

**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, 2019

or

- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number 001-00100

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Nevada

*(State or Other Jurisdiction of Incorporation
or Organization)*

87-0233535

(I.R.S. Employer Identification No.)

**951 Yamato Rd., Suite 220
Boca Raton, FL 33431
(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	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value \$0.001 per share	TXMD	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 whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer
Non-accelerated filer

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 (207,399,071 shares) based on the closing price of the registrant's common stock as reported on the Nasdaq Global Select Market on June 28, 2019, which was the last business day of the registrant's most recently completed second fiscal quarter, was \$539,237,585.

As of February 17, 2020, there were outstanding 271,526,176 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 2020 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, 2019.

THERAPEUTICSMD, INC.
ANNUAL REPORT ON FORM 10-K
Fiscal Year Ended December 31, 2019
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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.

This Annual Report includes our trademarks, trade names and service marks, such as vitaMedMD®, BocaGreenMD®, IMVEXXY®, BIJUVA® and ANNOVERA® which are protected under applicable intellectual property laws and are the property of, or licensed to, our company. This Annual Report also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this Annual Report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties’ trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

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

TherapeuticsMD is a women's healthcare company with a mission of creating and commercializing innovative products to support the lifespan of women from pregnancy prevention through 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 a patient-controlled, long-lasting contraceptive to advanced hormone therapy pharmaceutical products. We also have a portfolio of branded and generic prescription prenatal vitamins under the vitaMedMD and BocaGreenMD brands that furthers our women's healthcare focus.

Our portfolio of products focused on women's health allows us to efficiently leverage our sales and marketing plans to grow 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 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, which was approved by the FDA in May 2018.
- In April 2019, we launched our FDA-approved product, BIJUVA (estradiol and progesterone) capsules, our hormone therapy combination of bio-identical 17 β -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 in October 2018.
- In October 2019, we began a "test and learn" market introduction for our FDA-approved product ANNOVERA (segestosterone acetate and ethinyl estradiol vaginal system), the first and only patient-controlled, procedure-free, reversible prescription contraceptive option for women, which was approved by the FDA in August 2018 and which we have licensed for commercialization in the U.S. pursuant to an exclusive license agreement, or the Population Council License Agreement, with the Population Council, Inc., or the Population Council. We expect the full commercial launch of ANNOVERA in the first quarter of 2020.

We have also entered into license agreements with strategic partners to commercialize IMVEXXY and BIJUVA outside of the U.S.

- In July 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 June 2019, we entered into an exclusive license and supply agreement, or the Theramex License Agreement, with Theramex HQ UK Limited, or Theramex, a leading, global specialty pharmaceutical company dedicated to women's health, to commercialize BIJUVA and IMVEXXY outside of the U.S., excluding Canada and Israel.

Our Business Model

At TherapeuticsMD, our purposeful and continuous partnership with healthcare professionals and women is at the heart of our strategies for delivering innovative solutions for women. From pregnancy to post-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 health care practitioners, or HCPs, and as a result HCPs are looking for improved ways to provide better service to their patients. A study by IMS Health Inc. concluded that HCPs 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 offer HCPs a comprehensive product line of women's healthcare products across women's lifecycles.
- Our hormone therapy pharmaceutical products are designed to respond to both healthcare professional and patient needs in the marketplace – low dose, bio-identical and convenience where needed.
- Our contraceptive product is the only long-lasting 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 high quality products, such as Quatrefolic®, FOLMAX®, FePlus®, and pur-DHA™. All of our prenatal vitamins are gluten-, sugar-, and lactose-free.
- We focus on improved patient education, a high level of patient compliance, and a competitive cost of products, which can 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 physicians, and reimbursed by either government or private third-party payers is the foundation of providing valuable options to the patient. We are dedicated to enabling healthcare professionals to advance the health of women 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 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 HCPs, women, and payers cost-effective alternatives for top-quality care. We supply our prescription products to consumers through 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 established relationships with some of the largest OB/GYN practices in their respective markets. By delivering our portfolio to similar customer bases of women and OB/GYNs, we believe we can leverage our already deployed assets to increase sales of our products and achieve profitability. We leverage our existing infrastructure, including our sales force, to commercialize our VitaMedMD line of prenatal vitamins and our FDA-approved pharmaceutical products: IMVEXXY, BIJUVA, and ANNOVERA. In addition to our focus on direct selling from our sales organization, which comprises approximately 200 sales representatives, we utilize other commercial levers such as non-personal promotion to HCPs and direct-to-consumer marketing as appropriate to drive awareness and education of our product portfolio. Finally, we partner with strategic partners and licensees to commercialize our pharmaceutical products outside of the OB/GYN market and in non-U.S. markets.

As of December 31, 2019, we marketed and sold IMVEXXY, BIJUVA, and ANNOVERA under the TherapeuticsMD brand, 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 leverage our existing wholesale and retail partnerships to distribute and sell IMVEXXY, BIJUVA, and ANNOVERA, which enable us to drive efficiency as we drive increased volume across the portfolio.

Our Growth Strategy

We believe that the relationships our national sales force has developed with OB/GYN's, through our prescription prenatal vitamin products and our FDA-approved pharmaceutical products, will continue to grow as these products offer HCPs new opportunities to serve the needs of their patients. 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 our FDA-approved pharmaceutical products. We believe that our singular focus on women's health issues enables us to continue to build long-term relationships with women as they move through their life cycles of family planning to post-menopause.

Focus on Hormone Therapy Products. We continue our focus on the commercialization, development, and clinical trials 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) fill the large unmet need in this segment of the market.

Deepening focus on other parts of a women's reproductive lifecycle. With the acquisition and 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. BIJUVA is currently the only 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 compounded products, which are not FDA approved. 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 products. Our BIO-IGNITE program is focused on supporting the synergistic relationships between community pharmacies and HCPs so that offering BIJUVA and IMVEXXY as appropriate treatment alternatives is economically practical for independent and community-based pharmacies. A dedicated team of sales representatives and our Key Account Management, or KAM, team are focusing their efforts on growing BIJUVA through our BIO-IGNITE partners and as of December 31, 2019, there were over 160 BIO-IGNITE compounding pharmacies that were dispensing BIJUVA.

Multi-Channel Marketing Emphasis. We 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 work with strategic partners and licensees to commercialize and/or market our pharmaceutical products outside of the OB/GYN market and in non-U.S. markets. 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. As an example of the impact of technology on women's health, products such as ANNOVERA can be prescribed to patients via online platforms, such as the PlushCare virtual health platform and other direct-to-consumer telehealth platforms. Subject to state telemedicine and prescribing laws, prescribers affiliated with PlushCare and other direct-to-consumer telehealth platforms can prescribe or offer products to patients through a convenient virtual platform.

Multiple Distribution Partners. We have 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 have expanded our geographic marketing footprint in the United States and sales team to approximately 200 professionals as we continue to commercialize IMVEXXY, BIJUVA and ANNOVERA.

Industry and Market

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. In the U.S., there are approximately 42 million women in this age group with an additional 6,000 women reaching menopause age every day, or over 2 million additional women per year. Classic symptoms of menopause are VMS (including hot flashes and night sweats), vulvovaginal symptoms (including dyspareunia and vaginal dryness) and sleep disturbances. These symptoms are caused by the reduced levels of circulating estrogen as ovarian production shuts down. Common treatments for menopausal VMS and vulvovaginal symptoms of menopause ranges from prescription medications, including hormone therapy and non-hormonal options, to over-the-counter supplements and lubrication options.

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. Approved FDA prescriptions for menopausal hormone therapy in the United States dropped significantly following the Women's Health Initiative, or WHI, study results published 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. This study caused a significant change in hormone therapy prescribing habits. Since 2002, many women and HCPs have chosen compounded hormone therapy, a bio-identical solution for treating VMS, and the use of local vaginal therapy increased during this time. 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.

Our Menopause Portfolio

IMVEXXY

In May 2018, the FDA approved the 4- μ g and 10- μ g 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- μ g formulation of IMVEXXY represents the lowest FDA-approved dose of vaginal estradiol available. IMVEXXY 10- μ g became available for commercial distribution in July 2018 and both doses were commercially available in September 2018.

IMVEXXY is a small, digitally inserted, softgel vaginal insert that dissolves completely. It is administered mess-free, without the need for an applicator, and can be used any time of day. IMVEXXY provides a mechanism of action and dosing that are familiar and comfortable for patients, with no patient education required for dose application or applicators. IMVEXXY demonstrated efficacy as early as two weeks (secondary endpoint) and maintained efficacy through week 12 in clinical studies, with no increase in systemic hormone levels beyond the normal postmenopausal range (the clinical relevance of systemic absorption rates for vaginal estrogen therapies is not known).

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 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 on an annual basis. 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.

Based on prescription data from Symphony Health Solutions, the FDA-approved prescription market in the U.S. for the treatment of VVA symptoms includes seven products (including branded products and their generic equivalents), which generated an aggregate of approximately \$1.8 billion in gross sales on approximately 5.9 million prescriptions for the 12 months ended December 31, 2019. Approximately \$1.5 billion in gross 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 most commonly used product for the treatment of VVA is localized estrogen therapy, which generated an aggregate of approximately \$1.7 billion in gross sales in the U.S. on approximately 5.5 million prescriptions for the 12 months ended December 31, 2019. In 2017, generic forms of Estrace and Vagifem were introduced into the U.S. market with the generic equivalents capturing the vast majority of the sales for these two products. Estrace, including its generic equivalents, was the market leader in 2019 with approximately \$566 million in gross sales in the U.S. on approximately 2.1 million prescriptions. The two most recent FDA-approved product launches in this category were Osphena® (Duchesnay USA, Inc) and Intrarosa® (Amag Pharmaceuticals), each of which still has a relatively small market share.

BIJUVA

In October 2018, the FDA approved BIJUVA (estradiol and progesterone) capsules, 1 mg/100 mg, the first and only FDA-approved bioidentical hormone therapy combination of estradiol and progesterone in a single, oral capsule for the treatment of moderate-to-severe 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 molecular structure as the hormones that are naturally produced in a woman's body. We launched BIJUVA in April 2019.

BIJUVA offers the convenience of a single-capsule combination of two hormones (estradiol and progesterone), which may improve a user's compliance. The estradiol and progesterone in BIJUVA are plant-based, not animal-sourced, and contain no peanut allergens. BIJUVA provides a sustained steady state of estradiol which reduced the frequency and severity of hot flashes in clinical studies with no demonstrated impact on a patient's weight or blood pressure. Additionally, through clinical trials BIJUVA has demonstrated endometrial safety and greater than 90% amenorrhea rates, while providing no clinically meaningful changes in mammograms.

Estrogen (with or without a progestin) is most commonly used to treat VMS due to menopause that is a direct result of the decline in estrogen levels associated with ovarian shutdown at menopause. 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. According to NAMS, the most effective treatment for VMS due to menopause is estrogen therapy.

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. Progestins include the naturally occurring hormone progesterone and several synthetic progestin compounds that have pregestational activity. These agents are used for a variety of indications and conditions. 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.

According to Symphony Health Solutions, the total FDA-approved prescription market in the U.S. for all estrogen and progestin drug products for the treatment of VMS generated an aggregate of approximately \$2.2 billion of gross revenue on approximately 23.9 million prescriptions for the 12 months ended December 31, 2019. 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, and emulsions. For the 12 months ended December 31, 2019, gross sales in the U.S. of FDA-approved branded and generic products for estrogen only amounted to an aggregate of approximately \$1.4 billion on approximately 14.3 million prescriptions. For the 12 months ended December 31, 2019, gross sales in the U.S. of FDA-approved branded and generic products for progestins only amounted to an aggregate of approximately \$406 million on approximately 7.6 million prescriptions. For the 12 months ended December 31, 2019, gross sales in the U.S. of FDA approved branded and generic products for estrogens/progestins combined amounted to an aggregate of approximately \$463 million on approximately 2.0 million prescriptions.

Based on the Symphony Health Solutions data and the uses of these products, we estimate that sales of FDA-approved combinations of estrogen and progestins (the addressable market for BIJUVA) were approximately \$1.3 billion in the United States for the 12 months ended December 31, 2019. 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.

We submitted a New Drug Application, or NDA, efficacy supplement for the 0.5/100 mg dose of BIJUVA to the FDA in late January 2020 for review and potential approval. The NDA efficacy supplement uses existing data from our Phase 3 REPLENISH trial for BIJUVA, for which we announced results in December 2016, together with additional information and analyses. The REPLENISH trial was the first time that a combination of bio-identical estradiol and bio-identical progesterone used in a continuous combined daily fashion demonstrated safety and efficacy data to support FDA-approval. We do not anticipate that the FDA will require any new clinical trials in connection with our submission of the NDA efficacy supplement, however, there is no assurance that will be the case. If accepted for review by the FDA, we expect that the NDA efficacy supplement will be reviewed, under current Prescription Drug User Fee Act timeline goals, within ten months of receipt by the FDA.

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 the FDA as required in our approval.

Our hormone therapy pharmaceutical products are characterized by safety and efficacy profiles that can be consistently manufactured to target specifications. This provides an alternative to the non-FDA approved compounded bio-identical market. We believe that our FDA-approved pharmaceutical products 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.

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), with sales of PREMPRO® and Premarin constituting the largest branded products. None of the competing FDA-approved drugs for the treatment of moderate-to-severe VMS due to menopause are a combination of both bio-identical estradiol and progesterone produced by the ovaries. 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 has been approved in the U.S.

Reproductive 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. The contraceptive market includes non-hormonal methods, such as the non-hormonal intrauterine device, or 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. 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.

The most common synthetic estrogen approved in the U.S. for use in contraceptive products is ethynodiol (EE). There are 10 different progestins that have been used in contraceptives sold in the U.S. 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.

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 long-acting reversible contraceptives, or LARCs, 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 United States 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-lasting 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.

ANNOVERA

In July 2018, we entered into an exclusive license agreement with the Population Council to commercialize in the U.S. ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system), the first and only patient-controlled, procedure-free, reversible prescription contraceptive that can prevent pregnancy for up to a total of 13 cycles (one year), which was approved by the FDA in August 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 SA, and EE. EE is an approved active ingredient in many marketed hormonal contraceptive products. Segesterone acetate, an NCE, is a potent progestin that, based on pharmacopogical studies in animals and *in vitro*, does not bind to the androgen or estrogen receptors and has no glucocorticoid activity at contraceptive doses. SA 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, ANNOVERA does not require daily administration to obtain the contraceptive effect. After 21 days of use, the woman removes ANNOVERA for seven 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 (one year). ANNOVERA releases daily vaginal doses of both active ingredients (SA and EE). The claimed release rate of 150 µg/day SA 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.

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. In accordance with the post-marketing requirements, the full protocol for the study was submitted 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.

In October 2019, we began a “test and learn” market introduction phase of launch for ANNOVERA, with 36 of our existing sales representatives, our 23 regional sales managers and 12 compounding key account managers, or KAMs, introducing ANNOVERA to top targeted healthcare practitioners. A full-scale launch of ANNOVERA is expected in the first quarter of 2020.

We believe that ANNOVERA will compete across all the contraception options for women with focus on those women seeking a long-lasting option without a procedure.

For patients, ANNOVERA provides a single long-lasting reversible birth control product that does not require a procedure at the doctor’s office for insertion or removal, empowering women to be in complete control of their fertility and menstruation with a 21/7 regimen. We believe that ANNOVERA is a unique alternative for women who have previously chosen other forms of birth control. These include nulliparous women (or women who have never given birth), women who are considering an IUD but would rather not have a procedure, women who are between pregnancies but desire protection without a long-term commitment, and women who are not satisfied with oral options due to the daily usage or potential side effects.

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 HCPs 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 nonprescription 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, 2019, approximately 5.0 million prescriptions for prenatal vitamins were issued in the U.S. resulting in total sales of approximately \$286 million.

Our Prenatal Vitamin Products

We continue to manufacture and distribute our prescription prenatal vitamin 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 will continue to support the vitaMedMD and BocaGreenMD products as they are important products to our core customers and help provide us with continued access to sell our women's health portfolio. Our current prenatal vitamin product line features a unique, proprietary combination of FOLMAX™, FePlus™, and pur-DHA™ and includes the following products:

- *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, 2019, 2018, and 2017, approximately 20%, 93%, and 99.9%, respectively, of our consolidated revenue was generated by our prenatal vitamin products.

Commercialization Model

We are commercializing 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, we believe that 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 U.S. 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. 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 educate HCPs on our products primarily with our field sales organization. We have defined a sales force targeting approximately 200 territories, which includes the most significant part of the addressable markets across our product portfolio. 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.

