipient**" has the meaning set forth in Section 10.1.

1.44 "**Regulatory Approval**" means any approvals, permits, product and/or establishment licenses, registrations or authorizations, including approvals pursuant to U.S. Investigational New Drug Applications, New Drug Applications and Abbreviated New Drug Applications, as applicable, of any Regulatory Authorities that are necessary or advisable in connection with the development, manufacture, testing, use, storage, exportation, importation, transport, promotion, marketing, distribution or sale of API or Product in the Territory.

1.45 "**Regulatory Authority**" means the international, federal, state or local governmental or regulatory bodies, agencies, departments, bureaus, courts or other entities in the Territory that are responsible for (A) the regulation (including pricing) of any aspect of pharmaceutical or medicinal products intended for human use including, but not limited to, their manufacture, handling and storage, or (B) health, safety or environmental matters generally. In the United States, this includes the United States Food and Drug Administration.

1.46 "**Representatives**" of an entity mean such entity's duly-authorized officers, directors, employees, agents, accountants, attorneys or other professional advisors.

1.47 "**Review Period**" has the meaning set forth in Section 5.2.

1.48 "**Rolling Forecast**" has the meaning set forth in Section 4.2.

1.49 "**Sample**" has the meaning set forth in Section 5.1.

1.50 "**Softgel Technology**" means Catalent's proprietary technology, whether or not patented or patentable, for the manufacture of softgels for various uses, including the oral administration of pharmaceutically active ingredients (including health and nutritional substances). The Softgel Technology includes proprietary know how relating to (A) the development of fill and shell formulations, (B) the design and use of the encapsulation process to enhance stability, solubility, bioavailability and manufacturability of active ingredient chemical entities in softgels, (C) the selection and preparation of solvents, vehicles, excipients, surfactants, stabilizers, gelatin and gelatin substitutes, plasticizers and other components of the liquid fill and the shell and (D) certain encapsulation, drying and related manufacturing techniques and machinery for making experimental, clinical, or commercial quantities of softgels. For clarity, Softgel Technology does not encompass any technology or information provided by Client to Catalent, including, but not limited to, the formulation of the Product.

1.51 "**Specifications**" means the procedures, requirements, standards, quality control testing and other data and the scope of services as set forth in Attachment A, as modified from time to time in accordance with Article 8.

1.52 "**Term**" has the meaning set forth in Section 16.1.

1.53 "**Territory**" means the United States of America, and any other country that the parties agree in writing to add to this definition of Territory in an amendment to this Agreement, except shall not include countries that are targeted by the comprehensive sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States. Catalent shall not be obliged to Process Products for sale in any of such countries if it is prevented from doing so, or would be required to obtain or apply for special permission to do so, due to any restrictions (such as embargoes) imposed on it by any governmental authorities, including without limitation, those imposed by the U.S. Office of Foreign Asset Control.

1.54 "**Unit Pricing**" has the meaning set forth in Section 7.1(A).

1.55 "**Vendor**" has the meaning set forth in Section 3.2(B).

ARTICLE 2
PROCESSING & RELATED SERVICES

2.1 Supply and Purchase of Product. Catalent shall Process Product in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement.

2.2 Product Maintenance Services. Client will receive the following product maintenance services (the "**Product Maintenance Services**"): one annual audit (as further described in Section 9.5); regulatory audits (as further described in Section 9.4); one annual Product review (within the meaning of 21 CFR § 221.180); drug master file updates for the Territory, if applicable; access to document library over and above the Quality Agreement, including additional copies of Batch paperwork or other Batch documentation; assistance in preparing Regulatory Approvals; Product document and sample storage relating to cGMP requirements; vendor re-qualification; and maintenance, updates and storage of master batch records and audit reports. For avoidance of doubt, the following services and items are not included in Product Maintenance Services: technology transfer; analytical work; stability; and process rework.

2.3 Other Related Services. Catalent shall provide such Product-related services, other than Processing or Product Maintenance Services, as agreed to in writing by the parties from time to time. Such writing shall include the scope and fees for any such services and be appended to this Agreement. The terms and conditions of this Agreement shall govern and apply to such services.

2.4 Validation Services. Catalent shall Process validation Batches and perform validation services at prices to be agreed in writing between the parties.

ARTICLE 3
MATERIALS

3.1 Client-supplied Materials.

A. Client shall supply to Catalent for Processing, at Client's cost, all Client-supplied Materials, in quantities sufficient to meet Client's requirements for Product. Client shall deliver such items and associated certificates of analysis to the Facility no later than 60 days (but not earlier than 90 days, unless agreed to by the Parties or accepted by Catalent) before the Processing Date. Client's failure to fulfill the foregoing obligations in this Section 3.1 shall not by itself give rise to a cause of action in Catalent or a right by it to terminate this Agreement. Client shall be responsible at its expense for securing any necessary DEA, export or import, similar clearances, permits or certifications required in respect of such supply. Catalent shall use such items solely for Processing. Prior to delivery of any such items, Client shall provide to Catalent a copy of all associated material safety data sheets, safe handling instructions and health and environmental information and any Regulatory certifications or authorizations that may be required under Applicable Laws relating to the API and Product, and shall promptly provide any updates thereto.

B. Following receipt of Client-supplied Materials, Catalent shall inspect such items employing such measures as are set forth in the Specifications. Catalent will receive, handle, store and use all Client-supplied Materials in compliance with all Applicable Laws and labeled storage requirements, or lacking labeled storage requirement, the written instructions of Client, as agreed to by Catalent, such agreement not to be unreasonably withheld. Unless otherwise expressly required by the Specifications, Catalent shall have no obligation to test such items to confirm that they meet the associated specifications or certificate of analysis or otherwise; but in the event that Catalent detects a nonconformity with Specifications, Catalent shall give Client prompt notice of such nonconformity. Catalent shall not be liable for any defects in Client-supplied Materials, or in Product resulting from defective Client-supplied Materials, unless Catalent failed to properly perform the foregoing obligations. Catalent shall follow Client's reasonable written instructions in respect of return or disposal of defective Client-supplied Materials, at Client's cost.

C. Client shall retain title to Client-supplied Materials at all times and shall bear the risk of loss thereof, except for losses to the extent due to the negligent acts or omissions of Catalent or Catalent's failure to follow storage and handling requirements or mutually agreed to written instructions of Client, in each case, subject to Article 14.

3.2 Raw Materials.

A. Catalent shall be responsible for procuring, inspecting and releasing adequate Raw Materials as necessary to meet the Firm Commitment, unless otherwise agreed to by the parties in writing. Catalent shall not be liable for any delay in delivery of Product if (i) Catalent is unable to obtain, in a timely manner, a particular Raw Material necessary for Processing and (ii) Catalent placed orders for such Raw Materials promptly following receipt of Client's Firm Commitment. In the event that any Raw Material becomes subject to purchase lead time beyond the Firm Commitment time frame, the parties will negotiate in good faith an appropriate amendment to this Agreement, including Section 4.2.

B. In certain instances, Client may require a specific supplier, manufacturer or vendor ("**Vendor**") to be used for Raw Material. In such an event occurring after the Effective Date, (i) such Vendor will be identified in the Specifications and (ii) the Raw Materials from such Vendor shall be deemed Client-supplied Materials for purposes of this Agreement. If the cost of the Raw Material from any such Vendor is greater than Catalent's costs for the same raw material of equal quality from other vendors, Catalent shall add the difference between Catalent's cost of the Raw Material and the Vendor's cost of the Raw Material to the Unit Pricing. Client will be responsible for all costs associated with qualification of any Vendor specifically required to be used upon written instruction from Client, which Vendor has not been previously qualified by Catalent.

C. In the event of (i) a Specification change for any reason, (ii) obsolescence of any Raw Material or (iii) termination or expiration of this Agreement, Client shall bear the cost of any unused Raw Materials (including packaging), so long as Catalent purchased such Raw Materials in quantities consistent with Client's most recent Firm Commitment and the vendor's minimum purchase obligations. Such Raw Material shall be the property of Client upon payment therefor.

3.3 Artwork and Labeling. Client shall provide or approve, prior to the procurement of applicable Raw Material, all artwork, advertising and labeling information necessary for Processing, if any. Such artwork, advertising and labeling information is and shall remain the exclusive property of Client, and Client shall be solely responsible for the content thereof. Such artwork, advertising and labeling information or any reproduction thereof may not be used by Catalent in any manner other than performing its obligations hereunder.

ARTICLE 4
MINIMUM COMMITMENT, PURCHASE ORDERS & FORECASTS

4.1 Minimum Requirement. During each Contract Year, Client shall purchase the minimum number of units of Product set forth on Attachment B ("**Minimum Requirement**"). If Client does not purchase such Minimum Requirement during any Contract Year, then within [***] days after the end of such Contract Year, Client shall pay Catalent [***] of difference between (A) the total amount Client would have paid to Catalent if the Minimum Requirement had been fulfilled for the Product and (B) the sum of all purchases of Product from Catalent during such Contract Year. For the avoidance of doubt, validation Batches which are commercialized by Client shall count towards satisfaction of the Minimum Requirement in the first Contract Year.