As of December 31, 2019, at least 17,800 HCPs had written at least one prescription of IMVEXXY and at least 5,000 HCPs had written at least one prescription of BIJUVA, the majority of which are also IMVEXXY writers demonstrating the value of portfolio and focus. In addition, although still in soft launch mode, as of December 31, 2019, at least 800 HCPs had written at least one prescription of ANNOVERA.

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 and our products top of mind in the HCP community.

BIO-IGNITE - In addition to our sales organization calling on HCPs, we have a KAM team to support our BIO-IGNITE pharmacy 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. Our KAMs have national coverage and target over 1,900 community pharmacies that have a focus on compounded bio-identical hormones and the over 2,000 additional HCPs that are affiliated with these pharmacies. As of December 31, 2019, there were over 160 BIO-IGNITE compounding pharmacies that were dispensing BIJUVA.

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 products until the payers have the opportunity to make a coverage decision based upon their internal review of 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. Currently, both IMVEXXY and BIJUVA 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. As of December 31, 2019, we have obtained coverage for the majority of commercial payers for both products and continue to seek unrestricted coverage from the remaining commercial insurance plans that we have not yet contracted with to provide affordable access for patients. For IMVEXXY, we achieved unrestricted coverage with eight of the top ten commercial payers of VVA products by commercial payer lives and we continue to sign new agreements with payers to cover IMVEXXY. In addition, as of December 31, 2019, two of the top six Medicare Part D payers of VVA products were adjudicating IMVEXXY, with additional decisions for other Medicare Part D payers expected during 2020. For BIJUVA, through December 31, 2019, we have achieved unrestricted coverage with six of the top ten commercial payers of VMS products by commercial payer lives and we continue to sign new agreements with payers to cover BIJUVA. Although Medicare is a small percentage of the VMS market, as of December 31, 2019, two of the top six Medicare Part D payers of VMS products were adjudicating BIJUVA.

For ANNOVERA, we believe that its unique characteristics will assist us in pursuing favorable commercial payer coverage, including only one pharmacy fill fee per year and no office visit or procedure fees. We have made substantial progress in achieving unrestricted access to ANNOVERA through commercial payers, including having achieved adjudication with six of the top ten commercial payers by commercial payer lives as of December 31, 2019, and we continue to pursue discussions with several of the country’s largest commercial insurers to further expand coverage. As of December 31, 2019, approximately 64% of the commercial payer market covered ANNOVERA with unrestricted access under pharmacy benefits and approximately 11% covered ANNOVERA with step access.

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, there is no assurance that FDA will make such a determination and it is possible that other FDA-approved products could also be included in such a new class. For instance, the FDA may find that ANNOVERA fits into the vaginal contraceptive ring class, which it would share with NuvaRing and its generic equivalents, and potentially others. 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. Recently, some states have amended and expanded requirements to match the standard set in the ACA mandate, specifically requiring coverage for the full range of contraceptive methods, counseling and services used by women and eliminating out-of-pocket costs and limiting other health plan restrictions. As of January 2020, 29 states require insurers that cover prescription drugs to provide coverage of FDA-approved prescription contraceptive drugs and devices. However, the Trump administration has implemented new policies that permit certain employers to claim a religious or moral objection to the birth control coverage mandate under the ACA. Health plans sponsored by certain exempt religious employers and non-profit religious organizations that certify they have religious objections do not need to offer contraception coverage through their health benefit plans. As of January 2020, 21 states allow certain employers and insurers to refuse to comply with the ACA’s contraceptive coverage mandate. We anticipate that any impact on contraception coverage due to religious exemption will be low; however, healthcare reform, including potential repeal of or changes to the ACA, continues to attract significant legislative and administrative interest, legal challenges, regulatory and compliance requirements, new approaches and public attention that create uncertainty and the potential for additional changes. Healthcare reform implementation, additional legislation or regulations, and other changes in government policy or regulation may repeal the contraception coverage mandate, affect our reimbursement or impose additional coverage limitations and/or cost-sharing obligations on patients, any of which could have a material adverse effect on patient usage of ANNOVERA.

In February 2020, we entered into an agreement with Afaxys Pharma, LLC, a pharmaceutical company focused on serving women in the public health system, to market ANNOVERA in the U.S. public health sector. 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. We also have agreements to market ANNOVERA to the U.S. Department of Defense, the U.S. Veteran’s Administration, and in Puerto Rico.

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 with payers at profitable levels.

Supply - We want to ensure our products are available in all classes of trade and delivery systems. We 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 patients so that we can support appropriate use of our products by patients. Our co-pay assistance programs allow all patients to access our products at a reasonable cost.

- We continue to support our patient education and affordability program that allows all eligible patients who enroll to receive IMVEXXY and BIJUVA at a reasonable cost. When a product is not covered by a patient's commercial insurance, 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. Starting October 1, 2019, enrolled patients pay as little as \$35 for a prescription of IMVEXXY with commercial insurance coverage and pay as little as \$50 for a prescription of IMVEXXY without commercial insurance coverage. For ANNOVERA, for commercially insured patients, we offer patients assistance for as low as \$60 for an annual prescription. Many patients will not need a co-pay assistance program for ANNOVERA given the requirements of the ACA at the federal level and similar laws at the state level.
- We continue to dialogue with the FDA regarding the potential inclusion of ANNOVERA as a new class of contraception for women in the FDA's Birth Control Guide, which would require private health plans to cover ANNOVERA with no patient out-of-pocket costs as part of the ACA. While we are optimistic about our chances to secure a new contraception class for ANNOVERA, there is no assurance that the FDA will make such a determination and it is possible that other FDA-approved products could also be included in such a new class. The FDA may also find that ANNOVERA fits into the vaginal contraceptive ring class, which it would share with NuvaRing and its generic equivalents, and potentially others. Eight states require insurance coverage of prescription contraception with co-pay regardless of inclusion in the FDA's Birth Control Guide and 11 states, plus Washington D.C., require coverage of prescription contraception with no co-pay regardless of inclusion in the FDA's Birth Control Guide.

Patient Adherence - Establishing compliance and adherence programs that make getting on a prescription medication and obtaining prescribed refills easy and convenient for the patient and HCPs 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 have delivered effective patient engagement programs for both our prescription prenatal line and for IMVEXXY with average adherence rates above the averages in their respective categories.

Consumer Communication - Another critical level in the commercial model is consumer communication. Our initial focus is on those patients who are already predisposed to seek treatment, such as those patients new to therapy, and those patients dissatisfied with their current therapy. Next, we are focused on expanding the market by energizing patients who are experiencing bothersome symptoms but who have not been motived to seek treatment. Methods of communication 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.

License Agreements

License Agreement with the Population Council

Under the terms of the Population Council License Agreement, we paid the Population Council a milestone payment of \$20,000,000 within 30 days following approval by the FDA of the NDA for ANNOVERA. The first commercial batch of ANNOVERA was released during the third quarter of 2019 and we paid the Population Council \$20,000,000 as a result of the commercial batch release. The Population Council is eligible to receive additional 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.

The Population Council has agreed to perform and pay the costs and expenses associated with two 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 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. We and the Population Council formed a joint product committee responsible for overseeing activities under the Population Council License Agreement. We are 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.

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.

License Agreement with Knight

In July 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 the 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. In October 2019 and November 2019, Knight's New Drug Submissions for Joyesta (IMVEXXY) and BIJUVA, respectively, were accepted for review by Health Canada. 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 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.

License Agreement with Theramex

In June 2019, we entered into a licensing and supply agreement, or the Theramex License Agreement, with Theramex pursuant to which we granted Theramex an exclusive, perpetual license to commercialize BIJUVA and IMVEXXY for human use outside of the U.S., except for Canada and Israel, or the Theramex Territory. Pursuant to the terms of the Theramex License Agreement, Theramex paid us an upfront fee of EUR 14 million in cash. We are also eligible to receive up to an additional EUR 29.5 million in cash milestone payments, comprised of (i) an aggregate of EUR 2 million in regulatory milestone payments based on regulatory approvals for each of BIJUVA and IMVEXXY in certain specified markets and (ii) an aggregate of EUR 27.5 million in sales milestone payments to be paid in escalating tranches based on Theramex first attaining certain aggregate annual net sales milestones in the Theramex Territory ranging from EUR 25 million to EUR 100 million. We are also entitled to receive quarterly royalty payments based on net sales of BIJUVA and IMVEXXY in the Theramex Territory. Theramex has agreed to submit all regulatory applications, submissions and/or registrations required for regulatory approval to use and commercialize BIJUVA and IMVEXXY in certain specified markets within certain specified time periods and we may terminate the Theramex License Agreement if Theramex does not submit certain of such regulatory applications, submissions and/or registrations. We may also terminate the Theramex License Agreement if Theramex challenges our patents. Either party may terminate the Theramex 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. Theramex may sublicense its rights to commercialize BIJUVA and IMVEXXY in the Theramex Territory, except for certain specified markets. Pursuant to the terms of the Theramex License Agreement, we agreed to

supply, or cause to be supplied, BIJUVA and IMVEXXY to Theramex. We and Theramex have agreed to form a joint product committee responsible for advising and overseeing activities under the Theramex License Agreement.

Preclinical Development

We have four preclinical projects: a progesterone-alone transdermal cream (TX-005HR), a combination estradiol and progesterone transdermal cream (TX-006HR), and a pair of transdermal patch product candidates (TX-007HR and TX-008HR). *In vivo* and *in vitro* proof-of-concept preclinical studies were conducted to assess TX-005HR and TX-006HR with respect to penetration of the estradiol and progesterone, and successful opposition of subcutaneous estradiol on the endometrium. In addition to menopausal treatments, we are also evaluating various other indications targeted to women's health and wellness. We may, in the future, engage with a financing partner to advance one or more of these product candidates. We have one project in clinical development: an oral progesterone and estradiol formulation (TX-009HR). Previously, TX-009HR showed improved bioavailability in animals. In 2019, TX-009HR was tested in a Phase 1 study of healthy postmenopausal women and was well-tolerated in that study.

Sales Concentration

We sell our prescription prenatal vitamin products and pharmaceutical 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 Good Manufacturing Practice, or 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 also 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. We have also contracted with QPharma to manufacture the commercial supply for ANNOVERA. For the prenatal vitamins, our quality assurance team collaborates with Lang to monitor the cGMP compliance of Lang's contracted manufacturers and packagers. Although each of Catalent, QPharma and Lang have received Form FDA 483 observations from FDA inspections in the past, we are not aware of any open FDA investigations into the manufacturing and/or packaging processes at the facilities that are used for 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. Depending on their roles and activities, certain of our contractors are subject to applicable requirements to test incoming raw materials and finished goods to ensure they meet or exceed FDA and U.S. Pharmacopeia standards, 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 ships to national wholesale 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. We are subject to compliance responsibilities under the Drug Supply Chain Security Act, or the DSCSA, and the Prescription Drug Marketing Act, or PDMA, in relation to distribution of drug products in the commercial supply and dispensing chain and drug samples to HCPs respectively, and are further subject to state laws on these topics. 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.

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. Where permitted, patents for our hormone therapy drug products have been submitted to the Orange Book.

As of December 31, 2019, we had 29 issued domestic patents and 30 issued foreign patents, including:

- 12 domestic patents and six foreign patents that relate to BIJUVA as well as three domestic patents that relate to estradiol and progesterone product candidates. These patents establish an important intellectual property foundation 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, China, Europe, Israel, Japan, Mexico, New Zealand, Russia, South Africa, and South Korea;
- Six domestic patents (five utility and one design) and 13 foreign patents (three utility and ten 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 countries, 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 seven 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., Brazil, Canada, Mexico, and South Africa;
- Three domestic utility patents that relate to TX-009HR, a progesterone and estradiol product candidate, which are 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;
- Two domestic and four foreign patents that relate to formulations containing progesterone, which are owned by us. The domestic patents will expire between 2032 and 2036. The foreign patents will expire no earlier than 2033. In addition, we have pending patent applications with respect to formulations containing progesterone in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea; and
- One domestic utility patent that relates to our OPERA information-technology platform, which is owned by us and will expire in 2031.

The sponsor of an approved 505(b) drug product, which approval is the first permitted commercial marketing of a drug with that drug's active ingredient, may apply for a patent term extension (PTE) under 35 U.S.C. § 156. The length of a PTE is calculated based on the "regulatory review period," which consists of one-half of the time between the initial effective date of the Investigational New Drug, or IND, for the clinical study(ies) supporting FDA approval of the drug and the date of the NDA submission, plus the time between the submission of the NDA and the date of FDA approval. Any period of time during the regulatory review period in which the applicant is deemed to have not acted with due diligence will be deducted from regulatory review period calculation. A PTE may not exceed five years, and the remaining term of a patent as extended by a PTE will be limited as necessary such that the remaining term does not exceed 14 years from the date of the NDA approval. Only one patent may be extended based on a regulatory review period, and a patent may not receive more than one PTE. The rights provided during the term of a PTE generally are limited to the approved use(s) of the product.

As of December 31, 2019, we had filed over 120 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 189 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. See “– Pharmaceutical Regulation – Regulatory Exclusivity” below for information regarding our intellectual property and challenges thereto.

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, biologics, medical devices, 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 regarding pricing transparency, laws requiring the implementation of compliance programs, laws requiring the reporting of payments or other transfers of value to HCPs or other healthcare professionals, 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 investigational new drug, or 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. Requests to withdraw the INDs for TX-002HR and TX-003HR were submitted in December 2019. The INDs for TX-004HR, TX-001HR, TX-006HR, and TX-009HR remain active. The IND for ANNOVERA was transferred from the Population Council to us in May 2019 and is also 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 and central or each clinical trial site’s institutional review board, or 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. During Phase 2, the drug is administered to small populations of patients 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 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 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, among other things, negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling.

Once the NDA submission has been accepted for filing, the FDA's goal is to review standard applications within 10 months of the 60-day filing date for new molecular entity NDA and original BLA submissions, or within 10 months of receipt for non-NME and original BLA submissions. For Original Efficacy Supplements, the FDA's goal is to review the application within 10 months of the receipt date. The review process can be 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.

Post-Approval Regulation

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, to adhere to product sampling and distribution requirements, fulfill post-marketing study commitments, and to comply with requirements concerning advertising and promotional labeling for any of our drug products, which include, among other things, standards for direct-to-consumer advertising, restrictions that prohibit promoting products for uses or in patient populations that are not described in the product's approved uses or that are not otherwise consistent with the FDA-required label (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label use, if they deem such use to be appropriate in their professional medical judgment, manufacturers may not market or promote such off-label uses.

Also, quality control and manufacturing procedures must continue to conform to cGMPs to ensure and preserve the long-term stability of the drug product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are, depending on the nature and scope of their activities, subject to FDA and certain state agency requirements relating to establishing and maintaining product quality. 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.

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 2019 with respect to its softgel manufacturing plant. The observations and associated corrective actions identified in Catalent's response to the Form FDA 483 related to our BIJUVA product. The current inspection classification status of that Form FDA 483 is that the response was adequate and Voluntary Action Indicated. Voluntary Action Indicated status indicates that objectionable conditions or practices were found but the FDA is not prepared to take or recommend any administrative or regulatory action.

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 (for example, through adverse events observed in the post-marketing context, or in Phase 4 / post-marketing studies) 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.

Regulation of Compounding Pharmacies

Our hormone therapy pharmaceutical products and product 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 not approved by the FDA and are therefore not reviewed to evaluate their safety, effectiveness, or quality.

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 reinstating 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.

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 an active ingredient that has not previously been approved in any other 505(b) NDA (a "new chemical entity," or NCE), is eligible for a five-year NCE exclusivity period starting on the date of the NDA approval. During this period, an Abbreviated New Drug Application, or ANDA, or 505(b)(2) application for a drug containing the protected active ingredient of the NCE product generally cannot be submitted to FDA until the end of the five-year exclusivity period, except that such applications can be submitted at year four if the product is covered by an Orange Book listed patent and the ANDA or 505(b)(2) NDA includes a Paragraph IV Certification challenging such patent. Additional exclusivities may also apply.

The first approved Section 505(b) NDA applicant for a particular condition, or a supplemental NDA approval for a change to a marketed product, such as a new extended release formulation for a previously approved product, may be eligible for a three-year Hatch-Waxman exclusivity if one or more new 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 granting final approval to any ANDA or 505(b)(2) application for the same condition of use or change to the marketed product that was granted exclusivity until after that three-year exclusivity period has run.

Additionally, any ANDA or 505(b)(2) NDA that references the 505(b) product must include one of several types of patent certifications. If the Section 505(b) NDA drug has one or more unexpired patents listed in the Orange Book, an ANDA or 505(b)(2) NDA must include either a “Paragraph III Certification” or a “Paragraph IV Certification.” A Paragraph III Certification identifies the expiration date of the listed patent and requires FDA to withhold final approval until that patent has expired. A “Paragraph IV Certification” states that, in the applicant’s opinion, the relevant patent is invalid, unenforceable, or would not be infringed by the commercial marketing of the proposed ANDA or 505(b)(2) NDA product. The sponsor of a Paragraph IV ANDA or 505(b)(2) NDA must also provide the holder of the marketed product NDA, and the owner of the challenged patent, with notification of the Paragraph IV filing along with a detailed statement of the reasons the applicant believes the patent is invalid, unenforceable, or would not be infringed. If the patent owner brings an infringement action against the Paragraph IV applicant within 45 days of the notification, a statutory stay is imposed which prevents FDA from granting final approval of the Paragraph IV application for 30 months from the date of the Paragraph IV Notification. Generally, no more than one 30-month stay may be applied against any specific Paragraph IV ANDA or 505(b)(2) NDA. A 30-month stay can be terminated early, and the Paragraph IV application can be immediately approved, if the district court rules in favor of the Paragraph IV applicant that the patent is invalid, unenforceable, or would not be infringed.

On February 20, 2020, we received a Paragraph IV certification notice letter, or the Notice Letter, regarding an ANDA submitted to the FDA by Teva Pharmaceuticals USA, Inc., or Teva. The ANDA seeks approval from the FDA to commercially manufacture, use, or sell a generic version of the 4 mcg and 10 mcg doses of IMVEXXY. In the Notice Letter, Teva alleges that TherapeuticsMD patents listed in the FDA’s Orange Book that claim compositions and methods of IMVEXXY, or the IMVEXXY Patents, are invalid, unenforceable, and/or will not be infringed by Teva’s commercial manufacture, use, or sale of its proposed generic drug product. The IMVEXXY Patents identified in the Notice Letter expire in 2032 or 2033. We are currently reviewing the Notice Letter and intend to vigorously enforce our above-described intellectual property rights relating to IMVEXXY.

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 are intended to have a beneficial impact in prenatal women based upon scientific literature and input from HCPs; 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.

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. 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

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients’ rights, among other topics, are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we or our partners conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual or in return for the purchase, lease, or order of any good, facility item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, including, for example, the federal civil False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private), knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which impose obligations on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the ACA, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare or Medicaid to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. In 2022 the Sunshine Act will be extended to payments and transfers of value to physician assistants, nurse practitioners, and other mid-level practitioners (with reporting requirements going into effect in 2022 for payments made in 2021). In addition, Section 6004 of the ACA requires annual reporting of information about drug samples that manufacturers and authorized distributors provide to healthcare providers;
- federal and state laws requiring pricing transparency or limiting price increases, which are in existence today or are anticipated to be in existence in the near future, may limit the ability to raise prices, require disclosure of price increases or require disclosure of the wholesale acquisition cost of pharmaceutical products to governmental agencies and consumers; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be provided to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Pharmaceutical company interactions with HCPs, patient advocacy groups, and patients, including with respect to product and patient assistance programs and other education and support initiatives, have been and continue to be the subject of regulatory scrutiny for compliance with fraud and abuse laws.

In addition to the fraud and abuse laws, we continue to monitor the potential impact of proposals to lower prescription drug costs at the federal and state level. For example, on May 11, 2018, President Trump laid out his administration's "Blueprint" to lower drug prices and reduce out of pocket costs of drugs, as well as additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, and incentivize manufacturers to lower the list price of their products. Although some proposals related to the administration's Blueprint may require additional authorization to become effective, may ultimately be withdrawn, or may face challenges in the courts, the U.S. Congress and the Trump administration have indicated that they will continue to seek new legislative and administrative measures to control drug costs. Drug pricing remains a key bipartisan issue and drug pricing legislation has been introduced in both the Senate and the House. The Senate Finance Committee released "The Prescription Drug Pricing Reduction Act of 2019" in July 2019 which includes changes to Medicare and Medicaid drug pricing and targets certain pharmacy benefit manager (PBM) and pharmaceutical manufacturer pricing practices. In December 2019, the House passed a drug pricing bill, "Lower Drug Costs Now Act of 2019", which features Medicare Parts B and D direct negotiation with manufacturers, inflationary rebates, and a restructuring of the Part D benefit. Republicans in both chambers have opposed the drug pricing bills but the Trump administration has expressed support for the Senate bill and continues to push for drug pricing controls. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

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 HCPs, 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, U.S. Department of Health and Human Services, or HHS, or by other federal, state, local, or foreign regulatory authorities, or 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, 2019, we had 348 employees, six of whom are executive officers. Our sales force currently consists mainly of contract employees, with the sales management being employees. 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 951 Yamato Road, Suite 220, Boca Raton, Florida 33431. 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.

Risk Factors

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 \$176 million, \$133 million, and \$77 million for the years ended December 31, 2019, 2018, and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of approximately \$695 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 commercialization, research, development, and clinical trial activities. As a result, we may never achieve or maintain profitability, even if we successfully commercialize all of our pharmaceutical products. 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 or licenses of our women's healthcare 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 2019, we derived all of our revenue from sales or licenses of our women's healthcare products, including patient-controlled, long-acting contraceptive, hormone therapy pharmaceutical products, prenatal and women's multi-vitamins, and iron supplements. 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 non-authorized generic copies of our products;
- supply or distribution problems arising with any of our manufacturing and distribution partners;
- changed or increased regulatory restrictions or regulatory actions by the FDA;
- changes in healthcare laws and policy, including changes in requirements for drug pricing, rebates, reimbursement, and coverage by federal healthcare programs and commercial payers;
- 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 warnings, 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 all of our pharmaceutical products or commence or continue clinical trials to seek approval for any other products we may choose to develop in the future.

The commercial success of our existing products and other pharmaceutical products 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 pharmaceutical products and patient-controlled, long-acting contraceptive, 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 pharmaceutical products and patient-controlled, long-acting contraceptive are approved;
- 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 pharmaceutical 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 and devices;
- 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 potential inclusion of a new category for one-year multi-cycle hormonal birth control methods in the FDA Birth Control Guide, which payers may rely upon as guidance for coverage;
- the availability of coverage and adequate reimbursement by third parties, such as insurance companies and other healthcare payers, or by government healthcare 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 effective for their approved indications, physicians may not immediately be receptive to their use or may be slow to adopt our products as an accepted treatment for the symptoms for which they are intended. Labeling approved by the FDA may not 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 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, products themselves, or marketing campaigns for our products. 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 consumers as less than favorable or that may question earlier favorable research or publicity could have a material adverse effect on sales of our products and 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 use of our products or any other similar products with illness or other adverse effects, or that questions the benefits of our products or similar products, or that claims that such products do not have the effect intended, or that question the marketing of our products, could have a material adverse effect on our business, reputation, financial condition, or results of operations.

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 consumer 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 of our existing products to meet consumers' demand in a timely manner, our business, results of operations, and financial condition could be materially and adversely affected.

We may not be able to complete the commercialization of our pharmaceutical products and development of future product 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 pharmaceutical product 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, in each case to the extent permitted under the Financing Agreement, dated as of April 24, 2019, as amended, with TPG Specialty Lending, Inc., as administrative agent, or the Administrative Agent or Sixth Street, various lenders from time to time party thereto, and certain of our subsidiaries party thereto from time to time as guarantors, or the Financing 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 significantly delay, scale back, or discontinue our commercialization and product development efforts.

The Financing 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 commercialization and development 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 commercializing, including IMVEXXY, BIJUVA and ANNOVERA and our prenatal vitamins, and the pharmaceutical products we are developing and planning to develop in the future, are subject to extensive and rigorous domestic government regulation, including regulation by the FDA, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, including its Office of Inspector General, the U.S. Department of Justice, the Departments of Defense and Veterans Affairs, to the extent our products are paid for directly or indirectly by those departments, state and local governments, and their respective foreign equivalents. The FDA regulates dietary supplements, cosmetics, and drugs under different regulatory schemes. For example, the FDA regulates the processing, formulation, safety, manufacturing, packaging, labeling, and distribution of dietary supplements and cosmetics under its dietary supplement and cosmetic authority, respectively. The FDA also regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical products under various regulatory provisions. If any pharmaceutical 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 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, or AKS, prohibits, among other things, persons and entities, including pharmaceutical manufacturers, from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any good or service reimbursable, in whole or in part, for which payment may be made under federal healthcare programs, such as Medicare, Medicaid, TRICARE, and the State Children's Health Insurance Program. This statute has been interpreted broadly to apply to, among other things, arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. The term "remuneration" includes kickbacks, bribes or rebates and also has been broadly interpreted to include anything of value, including, for example, gifts, discounts, waivers of payment, ownership interest and providing anything at less than its fair market value. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, however, the exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny. The failure to meet the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not meet the criteria for safe harbor protection from AKS liability in all cases. Liability may be established without proving actual knowledge of the statute or specific intent to violate it to have committed a violation. 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 False Claims Act, or 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 healthcare 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 civil and criminal false claims laws and civil monetary penalty laws, including the 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 to, or approval by federally funded health care programs that are false, fictitious or fraudulent or knowingly making, using, or causing to be made to be used, a false record or statement material to a false or fraudulent claim to avoid, decrease, or conceal an obligation to pay money with respect to a federal program. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the federal government. Although we do not submit claims directly to payers, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, marketing products of sub-standard quality, or, as noted above, paying a kickback that results in a claim for items or services. In addition, our activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, several pharmaceutical and other healthcare companies have faced enforcement actions under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. 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 healthcare 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. In addition, AKS violations and certain marketing practices, including off-label promotion, may also implicate the FCA. Although the FCA is a civil statute, conduct that results in a FCA violation may also implicate various federal criminal statutes.
- Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for knowingly and willfully executing or attempting to execute a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including third-party private payers, knowingly and willfully falsifying, concealing, or covering up by trick, scheme, or device, a material fact or making any materially false, fictitious, or fraudulent statements in connection with the delivery of or payment for healthcare 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. Similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. State laws may also govern the privacy and security of health information or other personal information in certain circumstances.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, impose, among other things, obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, and business associates. Among other things, HITECH made certain aspects of HIPAA's rules (notably the Security Rule) directly applicable to business associates - independent contractors or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal court to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. The Department of Health and Human Services Office of Civil Rights, or the OCR, has increased its focus on compliance and continues to train state attorneys general for enforcement purposes. The OCR has recently increased both its efforts to audit HIPAA compliance and its level of enforcement, with one recent penalty exceeding \$5 million.
- According to the U.S. Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.
- 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 healthcare 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, and its implementing regulations, imposes annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under certain government healthcare programs (with certain exceptions) to annually report to CMS information related to certain payments or other "transfers of value" made or provided to physicians and teaching hospitals, or to other entities or individuals at the request of, or designated on behalf of, the 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 healthcare providers, pharmaceutical pricing information and marketing expenditures. On October 25, 2018, President Trump signed into law the "Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act." This law, in part (under a provision entitled "Fighting the Opioid Epidemic with Sunshine"), will extend the Sunshine Act to payments and transfers of value to physician assistants, nurse practitioners, and other mid-level healthcare providers (with reporting requirements going into effect in 2022 for payments made in 2021).
- Analogous state laws and regulations, such as state anti-kickback and false claims laws, and other state laws addressing the pharmaceutical and healthcare industries, may apply to interactions between pharmaceutical manufacturers and healthcare providers, sales or marketing arrangements, and claims involving healthcare items or services reimbursed by commercial third-party payers, including private healthcare insurers and health maintenance organizations, and in some cases that may apply regardless of payer, i.e., even if reimbursement is not available; further, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance program guidelines (the PhRMA Code) and the relevant compliance guidance promulgated by the federal government (HHS-OIG) in addition to requiring drug manufacturers to report pricing and marketing information, including, among other things, information related to gifts, payments, or other remuneration to physicians and other healthcare providers or marketing expenditures, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information and the use of prescriber-identifiable data in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. For example, California enacted legislation – the California Consumer Privacy Act, or CCPA – which went into effect January 1, 2020 and, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information, and creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach; the California Attorney General will issue final regulations, and although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our processing of personal information depending on the context, and it remains unclear what language the final Attorney General regulations will contain or how the statute and regulations will be interpreted.

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 healthcare entities, including substantially increased funding for healthcare 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 healthcare laws and regulations could be costly. In connection with the commercial launches of IMVEXXY, BIJUVA and ANNOVERA, 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 patient 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 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 government healthcare 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 healthcare 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 stockholder 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 prescription vitamins, will depend on coverage and reimbursement policies and may be affected by healthcare reform measures. Government healthcare programs and third-party payers decide which prescription pharmaceutical 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 pharmaceutical 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 healthcare 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 U.S. and some foreign jurisdictions, there have been several legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. In the U.S., 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 pharmaceutical 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 healthcare program reimbursement for any new pharmaceutical 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 healthcare 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. For instance, the FDA may find that ANNOVERA fits into the vaginal contraceptive ring class, which it would share with NuvaRing and its generic equivalents, and potentially others. 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. Private payers may interpret the statute and its associated rules in ways in which they decline to cover ANNOVERA, even if we believe ANNOVERA should be covered without cost sharing under the ACA framework. 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. Recently, some states have amended and expanded requirements to match the standard set in the ACA mandate, specifically requiring coverage for the full range of contraceptive methods, counseling and services used by women and eliminating out-of-pocket costs and limiting other health plan restrictions. Despite this favorable development, there is no guarantee that other states will follow and no guarantee that states will retain this mandate, particularly if the ACA mandate is repealed or otherwise eroded. The Trump administration has implemented new policies that permit certain employers to claim a religious or moral objection to the birth control coverage mandate under the ACA. Health plans sponsored by certain exempt religious employers and non-profit religious organizations that certify they have religious objections do not need to offer contraception coverage through their health benefit plans. Further, despite our progress with commercial payers, there is no guarantee that we will be able to retain these agreements or obtain new agreements or that we will be able to negotiate favorable reimbursement or pricing terms for our products in the future. In addition, healthcare reform, including potential repeal of or changes to the ACA, continues to attract significant legislative and administrative interest, legal challenges, regulatory and compliance requirements, new approaches and public attention that create uncertainty and the potential for additional changes. Healthcare reform implementation, additional legislation or regulations, and other changes in government policy or regulation may repeal the contraception coverage mandate, affect our reimbursement or impose additional coverage limitations and/or cost-sharing obligations on patients, any of which could have a material adverse effect on coverage and reimbursement of our products, and our business, financial condition, results of operations, and prospects could be harmed.

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 reporting requirements and price concessions. Manufacturer compliance with 340B Program requirements can be costly. 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 healthcare, 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 healthcare and substantially change the way healthcare is financed by both government healthcare programs and third-party payers. Among other measures, the ACA increased rebates on manufacturers for certain covered pharmaceutical products reimbursed by state Medicaid programs. While we cannot predict the full effect that the ACA will have on government healthcare 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 healthcare 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 healthcare providers of up to 2.0% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Under the Trump administration, there have been ongoing efforts to modify or repeal all or certain provisions of the ACA. On December 14, 2018, the U.S. District Court for the Northern District of Texas struck down the ACA in *Texas v. Azar*, deeming it unconstitutional given that Congress repealed the individual mandate in 2017; on July 9, 2019, the U.S. Court of Appeals for the Fifth Circuit heard arguments on appeal in this matter. On December 15, 2019, the Fifth Circuit struck down the ACA in its entirety given that the TCJA eliminated the tax penalty associated with the individual mandate and therefore it was unconstitutional. The Fifth Circuit further remanded the case to the U.S. District Court for the Northern District of Texas to further analyze whether the other provisions of the ACA are severable as they currently exist under the law. 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 pharmaceutical product candidates, these new laws and policies (as well as proposed legislation, if enacted) may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

On December 13, 2016, President Obama signed into law the 21st Century Cures Act, which, among other things, may increase the types of clinical trial designs that would be acceptable to support an NDA. It is unclear, at this time, how these provisions will be implemented or whether they would have any effect on our company. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on our pharmaceutical products and product 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. For example, on December 23, 2019, the Trump administration released a Notice for Proposed Rulemaking to amend the FDA regulations regarding the importation of certain prescription drugs from Canada. If this rule is finalized as proposed, states and certain other non-federal governmental entities would be able to submit important program proposed to the FDA for review and authorization. Proposals to the FDA would need to demonstrate that any drug importation program does not pose any additional risk to the public's health and safety and an explanation of any results in significant reduction in the cost of covered products to consumers. Additionally, there has recently 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 instance, on May 11, 2018, President Trump laid out his administration's "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs, as well as additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, and incentivize manufacturers to lower the list price of their products. Although some proposals related to the administration's Blueprint may require additional authorization to become effective, may ultimately be withdrawn, or may face challenges in the courts, the U.S. Congress and the Trump administration have each indicated that they will continue to

seek new legislative and administrative measures to control drug costs, including by addressing the role of pharmacy benefit managers in the supply chain.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, rebate transparency, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The ACA and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations. 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 healthcare products and our pharmaceutical product 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 healthcare products, IMVEXXY, BIJUVA and ANNOVERA, or our pharmaceutical product 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, including cGMPs. 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. We have also entered into a long-term supply contract with QPharma AB 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 our vitaMedMD and BocaGreen products. We do not have long-term contracts for the commercial supply of our vitaMedMD and BocaGreen products, however, in certain circumstances, including our failure to satisfy our production forecasts to Lang, we may be obligated to reimburse Lang for the costs of excess raw materials purchased by Lang that it cannot use in another product category that it then sells.