4.2 Forecast. On or before the [***] of each calendar month, beginning at least [***] prior to the anticipated Commencement Date, Client shall furnish to Catalent a written [***] rolling forecast of the quantities of Product that Client intends to order from Catalent during such period ("**Rolling Forecast**"); *provided*, that the quantities forecasted to be purchased in any rolling [***] period commencing on the [***] of the Commencement Date shall not be less than [***] of the Minimum Requirement for the relevant Contract Year. The first [***] of each such Rolling Forecast shall constitute a binding order for the quantities of Product specified therein ("**Firm Commitment**") and the following [***] of the Rolling Forecast shall be non-binding, good faith estimates.

4.3 Purchase Orders.

A. From time to time as provided in this Section 4.3(A), Client shall submit to Catalent a binding, non-cancelable purchase order for Product specifying the number of Batches to be Processed, the Batch size (to the extent the Specifications permit Batches of different sizes) and the requested delivery date for each Batch ("**Purchase Order**"); *provided*, that no Purchase Order may be for less than [***]. Concurrently with the submission of each Rolling Forecast, Client shall submit a Purchase Order for the Firm Commitment. Purchase Orders for quantities of Product in excess of the Firm Commitment shall be submitted by Client at least [***] days in advance of the delivery date requested in the Purchase Order.

B. Promptly following receipt of a Purchase Order, Catalent shall issue a written acknowledgement ("**Acknowledgement**") that it accepts or rejects such Purchase Order. Each acceptance Acknowledgement shall either confirm the delivery date set forth in the Purchase Order or set forth a reasonable alternative delivery date, and shall include the Processing Date. Catalent may reject any Purchase Order in excess of the Firm Commitment or otherwise not given in accordance with this Agreement; provided, however, Catalent shall accept any Purchase Order that meets the requirements of this Agreement if Client is not in arrears in paying amounts due and payable under this Agreement.

C. Notwithstanding Section 4.3(B), Catalent shall use commercially reasonable efforts to supply Client with quantities of Product which are up to [***] in excess of the quantities specified in the Firm Commitment, subject to Catalent's other supply commitments and manufacturing, packaging and equipment capacity.

D. In the event of a conflict between the terms of any Purchase Order or Acknowledgement and this Agreement, the terms of this Agreement shall control.

4.4 Catalent's Cancellation of Purchase Orders. Notwithstanding Section 4.5, Catalent reserves the right to cancel all, or any part of, a Purchase Order upon written notice to Client, and Catalent shall have no further obligations or liability with respect to such Purchase Order, if Client refuses or fails to timely supply conforming Client-supplied Materials in accordance with Section 3.1. Any such cancellation of Purchase Orders shall not constitute a breach of this Agreement by Catalent nor shall it absolve Client of its obligation in respect of the Minimum Requirement. Catalent shall use reasonable efforts to re-schedule Processing reflected on such Purchase Order promptly after conforming Client-supplied Materials are delivered to Catalent.

4.5 Client's Modification or Cancellation of Purchase Orders.

A. Client may modify the delivery date or quantity of Product in a Purchase Order only by submitting a written change order to Catalent at least [***] business days in advance of the earliest Processing Date covered by such change order. Such change order shall be effective and binding against Catalent only upon the written approval of Catalent, and notwithstanding the foregoing, Client shall remain responsible for the Firm Commitment.

B. Notwithstanding any amounts due to Catalent under Section 4.4 or Section 4.1, if Client fails to place Purchase Orders sufficient to satisfy the Firm Commitment, Client shall pay to Catalent the Unit Pricing for all Units that would have been Processed if Client has placed Purchase Orders sufficient to satisfy the Firm Commitment and Catalent shall Process and deliver such quantity of Product as if Purchase Orders sufficient to satisfy the Firm Commitment had been placed.

C. Neither changes to nor postponement of any Batch of Product, nor the payment of the fees described in this Section 4.5, will reduce or in any way effect Client's Minimum Requirement obligations set forth in Section 4.1; provided, however, any payment pursuant to this Section 4.5 shall be applied towards the Minimum Requirement.

4.6 Unplanned Delay or Elimination of Processing. Catalent shall use commercially reasonable efforts to meet the Purchase Orders, subject to the terms and conditions of this Agreement. Catalent shall provide Client with as much advance notice as practicable if Catalent determines that any Processing will be delayed or eliminated for any reason. Any delay in Processing by Catalent in excess of [***], but less than [***], days shall result in a proportional reduction of the Minimum Requirement pertaining to the then-current Contract Year, based on the actual number of days of delay until normal, orderly Processing re-commences. Any delay in Processing subsisting for a continuous period of [***] days, or the elimination of Processing representing in excess of [***] of the Minimum Requirement for the Contract Year in which the relevant Purchase Orders were submitted shall result in an elimination of the Minimum Requirement for the balance of such Contract Year, so long as such delay or elimination was not attributable to an act or omission of Client.

4.7 Observation of Processing. In addition to Client's audit right pursuant to Section 9.4, Client may send up to 2 Representatives to the Facility to observe Processing for a maximum of 10 days per Contract Year (unless otherwise agreed by Catalent in writing), upon at least 10 business days' prior notice, at reasonable times during regular business hours. The foregoing limitations shall not apply to time spent by Client Representatives on site at the Facility to participate in or witness research and development activities or to witness Processing of validation Batches of Product. Such Representatives shall abide by all Catalent safety rules and other applicable employee policies and procedures, and Client shall be responsible for such compliance. Client shall indemnify and hold harmless Catalent for any action, omission or other activity of such Representatives while on Catalent's premises. Client's Representatives who are not employees of Client shall be required to sign Catalent's standard visitor confidentiality agreement prior to being allowed access to the Facility.

ARTICLE 5
TESTING; RELEASE

5.1 Batch Release. After Catalent completes Processing of a Batch, Catalent shall also provide Client or its designee with Catalent's certificate of analysis and certificate of compliance for such Batch. Issuance of a certificate of analysis and a certificate of compliance by Catalent constitutes release of the Batch by Catalent to Client. Client shall be responsible for final release of Product to the market.

5.2 Testing; Rejection. No later than [***] days after receipt of the Batch ("**Review Period**"), Client or its designee shall notify Catalent whether the Batch conforms to Specifications. Upon receipt of notice from Client that a Batch meets Specifications, or upon failure of Client to respond by the end of the Review Period, the Batch shall be deemed accepted by Client and Client shall have no right to reject such Batch other than for defects which existed at the time of delivery and were not discovered or discoverable in the exercise of reasonable care ("**Latent Defects**"). For the avoidance of doubt, (i) Batches failing to meet Specifications at the time of delivery due to Latent Defects may be rejected, if at all, only upon notice to Catalent within [***] days following the date on which such Latent Defect was discovered or should have been discovered in the exercise of reasonable care and (ii) in no event may Client reject Product after such Product's expiration date. If Client or its designee timely notifies Catalent in writing (an "**Exception Notice**") that a Batch does not conform to the Specifications or otherwise does not meet the warranty set forth in Section 12.1(A), whether due to a Latent Defect or otherwise ("**Defective Product**"), and provides a sample of the alleged Defective Product, Catalent shall conduct an appropriate investigation in its discretion to determine whether or not it agrees with Client that Product is Defective Product and to determine the cause of any nonconformity. If Catalent agrees that Product is Defective Product and determines that the cause of nonconformity is attributable to Catalent's failure to perform the Processing in accordance with the Specifications ("**Catalent Defective Processing**"), then Section 5.4 shall apply. For avoidance of doubt, where the cause of nonconformity cannot be determined or assigned, it shall be deemed not Catalent Defective Processing.

5.3 Discrepant Results. If the parties disagree as to whether Product is Defective Product and/or whether the cause of the nonconformity is Catalent Defective Processing, and this is not resolved within 30 days of the Exception Notice date, the parties shall cause a mutually acceptable independent third party to review records, test data and to perform comparative tests and/or analyses on samples of the alleged Defective Product and its components, including Client-supplied Materials. The independent party's results as to whether or not Product is Defective Product and the cause of any nonconformity shall be final and binding. Unless otherwise agreed to by the parties in writing, the costs associated with such testing and review shall be borne by Catalent if Product is Defective Product attributable to Catalent Defective Processing, and by Client in all other circumstances. Client will be apprised in writing of all Defective Product investigations executed by Catalent on Client's materials/products, including Product and Client-supplied Materials, as well as final investigation outcome and conclusion(s).

5.4 Defective Processing. Catalent shall, at Client's option, either (A) replace at its cost another Batch of Product (as a replacement for any Batch of Defective Product attributable to Catalent Defective Processing) using Client-supplied Materials provided at Client's cost or (B) credit any payments made by Client for such Batch. THE OBLIGATION OF CATALENT TO REPLACE CATALENT DEFECTIVE PROCESSING IN ACCORDANCE WITH THE SPECIFICATIONS OR CREDIT PAYMENTS MADE BY CLIENT FOR DEFECTIVE PRODUCT ATTRIBUTABLE TO CATALENT DEFECTIVE PROCESSING SHALL BE CLIENT'S SOLE AND EXCLUSIVE REMEDY UNDER THIS AGREEMENT FOR DEFECTIVE PRODUCT AND IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED.