Regulatory requirements could pose barriers to the manufacture of our women's healthcare products and our pharmaceutical product 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. The CMO that manufactures ANNOVERA, has previously been inspected by the FDA and received Form 483 observations with respect to its facility that will be used for the commercial supply of ANNOVERA. We believe that corrective actions to address the compliance issues identified in the referenced Forms 483 have been implemented by the CMOs; however, the FDA has not yet reinspected the CMOs to confirm that the corrective actions were implemented as described to the agency in the respective Form 483 responses.

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 products, we may need to find alternative manufacturing facilities, which would result in substantial disruptions of our sales of existing products and significant delays of up to several years in obtaining approval for our pharmaceutical product 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, and if we do enter into agreements with alternative manufacturers, those alternative manufacturers may not be approved by the FDA, any of 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 products or pharmaceutical product 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 products or pharmaceutical product candidates, which could impair our ability to supply our products or pharmaceutical product 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 other pharmaceutical product 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, or REMS, 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 pharmaceutical product 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 pharmaceutical 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 cGMP 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.

Commercial products must now meet the requirements of the Drug Supply Chain Security Act, or DSCSA, which imposes obligations on manufacturers of prescription pharmaceutical products for commercial distribution, regulating the distribution of the products at the federal level, and sets certain standards for federal or state registration and compliance of entities in the supply chain (manufacturers and re-packagers, wholesale distributors, third-party logistics providers, and dispensers). The DSCSA preempts previously enacted state pedigree laws and the pedigree requirements of the Prescription Drug Marketing Act, or PDMA, and its implementing regulations. Trading partners within the drug supply chain must now ensure certain product tracing requirements are met that they are doing business with other authorized trading partners; and they are required to exchange transaction information, transaction history, and transaction statements. Further, the DSCSA limits the distribution of prescription pharmaceutical products and imposes requirements to ensure overall accountability and security in the drug supply chain. As of November 27, 2018, product identifier information (an aspect of the product tracing scheme) is required. Although the PDMA no longer mandates pedigree requirements, manufacturers must follow the requirements pertaining to drug samples for health care professionals. Some states also have their own regulations on drug samples and related interactions with health care professionals.

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 healthcare programs, such as Medicare and Medicaid, and refuse to allow us to enter into supply contracts, including government contracts.

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.

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. Our practices with respect to interactions with healthcare 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 or limit certain marketing-related activities, including the provision of gifts, meals or other items to certain healthcare providers.

The FDA also strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. A company can make only those claims relating to safety and efficacy, purity, and potency that are approved by the FDA. Physicians, in their independent professional medical judgment, may prescribe legally available products for unapproved indications that are not described in the product's labeling and that differ from those tested and approved by the FDA. Pharmaceutical companies, however, are required to promote their pharmaceutical products only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability, including, but not limited to, criminal and civil penalties under the FDCA and the FCA, exclusion from participation in federal healthcare programs, mandatory compliance programs under corporate integrity agreements, debarment, and refusal of government contracts.

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 (PAPs), 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 healthcare 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 and BIJUVA, including co-pay assistance and free drug sample packs for IMVEXXY and BIJUVA, and potentially will enter into similar programs for ANNOVERA. While the HHS Office of Inspector General (OIG) has approved certain independent charitable PAPs that help financially needy beneficiaries, advisory opinions on this issue have primarily focused on charities that provide assistance to patients who cannot afford cost-sharing obligations for prescription drugs. A key element for the OIG has been whether the charities are sufficiently independent from drug manufacturer donors. In May 2014, the OIG issued a Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs, or the 2014 Special Advisory Bulletin, which updated its 2005 Special Advisory Bulletin relating to PAPs. In the 2014 Special Advisory Bulletin, the OIG stated that although PAPs provide important safety net assistance to financially needy patients, these programs also present a risk of fraud, waste, and abuse with respect to federal health care programs. One of the three factors set forth in the revised guidance was that the PAP could not limit assistance to a single product. In September of 2014, the OIG also released a Special Advisory Bulletin on pharmaceutical manufacturer copayment coupons, specifically stating that manufacturers that did not comply with the law may be subject to sanctions if they fail to take appropriate steps to ensure that such coupons do not induce the purchase of Federal health care program items or services, including, but not limited to, drugs paid for by Medicare Part D. Failure to take such steps may be evidence of intent to induce the purchase of drugs paid for by these programs, in violations of the AKS. PAPs have also been the subject of recent Congressional review. If we fail to structure our patient assistance and 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. 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 government healthcare programs, and the curtailment or restructuring of our operations. 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, which could also have an adverse effect on our business, financial condition and results of operations. 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, healthcare professionals, pharmacies, or other individuals or entities, 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 state licensing of pharmacies and pharmacists and 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.

Some of our products can be prescribed to patients via virtual health platform, such as PlushCare, a direct-to-consumer telehealth platform offering primary care medical services, subject to state telemedicine and prescribing laws. The federal Ryan Haight Act substantially limits the ability of prescribers to prescribe controlled substances via telehealth. While this federal law applies only to federally controlled substances, the permissibility of prescribing other non-controlled substances via a telehealth encounter is addressed at the state level. Constant changes to the telemedicine laws and regulations as well as state pharmacy and prescribing laws and emerging enforcement priorities by state legislatures, licensing bodies, and attorney generals' offices, make it difficult to predict our ability to effectively penetrate the market for our products via virtual care offerings. We cannot guarantee that prescribers will be able, or willing, to prescribe our products to patients via a telehealth encounter and any limitations on such remote prescribing at the state level may impede our ability to expand access to our products.

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 products and product candidates. 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 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 covering ANNOVERA; and
- the Population Council owns any program improvements, as defined in the agreement.

We have also entered into licensing and supply agreements with Knight pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY and BIJUVA in Canada and Israel and with Theramex pursuant to which we granted Theramex an exclusive license to commercialize BIJUVA and IMVEXXY outside of the U.S., except for Canada and Israel.

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. or for sale outside of the U.S. under the terms of these licensing and supply agreements are reimported and sold in the U.S. In addition, our rights to receive royalties with respect to our products sold outside the U.S. could be adversely affected if our licensees fail to diligently pursue approval of our products, or opt not to sell our products, in certain jurisdictions where they are not required to do so.

Our level of indebtedness and the terms of the Financing 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 Financing Agreement, we will be unable to draw down the remaining the facility and if we are unable to comply with restrictions in the Financing Agreement, the repayment of our existing indebtedness could be accelerated.

Under the Financing Agreement, we have incurred a substantial amount of debt, which could adversely affect our business. In April 2019, we drew down the first tranche of \$200.0 million under the Financing Agreement and in February 2020 we drew down the second tranche of \$50.0 million under the Financing Agreement. We intend to draw an additional \$50.0 million tranche under the terms of the Financing Agreement, when and if the conditions precedent to such tranche have been met; however, the Administrative Agent has the sole and absolute discretion to make this additional \$50.0 million tranche available to us and there is no assurance that the Administrative Agent will do so. 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 third tranche of \$50.0 million under the Financing Agreement. The third tranche may be drawn by us on or before September 22, 2020 (or such later date as may be consented to by the lenders in their sole discretion) in TPG's sole and absolute discretion either contemporaneously with the delivery of our financial statements for the fiscal quarter ending June 30, 2020 or at such earlier date as TPG shall have consented to. If we are unable to satisfy those conditions, we would not be able to draw down the tranche of financing and may not be able to obtain alternative financing on commercially reasonable terms or at all.

The Financing Agreement requires us to make certain payments of principal and interest over time and contains several other restrictive covenants. Among other requirements of the Financing Agreement, we and our subsidiaries party to the Financing Agreement must (i) maintain a minimum unrestricted cash balance of \$50.0 million, which amount increased to \$60.0 million when we drew down the second tranche of the facility, and (ii) achieve certain minimum consolidated net revenue amounts attributable to commercial sales of our products beginning with the fourth quarter of 2020. The Financing Agreement also contains covenants that limit, among other things, the ability of us and our subsidiaries party to the Financing 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 Financing 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 dietary supplement, hormone therapy pharmaceutical products or patient-controlled, long-acting contraceptive products do not have the effects intended or cause undesirable side effects, our business may suffer.

Although many of the ingredients in our 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. Furthermore, our hormone therapy or patient-controlled, long-acting contraceptive pharmaceutical products have been approved by the FDA based on its assessment of the safety and efficacy of these products. 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. In addition, these products may not have the effect intended if they are not taken in accordance with certain instructions, which include certain dietary or other labeling 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.

Even following regulatory approval for our hormone therapy pharmaceutical products and patient-controlled, long-acting contraceptive, we will still face extensive, ongoing regulatory requirements and review, and our products may face future development and regulatory difficulties.

Even following regulatory approval for our pharmaceutical products in the U. S., the FDA may still impose significant restrictions on a product's doses, 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 conducting 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 data 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 pharmaceutical products 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 pharmaceutical products are also 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 requirements and related 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 pharmaceutical products, 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 pharmaceutical 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 cGMP 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 PDMA. Sales, marketing, and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the FCA, and similar state laws. We would also be required under the Sunshine provision of the ACA to report annually to CMS 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 healthcare 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.

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 consumer base and maintaining adequate pricing through our exclusivities. The pharmaceutical and dietary supplement 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 consumers.

On February 20, 2020, we received the Notice Letter regarding an ANDA submitted to the FDA by Teva. The ANDA seeks approval from the FDA to commercially manufacture, use, or sell a generic version of the 4 mcg and 10 mcg doses of IMVEXXY. In the Notice Letter, Teva alleges that IMVEXXY Patents listed in the FDA's Orange Book that claim compositions and methods of IMVEXXY are invalid, unenforceable, and/or will not be infringed by Teva's commercial manufacture, use, or sale of its proposed generic drug product. The IMVEXXY Patents identified in the Notice Letter expire in 2032 or 2033. We are currently reviewing the Notice Letter and intend to vigorously enforce our intellectual property rights relating to IMVEXXY. Under the Hatch-Waxman Act, we have 45 days from receipt of the Notice Letter to initiate a patent infringement lawsuit against Teva. Such a lawsuit would automatically preclude the FDA from approving Teva's ANDA until the earlier of 30 months or entry of a district court decision finding the IMVEXXY Patents invalid, unenforceable, or not infringed. We cannot assure you that any patent infringement lawsuit that we may file will prevent the introduction of a generic version of IMVEXXY for any particular length of time, or at all. If Teva's ANDA is approved, and a generic version of IMVEXXY is introduced, our sales of IMVEXXY could be adversely affected. In addition, we cannot predict what additional ANDAs could be filed by Teva or other potential generic competitors requesting approval to market generic forms of our products, which could require us to incur significant additional expense and result in distraction for our management team, and if approved, result in significant decreases in the revenue derived from sales of our marketed products and thereby materially harm our business and financial condition.

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

We have entered into licensing and supply agreements with Knight and Theramex to commercialize IMVEXXY and BIJUVA in non-U.S. markets. To market these products in the European Union and many other non-U.S. jurisdictions, our licensees 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, our licensees may not obtain them on a timely basis, if at all. Our licensees' failure to receive necessary non-U.S. regulatory approvals to commercialize IMVEXXY and BIJUVA 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 IMVEXXY and BIJUVA in one or more non-U.S. markets, we and/or our licensees will be subject to rules and regulations in those markets relating to our products. 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, our licensees may be required to conduct a clinical trial that compares the cost-effectiveness of our pharmaceutical product to other available products. If reimbursement of our pharmaceutical product is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels,

our licensees 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 our licensees obtain approval to market IMVEXXY or BIJUVA 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 in which our licensees distribute our products 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 commercial availability of our current products and the clinical testing of our pharmaceutical product 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 therapy products and contraceptives, we will face an even greater risk through commercialization of our 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 associated with the use of the product, negligence, strict liability, or breaches of warranties. Claims could also be asserted under state consumer fraud and protection statutes. 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 pharmaceutical product candidates. Regardless of the merits or eventual outcome, product liability claims may result in any of the following:

- the inability to commercialize our products or pharmaceutical product candidates;
- difficulty recruiting subjects for clinical trials or withdrawal of these subjects before a trial is completed;
- labeling, marketing, or promotional changes and/or 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 or actions by state attorney generals or the U.S. Department of Justice;
- 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 products and product 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.

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

Our manufacturing and 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 U.S. 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. Although we have employment agreements with several of our key employees, 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 products to wholesale distributors and retail pharmacy distributors. During 2019, four customers each generated more than 10% of our total revenues; revenue generated from these four customers combined accounted for approximately 73% of our total revenue during 2019. 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 or commence or continue product sales.

We may experience delays in future clinical trials for our pharmaceutical product candidates or required post-approval clinical trials for our approved products. Clinical trials might not begin on time; may be interrupted, delayed, suspended, or terminated once commenced; might need to be amended or 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 central or local IRB approval for each clinical 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 or due to a lack of ability to enroll a certain number of patients in a trial;
- 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 pharmaceutical product candidates, or continue to generate revenue from our approved products subject to post-approval clinical trials for our approved products, subject to the trial.

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. 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 pharmaceutical product candidates fail to demonstrate safety or efficacy to the satisfaction of the FDA, the FDA will not approve those product candidates and we will not be able to commercialize, 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 pharmaceutical product 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 pharmaceutical product 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 pharmaceutical product 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.

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 pharmaceutical product 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 pharmaceutical product 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 pharmaceutical product candidates, as well as for the execution of clinical studies. Although we control only certain aspects of our CROs' activities, we are ultimately 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 Good Clinical Practice, or cGCP, regulations and guidelines enforced by the FDA for all of our products in clinical development. The FDA enforces these cGCPs through periodic and pre-approval 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 pharmaceutical product 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 pharmaceutical product candidates that we seek to develop. As a result, our financial results and the commercial prospects for our pharmaceutical product 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 pharmaceutical product 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, 2019, we had federal net operating loss carryforwards, or NOLs, of approximately \$620.4 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, 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. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse.

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 operations are concentrated in Boca Raton, Florida and interruptions affecting us or our suppliers due to natural disasters or other unforeseen events could materially and adversely affect our operations.

Our current operations are concentrated in Boca Raton, Florida. A hurricane or other disaster or unforeseen event resulting in significant damage to our facilities could significantly disrupt or curtail or require us to cease our operations. It would be difficult, costly and time-consuming to transfer resources from one facility to another or to repair or replace our facility if it is significantly damaged. In addition, our insurance may be insufficient to cover all of our losses and may not continue to be available to us on acceptable terms, or at all. In addition, if one of our suppliers, such as Catalent at its manufacturing facility in St. Petersburg, Florida, experiences a similar disaster or unforeseen event, we could face significant delays in obtaining our products. Any significant uninsured loss, prolonged or repeated disruption to operations or inability to operate, experienced by us or by our suppliers, could materially and adversely affect our business, financial condition and results of operations.

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

We are substantially dependent on a sales force – both those directly employed by us and those engaged through our contract sales organization – to attract new business and to manage existing customer relationships. We 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 sales personnel may not become as productive as expected, and we may be unable to hire or engage enough qualified individuals in the future in the markets in which we do business. If we are unable to hire, engage and develop enough productive sales personnel or are required to hire or engage more sales personnel than we expect our business prospects could suffer. In addition to utilizing a contract sales organization for part of our sales force, we also utilize this organization for certain sales support functions, such as fleet and sample management. We currently intend to insource at least some of these functions and personnel in the future. If we are unsuccessful in insourcing these functions or personnel, we may face delays or additional costs in commercializing our pharmaceutical products, which could materially and adversely affect our business, financial condition and results of operations.

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.

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, 2019, we had 348 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 pharmaceutical product 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 pharmaceutical products 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 patients 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 failure to comply with foreign data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

European Union member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the European Union, which was formerly governed by the provisions of the European Union Data Protection Directive, was replaced with the European Union General Data Protection Regulation, or the GDPR, in May 2018. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the U.S., provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the non-compliant company, whichever is greater. The recent implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the U.S., the European Union and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

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 healthcare 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 healthcare 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 competing pharmaceutical products and obtain FDA regulatory exclusivity in the U.S. before we do, potentially preventing our ability to commercialize our pharmaceutical products and other products in development.

We plan to seek to obtain market exclusivity for our pharmaceutical products and any other pharmaceutical product candidates we develop in the future. To the extent that patent protection is not available or has expired, FDA exclusivity may be the only available form of exclusivity available for these proposed products. These FDA exclusivities can delay the submission or the approval of certain drug applications. Potentially competitive products may also be seeking FDA exclusivities 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 exclusivities before we do, which could delay our ability to submit an application or obtain necessary regulatory approvals, result in lost market opportunities with respect to our pharmaceutical product 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 pharmaceutical products 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 pharmaceutical products 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 U.S., 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 U.S., 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 U.S. or in foreign jurisdictions;
- 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 invent or file patent applications for these technologies in the U.S. 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 pharmaceutical product 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 pharmaceutical products 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 pharmaceutical products. 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 pharmaceutical products 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. On February 20, 2020, we received the Notice Letter regarding an ANDA submitted to the FDA by Teva. The ANDA seeks approval from the FDA to commercially manufacture, use, or sell a generic version of the 4 mcg and 10 mcg doses of IMVEXXY. In the Notice Letter, Teva alleges that IMVEXXY Patents listed in the FDA’s Orange Book that claim compositions and methods of IMVEXXY are invalid, unenforceable, and/or will not be infringed by Teva’s commercial manufacture, use, or sale of its proposed generic drug product. The IMVEXXY Patents identified in the Notice Letter expire in 2032 or 2033. We are currently reviewing the Notice Letter and intend to vigorously enforce our intellectual property rights relating to IMVEXXY. Under the Hatch-Waxman Act, we have 45 days from receipt of the Notice Letter to initiate a patent infringement lawsuit against Teva. Such a lawsuit would automatically preclude the FDA from approving Teva’s ANDA until the earlier of 30 months or entry of a district court decision finding the IMVEXXY Patents invalid, unenforceable, or not infringed. We cannot assure you that any patent infringement lawsuit that we may file will prevent the introduction of a generic version of IMVEXXY for any particular length of time, or at all. If Teva’s ANDA is approved, and a generic version of IMVEXXY is introduced, our sales of IMVEXXY could be adversely affected. In addition, we cannot predict what additional ANDAs could be filed by Teva or other potential generic competitors requesting approval to market generic forms of our products, which could require us to incur significant additional expense and result in distraction for our management team, and if approved, result in significant decreases in the revenue derived from sales of our marketed products and thereby materially harm our business and financial condition.

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 pharmaceutical product 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 technical areas of our pharmaceutical products, including compounds, formulations, treatment methods, and synthetic processes, which may be applied towards the synthesis of hormones, for example. 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 product 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 product 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 product candidates, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product 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 pharmaceutical product 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 pharmaceutical product candidates, which could adversely affect our business, financial condition, results of operations, and prospects.

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, including with respect to Teva's ANDA and Notice Letter, 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 U.S. 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 products;
- 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 supply for our products 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 licensees' commercialization efforts;
- 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, 2019, our executive officers, directors, holders of 5% or more of our stock, and their affiliates beneficially owned approximately 51% of our common stock, inclusive of vested options and warrants to acquire shares of our common stock. 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.

Future sales and issuances of equity securities, convertible securities or other securities could result in additional dilution of the percentage ownership of holders of our common stock.

Our stockholders may experience dilution upon future equity issuances, including convertible debt or equity securities we may issue in the future, the exercise of stock options to purchase common stock granted to our employees, consultants and directors, including options to purchase common stock granted under our stock option and equity incentive plans or the issuance of common stock in settlement of previously issued awards under our stock option and equity incentive plans that may vest in the future.

We expect that additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell equity securities, convertible securities or other securities in one or more transactions at prices and in a manner we determine from time to time. If we sell equity securities, convertible securities or other securities current investors may be materially diluted by subsequent sales. We may also need our stockholders to authorize the issuance of additional shares of common stock under our articles of incorporation if we do not have sufficient authorized shares to raise such additional capital or issue future awards under our stock option and equity incentive plans. New investors could also gain rights, preferences and privileges senior to those of holders of our existing equity securities.

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. In addition, the terms of the Financing Agreement preclude us from paying dividends, and any future debt agreements may also preclude us from paying dividends. Any return to stockholders will be limited to the capital appreciation, if any, 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

In October 2018, we entered into a lease for new corporate headquarter offices in Boca Raton, Florida. The lease includes 56,212 rentable square feet, or the full premises, of which the lease on 7,561 square feet commenced in 2018 and the lease on the remaining 48,651 square feet commenced in August 2019, or the full premises commencement date. The lease will expire 11 years after the 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 extension option is not included in the determination of the lease term as it is not reasonably certain to be exercised. 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 June 2019, we entered into an agreement with the same lessors to lease additional 6,536 square feet of administrative office space in the same location, pursuant to an addendum to such lease, which is expected to commence as soon as the first quarter of 2020.

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for 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.

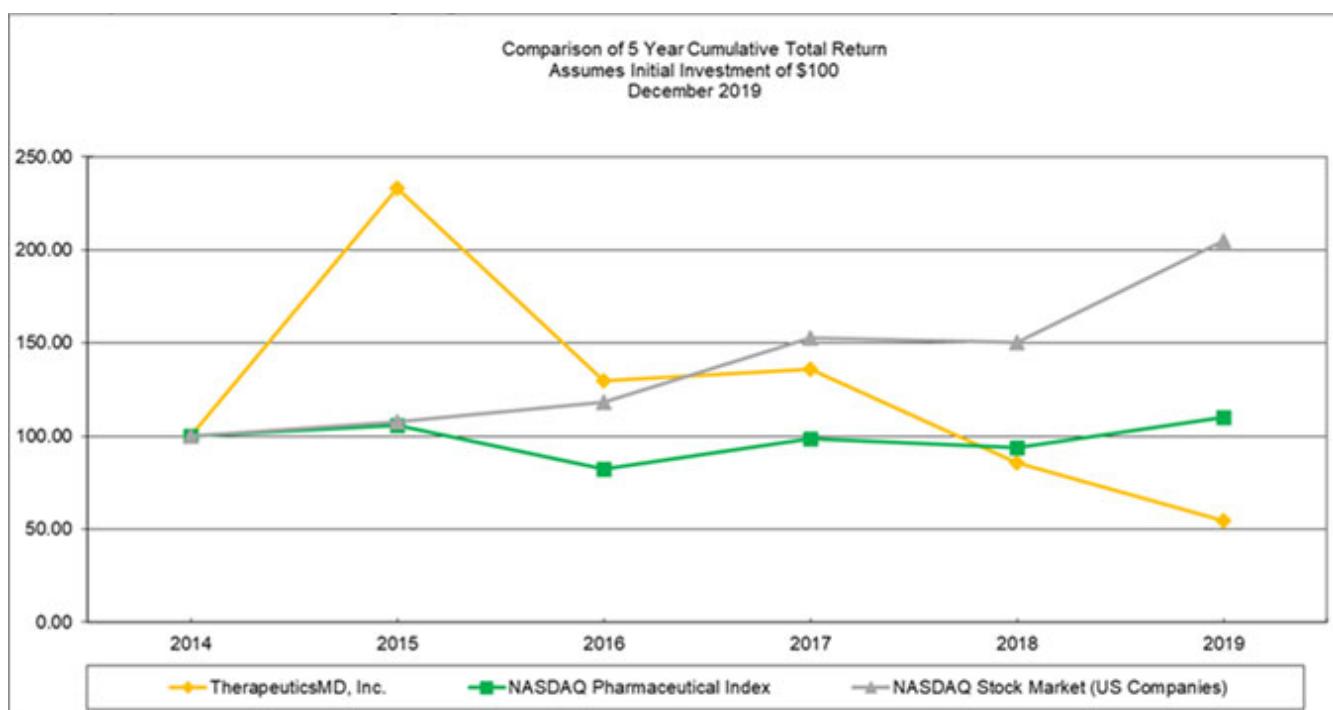
As of February 3, 2020, there were approximately 192 record holders and 25,445 beneficial owners of our common stock.

Dividends

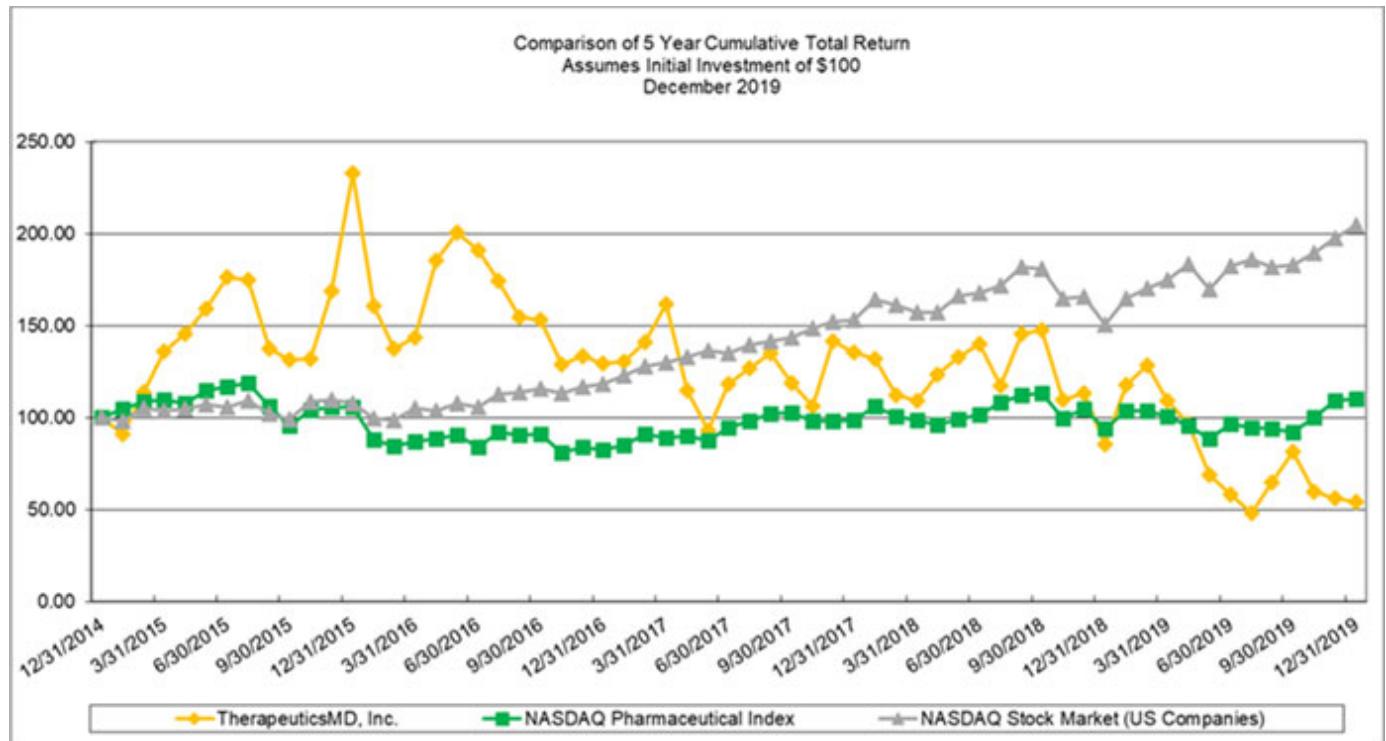
Historically, we have not paid dividends on our common stock, and we currently do not intend to pay any dividends on our common stock in the foreseeable future. We currently plan to retain any earnings to finance the growth of our business rather than to pay cash dividends. Payments of any cash dividends 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 stockholder return for the five years ended December 31, 2019 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, 2014 and includes reinvestment of dividends. Measurement points are at December 31, 2014 and the last trading day of the fiscal years ended December 31, 2015, 2016, 2017, 2018, and 2019. The stock price performance on the following graph is not necessarily indicative of future stock price performance.



The following line graph compares cumulative total stockholder return for the five years ended December 31, 2019 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, 2014 and includes reinvestment of dividends. Measurement points are December 31, 2014 and the last trading day of the fiscal years ended December 31, 2019, 2018, 2017, 2016, and 2015 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 of 1933, as amended, or the Securities Act.

Recent Sales of Unregistered Equity Securities

During the year ended December 31, 2019, warrants to purchase an aggregate of 1,250,000 shares of our common stock that were previously issued to an outside service provider were exercised pursuant to the warrants’ cashless exercise provisions, which resulted in 471,184 shares of our common stock being issued. The shares of common stock were issued in reliance on the exemption from registration provided by Section 4(a)(2) of 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, 2019, 2018, and 2017 and the consolidated balance sheet data as of December 31, 2019 and 2018 are derived from our audited consolidated financial statements included in this Annual Report. The consolidated statements of operations for the years ended December 31, 2016 and 2015, and the consolidated balance sheet data as of December 31, 2017, 2016, and 2015 are derived from our audited consolidated financial statements not included in this Annual Report.

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

Consolidated Statements of Operations Data	Year Ended December 31,				
	2019	2018	2017	2016	2015
Product revenue, net	\$ 34,141	\$ 16,099	\$ 16,778	\$ 19,356	\$ 20,143
License revenue	15,506	—	—	—	—
Cost of goods sold	6,335	2,737	2,637	4,185	4,506
Gross profit	<u>43,312</u>	<u>13,362</u>	<u>14,141</u>	<u>15,171</u>	<u>15,637</u>
Operating expenses:					
Sales, general, and administration	174,113	115,989	57,703	51,348	28,721
Research and development	19,792	27,299	33,853	53,943	72,043
Depreciation and amortization	613	294	213	133	63
Total operating expense	<u>194,518</u>	<u>143,582</u>	<u>91,769</u>	<u>105,424</u>	<u>100,827</u>
Operating loss	(151,206)	(130,220)	(77,628)	(90,253)	(85,190)
Other (expense) income, net	(24,939)	(2,397)	703	378	113
Net loss	<u>\$ (176,145)</u>	<u>\$ (132,617)</u>	<u>\$ (76,925)</u>	<u>\$ (89,875)</u>	<u>\$ (85,077)</u>
Net loss per share, basic and diluted	\$ (0.72)	\$ (0.59)	\$ (0.37)	\$ (0.46)	\$ (0.49)
Weighted average number of common shares outstanding, basic and diluted	246,353	225,026	205,523	196,088	173,174
Consolidated Balance Sheet Date (at end of period)					
Total assets	\$ 265,986	\$ 211,984	\$ 143,230	\$ 142,472	\$ 73,729
Total liabilities	\$ 256,785	\$ 114,460	\$ 13,321	\$ 14,983	\$ 10,666
Total stockholders’ equity	<u>\$ 9,201</u>	<u>\$ 97,524</u>	<u>\$ 129,909</u>	<u>\$ 127,489</u>	<u>\$ 63,063</u>
Other Data:					
Capital expenditures (for the period)	\$ 3,892	\$ 1,322	\$ 827	\$ 1,241	\$ 584
Working capital (at the end of the period)	\$ 155,411	\$ 145,700	\$ 126,233	\$ 124,428	\$ 60,014

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

TherapeuticsMD is a women’s healthcare company with a mission of creating and commercializing innovative products to support the lifespan of women from pregnancy prevention through 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 a patient-controlled, long-lasting contraceptive to advanced hormone therapy pharmaceutical products. We also have a portfolio of branded and generic prescription prenatal vitamins under the vitaMedMD and BocaGreenMD brands that furthers our women’s healthcare focus.

Our portfolio of products focused on women’s health allows us to efficiently leverage our sales and marketing plan to grow 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 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, which was approved by the FDA in May 2018.
- In April 2019, we launched our FDA-approved product, BIJUVA (estradiol and progesterone) capsules, our hormone therapy combination of bio-identical 17 β -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 in October 2018.
- In October 2019, we began a “test and learn” market introduction for our FDA-approved product ANNOVERA (segestosterone acetate and ethinyl estradiol vaginal system), the first and only patient-controlled, procedure-free, reversible prescription contraceptive option for women, which was approved by the FDA in August 2018 and which we have licensed for commercialization in the U.S. pursuant to an exclusive license agreement, or the Population Council License Agreement, with the Population Council, Inc., or the Population Council . We expect the full commercial launch of ANNOVERA in the first quarter of 2020.

We have also entered into license agreements with strategic partners to commercialize IMVEXXY and BIJUVA outside of the U.S.

- In July 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 June 2019, we entered into an exclusive license and supply agreement, or the Theramex License Agreement, with Theramex HQ UK Limited, or Theramex, a leading, global specialty pharmaceutical company dedicated to women’s health, to commercialize BIJUVA and IMVEXXY outside of the U.S., excluding 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 prenatal vitamin 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.