ARTICLE 6
DELIVERY

6.1 Delivery. Catalent shall deliver Product ExWorks (Incoterms 2010) at the Facility promptly following Catalent's release of Product; provided, however, Catalent shall be responsible for loading the Product on the carrier's vehicle using due care. Catalent shall segregate and store all Product until tender of delivery. Title to Product shall transfer to Client upon such delivery. Client shall qualify at least 2 carriers to ship Product and then designate the priority of such qualified carriers to Catalent.

6.2 Storage Fees. If Client fails to take delivery of any Product on any scheduled delivery date, Catalent shall store such Product until otherwise instructed by Client and Client shall be invoiced on the first day of each month following such scheduled delivery for reasonable administration and storage costs ([***] per pallet per month). Client will have at least [***] days after being notified that Product is released to take delivery, and Catalent will provide reasonable notification of the scheduled dates when Product is expected to be released. Such items shall be stored in compliance with requirements set forth in the Specification, or if no such storage Specification exists for such item, Catalent shall store such items using due care taking into account the identity of such item.

6.3 Subcontracting. Catalent may utilize third parties to provide any part of the Processing only with the prior written approval of Client, provided that the foregoing will not apply to generally available goods and services or to subcontracting to Catalent Affiliates. If Client approves a subcontractor, then Catalent shall enter a written agreement with such subcontractor that enables Catalent to comply with its obligations under this Agreement and places such subcontractors under obligations of confidentiality, non-use and intellectual property ownership no less burdensome than those set forth herein and applicable to Catalent. Catalent will oversee all services performed by any subcontractor, and will be responsible for such services as if such services were performed by Catalent. Catalent shall remain liable for the performance of its subcontractors under this Agreement. The use of subcontractors shall not relieve Catalent of any responsibility under this Agreement.

ARTICLE 7
PAYMENTS

7.1 Fees. In consideration for Catalent performing services hereunder:

A. Client shall pay Catalent the unit pricing for Product set forth on Attachment B ("**Unit Pricing**"). Catalent shall submit an invoice to Client for such fees upon tender of delivery of Product as provided in Section 6.1.

B. Client shall pay Catalent the annual fees for Product Maintenance Services set forth on Attachment B. Catalent shall submit an invoice to Client for such fees upon the Effective Date and upon each anniversary of the Effective Date during the Term.

C. Other Fees. Client shall pay Catalent for all other fees and expenses of Catalent owing in accordance with the terms of this Agreement, including pursuant to Sections 2.3, 4.1, 6.2 and 16.3. Catalent shall submit an invoice to Client for such fees as and when appropriate.

7.2 Unit Pricing Increase. The Unit Pricing shall be adjusted on an annual basis, effective on each July 1st (with the first price adjustment to be effective on July 1, 2017), upon 60 days' prior written notice from Catalent to Client, to reflect increases in labor, utilities and overhead and shall be in an amount equal to the change in the Producer Price Index ("PPI"), "Pharmaceutical Preparation Manufacturing" (Series ID: PCU325412325412), not seasonally adjusted, as published by the U.S. Department of Labor, Bureau of Labor Statistics. The initial base period for comparison shall be the twelve (12) month period ending on the date most closely preceding July 1, 2017, but which allows enough time for Catalent to provide to Client the notice required by this Section 7.2. In addition, price increases for raw materials, and components shall be passed through to Client. For the avoidance of doubt, no such annual increase shall exceed [***] in the aggregate for the PPI and raw materials and component costs.

7.3 Payment Terms. Payment of all Catalent invoices shall be due 30 days after the date of invoice. No invoice shall be issued to Client for Processing until the Batch so Processed has been delivered to Client pursuant to Section 6.1. Client shall make payment in U.S. dollars, and otherwise as directed in the applicable invoice. If any payment is not received by Catalent by its due date, then Catalent may, in addition to any other remedies available at equity or in law, charge interest on the outstanding sum from the due date (both before and after any judgment) at 1.5% per month until paid in full (or, if less, the maximum amount permitted by Applicable Laws).

7.4 Advance Payment. Notwithstanding any other provision of this Agreement, if at any time Catalent reasonably determines that Client's credit has materially eroded as compared to its status as of the Effective Date, and Client is in arrears in paying amounts due under this Agreement, Catalent may require payment in advance before performing any further services or making any further shipment of Product. If Client shall fail, within a reasonable time, to make such payment in advance, or if Client shall fail to make any payment when due, Catalent shall have the right, at its option, to suspend any further performance hereunder until such default is corrected, without thereby releasing Client from its obligations under this Agreement.

7.5 Taxes. All taxes, duties and other amounts assessed (excluding tax based on net income and franchise taxes) on Client-supplied Materials, services or Product prior to or upon provision or sale to Catalent or Client, as the case may be, are the responsibility of Client, and Client shall reimburse Catalent for all such taxes, duties or other expenses paid by Catalent or such sums will be added to invoices directed at Client, where applicable.

7.6 Client and Third Party Expenses. Except as may be expressly covered by Product Maintenance Service fees, Client shall be responsible for 100% of its own and all third-party expenses associated with the development, Regulatory Approvals and commercialization of Product, including regulatory filings and post-approval marketing studies. The preceding sentence shall not be construed in derogation of Catalent's obligations pursuant to Section 9.2 herein.

7.7 Development Batches. Development Batches produced after the Effective Date shall be deemed to have been produced under the Development Agreement. Client will be responsible for the cost of such Development Batches, including those necessary to support the validation portion of Client's submissions for Regulatory Approvals, which fail to meet the Specifications as set forth in Section 4.1 of the Development Agreement. Catalent and Client shall cooperate in good faith to resolve any problems causing the out-of-Specification Batch.

ARTICLE 8
CHANGES TO SPECIFICATIONS

8.1 All Specifications and any changes thereto agreed to by the parties from time to time shall be in writing, dated and signed by the parties. No change in the Specifications shall be implemented by Catalent, whether requested by Client or requested or required by any Regulatory Authority, until the parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in costs, expenses or fees associated with such change (including any change to Unit Pricing). Catalent shall respond promptly to any request made by Client for a change in the Specifications, and both parties shall use commercially reasonable, good faith efforts to agree to the terms of such change in a timely manner. As soon as possible after a request is made for any change in Specifications, Catalent shall notify Client of the costs associated with such change and shall provide such supporting documentation as Client may reasonably require. Client shall pay all costs associated with such agreed upon changes. If there is a conflict between the terms of this Agreement and the terms of the Specifications, this Agreement shall control. Catalent reserves the right to postpone effecting changes to the Specifications until such time as the parties agree to and execute the required written amendment.

ARTICLE 9
RECORDS; REGULATORY MATTERS

9.1 Recordkeeping. Catalent shall maintain complete and accurate Batch, laboratory data, reports and other technical records relating to Processing in accordance with Catalent standard operating procedures. Such information shall be maintained for a period of at least 2 years from the relevant finished Product expiration date or longer if required under Applicable Laws or the Quality Agreement. Catalent will retain samples required by cGMP and such samples shall be stored at the Facility pursuant to Catalent's standard operating procedures. Prior to the destruction of any such Product specific items, Catalent shall notify Client of the impending destruction and provide Client a reasonable opportunity to receive any or all such items.

9.2 Regulatory Compliance. Catalent shall obtain and maintain, at its cost and expense, all permits and licenses with respect to general Facility operations required by any Regulatory Authority in the jurisdiction in which Catalent Processes Product. Client shall obtain and maintain, at its cost and expense, all other Regulatory Approvals, authorizations and certificates, including those necessary for Catalent to commence Processing. Client shall reimburse Catalent for any payments Catalent is required to make to any Regulatory Authority pursuant to Applicable Laws resulting from Catalent's formulation, development, manufacturing, processing, filling, packaging, storing or testing of Client's Product or Client-supplied Materials at the Facility (including without limitation any payments or fees Catalent is required to make pursuant to the Generic Drug User Fee Amendments of 2012 ("GDUFA") and pursuant to Applicable Laws similar to GDUFA; provided, however, that on a Facility by Facility basis, in the event Catalent's Facility is referenced in a third party(ies) regulatory filing, the pertinent fee shall be apportioned and reduced accordingly between the third party(ies) and Client for each year thereafter (e.g., in the event that Catalent is required to pay such fee as a result of Client and a single third party, Client shall only be obligated to reimburse Catalent for [***] of such fee payment). Catalent and Client hereby acknowledge that as of the Effective Date, GDUFA does not apply to the Product or its Processing. Upon reasonable written request, Client shall provide Catalent with a copy of applicable Regulatory Approvals required to distribute, market and sell Product in the Territory. If Client is unable to provide such information, Catalent shall have no obligation to deliver Product to Client, notwithstanding anything to the contrary in this Agreement. During the Term, Catalent will assist Client with all regulatory matters relating to Processing and review the Common Technical Document pertaining to the Product and make such corrections as are necessary to accurately reflect the Product, in each case at Client's request and reasonable expense; provided, however, Catalent shall review and correct such documents as they relate to Catalent activities at no charge to Client. In addition, Catalent will maintain at Catalent's expense, the relevant Drug Master File, including any updates thereto, and shall provide a letter authorizing Client to reference Catalent Drug Master Files on file with the FDA and other regulatory authorities in connection with the pursuit of Regulatory Approval for the Product. The parties intend and commit to cooperate to allow each party to satisfy its obligations under Applicable Laws relating to Processing under this Agreement.

9.3 Regulatory Communications.

A. Each party may communicate with any governmental agency, including, but not limited to, governmental agencies responsible for granting regulatory approval for the Products, regarding such Products if in the opinion of that party's counsel, such communication is necessary to comply with the terms of this Agreement or the requirements of any Applicable Law; provided, however, that unless in the reasonable opinion of its counsel there is a legal prohibition against doing so, such party will permit the other party to review and take part in any communications with the applicable agency, and to receive copies of all such communications from that agency.

B. Catalent will notify Client promptly if Catalent receives any warning letters from or on behalf of a governmental agency directly related to the Product or systems utilized in Processing the Product including, without limitation, any Form FDA-483. Catalent will provide Client copies of any written communication from a governmental agency relating to a Client Product within three (3) business days of its receipt.

C. Catalent will promptly notify Client upon receipt of a notice from a Regulatory Authority for an inspection of any Facility where the Processing is being performed due to an issue related to the Product or a system used in the performance of such services, or, in the event of an unannounced inspection, Catalent will provide such prior notice as is possible and permissible. If not prohibited by the Regulatory Authority, Client will have the right to be present during such audit or inspection and any wrap-up meeting with such Regulatory Authority as it applies to the Product. If Catalent receives any request by a Regulatory Authority with respect to the Product, including, but not limited to, a notice of deficiency or FDA-483 that requires a written response regarding Client-supplied Materials, project, or protocol, Catalent will provide a copy to Client of the deficiency notice within forty-eight (48) hours of Catalent's receipt of the notice. Catalent will provide Client a draft of the response prior to the response being submitted to the Regulatory Authority so as to provide Client with reasonable time to review and comment on the response, which comments Catalent, in good faith, will consider incorporating into the response.

9.4 Governmental Inspections and Requests. Catalent shall promptly advise Client if an authorized agent of any Regulatory Authority notifies Catalent that it intends to or does visit a Facility or any other site for the purpose of reviewing the Processing or testing. Upon request, Catalent shall provide Client with a copy of any report issued by such Regulatory Authority received by Catalent following such visit, redacted as appropriate to protect any confidential information of Catalent and Catalent's other customers. Client acknowledges that it may not direct the manner in which Catalent fulfills its obligations to permit inspection by and to communicate with Regulatory Authorities, but such acknowledgement shall not be construed to vitiate Catalent's obligations to Client pursuant to this Agreement. Client shall reimburse Catalent for all reasonable and documented costs, at a rate of [***] per hour, associated with inspections by Regulatory Authorities specifically concerning the Product, such as the pre-approval inspection. Client will not be required to pay costs to mitigate any deficiencies cited in a Form 483 or Catalent's Facility deficiencies. Such documentation will include a description of the activities and time expended for such inspections.

9.5 Client Facility Audits. During the Term, Client's Representatives shall be granted access upon at least 10 business days' prior notice, at reasonable times during regular business hours, to (A) the portion of the Facility where Catalent performs Processing, (B) relevant personnel involved in Processing and (C) Processing records described in Section 9.2, in each case solely for the purpose of verifying that Catalent is Processing in accordance with cGMPs, Applicable Laws, the Specifications and the Product master Batch records. Client may not conduct an audit under this Section more than once during any 12-month period; provided, that additional inspections may be conducted by or on behalf of Client as deemed appropriate by Client in the event there is a material quality or compliance issue concerning Product or its Processing or to measure remediation following an audit by either Client or a Regulatory Authority that resulted in a finding of deficiency. Client's Quality Assurance Manager will arrange Client audits with Catalent Quality Management. Audits shall be designed to minimize disruption of operations at the Facility. Client's Representatives who are not employees of Client shall be required to sign Catalent's standard visitor confidentiality agreement prior to being allowed access to the Facility. Such Representatives shall comply with the Facility's rules and regulations which are made known in advance to Client. Client shall indemnify and hold harmless Catalent for any action or activity of such Representatives while on Catalent's premises.

9.6 Recall. If a Regulatory Authority orders or requires the recall of any Product supplied hereunder or if either Catalent or Client believes a recall, field alert, Product withdrawal or field correction ("**Recall**") may be necessary with respect to any Product supplied under this Agreement, the party receiving the notice from the Regulatory Authority or that holds such belief shall promptly notify the other party in writing. With respect to any Recall, Catalent shall provide all necessary cooperation and assistance to Client. Client shall provide Catalent with an advance copy of any proposed submission to a Regulatory Authority in respect of any Recall, and shall consider in good faith any comments from Catalent. The cost of any Recall shall be borne by Client, and Client shall reimburse Catalent for expenses incurred in connection with any Recall, in each case except to the extent such Recall is caused by Catalent's breach of its Processing obligations under this Agreement or Catalent's violation of Applicable Laws, then such cost shall be borne by Catalent in proportion to Catalent's contribution to the cause of the Recall. For purposes hereof, such Catalent cost shall be limited to reasonable, actual and documented administrative costs incurred by Client for such Recall and if applicable, replacement of the Product subject to Recall both in accordance with Article 5.

9.7 Quality Agreement. Within 6 months after the Effective Date, and in any event prior to the first Processing of Product hereunder, the parties shall negotiate in good faith and enter into a quality agreement on Catalent's standard template or such other template agreed to by the parties (the "**Quality Agreement**"). The Quality Agreement shall in no way determine liability or financial responsibility of the parties for the responsibilities set forth therein. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with cGMP, the provisions of the Quality Agreement shall govern. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to any commercial matters, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

ARTICLE 10
CONFIDENTIALITY AND NON-USE

10.1 Definition. As used in this Agreement, the term "**Confidential Information**" includes all information furnished by or on behalf of Catalent or Client, their respective Affiliates or any of its or their respective Representatives (the "**Discloser**"), to the other party (the "**Recipient**"), its Affiliates or any of its or their respective Representatives, whether furnished before, on or after the Effective Date and furnished in any form, including written, verbal, visual, electronic or in any other media or manner and information acquired by observation or otherwise during any site visit at the other party's facility. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other intellectual property (whether or not patented), analyses, data, regulatory submission Information, compilations, business or technical information, strategies, or plan, samples, and other materials prepared or possessed by either party, their respective Affiliates, or any of its or their respective Representatives, containing or based in whole or in part on any information furnished by the Discloser, its Affiliates or any of its or their respective Representatives. Confidential Information also includes the existence of this Agreement and its terms. The manufacturing process parameters which are being provided to Catalent from Client, the Specifications and data resulting from performance of this Agreement by Catalent shall be considered Client's Confidential Information. Items and information for which ownership has been allocated to Client under the Development Agreement shall be deemed to be the Confidential Information of Client under this Agreement.

10.2 Exclusions. Notwithstanding Section 10.1, Confidential Information does not include information that (A) is or becomes generally available to the public or within the industry to which such information relates other than as a result of a breach of this Agreement, (B) is already known by the Recipient at the time of disclosure as evidenced by the Recipient's written records created in the ordinary course of business, (C) becomes available to the Recipient on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis or (D) was or is independently developed by or for the Recipient without reference to the Confidential Information of the Discloser as evidenced by the Recipient's contemporaneously created written records.

10.3 Mutual Obligation. The Recipient agrees that it will not use the Discloser's Confidential Information except in connection with the performance of its obligations or the exercise of its rights under this Agreement, and will not disclose, without the prior written consent of the Discloser, Confidential Information of the Discloser to any third party, except that the Recipient may disclose the Discloser's Confidential Information to any of its Affiliates and its or their respective Representatives and subcontractors for which consent has been given pursuant to Section 6.3 and who have obligations of confidentiality and non-use at least as rigorous as those terms herein, in each case, that (A) need to know such Confidential Information for the purpose of performing under this Agreement, (B) are advised of the contents of this Article and (C) are bound to the Recipient by obligations of confidentiality at least as restrictive as the terms of this Article. Each party shall be responsible for any breach of this Article by its Affiliates or any of its or their respective Representatives or any person receiving Confidential Information directly or indirectly from or through the Recipient.

10.4 Permitted Disclosure. The Recipient may disclose the Discloser's Confidential Information to the extent required by law or regulation; *provided*, that prior to making any such legally required disclosure, the Recipient shall give the Discloser as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances. Any such disclosure, however, shall not relieve the Recipient of its obligations contained herein.

10.5 No Implied License. Except as expressly set forth in Section 10.1, the Recipient will obtain no right of any kind or license under any Confidential Information of the Discloser, including any patent application or patent, by reason of this Agreement. All Confidential Information will remain the sole property of the Discloser, subject to Article 11.