BIJUVA

In October 2018, the FDA approved BIJUVA (estradiol and progesterone) capsules, 1 mg/100 mg, the first and only FDA-approved bioidentical hormone therapy combination of estradiol and progesterone in a single, oral capsule for the treatment of moderate-to-severe 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. We launched BIJUVA in April 2019.

Following meetings with the FDA, we submitted a New Drug Application, or NDA, efficacy supplement for the 0.5/100 mg dose of BIJUVA to the FDA in late January 2020 for review and potential approval. The NDA efficacy supplement uses existing data from our Phase 3 REPLENISH trial for BIJUVA, for which we announced results in December 2016, together with additional information and analyses. The REPLENISH trial was the first time that a combination of bio-identical estradiol and bio-identical progesterone used in a continuous combined daily fashion demonstrated safety and efficacy data to support FDA-approval. We do not anticipate that the FDA will require any new clinical trials in connection with our submission of the NDA efficacy supplement, however, there is no assurance that will be the case. If accepted for review by the FDA, we expect that the NDA efficacy supplement will be reviewed, under current Prescription Drug User Fee Act timeline goals, within ten months of receipt by the FDA.

IMVEXXY

In May 2018, the FDA approved the 4- μ g and 10- μ g 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- μ g formulation of IMVEXXY represents the lowest FDA-approved dose of vaginal estradiol available. IMVEXXY 10- μ g became available for commercial distribution in 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

In July 2018, we entered into an exclusive license agreement with the Population Council to commercialize in the U.S. ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system), the first and only patient-controlled, procedure-free, reversible prescription contraceptive that can prevent pregnancy for up to a total of 13 cycles (one year), which was approved by the FDA in August 2018. ANNOVERA was classified by the FDA as an 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 SA and EE. EE is an approved active ingredient in many marketed hormonal contraceptive products. Segesterone acetate, an NCE, is a potent progestin and ANNOVERA is the only product with segesterone acetate. Segesterone acetate also does not bind to the androgen or estrogen receptors and has no glucocorticoid effects at contraceptive doses. SA 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 seven 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 (one year).

ANNOVERA releases daily vaginal doses of both active ingredients (SA and EE). The claimed release rate of 150 μ g/day SA and 13/day μ g 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.

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. In accordance with the post-marketing requirements, the full protocol for the study was submitted 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 \$20,000,000, 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. The Population Council has agreed to perform and pay the costs and expenses associated with two post-approval studies required by the FDA for ANNOVERA.

In October 2019, we began a “test and learn” market introduction phase of launch for ANNOVERA, with 36 of our existing sales representatives currently promoting ANNOVERA in addition to our other products, and our 23 regional sales managers and 12 compounding key account managers, or KAMs, introducing ANNOVERA to top targeted healthcare practitioners outside of these 36 territories. A full-scale launch of ANNOVERA is expected in the first quarter of 2020.

License Agreement with the Population Council

Under the terms of the Population Council License Agreement, we paid the Population Council a milestone payment of \$20,000,000 within 30 days following approval by the FDA of the NDA for ANNOVERA. The first commercial batch of ANNOVERA was released during the third quarter of 2019 and we paid the Population Council \$20,000,000 as a result of the commercial batch release. The Population Council is eligible to receive additional 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, 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.

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.

License Agreement with Knight

In July 2018, we entered into 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 the 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. In October 2019 and November 2019, Knight’s New Drug Submissions for Joyesta (IMVEXXY) and BIJUVA, respectively, were accepted for review by Health Canada. 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 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.

License Agreement with Theramex

In June 2019, we entered into the Theramex License Agreement with Theramex pursuant to which we granted Theramex an exclusive, perpetual license to commercialize BIJUVA and IMVEXXY for human use outside of the Theramex Territory. Pursuant to the terms of the Theramex License Agreement, Theramex paid us an upfront fee of EUR 14 million in cash. We are also eligible to receive up to an additional EUR 29.5 million in cash milestone payments, comprised of (i) an aggregate of EUR 2 million in regulatory milestone payments based on regulatory approvals for each of BIJUVA and IMVEXXY in certain specified markets and (ii) an aggregate of EUR 27.5 million in sales milestone payments to be paid in escalating tranches based on Theramex first attaining certain aggregate annual net sales milestones in the Theramex Territory ranging from EUR 25 million to EUR 100 million. We are also entitled to receive quarterly royalty payments based on net sales of BIJUVA and IMVEXXY in the Theramex Territory. Theramex has agreed to submit all regulatory applications, submissions and/or registrations required for regulatory approval to use and commercialize BIJUVA and IMVEXXY in certain specified markets within certain specified time periods and we may terminate

the Theramex License Agreement if Theramex does not submit certain of such regulatory applications, submissions and/or registrations. We may also terminate the Theramex License Agreement if Theramex challenges our patents. Either party may terminate the Theramex 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. Theramex may sublicense its rights to commercialize BIJUVA and IMVEXXY in the Theramex Territory, except for certain specified markets. Pursuant to the terms of the Theramex License Agreement, we agreed to supply, or cause to be supplied, BIJUVA and IMVEXXY to Theramex. We and Theramex have agreed to form a joint product committee responsible for advising and overseeing activities under the Theramex License Agreement.

Research and Development Expenses

A significant portion of our historical operating expenses have been incurred in research and development activities. Research and development expenses relate primarily to the discovery and development of our drug candidates. Our research and development expenses consist primarily of expenses incurred under agreements with contract research organizations, or CROs, and consultants that conduct our clinical and 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 Investigational New Drug Application approval from the FDA.

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

	Years Ended December 31,		
	2019	2018	2017
	(000s)		
TX 001-HR (BIJUVA)	\$ 3,848	\$ 11,790	\$ 19,381
TX 004-HR (IMVEXXY)	2,522	4,890	8,043
ANNOVERA	2,637	—	—
Other research and development	10,785	10,619	6,429
Total	\$ 19,792	\$ 27,299	\$ 33,853

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.

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, 2019, 2018, and 2017:

Year ended December 31, 2019 compared with year ended December 31, 2018

	Years Ended December 31,		
	2019	2018	Change
	(000s)		
Product revenue, net	\$ 34,141	\$ 16,099	\$ 18,042
License revenue	15,506	—	15,506
Cost of goods sold	6,335	2,737	3,598
Operating expenses	194,518	143,582	50,936
Operating loss	(151,206)	(130,220)	(20,986)
Other (expense) income, net	(24,939)	(2,397)	(22,542)
Net loss	\$ (176,145)	\$ (132,617)	\$ (43,528)

Revenue

Product revenue is recorded net of sales discounts, chargebacks, wholesaler fees, customer rebates, coupons and estimated returns. Product revenue for the year ended December 31, 2019 increased approximately \$18,042,000, or 112%, to approximately \$34,141,000, compared with approximately \$16,099,000 for the year ended December 31, 2018. Product revenue increased primarily due to an increase in sales of approximately \$15,194,000 of IMVEXXY in the current period, partially offset by a decrease in prenatal vitamin sales of approximately \$5,155,000. Product revenue for the year ended December 31, 2019 also included sales of BIJUVA of approximately \$1,836,000 and sales of ANNOVERA of approximately \$6,167,000. The revenue decrease related to our prenatal vitamins was primarily affected by lower number of units sold as compared to the prior year period. We launched IMVEXXY in the third quarter of 2018 and BIJUVA in the second quarter of 2019. We started selling ANNOVERA in the third quarter of 2019 and we expect the full commercial launch of ANNOVERA in the first quarter of 2020. Since the launches, revenues related to IMVEXXY and BIJUVA have been greatly affected by the co-pay assistance programs that we introduced to launch these products, which allow eligible enrolled patients to access the products at a reasonable cost regardless of insurance coverage. We expect our product revenue to improve as commercial and Medicare payer coverage increases, and plans complete the process needed to adjudicate IMVEXXY, BIJUVA and ANNOVERA prescriptions at pharmacies. In addition to our product revenue, during the year ended December 31, 2019, we recognized license revenue of approximately \$15,506,000 from the upfront fee, which was a non-refundable payment, paid to us by Theramex under the terms of the Theramex License Agreement, which we recognized at the point in time when Theramex was able to use and benefit from the license, which was when the knowledge transfer of regulatory documents occurred.

Cost of Goods Sold

Cost of goods sold increased by approximately \$3,598,000, or 131%, to approximately \$6,335,000 for the year ended December 31, 2019, compared with approximately \$2,737,000 for the year ended December 31, 2018, primarily related to product costs attributable to our prescription pharmaceutical products, as well as royalty fees of \$308,328 and the amortization of our license fee of \$778,692 related to ANNOVERA. Our gross margin related to our prescription pharmaceutical products was 81% for the year ended December 31, 2019 as compared to 83% for the year ended December 31, 2018. The change in our gross margin is primarily related to the change in product mix between the two periods.

Operating Expenses

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

	Years Ended December 31,	
	2019	2018
Sales and marketing costs, excluding human resource costs	45%	43%
Human resource related costs	28%	25%
Product research and development costs	10%	19%
Professional fees and consulting costs	7%	5%
Other operating expenses	10%	8%

Operating expenses increased by approximately \$50,936,000, or 35%, to approximately \$194,518,000 for the year ended December 31, 2019, compared with approximately \$143,582,000 for the year ended December 31, 2018, as a result of the following items:

	Years Ended December 31,		
	2019	2018	Change
	(000s)		
Sales and marketing, excluding human resources costs	\$ 86,459	\$ 61,845	\$ 24,614
Human resources related costs	54,120	35,003	19,117
Research and development costs	19,792	27,299	(7,507)
Professional and consulting costs	13,913	7,661	6,252
Other operating expenses	20,234	11,774	8,460
Total operating expenses	\$ 194,518	\$ 143,582	\$ 50,936

Sales and marketing costs increased by approximately \$24,614,000 or 40%, to approximately \$86,459,000 for the year ended December 31, 2019, compared with approximately \$61,845,000 for the year ended December 31, 2018, primarily as a result of increased expenses associated with sales and marketing efforts to support launch and commercialization of our pharmaceutical products, including an increase of \$7.4 million related to advertising expenses related to our pharmaceutical products, an increase of \$6.5 million in consulting projects including costs for outsourced sales personnel and their related expenses, an increase of \$6.0 million in marketing initiatives related to the launch of our pharmaceutical products as well as an increase in costs related to physician education, conferences and travel expenses related to product commercialization. We expect sales and marketing expenses to continue to increase as we continue to support the commercialization of our pharmaceutical products.

Human resource related costs, including salaries and benefits increased by approximately \$19,117,000, or 55%, to approximately \$54,120,000 for the year ended December 31, 2019, compared with approximately \$35,003,000 for the year ended December 31, 2018, primarily as a result of an increase of approximately \$16,844,000 primarily due to higher employee count which increased from 241 in 2018 to 348 in 2019 primarily in sales, marketing and regulatory areas to support commercialization of our pharmaceutical products and an increase in non-cash compensation expense included in this category of approximately \$2,273,000 related to employee stock option amortization during 2019 as compared to 2018.

Research and development costs decreased by approximately \$7,507,000, or 27%, to approximately \$19,792,000 for the year ended December 31, 2019, compared with approximately \$27,299,000 for the year ended December 31, 2018. Research and development costs include costs related to manufacturing validation and early development trials, as well as salaries, wages, non-cash compensation and benefits of personnel involved in research and development activities. Research and development costs decreased primarily as a result of certain employees and activities that were previously classified as research and development being transferred into operations as they began to support commercial and launch efforts after the FDA approvals of IMVEXXY and BIJUVA.

- Since the project's inception in February 2013, we have incurred approximately \$131,035,000 in research and development costs with respect to BIJUVA.
- Since the project's inception in August 2014, we have incurred approximately \$48,261,000 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 — 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 \$6,252,000, or 82%, for the year ended December 31, 2019, to approximately \$13,913,000 compared with approximately \$7,661,000 for the year December 31, 2018, primarily as a result of increased medical safety consulting fees to support commercialization of our pharmaceutical products.

All other costs increased by approximately \$8,460,000, or 72%, to approximately \$20,234,000 for the year ended December 31, 2019, compared with approximately \$11,774,000 for the year ended December 31, 2018, as a result of increased contract labor, dues and subscriptions, information technology, travel, 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 \$20,986,000, or 16%, to approximately \$151,206,000 for the year ended December 31, 2019, compared with approximately \$130,220,000 for the year ended December 31, 2018, primarily as a result of an increase in total operating expenses to support commercialization of our pharmaceutical products, partially offset by increased total net revenue.

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, BIJUVA and ANNOVERA will be successful.

Other (Expense) Income, net

Other non-operating (expense) income, net changed by approximately \$22,542,000, or 940%, to an expense of approximately \$24,939,000 for the year ended December 31, 2019 compared with an expense of approximately \$2,397,000 for 2018, primarily as a result of a one-time charge of \$10.1 million in loss on extinguishment of debt and increased interest expense related to our Financing Agreement that we recorded in 2019 as compared to 2018.

Net Loss

Because of the net effects of the foregoing, net loss increased approximately \$43,528,000, or 33%, to approximately \$176,145,000 for the year ended December 31, 2019, compared with approximately \$132,617,000 for the year ended December 31, 2018. Net loss per share of common stock, basic and diluted, was (\$0.72) for the year ended December 31, 2019, compared with (\$0.59) per share of common stock for the year ended December 31, 2018.

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

	Years Ended December 31,		
	2018	2017 (000s)	Change
Product revenue, net	\$ 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	<u>\$ (132,617)</u>	<u>\$ (76,925)</u>	<u>\$ (55,692)</u>

Revenue

Product revenue is recorded net of sales discounts, chargebacks, wholesaler fees, customer rebates, coupons, and estimated returns. Product 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. Product revenue 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 product 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, product revenue 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 product revenue 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,			Change	
			(000s)		
	2018	2017			
Sales and marketing, excluding human resources costs	\$ 61,845	\$ 19,614	\$ 42,231		
Human resources 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 — 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.

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, 2019, we received approximately \$236,000,000 in net proceeds from the issuance of shares of our common stock. As of December 31, 2019, we had a cash balance of approximately \$160,830,000, 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 October 29, 2019, we closed an underwritten public offering of 29,900,000 shares of our common stock at a price to the public of \$2.75 per share, inclusive of the underwriters' option to purchase additional shares of common stock, which option was exercised in full. We received net proceeds from the offering of approximately \$77.0 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

On June 6, 2019, we entered into the Theramex License Agreement with Theramex, a leading, global specialty pharmaceutical company dedicated to women's health, to commercialize BIJUVA and IMVEXXY for human use outside of the U.S., except for Canada and Israel, or the Theramex Territory. Under the terms of the Theramex License Agreement, Theramex paid us EUR 14 million in cash as an upfront fee on August 5, 2019. Within thirty days of signing the Theramex License Agreement, we provided Theramex the regulatory materials and clinical data that were necessary for Theramex to obtain marketing authorizations and other applicable regulatory approvals for commercializing BIJUVA and IMVEXXY. We recognized the revenue related to the upfront fee, which was a nonrefundable payment, during the third quarter of 2019, at a point in time when Theramex was able to use and benefit from the license which was when the knowledge transfer of regulatory documents occurred. We are eligible to receive additional milestone payments comprised of (i) up to an aggregate of EUR 2 million in regulatory milestone payments based on regulatory approvals for BIJUVA and IMVEXXY in certain specified markets and (ii) up to an aggregate of EUR 27.5 million in sales milestone payments to be paid in escalating tranches based on Theramex first attaining certain aggregate annual net sales milestones of BIJUVA and IMVEXXY in the Theramex Territory ranging from EUR 25 million to EUR 100 million. We are also entitled to receive quarterly royalty payments on net sales of BIJUVA and IMVEXXY in the Theramex Territory. Theramex will be responsible for all regulatory and commercial activities for BIJUVA and IMVEXXY in the Theramex Territory. Theramex may sublicense its rights to commercialize BIJUVA and IMVEXXY in the Theramex Territory, except for certain specified markets. We may terminate the Theramex License Agreement if Theramex does not submit all regulatory applications, submissions and/or registrations required for regulatory approval to use and commercialize BIJUVA and IMVEXXY within certain specified time periods. We also may terminate the Theramex License Agreement if Theramex challenges our patents. Either party may terminate the Theramex 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.

On April 24, 2019, we entered into a Financing Agreement, as amended on December 27, 2019, or the Financing Agreement, with TPG Specialty Lending, Inc., as administrative agent, or the Administrative Agent, various lenders from time to time party thereto, and certain of our subsidiaries party thereto from time to time as guarantors, which provides us with a \$300,000,000 first lien secured term loan credit facility, or the Facility. The Facility provides for availability to us in three tranches: (i) \$200,000,000 was drawn upon entering into the Financing Agreement; (ii) \$50,000,000 was drawn on February 18, 2020; and (iii) \$50,000,000 will be available to us in the Administrative Agent's sole and absolute discretion either contemporaneously with the delivery of our financial statements for the fiscal quarter ending June 30, 2020 or at such earlier date as the Administrative Agent shall have consented to. Borrowings under the Facility accrue interest at either (i) 3-month LIBOR plus 7.75%, subject to a LIBOR floor of 2.70% or (ii) the prime rate plus 6.75%, subject to a prime rate floor of 5.20% as selected by us. Interest on amounts borrowed under the Facility is payable quarterly. The outstanding principal amount of the Facility is payable in four equal quarterly installments beginning on June 30, 2023, with the Facility maturing on March 31, 2024. A portion of the initial tranche of borrowing under the Facility in the amount of approximately \$81,661,000 was used to repay all amounts outstanding under our prior financing agreement with MidCap Financial Trust, or the MidCap Agreement. As a result of the termination of the MidCap Agreement, we recorded \$10,057,632 in loss on extinguishment of debt in our unaudited consolidated financial statements.

We believe that our existing cash and availability under the Facility 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 Facility, 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 Facility. If our available cash is insufficient to satisfy our liquidity requirements, we may curtail our sales, marketing and other commercialization efforts and we may seek to sell additional equity or debt securities. Our ability to sell equity securities will be limited by the authorized shares that we have available to issue. Our ability to sell debt securities or obtain additional debt financing is restricted pursuant to the Financing Agreement. To the extent that we raise additional capital through the sale of equity or convertible debt securities, to the extent permitted under the Financing Agreement, the ownership interests 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, certain of which are restricted under the Financing Agreement, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or proposed products, if permitted under the Financing Agreement. Additionally, we may have to grant licenses on terms that may not be favorable to us.

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 2019. 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 2019. For the quarter ended December 31, 2019, our gross DSO was 55 days compared to 77 days for the quarter ended December 31, 2018 and our net DSO was 141 days for the quarter ended December 31, 2019 compared to 200 days for the quarter ended December 31, 2018. Our DSO decreased primarily due to more favorable arrangements with customers that we entered into in the second quarter of 2019. 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 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

	Years Ended December 31,		
	2019	2018	2017
Net cash used in operating activities	\$(165,697,595)	\$(106,811,781)	\$(76,155,614)
Net cash used in investing activities	\$ (23,912,694)	\$ (21,497,857)	\$ (827,108)
Net cash provided by financing activities	\$ 188,826,925	\$ 162,787,087	\$ 72,584,249

Operating Activities

The principal use of cash in operating activities for the year ended December 31, 2019 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 \$58,886,000 in cash used in operating activities for the year ended December 31, 2019 in comparison to the year ended December 31, 2018 was due primarily to an increase in our net loss coupled with changes in the components of working capital which were primarily due to the launch and commercialization of our pharmaceutical products.

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.

Investing Activities

During the year ended December 31, 2019, we paid \$20,000,000 to the Population Council in connection with the commercial batch release of ANNOVERA, based on the Population Council License Agreement. In addition, an increase in spending on fixed assets, patents and trademarks resulted in an increase in cash used in investing activities for the year ended December 31, 2019 compared with the same period in 2018.

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.

Financing Activities

Financing activities represent the principal source of our cash flow. Our financing activities for the year ended December 31, 2019 provided net cash of approximately \$188,827,000. The cash provided by financing activities during the year ended December 31, 2019 included approximately \$77,031,000 in proceeds from the sale of our common stock and approximately \$109,000 in proceeds from the exercise of options as well as funding from our Financing Agreement of approximately \$200,000,000 partially offset by the payment of financing fees of approximately \$6,652,000 in connection with the Financing Agreement and the repayment of the MidCap Agreement of \$81,661,000.

On October 29, 2019, we closed an underwritten public offering of 29,900,000 shares of our common stock at a price to the public of \$2.75 per share, inclusive of the underwriters' option to purchase additional shares of common stock, which option was exercised in full. We received net proceeds from the offering of approximately \$77.0 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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 and approximately \$1,666,000 in proceeds from the exercise of options, as well as funding from the MidCap Agreement of approximately \$75,000,000, partially offset by the payment of financing fees of approximately \$3,787,000 in connection with the MidCap Agreement.

On August 6, 2018, we closed an underwritten public offering of 14,656,862 shares of our common stock at a price to the public of \$5.10 per share, inclusive of the underwriters' option to purchase additional shares of common stock. The net proceeds to us from the offering were approximately \$69,908,000, after deducting the underwriting discount and offering expenses payable by us. 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 per share, for proceeds to us of \$20,000,000.

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 from Contracts with Customers*, or ASC 606. 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.

As of December 31, 2019, our products consisted primarily of prescription vitamins and our FDA-approved products: IMVEXXY, which we began selling during the third quarter of 2018 and BIJUVA, which we began selling in the second quarter of 2019. We started selling ANNOVERA in the third quarter of 2019 and we expect the full commercial launch of ANNOVERA in the first quarter of 2020. We sell our name brand and generic prescription products primarily through wholesale distributors and retail pharmacies. 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 pharmacies, 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. 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). 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.

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.

We generally recognize the compensation expense on a straight-line basis over the employee's requisite service period. Effective January 1, 2017, we account for forfeitures when they occur. On January 1, 2019, we adopted ASU 2018-07 which simplified 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 expanded 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 superseded the guidance in ASC 505-50. Prior to January 1, 2019, equity instruments issued to non-employees were recorded on a fair value basis, as required by ASC 505, *Equity - Based Payments to Non-Employees*.

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, 2019 and 2018, 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 Financial Accounting Standards Board, or 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 do not expect that the adoption of this standard will have a material effect 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 fiscal years. 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 adopted this standard on January 1, 2019 and the adoption of this standard did not have a material effect on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases. This guidance requires lessees to record most leases on their balance sheets while recognizing 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 was effective for public business entities for annual periods beginning after December 15, 2018, and interim periods within those years. 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 adopted ASU 2016-02 on January 1, 2019 utilizing the alternative transition method allowed for under ASU 2018-11 and we recorded a \$3.8 million right of use asset and a \$4.1 million liability related to adoption of this standard. In addition, upon commencement of additional lease space in the third quarter of 2019 (as disclosed in Note 13), we recorded an additional \$7.4 million right of use asset and an additional \$7.2 million liability related to our new lease space. Comparative financial information was not 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 did 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 elected not to separate lease components from non-lease components for our specified asset classes. Additionally, the adoption of the new standard resulted in increased disclosure requirements in our quarterly and annual filings.

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, 2019, 2018, and 2017, 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, 2019, 2018, and 2017.

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, 2019, 2018, and 2017, our business and operations have not been materially affected by inflation.

Contractual Obligations

A summary of contractual obligations as of December 31, 2019 is as follows:

	Total	Payments Due by Period			
		Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations	\$ 15,684,456	\$ 1,566,617	\$ 3,460,843	\$ 2,620,065	\$ 8,036,931
Debt payments ⁽¹⁾	200,000,000	—	—	200,000,000	—
Interest payment ⁽²⁾	80,929,444	20,900,000	41,800,000	18,229,444	—
Purchase commitments ⁽³⁾	34,671,190	6,700,603	9,643,326	13,204,246	5,123,015
Total	<u>\$331,285,090</u>	<u>\$ 29,167,220</u>	<u>\$ 54,904,169</u>	<u>\$234,053,755</u>	<u>\$ 13,159,946</u>

- (1) The outstanding principal amount of the Financing Agreement is payable in four equal quarterly installments beginning on June 30, 2023, with the Financing Agreement maturing on March 31, 2024.
- (2) Interest calculation is based on interest rates in place on December 31, 2019.
- (3) Includes manufacturing purchase commitments described below. The amounts presented here represent our estimates of the minimum required payments under our agreements.

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 manufacturing and supply agreements whereby we are required to purchase from Catalent a minimum number of softgels during the first contract year and a higher number of 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. In addition, we have a manufacturing and supply agreement whereby we are required to purchase a minimum number of units of ANNOVERA during a contract year. As of December 31, 2019, we have met our minimum purchase commitments with our manufacturers related to fiscal year 2019.

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, however, we anticipate that high deductible and annual prescription copay resets under commercial insurance plans at the beginning of the calendar year will affect our first quarter net revenue.

Item 7A Quantitative and Qualitative Disclosures About Market Risk

We had a cash balance of approximately \$160,830,000 as of December 31, 2019. 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 an investment 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.

As of April 24, 2019, we repaid all amounts outstanding under the MidCap Agreement and became subject to market risk in connection with borrowings under the Financing Agreement. Amounts borrowed under the Financing Agreement will accrue interest at either (i) 3-month LIBOR plus 7.75%, subject to a LIBOR floor of 2.70% or (ii) the prime rate plus 6.75%, subject to a prime rate floor of 5.20%. Considering the total outstanding principal balance under the Financing Agreement of approximately \$200,000,000 at December 31, 2019, a 1.0% change in interest rates would result in an impact to income before income taxes of approximately \$2,000,000 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. Change in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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, 2019, 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) 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, 2019. 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, 2019.

The effectiveness of our internal control over financial reporting as of December 31, 2019 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, 2019, which appears below.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
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, 2019, 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, 2019, 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, 2019, and our report dated February 24, 2020 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 24, 2020

Item 9B. Other Information

On February 20, 2020, following its fourth quarter 2019 earnings call, TherapeuticsMD received a Paragraph IV certification notice letter (the “Notice Letter”), regarding an Abbreviated New Drug Application (“ANDA”) submitted to the U.S. Food and Drug Administration (the “FDA”) by Teva Pharmaceuticals USA, Inc. (“Teva”). The ANDA seeks approval from the FDA to commercially manufacture, use, or sell a generic version of the 4 mcg and 10 mcg doses of IMVEXXY® (estradiol vaginal inserts). In the Notice Letter, Teva alleges that TherapeuticsMD patents listed in the FDA’s Orange Book that claim compositions and methods of IMVEXXY (the “IMVEXXY Patents”) are invalid, unenforceable, and/or will not be infringed by Teva’s commercial manufacture, use, or sale of its proposed generic drug product. The IMVEXXY Patents identified in the Notice Letter expire in 2032 or 2033.

TherapeuticsMD is currently reviewing the Notice Letter and intends to vigorously enforce its intellectual property rights relating to IMVEXXY. Under the Hatch-Waxman Act, TherapeuticsMD has 45 days from receipt of the Notice Letter to initiate a patent infringement lawsuit against Teva. Such a lawsuit would automatically preclude the FDA from approving Teva’s ANDA until the earlier of 30 months or entry of a district court decision finding the IMVEXXY Patents invalid, unenforceable, or not infringed.

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 2020 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 2020 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 2020 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 2020 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 Statements to be filed pursuant to Regulation 14A of the Exchange Act for our 2020 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits and 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
<u>2.1</u>	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⁾
<u>2.2</u>	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⁾
<u>2.3</u>	October 25, 2007	Croff Enterprises, Inc. Plan of Corporate Division and Reorganization ⁽³⁾
<u>2.4</u>	July 18, 2011	Agreement and Plan of Merger among VitaMedMD, LLC, AMHN, Inc., and VitaMed Acquisition, LLC ⁽⁴⁾
<u>3.1</u>	July 20, 2010	Articles of Conversion of AMHN, Inc. filed in the State of Nevada ⁽⁵⁾
<u>3.2</u>	July 20, 2010	Articles of Incorporation of AMHN, Inc. filed in the State of Nevada ⁽⁵⁾
<u>3.3</u>	n/a	Composite Amended and Restated Articles of Incorporation of the Company, as amended ⁽⁶⁾
<u>3.4</u>	n/a	Bylaws of AMHN, Inc. ⁽⁷⁾
<u>3.5</u>	December 17, 2015	First Amendment to Bylaws of the Company ⁽⁸⁾
<u>4.1</u>	n/a	Form of Certificate of Common Stock ⁽⁹⁾
<u>4.2†</u>	n/a	Description of Securities of the Company
<u>10.1</u>	n/a	Form of Common Stock Purchase Warrant ⁽¹⁰⁾
<u>10.2*</u>	n/a	Form of Non-Qualified Stock Option Agreement ⁽¹⁰⁾
<u>10.3*</u>	n/a	TherapeuticsMD, Inc. 2019 Stock Incentive Plan ⁽¹¹⁾
<u>10.4*</u>	n/a	Amended and Restated 2012 Stock Incentive Plan ⁽¹²⁾
<u>10.5*</u>	n/a	2009 Long Term Incentive Compensation Plan, as amended ⁽¹³⁾
<u>10.6</u>	October 23, 2011	Common Stock Purchase Warrant to Lang Naturals, Inc. ⁽¹⁴⁾
<u>10.7</u>	February 24, 2012	Form of Common Stock Purchase Warrant ⁽¹⁵⁾
<u>10.8***</u>	April 24, 2019	Financing Agreement, by and among TherapeuticsMD, Inc., VitaMedMD, LLC, BocagreenMD, Inc., VitaCare Prescription Services, Inc., TPG Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC ⁽¹⁸⁾
<u>10.9***</u>	April 24, 2019	Pledge and Security Agreement, by and among TherapeuticsMD, Inc., VitaMedMD, LLC, BocagreenMD, Inc., VitaCare Prescription Services, Inc. and TPG Specialty Lending, Inc. ⁽¹⁸⁾
<u>10.10*</u>	November 8, 2012	Form of Employment Agreement ⁽¹⁹⁾
<u>10.11</u>	January 31, 2013	Common Stock Purchase Warrant, issued to Plato & Associates, LLC ⁽²⁰⁾
<u>10.12***</u>	September 28, 2018	Commercial Supply Agreement by and between TherapeuticsMD, Inc. and QPharma AB ⁽²³⁾
<u>10.13*</u>	May 8, 2013	Agreement to Forfeit Non-Qualified Stock Options between the Company and Robert G. Finizio ⁽²²⁾
<u>10.14***</u>	October 5, 2018	Lease by and between 951 Yamato Acquisition Company, LLC and TherapeuticsMD, Inc. ⁽²³⁾
<u>10.15**</u>	April 20, 2016	Softgel Commercial Supply Agreement by and between TherapeuticsMD, Inc. and Catalent Pharma Solutions, LLC ⁽¹⁶⁾
<u>10.16**</u>	June 24, 2016	Softgel Commercial Supply Agreement by and between TherapeuticsMD, Inc. and Catalent Pharma Solutions, LLC ⁽¹⁷⁾

<u>10.17</u> ^{**}	July 30, 2018	Population Council License Agreement by and between TherapeuticsMD, Inc. and The Population Council, Inc. ⁽²¹⁾
<u>10.18</u> [†]	December 27, 2019	Amendment No. 1 to the Financing Agreement, by and among TherapeuticsMD, Inc., VitaMedMD, LLC, BocagreenMD, Inc., VitaCare Prescription Services, Inc., TPG Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC
<u>10.19</u> [*]	December 17, 2015	Employment Agreement between the Company and Brian Bernick ⁽⁸⁾
<u>10.20</u> [*]	December 17, 2015	Employment Agreement between the Company and Michael Donegan ⁽⁸⁾
<u>10.21</u> [*]	December 17, 2015	Employment Agreement between the Company and Mitchell Krassan ⁽⁸⁾
<u>10.22</u> ^{***}	June 6, 2019	License and Supply Agreement, by and between TherapeuticsMD, Inc. and Theramex HQ UK Limited ⁽¹⁸⁾
<u>21.1</u> [†]	February 24, 2020	Subsidiaries of the Company
<u>23.1</u> [†]	February 24, 2020	Consent of Grant Thornton LLP
<u>31.1</u> [†]	February 24, 2020	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
<u>31.2</u> [†]	February 24, 2020	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
<u>32.1</u> ^{††}	February 24, 2020	Certification pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
<u>32.2</u> ^{††}	February 24, 2020	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INST	n/a	XBRL Instance Document – the instance document does not appear in the Interactive Data file because its XBRL tags are embedded within the Inline XBRL 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
104 [†]	n/a	Cover Page Interactive Data File (formatted as Inline XBRL and Contained in Exhibit 101)

* 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. Confidential treatment has been granted with respect to this omitted information.

*** Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10). The omitted information is not material and would likely cause competitive harm to the Company if publicly disclosed.

† Filed herewith.

†† Furnished 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 the 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 the 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 S-8 filed with the Commission on June 21, 2019 and incorporated herein by reference (SEC File No. 333-232268).
- (12) 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).
- (13) 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).
- (14) 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).
- (15) 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).
- (16) Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2018 filed with the Commission on July 30, 2018 and incorporated herein by reference (SEC File No. 001-00100).
- (17) Filed as an exhibit to Form 10-K for the year ended December 31, 2018 filed with the Commission on February 27, 2019 and incorporated herein by reference (SEC File No. 001-00100).
- (18) Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2019 filed with the Commission on August 9, 2019 and incorporated herein by reference (SEC File No. 001-00100).
- (19) Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2012 filed with the Commission on November 13, 2012 and incorporated herein by reference (SEC File No. 000-16731).
- (20) 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).
- (21) Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2018 filed with the Commission on November 8, 2018 and incorporated herein by reference (SEC File No. 001-00100).
- (22) Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 filed with the Commission on May 10, 2013 and incorporated herein by reference (SEC File No. 001-00100).
- (23) Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2019 filed with the Commission on November 8, 2019 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 24, 2020

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.