10.6 Return of Confidential Information. Upon expiration or termination of this Agreement, the Recipient will (and will cause its Affiliates and its and their respective Representatives to) cease its use and, upon written request, within 30 days either return or destroy (and certify as to such destruction) all Confidential Information of the Discloser, including any copies thereof, except for a single copy which may be retained for the sole purpose of ensuring compliance with its continuing obligations under this Agreement.

10.7 Survival. The obligations of this Article will terminate with respect to items of Confidential Information upon the entry thereof into general knowledge in the public domain, other than due to breach of this Agreement by the Recipient thereof or by a person receiving such Confidential Information from or through the Recipient, but in no event earlier than five (5) years from the expiration or earlier termination of this Agreement.

10.8 Reverse Engineering. Unless otherwise consented to by the Discloser in writing or provided for in a separate agreement between the parties, the Recipient will not analyze for chemical composition any samples or materials that are the Confidential Information of Discloser, nor to allow or cause any such samples or materials that are the Confidential Information of Discloser to be released to third parties for analysis; provided, however, (i) this Section 10.8 shall not be construed to prevent Client from testing Product or items related to Product itself or through third parties, as it sees fit in its sole and absolute discretion; and (ii) this Section 10.8 shall not be construed to prevent Catalent from analyzing for chemical composition samples or materials that are commercially available or from developing or manufacturing products containing both, or either, Estradiol and Progesterone, including Generic Products so long as Catalent does not utilize Client's Confidential Information to do so.

ARTICLE 11
INTELLECTUAL PROPERTY

11.1 The parties hereby acknowledge that it is neither their intention nor the purpose of this Agreement to engage in inventive steps in the conception, reduction to practice or development of intellectual property. Nevertheless, in the event, and to the extent, that intellectual property is conceived, reduced to practice, developed or otherwise created by or on behalf of either or both of the parties in connection with this Agreement, the ownership of such intellectual property shall be subject to the terms and conditions of Sections 7.1 and 7.2 of the Development Agreement, as if such intellectual property was conceived, reduced to practice or developed pursuant to the Development Agreement.

11.2 Transfer. Following notice given by Client to Catalent, Catalent will provide reasonable assistance to effect the timely and orderly transfer of the Process Know-How, and pertinent books and records (or copies thereof, as the case may be) pursuant to the Process Know-How Transfer Plan to Client pursuant to this Section 11.2 and the Process Know-How Transfer Plan whether to establish a second source during the term of this Agreement or at or about the time of termination or expiration of this Agreement. Catalent shall only be obligated to use its commercially reasonable efforts in the implementation of the Process Know-How Transfer Plan, and in no case shall Catalent personnel visit the site of Client or any third party manufacturer of softgels, as the case may be. For the avoidance of doubt, the foregoing prohibition shall not be construed as a basis for Catalent refusing to assist in the transfer of analytical methods to an independent laboratory, including a visit by Catalent personnel to such site to assist in method transfer, if, and only as, reasonably necessary, and at Client's cost and expense.

11.3 Books and Records. Where any document, or books and records contain Process Know-How together with other information of Catalent, its Affiliates or their respective subcontractors, or other Catalent customers, Catalent shall only be required to provide to Client a copy of that portion of that document or books and records that discloses the Process Know-How that pertains to the Product. When transferred to Client, such copies will be the property of Client. Catalent may retain the original books and records and any documents required by Applicable Laws to be retained by Catalent, which disclose the Process Know-How. After completion of performance of the Process Know-How Transfer Plan, before destroying any documents, or books and records which contain material disclosures of Process Know-How that have not been previously been provided to Client (whether in the same form or some other form), Catalent will notify Client of such intended destruction and provide Client with thirty (30) days to notify Catalent in writing whether Client wishes to obtain the same to the extent it is entitled to under this Agreement, in which case Catalent will deliver the requested document or books and records (or copies of all or a portion thereof, as the case may be) to Client at Client's sole cost and expense.

11.4 Client Marks. Catalent will not use Client's Marks without prior written authorization from Client. The Marks are, and will remain, Client's sole and exclusive property, and Catalent has not acquired, and will not acquire (by operation of law, this Agreement, or otherwise), any right, title, or interest in any of Client's Marks other than as explicitly provided in writing by Client. Any and all goodwill and rights that arise under trademark and copyright law, and all other intellectual property rights that arise in favor of Client's Marks as a result of this Agreement or otherwise, will inure to the sole and exclusive benefit of Client. Subject to the next sentence, during the Term of this Agreement, Catalent will not attack, dispute, or challenge Client's right, title, and interest in and to Client's Marks or assist others in so doing. Catalent reserves the right to attack, dispute, or challenge Client's right, title, and interest in and/or to Client's Marks or assist others in so doing, if Catalent believes in good faith that Client's Mark infringes a Mark owned by or licensed to Catalent or one of its Affiliates.

11.5 Analytical Methods. Catalent, in the development of analytical methods for a Generic Product, whether on its own behalf or on behalf of a third party, shall not use the services of any person, whether an employee or contractors, in the development of such methods, who either (i) provided analytical method development services on behalf of Catalent under this Agreement or the Development Agreement, or (ii) has such intimate knowledge of the Client's analytical methods or the manner in which such methods were developed that such persons participation in the development of the analytical method for a Generic Product could reasonably be determined to materially accelerate the development of such methods for the Generic Product. "Generic Product" shall mean [***].

ARTICLE 12
REPRESENTATIONS AND WARRANTIES AND COMPLIANCE

12.1 Catalent. Catalent represents, warrants and undertakes to Client that:

A. at the time of delivery by Catalent as provided in Section 6.1, Product shall have been Processed in accordance with this Agreement and with Applicable Laws and in conformance with the Specifications and shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws; *provided*, that Catalent shall not be liable for defects attributable to Client-supplied Materials (including artwork, advertising and labeling);

B. all personnel, employees, and agents of Catalent and its Affiliates and their respective subcontractors who perform services, are and will continue to be qualified and to have sufficient technical expertise to perform Catalent's obligations under this Agreement;

C. Catalent has the full power and authority to execute and deliver this Agreement and perform its covenants, duties, and obligations described in this Agreement, and once executed, this Agreement will be a valid, legal, and binding obligation upon Catalent;

D. Catalent is not now, nor will it be, a party to any agreement which would prevent Catalent from fulfilling its obligations under this Agreement, and that during the Term of this Agreement will not enter into any agreement with any other party that would in any way prevent Catalent from performing its obligations under this Agreement;

E. Catalent will maintain all records and reports as required under this Agreement, and as required to comply with Applicable Laws.

F. Catalent will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended (or subject to debarment or suspension) under 21 U.S.C. §335(a) or (b) or otherwise disqualified by Applicable Law;

G. (i) Catalent is not nor has it ever been, and (ii) Catalent has not used, and will not use, the services of any person excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs, and has not used, and will not use, the services of any person listed on the HHS/OIG List of Excluded Individuals/Entities (http://www.oig.hhs.gov), the GSA's List of Parties Excluded from Federal Programs (http://www.epls.gov), or the FDA Debarment List (http://www.fda.gov/ora/compliance_ref/debar/default.htm), as amended or replaced from time to time, in connection with any of the services performed under this Agreement. Catalent further certifies that it, and any other person or entity used by Catalent in performing any of the services under this Agreement, has not been convicted of a criminal offense that falls within the ambit of 42 U.S.C. §1320a-7(a). Catalent agrees to notify Client promptly in the event Catalent, or any person used by Catalent in connection with this Agreement, ever becomes excluded, debarred, suspended, or otherwise ineligible to participate in Federal health care programs or in Federal procurement or non-procurement programs. This certification applies to Catalent and its respective officers, agents, and employees as well as subcontractors performing on behalf of Catalent under this Agreement;

H. Catalent has all necessary authority to use the Catalent technology utilized with the Product and as contemplated by this Agreement; there are no patents owned by others related to the Catalent IP utilized with the Product that would be infringed or misused by Catalent's performance of the Agreement; and, to its knowledge, no trade secrets or other proprietary rights of others related to the Catalent IP utilized with the Product that would be infringed or misused by Catalent's performance of this Agreement;

I. Catalent will not release any Batch of Product if the required certificates of conformance indicate that Product does not comply with the Specifications; and

J. no transactions or dealings under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States.

12.2 Client. Client represents, warrants and undertakes to Catalent that:

A. all Client-supplied Materials shall have been produced in accordance with Applicable Laws, shall comply with all applicable specifications, including the Specifications, shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws, and shall have been provided in accordance with the terms and conditions of this Agreement;

B. the content of all artwork provided to Catalent shall comply with all Applicable Laws;

C. all Product delivered to Client by Catalent shall be held, used and disposed of by or on behalf of the Client in accordance with all Applicable Laws, and Client will otherwise comply with all laws, rules, regulations and guidelines applicable to Client's performance under this Agreement;

D. Client will not release any Batch of Product if the required certificates of conformance indicate that Product does not comply with the Specifications or if Client does not hold all necessary Regulatory Approvals to market and sell the Product;

E. Client has all necessary authority to use and to permit Catalent to use pursuant to this Agreement all intellectual property related to Product or Client-supplied Materials (including artwork), and the Processing by Catalent of the foregoing, including any copyrights, trademarks, trade secrets, patents, inventions and developments; to Client's knowledge there are no patents owned by others related to the Client IP utilized with the Product that would be infringed or misused by Client's performance of the Agreement; and, to its knowledge, no trade secrets or other proprietary rights of others related to the Client IP utilized with the Product that would be infringed or misused by Client's performance of this Agreement;

F. To Client's knowledge the services to be performed by Catalent under this Agreement will not violate or infringe upon any trademark, tradename, copyright, patent, trade secret, or other intellectual property or other right held by any person or entity; provided that Client makes no representation with respect to the Catalent IP;

G. Client has all authorizations and permits required to deliver API (or have delivered) to Catalent's Facility.

H. Client has the full power and authority to execute and deliver this Agreement and perform its covenants, duties, and obligations described in this Agreement, and once executed, this Agreement will be a valid, legal, and binding obligation upon Client; and I. no transactions or dealings under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States.

12.3 Limitations. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER PARTY, AND NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS, WARRANTIES OR GUARANTEES OF ANY KIND WHATSOEVER, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

12.4 Compliance with Anti-Corruption Laws.

Each party agrees that, in the performance of its obligations under this Agreement, it will not: (i) provide or promise to provide, directly or indirectly, any unlawful contribution, gift, entertainment, or other unlawful payment to any foreign or domestic government employee relating to political activity; (ii) take any action, directly or indirectly, that violates Foreign Corrupt Practices Act ("FCPA"), or any other applicable anti-corruption law of any foreign jurisdiction, including, without limitation, "use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay, or authorization of the payment of any money, or offer, gift, promise to give, or authorization of the giving of anything of value" to any "foreign official" (as is defined in the FCPA), any foreign political party or official thereof, or any candidate for foreign political office, to influence their acts or decisions in their official capacity, to induce them to do or omit from doing any act in violation of their lawful duty, or to secure any improper advantage in order to assist in obtaining business, or retaining business, or directing business to any person; and (iii) make or propose to make any bribe, payoff, influence payment, kickback, unlawful rebate, or other similar unlawful payment of any nature, including to healthcare providers or those employed by any governmental institutions.

ARTICLE 13
INDEMNIFICATION

13.1 Indemnification by Catalent. Catalent shall indemnify, defend and hold harmless Client, its Affiliates, and their respective shareholders, directors, officers and employees ("**Client Indemnitees**") from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys' fees and reasonable investigative costs) in connection with any suit, demand or action brought by any third party ("**Losses**") directly or indirectly arising out of or resulting from (a) any breach of its representations, warranties or obligations set forth in this Agreement; (b) any negligence or willful misconduct by Catalent, its Affiliates, subcontractors, employees or agents; (c) any misrepresentation made by Catalent in this Agreement; (d) a violation of, or non-compliance with any Applicable Law by Catalent, its Affiliates, subcontractors, employees or agents in the performance of this Agreement; or (e) the infringement or alleged infringement of any trade secrets, copyrights, trademarks, trade names, or other proprietary or contractual rights of any third party arising from Catalent's performance of services under this Agreement (except to the extent arising from the making or using of Client-supplied Materials, Client Confidential Information, or API), in each case of clauses (a) through (e) above, except to the extent that Client is obligated to indemnify any of the Catalent Indemnitees pursuant to Section 13.2 for such events.

13.2 Indemnification by Client. Client shall indemnify, defend and hold harmless Catalent, its Affiliates, and their respective shareholders, directors, officers and employees ("**Catalent Indemnitees**") from and against any and all Losses directly or indirectly arising out of or resulting from (a) any manufacture (other than due to negligence by or on behalf of Catalent), packaging (other than due to negligence by or on behalf of Catalent), promotion, distribution, sale or use of or exposure to the Product or Client-supplied Materials, including API and including product liability or strict liability, other than claims by Catalent employees arising from their handling of Client-supplied Materials in performing the services under this Agreement; provided, however, Client delivered to Catalent all known material information regarding such risks of handling or such information was otherwise in the public domain; (b) any negligence or willful misconduct of Client, its Affiliates, subcontractors, employees or agents, (c) any breach of its representations, warranties or obligations set forth in this Agreement; (d) the content of Client's instructions to the extent they are followed by Catalent and violate Applicable Laws; (e) the conduct of any clinical trials utilizing Product or API; (f) Client's exercise of control over the Processing, to the extent that Client's instructions or directions violate Applicable Laws, (g) any actual or alleged infringement or violation of any third party patent, trade secret, copyright, trademark or other proprietary right by the use, as authorized, of intellectual property or other information provided by Client to Catalent, including Client-supplied Material; in each case of clauses (a) through (g) above, except to the extent that Catalent is obligated to indemnify any of the Client Indemnitees pursuant to Section 13.1 for such events.

13.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the indemnified party (a) promptly notifying the indemnifying party of any claim or liability of which the indemnified party becomes aware (including a copy of any related complaint, summons, notice or other instrument); provided, that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying party of any of its obligations hereunder except to the extent the indemnifying party is prejudiced by such failure, (b) allowing the indemnifying party to conduct and control the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense), (C) cooperating with the indemnifying party in the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense) and (D) not compromising or settling any claim or liability without prior written consent of the indemnifying party.

ARTICLE 14
LIMITATIONS OF LIABILITY

14.1 CATALENT'S LIABILITY UNDER THIS AGREEMENT FOR ANY AND ALL CLAIMS FOR LOST, DAMAGED OR DESTROYED CLIENT-SUPPLIED MATERIALS, WHETHER OR NOT SUCH CLIENT SUPPLIED MATERIALS ARE USED IN THE SERVICES OR INCORPORATED INTO PRODUCT, CAUSED BY CATALENT'S NEGLIGENCE OR BREACH SHALL NOT EXCEED [***] PER INCIDENT.

14.2 CATALENT'S TOTAL LIABILITY UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED THE TOTAL FEES PAID BY CLIENT TO CATALENT OR INVOICED BY CATALENT UNDER THIS AGREEMENT DURING THE TWELVE (12) MONTHS PRECEDING RELEASE OF THE BATCH OR SERVICES GIVING RISE TO THE CLAIM. DURING THE FIRST CONTRACT YEAR, SUCH LIMITATION SHALL BE THE GREATER OF (I) TOTAL FEES PAID BY CLIENT TO CATALENT OR INVOICED BY CATALENT FROM THE COMMENCEMENT DATE, OR (II) [***]. THE FOREGOING LIMITATION SHALL NOT BE DEEMED TO LIMIT CATALENT'S LIABILITY UNDER SECTION 13.1 (INDEMNIFICATION) WITH RESPECT TO AMOUNTS PAID BY CLIENT TO THIRD PARTIES FOR BODILY INJURY.

14.3 NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR LOSS OF REVENUES, PROFITS OR DATA ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, WHETHER IN CONTRACT OR IN TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 15
INSURANCE

15.1 Each of Catalent and Client shall, at its own cost and expense, obtain and maintain in full force and effect during the Term the following: (A) Commercial General Liability Insurance with a per-occurrence limit of not less than $[***]; (B) Products and Completed Operations Liability Insurance with a per-occurrence limit of not less than $[***]; (C) Workers' Compensation Insurance with statutory limits and Employers Liability Insurance with limits of not less than $[***] per accident; and (D) All Risk Property Insurance, including transit coverage, in an amount equal to the full replacement value of its property while in, or in transit to, a Catalent facility as required under this Agreement. Each party may self-insure all or any portion of the required insurance as long as, together with its Affiliates, its US GAAP net worth is greater than $[***] million or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than $[***] million. If any of the required policies of insurance are written on a claims made basis, such policies shall be maintained throughout the Term and for a period of at least [***] years thereafter. Each required insurance policy, other than self-insurance, shall be obtained from an insurance carrier with an A.M. Best rating of at least A- VII. To secure the performance of its obligations under this Agreement, Client will at all times during the Term of this Agreement, maintain commercial general liability insurance providing coverage of no less than $[***] per occurrence, professional liability insurance providing coverage of no less than $[***] per occurrence, errors and omissions insurance providing coverage of no less than $[***] per occurrence and Workers' Compensation Insurance with statutory amounts and Employers Liability Insurance with limits of not less than $[***] per accident; and Auto Liability insurance for owned, hired and non-owned vehicles in a minimum amount of $[***] combined single limit. If requested by the other party, the party will furnish certificates of insurance evidencing such coverages or the original of the insurance policies. No such policies required hereunder will be cancelable or subject to reduction of coverage or other modification except after [***] days' prior written notice to the other party.

ARTICLE 16
TERM AND TERMINATION

16.1 Term. This Agreement shall commence on the Effective Date and shall continue until the end of the seventh Contract Year, unless earlier terminated in accordance with Section 16.2 (as may be extended in accordance with this Section, the "**Term**"). The Term shall automatically be extended for successive 2-year periods unless and until one party gives the other party at least 12 months' prior written notice of its desire to terminate as of the end of the then-current Term.

16.2 Termination. This Agreement may be terminated immediately without further action:

A. by either party if the other party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver, administrative receiver, trustee or administrator, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within 30 days, or takes any equivalent or similar action in consequence of debt in any jurisdiction; or

B. by either party if the other party materially breaches any of the provisions of this Agreement and such breach is not cured within 60 days after the giving of written notice requiring the breach to be remedied; *provided*, that in the case of a failure of Client to make payments in accordance with the terms of this Agreement, Catalent may terminate this Agreement if such payment breach is not cured within 30 days of receipt of notice of non-payment from Catalent.

C. By Client upon one hundred eighty (180) days prior written notice to Catalent in the event Client ceases pursuit of Regulatory Approval for, or to offer for sale or to sell, Product, due to material regulatory, patient health, or intellectual property issues.

16.3 Effect of Termination. Expiration or termination of this Agreement shall be without prejudice to any rights or obligations that accrued to the benefit of either party prior to such expiration or termination. In the event of a termination of this Agreement:

A. Catalent shall promptly return to Client, at Client's expense and direction, any remaining inventory of Product or Client-supplied Materials; *provided*, that all outstanding invoices have been paid in full;

B. Client shall pay Catalent all invoiced amounts outstanding hereunder, plus, upon receipt of invoice therefor, for any (i) Product that has been shipped pursuant to Purchase Orders but not yet invoiced, (ii) Product Processed pursuant to Purchase Orders that has been completed but not yet shipped, and (iii) in the event that this Agreement is terminated for any reason other than by Client pursuant to Section 16.2(A) or (B), or by Catalent pursuant to Section 16.2(C), all Product in process of being Processed pursuant to Purchase Orders (or, alternatively, Client may instruct Catalent to complete such work in process, and the resulting completed Product shall be governed by clause (ii)); and

C. in the event that this Agreement is terminated for any reason other than by Client pursuant to Section 16.2(A) or (B), or by Catalent pursuant to Section 16.2(C), Client shall pay Catalent for all costs and expenses incurred, and all noncancellable commitments made, in connection with Catalent's performance of this Agreement, so long as such costs, expenses or commitments were made by Catalent consistent with Client's most recent Firm Commitment and the vendor's minimum purchase obligations.

16.4 Survival. The rights and obligations of the parties shall continue under Articles 11 (Intellectual Property), 13 (Indemnification), 14 (Limitations of Liability), 17 (Notice), 18 (Miscellaneous); under Articles 10 (Confidentiality and Non-Use) and 15 (Insurance), in each case to the extent expressly stated therein; and under Sections 7.3 (Payment Terms), 7.5 (Taxes), 7.6 (Client and Third Party Expenses), 9.1 (Recordkeeping), 9.6 (Recall), 12.3 (Limitations on Warranties), 16.3 (Effect of Termination) and 16.4 (Survival), in each case in accordance with their respective terms if applicable, notwithstanding expiration or termination of this Agreement.

ARTICLE 17
NOTICE

All notices and other communications hereunder shall be in writing and shall be deemed given: (A) when delivered personally or by hand; (B) when delivered by facsimile transmission (receipt verified); (C) when received or refused, if sent by registered or certified mail (return receipt requested), postage prepaid; or (D) when delivered, if sent by express courier service; in each case to the parties at the following addresses (or at such other address for a party as shall be specified by like notice; *provided*, that notices of a change of address shall be effective only upon receipt thereof):

To Client:	TherapeuticsMD, Inc. 6800 Broken Sound Parkway NW, Third Floor Boca Raton, Florida 33487 Attn: President
With a copy to:	Chief Legal Counsel at the above address
To Catalent:	Catalent Pharma Solutions, LLC 2725 Scherer Drive N. St. Petersburg, FL 33716 Attn: President, Softgel
With a copy to:	Catalent Pharma Solutions 14 Schoolhouse Road Somerset, NJ 08873 Attn: General Counsel (Legal Department) Facsimile: +1 (732) 537-6491

ARTICLE 18
MISCELLANEOUS

18.1 Entire Agreement; Amendments. This Agreement, together with the Quality Agreement, constitutes the entire understanding between the parties, and supersedes any contracts, agreements or understandings (oral or written) of the parties, with respect to the subject matter hereof. For the avoidance of doubt, this Agreement does not supersede any existing generally applicable confidentiality agreement between the parties as it relates to time periods prior to the date hereof or to business dealings not covered by this Agreement. No term of this Agreement may be amended except upon written agreement of both parties, unless otherwise expressly provided in this Agreement.

18.2 Captions; Certain Conventions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires, (A) words of any gender include each other gender, (B) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (C) words using the singular shall include the plural, and vice versa, (D) the words “include(s)” and “including” shall be deemed to be followed by the phrase “but not limited to”, “without limitation” or words of similar import, (E) the word “or” shall be deemed to include the word “and” (e.g., “and/or”) and (F) references to “Article,” “Section,” “subsection,” “clause” or other subdivision, or to an Attachment or other appendix, without reference to a document are to the specified provision or Attachment of this Agreement. This Agreement shall be construed as if it were drafted jointly by the parties.

18.3 Further Assurances. The parties agree to execute, acknowledge and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

18.4 No Waiver. Failure by either party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed to be a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

18.5 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.

18.6 Independent Contractors. The relationship of the parties is that of independent contractors, and neither party will incur any debts or make any commitments for the other party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the parties the relationship of joint ventures, co-partners, employer/employee or principal and agent. Neither party shall have any responsibility for the hiring, termination or compensation of the other party's employees or contractors or for any employee benefits of any such employee or contractor.

18.7 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the parties, their successors and permitted assigns. Neither party may assign this Agreement, in whole or in part, without the prior written consent of the other party, except that either party may, without the other party's consent (but subject to prior written notice), assign this Agreement in its entirety to an Affiliate or to a successor to substantially all of the business or assets of the assigning party or the assigning party's business unit responsible for performance under this Agreement.

18.8 No Third Party Beneficiaries. This Agreement shall not confer any rights or remedies upon any person or entity other than the parties named herein and their respective successors and permitted assigns.

18.9 Governing Law. This Agreement shall be governed by and construed under the laws of the State of Delaware, USA, excluding its conflicts of law provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

18.10 Dispute Resolution. Any dispute that arises between the parties in connection with this Agreement shall first be presented to the senior executives of the parties for consideration and resolution. If such executives cannot reach a resolution of the dispute within a reasonable time, then the parties may seek remedies in a court of law.

18.11 Prevailing Party. In any dispute resolution proceeding between the parties in connection with this Agreement, the prevailing party may be entitled to recover its reasonable attorney's fees and costs in such proceeding from the other party.

18.12 Publicity. Neither party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other party's express prior written consent, except as required under Applicable Laws, by any governmental agency or by the rules of any stock exchange on which the securities of the disclosing party are listed, in which case the party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

18.13 Right to Dispose and Settle. If Catalent requests in writing from Client direction with respect to disposal of any inventories of Product, Client-supplied Materials, equipment, samples or other items belonging to Client and is unable to obtain a response from Client within a reasonable time period after making reasonable efforts to do so, Catalent shall be entitled in its sole discretion to (A) dispose of all such items and (B) set-off any and all amounts due to Catalent or any of its Affiliates from Client against any credits Client may hold with Catalent or any of its Affiliates.

18.14 Force Majeure. Except as to payments required under this Agreement, neither party shall be liable in damages for, nor shall this Agreement be terminable or cancelable by reason of, any delay or default in such party's performance hereunder if such default or delay is caused by events beyond such party's reasonable control, including acts of God, law or regulation or other action or failure to act of any government or agency thereof, war or insurrection, civil commotion, destruction of production facilities or materials by earthquake, fire, flood or weather, labor disturbances, epidemic or failure of suppliers, vendors, public utilities or common carriers; *provided*, that the party seeking relief under this Section shall immediately notify the other party of such cause(s) beyond such party's reasonable control. The party that may invoke this Section shall use commercially reasonable efforts to reinstate its ongoing obligations to the other party as soon as practicable. If the cause(s) shall continue unabated for 180 days, then both parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from such cause(s).

18.15 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.

[Signature page follows]

IN WITNESS WHEREOF, the parties have caused their respective duly authorized Representatives to execute this Agreement effective as of the Effective Date.

CATALENT PHARMA SOLUTIONS, LLC		**THERAPEUTICSMD, INC.**	
By:	/s/ Aris Gennadios	By:	/s/ Robert Finizio
Name:	Aris Gennadios, Ph.D.	Name:	Name: Robert Finizio
Title:	President Softgel Technologies	Title:	Title: CEO

Signature Page to Softgel Commercial Supply Agreement

ATTACHMENT A

SPECIFICATIONS

I. Client-supplied Materials (and associated specifications)

- **API**
  - **Estradiol**

Test	**Acceptance Criteria**	**Analytical Method**
Appearance	[***]	[***]
Identification A (IR)	[***]	[***]
Identification B (UV)	[***]	[***]
Melting range	[***]	[***]
Specific rotation	[***]	[***]
Water	[***]	[***]
Assay (HPLC)	[***]	[***]
Microbial limits Total aerobic microbial count (TAMC):	[***]	[***]
Total combined yeasts and mold count (TYMC):	[***]	
Escherichia in 1 g	[***]	

Related substances (HPLC): Estrone (Ph.Eur.A)	[***]	[***]
17α-estradiol (Ph.Eur.B)	[***]	
Δ9(11)-estradiol (Ph.Eur.D)	[***]	
4-Cl-estradiol	[***]	
Individual unspecified impurity	[***]	
Total impurities	[***]	
Residual Solvents (GC): [***]	[***]	[***][1]
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
Particle size by laser diffraction	[***]	[***][2]

[1] [***]

[2] [***]

[***]

HPLC = high performance liquid chromatography
UV = ultraviolet
IR = infrared
GC = gas chromatograph
Ph. Eur. or EP = European Pharmacopeia
USP = United States Pharmacopeia
cfu = colony forming unit
ppm = parts per million

- **Progesterone**

Heavy Metals	[***]		[***]
Assay of Progesterone-HPLC	[***]		[***]
Related Substances HPLC	[***]	[***]	[***]
	[***]	[***]	
	[***]	[***]	
	[***]	[***]	
	[***]	[***]	
	[***]	[***]	
	[***]	[***]	
	[***]	[***]	
	[***]	[***]	
	[***]	[***]	
	[***]	[***]	
	[***]	[***]	
Residual Solvents	[***]	[***]	[***]
	[***]	[***]	
	[***]	[***]	
	[***]	[***]	
	[***]	[***]	
	[***]	[***]	

Palladium	[***]	[***]

USP = United States Pharmacopeia, EP = European Pharmacopoeia
RS = reference standard, CSR = current reference substance
NLT = not less than; NMT = not more than
HPLC = high performance liquid chromatography; GC = gas cinematograph; TLC = thin layer chromatography
ICP-MS = inductively coupled plasma mass spectrometry
ppm = parts per million
DMF = drug master file

II. Product Specifications

Progesterone 100 mg/Estradiol 0.5mg

Test	**Method**	**Limit**
Appearance	[***]	[***]
Assay Estradiol (LC = 0.5mg/capsule (Tested at Lancaster Labs)	[***]	[***]
Assay Progesterone (LC= 100mg/capsule (Tested at Lancaster Labs)	[***]	[***]
Estradiol Related Compounds/Degradants (Tested at Lancaster Labs	[***]	[***]
		[***]
		[***]
		[***]
Progesterone Related Compounds/Degradants (Tested at Lancaster Labs)	[***]	[***]
		[***]
Estradiol Dissolution (Tested al KTP)	[***]	[***]
		[***]

Progesterone Dissolution	[***]	[***]
		[***]
Water Content to Fill	[***]	[***]
Total Aerobic Microbial Count	[***]	[***]
Total Combined Yeasts and Molds	[***]	[***]
E. coli	[***]	[***]
Salmonella	[***]	[***]
S.aureus	[***]	[***]

Progesterone 50mg/Estradiol 0.5mg

Test	**Method**	**Limits**
Appearance	[***]	[***]
Assay Estradiol (LC=0.5mg/capsule) (Tested at Lancaster Labs)	[***]	[***]
Assay Progesterone (LC=50mg/capsule) (Tested at Lancaster Labs)	[***]	[***]
Estradiol Related Compounds/Degradants (Tested at Lancaster Labs)	[***]	[***]
		[***]
		[***]
		[***]
Progesterone Related Compounds/Degradants (Tested at Lancaster Labs)	[***]	[***]
		[***]

Estradiol Dissolution (Tested at RTP)	[***]	[***]
		[***]
Progesterone Dissolution	[***]	[***]
		[***]
Water Content to Fill	[***]	[***]
Total Aerobic Microbial Count	[***]	[***]
Total Combined Yeasts and Molds	[***]	[***]
E. coli	[***]	[***]
Salmonella	[***]	[***]
S. aureus	[***]	[***]

Progesterone 50mg/Estradiol 0.25mg

Test	**Method**	**Limits**
Appearance	[***]	[***]
Assay Estradiol (LC=0.25mg/capsule) (Tested at Lancaster Labs)	[***]	[***]
Assay Progesterone (LC=50mg/capsule) Tested at Lancaster Labs)	[***]	[***]
Estradiol Related Compounds/Degradants (Tested at Lancaster Labs)	[***]	[***]
		[***]
		[***]
		[***]

Progesterone Related Compounds/Degradants (Tested at Lancaster Labs)	[***]	[***]
		[***]
Estradiol Dissolution (Tested at RTP)	[***]	[***]
		[***]
Progesterone Dissolution	[***]	[***]
		[***]
Water Content to Fill	[***]	[***]
Total Aerobic Microbial Count	[***]	[***]
Total Combined Yeasts and Molds	[***]	[***]
E. coli	[***]	[***]
Salmonella	[***]	[***]
S. aureus	[***]	[***]

Progesterone 100mg/Estradiol 1.0mg

Test	**Method**	**Limits**
Appearance	[***]	[***]
Assay Estradiol (LC=1.0mg/capsule) (Tested at Lancaster Labs)	[***]	[***]
Assay Progesterone (LC=100mg/capsule) (Tested at Lancaster Labs)	[***]	[***]

Estradiol Related Compounds/Degradants (Tested at Lancaster Labs)	[***]	[***]
		[***]
		[***]
		[***]
Progesterone Related Compounds/Degradants (Tested at Lancaster Labs)	[***]	[***]
		[***]
Estradiol Dissolution (Tested at RTP)	[***]	[***]
		[***]
Progesterone Dissolution	[***]	[***]
		[***]
Water Content to Fill	[***]	[***]
Total Aerobic Microbial Count	[***]	[***]
Total Combined Yeasts and Molds	[***]	[***]
E. coli	[***]	[***]
Salmonella	[***]	[***]
S. aureus	[***]	[***]

ATTACHMENT B

UNIT PRICING, FEES AND MINIMUM REQUIREMENT

Product Unit Strength	**Product Size**	**Batch Size**	**Initial Unit* Price for Total Softgels Shipped in Calendar Year**			
			[***]	[***]	**For Incremental Volume over** [***]	**For Incremental Volume over** [***]
100mg Progesterone + 1mg Estradiol	[***] oval	[***]	$[***]	$[***]	$[***]	$[***]
100mg Progesterone + 0.5mg Estradiol	[***] oval	[***]	$[***]	$[***]	$[***]	$[***]
50mg Progesterone + 0.5mg Estradiol	[***] oval	[***]	$[***]	$[***]	$[***]	$[***]
50mg Progesterone + 0.25mg Estradiol	[***] oval	[***]	$[***]	$[***]	$[***]	$[***]
50mg Progesterone + 0.5mg Estradiol	[***] oval	[***]	$[***]	$[***]	$[***]	$[***]
50mg Progesterone + 0.25mg Estradiol	[***] oval	[***]	$[***]	$[***]	$[***]	$[***]

* One unit is [***] softgel capsules. Prices include full API release testing, cost of Processed softgels, Product full release testing and bulk packaging. Prices do not include cost of API, tooling or other Product-specific capital items, artwork, shipping, insurance or duty. Prices also do not include any testing, retesting or testing supplies other than as expressly set forth in the Specifications. Prices are based on certain assumptions as to manufacturing processes, storage conditions, etc. Accordingly, prices are subject to adjustment in the event any such assumptions are subject to revision in connection with the validation of the Product. The foregoing prices are for the United States only. Prices will be adjusted for the Processing of Product for use in other jurisdictions based upon actual differences in cost resulting from the intended use of Product in countries other than the United States.

MINIMUM REQUIREMENT		
Contract Year	**Product**	**Minimum Requirement***
[***]	Across all four strengths	[***] Softgels
[***]	Across all four strengths	[***] Softgels
[***]	Across all four strengths	[***] Softgels
[***]	Across all four strengths	[***] Softgels
[***]	Across all four strengths	[***] Softgels
[***]	Across all four strengths	[***] Softgels

* Softgels shipped per Contract Year qualify towards the Minimum Requirement.

ADDITIONAL FEES		
Type of Fee	**Amount**	**Payable**
Product Maintenance Fee	$[***] for the first strength; $[***] for each additional strength	[***]
Hormone Suite Occupancy Fee	Waived based on minimum volume guarantees	N/A

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 27, 2019, 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, 2018. We consent to the incorporation by reference of said reports in the Registration Statements of TherapeuticsMD, Inc. on Form S-3 (File No. 333-226452) and on Form S-8 (File No. 333-191730).

/s/ Grant Thornton LLP

Fort Lauderdale, Florida
February 27, 2019

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 27, 2019

/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 27, 2019

/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, 2018 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 27, 2019

/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, 2018 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 27, 2019

/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.