<u>Signature</u>	<u>Capacity</u>	<u>Date</u>
<u>/s/ Robert G. Finizio</u> Robert G. Finizio	Chief Executive Officer, Director (Principal Executive Officer)	February 24, 2020
<u>/s/ John C.K. Milligan, IV</u> John C.K. Milligan, IV	President, Secretary, Director	February 24, 2020
<u>/s/ Daniel A. Cartwright</u> Daniel A. Cartwright	Chief Financial Officer, Treasurer (Principal Financial and Accounting Officer)	February 24, 2020
<u>/s/ Tommy G. Thompson</u> Tommy G. Thompson	Chairman	February 24, 2020
<u>/s/ Brian Bernick</u> Brian Bernick	Director	February 24, 2020
<u>/s/ Jane F. Barlow</u> Jane F. Barlow	Director	February 24, 2020
<u>/s/ J. Martin Carroll</u> J. Martin Carroll	Director	February 24, 2020
<u>/s/ Cooper C. Collins</u> Cooper C. Collins	Director	February 24, 2020
<u>/s/ Robert V. LaPenta, Jr.</u> Robert V. LaPenta, Jr	Director	February 24, 2020
<u>/s/ Jules Musing</u> Jules Musing	Director	February 24, 2020
<u>/s/ Angus C. Russell</u> Angus C. Russell	Director	February 24, 2020
<u>/s/ Nicholas Segal</u> Nicholas Segal	Director	February 24, 2020

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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, 2019 and 2018, the related consolidated statements of operations, stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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 24, 2020 expressed an unqualified opinion.

Change in accounting principle

As discussed in Note 13 to the consolidated financial statements, the Company has changed its method of accounting for leases due to the adoption of Accounting Standard Update No. 2016-02 “Leases (Topic 842).”

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.

Critical audit matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Calculation of variable consideration related to sales deductions

As described further in Note 2 to the consolidated financial statements, the transaction price of the Company’s revenue contracts is variable as it is calculated net of estimated product returns, chargebacks, rebates, coupons, discounts and wholesaler fees (collectively “sales deductions”). We identified the calculation of variable consideration related to sales deductions as a critical audit matter.

The principal consideration for our determination that the calculation of variable consideration related to sales deductions is a critical audit matter is that auditing the estimation of variable consideration requires significant judgement and the amounts are material to the financial statements taken as a whole. These estimates require the consideration of key assumptions such as expected return rates, estimated levels of inventory in the distribution channel, expected coupon utilization, and expected insurance coverage levels, all of which have estimation uncertainty.

Our audit procedures related to testing the calculation of variable consideration related to sales deductions included the following, among others:

- We tested the design and operating effectiveness of controls relating to management’s calculation and review of variable consideration related to sales deductions by verifying management’s controls over the completeness of the input data, mathematical accuracy of the calculations and evaluating the reasonableness of key assumptions used in the calculations.
- We tested management’s estimates by performing one of the following procedures based on the sales deduction being tested, (1) developing independent expectations to corroborate the reasonableness of management’s estimate, (2) testing management’s process to develop the estimate, or (3) reviewing subsequent events or transactions. Our procedures included reviewing

subsequent data to estimate levels of inventory in the distribution channel for which coupons would be redeemed and subsequent information related to coupon and rebate settlements. We used historical sales and return data in developing our independent expectations and testing management's process. We tested the completeness and accuracy of the historical sales and return data used in the calculations by agreeing total sales to accounting records and tracing a sample of individual sale transactions to supporting audit evidence, such as purchase orders, shipping documents and invoices. We also evaluated the average assistance paid in the co-pay assistance program by testing a sample of transactions settled during the year to source documentation.

/s/ GRANT THORNTON LLP

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

Fort Lauderdale, Florida
February 24, 2020

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2019	2018
ASSETS		
Current Assets:		
Cash	\$ 160,829,713	\$ 161,613,077
Accounts receivable, net of allowance for doubtful accounts of \$904,040 and \$596,602, respectively	24,395,958	11,063,821
Inventory	11,860,716	3,267,670
Other current assets	11,329,793	10,834,693
Total current assets	<u>208,416,180</u>	<u>186,779,261</u>
Fixed assets, net	2,507,775	472,683
Other Assets:		
License rights, net	39,221,308	20,000,000
Intangible assets, net	5,258,211	4,092,679
Right of use asset	10,109,154	—
Other assets	473,009	639,301
Total other assets	<u>55,061,682</u>	<u>24,731,980</u>
Total assets	<u>\$ 265,985,637</u>	<u>\$ 211,983,924</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 19,181,212	\$ 22,743,841
Other current liabilities	33,823,613	18,334,948
Total current liabilities	<u>53,004,825</u>	<u>41,078,789</u>
Long-Term Liabilities:		
Long-term debt	194,634,643	73,381,014
Operating lease liability	9,145,049	—
Total liabilities	<u>256,784,517</u>	<u>114,459,803</u>
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: 271,177,076 and 240,462,439 issued and outstanding, respectively	271,177	240,463
Additional paid-in capital	704,351,222	616,559,938
Accumulated deficit	(695,421,279)	(519,276,280)
Total stockholders' equity	<u>9,201,120</u>	<u>97,524,121</u>
Total liabilities and stockholders' equity	<u>\$ 265,985,637</u>	<u>\$ 211,983,924</u>

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2019	2018	2017
Product revenues, net	\$ 34,140,537	\$ 16,099,460	\$ 16,777,713
License revenue	15,506,400	—	—
Total revenue, net	<u>49,646,937</u>	<u>16,099,460</u>	<u>16,777,713</u>
Cost of goods sold	6,334,585	2,737,652	2,636,943
Gross profit	<u>43,312,352</u>	<u>13,361,808</u>	<u>14,140,770</u>
Operating expenses:			
Sales, general, and administrative	174,112,612	115,988,954	57,703,370
Research and development	19,792,212	27,299,138	33,852,993
Depreciation and amortization	612,786	293,886	213,117
Total operating expenses	<u>194,517,610</u>	<u>143,581,978</u>	<u>91,769,480</u>
Operating loss	<u>(151,205,258)</u>	<u>(130,220,170)</u>	<u>(77,628,710)</u>
Other (expense) income			
Loss on extinguishment of debt	(10,057,632)	—	—
Miscellaneous income	2,500,106	2,280,844	695,631
Interest expense	(17,382,215)	(4,677,834)	—
Accreted interest	—	—	7,699
Total other (expense) income	<u>(24,939,741)</u>	<u>(2,396,990)</u>	<u>703,330</u>
Loss before income taxes	<u>(176,144,999)</u>	<u>(132,617,160)</u>	<u>(76,925,380)</u>
Provision for income taxes	—	—	—
Net loss	<u>\$ (176,144,999)</u>	<u>\$ (132,617,160)</u>	<u>\$ (76,925,380)</u>
Loss per share, basic and diluted:			
Net loss per share, basic and diluted	<u>\$ (0.72)</u>	<u>\$ (0.59)</u>	<u>\$ (0.37)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>246,353,318</u>	<u>225,026,300</u>	<u>205,523,288</u>

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, 2019, 2018 AND 2017

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance, January 1, 2017	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 options, net	102,546	103	212,512	—	212,615
Shares issued for exercise of warrants, net	7,238,874	7,239	3,791,760	—	3,798,999
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
Shares issued in offerings, net of cost	29,900,000	29,900	77,001,358	—	77,031,258
Shares issued for exercise of options and warrants, net	814,637	814	107,842	—	108,656
Share-based compensation	—	—	10,682,084	—	10,682,084
Net loss	—	—	—	(176,144,999)	(176,144,999)
Balance, December 31, 2019	<u>271,177,076</u>	<u>\$ 271,177</u>	<u>\$ 704,351,222</u>	<u>\$ (695,421,279)</u>	<u>\$ 9,201,120</u>

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,		
	2019	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	\$ (176,144,999)	\$ (132,617,160)	\$ (76,925,380)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of fixed assets	415,193	181,412	141,601
Amortization of intangible assets	197,593	112,474	71,516
Write off of patent and trademark cost	78,864	—	—
Non-cash operating lease expense	1,062,318	—	—
Provision for doubtful accounts	307,438	216,022	4,206
Loss of extinguishment of debt	10,057,632	—	—
Share-based compensation	10,693,662	8,661,967	6,889,323
Amortization of intellectual property license fee	778,692	—	—
Amortization of deferred financing costs	856,302	269,859	—
Changes in operating assets and liabilities:			
Accounts receivable	(13,639,575)	(6,951,041)	167,691
Inventory	(8,593,046)	(1,782,312)	(409,037)
Other assets	(1,880,048)	(2,657,190)	(4,434,130)
Accounts payable	(3,562,629)	18,646,241	(3,260,914)
Accrued expenses and other liabilities	13,675,008	9,107,947	1,599,510
Net cash used in operating activities	<u>(165,697,595)</u>	<u>(106,811,781)</u>	<u>(76,155,614)</u>
CASH FLOWS FROM INVESTING ACTIVITIES			
Payment for intellectual property license	(20,000,000)	(20,000,000)	—
Patent costs	(1,441,989)	(1,105,407)	(765,291)
Purchase of fixed assets	(2,450,285)	(217,040)	(61,817)
Payment of security deposit	(20,420)	(175,410)	—
Net cash used in investing activities	<u>(23,912,694)</u>	<u>(21,497,857)</u>	<u>(827,108)</u>
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from exercise of options and warrants	108,656	1,666,208	4,011,614
Proceeds from sale of common stock, net of costs	77,031,258	89,907,797	68,572,635
Proceeds from Financing Agreement	200,000,000	—	—
Proceeds from Credit Agreement	—	75,000,000	—
Payment of deferred financing fees	(6,652,270)	(3,786,918)	—
Repayment of Credit Agreement	(81,660,719)	—	—
Net cash provided by financing activities	<u>188,826,925</u>	<u>162,787,087</u>	<u>72,584,249</u>
(Decrease) increase in cash	(783,364)	34,477,449	(4,398,473)
Cash, beginning of period	161,613,077	127,135,628	131,534,101
Cash, end of period	<u>\$ 160,829,713</u>	<u>\$ 161,613,077</u>	<u>\$ 127,135,628</u>
Supplemental disclosure of cash flow information			
Interest paid	<u>\$ 17,787,903</u>	<u>\$ 1,890,166</u>	<u>\$ —</u>

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES
NOTES TO 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.” TherapeuticsMD®, vitaMedMD®, BocaGreenMD®, IMVEXXY® and BIJUVA® are registered trademarks of our company and ANNOVERA™ is a licensed trademark of our company.

Nature of Business

We are a women’s healthcare company with a mission of creating and commercializing innovative products to support the lifespan of women from pregnancy prevention through 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 a patient-controlled, long-lasting contraceptive to advanced hormone therapy pharmaceutical products. We also manufacture and distribute branded and generic prescription prenatal vitamins under the vitaMedMD and BocaGreenMD brands. Our portfolio of products focused on women’s health allows us to efficiently leverage our sales and marketing plan to grow our recently approved products. During 2018, the U.S. Food and Drug Administration, or FDA, approval of our pharmaceutical products has transitioned our company from predominately focused on conducting research and development to one focused on commercializing our pharmaceutical products. In July 2018, we launched our 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. In April 2019, we launched our FDA-approved product BIJUVA (estradiol and progesterone) capsules, our hormone therapy combination of bio-identical 17 β -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. In October 2019, we began a test and learn market introduction for our FDA-approved product ANNOVERA (segesterone acetate and ethynodiol diacetate vaginal system), the first and only patient-controlled, procedure-free, reversible prescription contraceptive option for women. We expect the full commercial launch of ANNOVERA in the first quarter of 2020. 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, or the Knight License 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. On June 6, 2019, we entered into an exclusive license and supply agreement, or the Theramex License Agreement, with Theramex HQ UK Limited, or Theramex, to commercialize BIJUVA and IMVEXXY outside of the U.S., excluding Canada and Israel, or the Theramex Territory.

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 chargebacks and provide an allowance for doubtful accounts, which is based upon a review of outstanding receivables, historical collection information, and existing economic conditions. We evaluate trade accounts receivable aged more than 90 days for delinquency. 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, 2019, four different customers represented 36%, 21%, 16% and 11% of our gross accounts receivable. At December 31, 2018, three different customers represented 42%, 24% and 13% of our gross accounts receivable.

Inventories

Inventories represent pharmaceutical products, packaged vitamins and raw materials which are valued at the lower of cost or net realizable value. Our pharmaceutical products are valued using first in first out method and our vitamins are valued 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

Pre-launch 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, 2019, we had 29 issued domestic, or U.S., patents and 30 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, 2019, 2018, and 2017.

We perform impairment tests for intangible assets with indefinite useful lives annually, in the fourth quarter, 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.

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.

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. The carrying amount for long-term debt as of December 31, 2019 and 2018 (as disclosed in Note 8), approximates fair value based on market activity for other debt instruments with similar characteristics and comparable risk (Level 2).

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*, or ASC 820. 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 assets or liabilities.

At December 31, 2019 and 2018, 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. During the year ended December 31, 2019, we wrote off \$78,864 in costs related to trademarks and patents, including the net carrying amount of our OPERA software patent. There was no impairment of intangible assets during the years ended December 31, 2018, and 2017.

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, 2019 and 2018, 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. 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 and in 2019 we started using only our own stock price in the volatility calculation. 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 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. We recognize the compensation expense for 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. Effective January 1, 2017, we account for forfeitures when they occur. On January 1, 2019, we adopted ASU 2018-07 which simplified the accounting for share-based payments to non-employees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance expanded the scope of ASC 718 to include share-based payments granted to non-employees in exchange for goods or services used or consumed in an entity's own operations and superseded the guidance in ASC 505-50. Prior to January 1, 2019, equity instruments issued to non-employees were recorded on a fair value basis, as required by ASC 505, *Equity - Based Payments to Non-Employees*.

Revenue Recognition

We adopted ASC 606, *Revenue from Contracts with Customers*, or 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 was recognized under ASC 605 prior to the date of initial application of the new standard, the contracts were 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

As of December 31, 2019, our products consisted primarily of prescription vitamins and our FDA-approved products: IMVEXXY, which we began selling during the third quarter of 2018, and BIJUVA, which we began selling in the second quarter of 2019. We started selling ANNOVERA in the third quarter of 2019 and we expect the full commercial launch of ANNOVERA in the first quarter of 2020. We sell our name brand and generic prescription products primarily through wholesale distributors and retail pharmacies. 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 pharmacies, 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. 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 vitamins and IMVEXXY currently have a shelf life of 24 months from the date of manufacture and BIJUVA and ANNOVERA currently have a shelf life of 18 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 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 distributor 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 commercial launches for our FDA-approved prescription products, we introduced a co-pay assistance program for eligible enrolled patients whose out of pocket costs are reduced to a more affordable price. This allows patients to access the product at a reasonable cost and is in line with our responsible pricing approach. We reimburse pharmacies for this discount through third-party vendors. We consider certain 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 our prescription products 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 our prescription products is susceptible to such changes in coverage levels, which are outside the influence of the Company. As a result, we constrain variable consideration for our prescription products to an amount that will not result in a significant revenue reversal in future periods. Our ability to estimate the net transaction price for our prescription products is constrained by our estimates of the amount to be paid for the co-pay assistance program 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 variable consideration each reporting period.

License Revenue

License arrangements may consist of non-refundable upfront license fees, exclusive licensed rights to patented or patent pending technology, and various performance or sales milestones and future product royalty payments. Some of these arrangements may include multiple performance obligations. Non-refundable up-front fees that are not contingent on any future performance by us, and do not require continuing involvement on our part, are recognized as revenue when the right to use functional IP is transferred to the customer.

License Agreement with Knight Therapeutics Inc.

On July 30, 2018, we entered into 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 shares of our Common Stock concurrent with the closing of the underwritten public offering of Common Stock on August 6, 2018 at a price of \$5.10, for proceeds of \$20,000,000.

License Agreement with Theramex

On June 6, 2019, we entered into the Theramex License Agreement with Theramex to commercialize BIJUVA and IMVEXXY in the Theramex Territory. Under the terms of the Theramex License Agreement, Theramex paid us EUR 14 million, or \$15,506,400, in cash as an upfront fee on August 5, 2019. Within thirty days of signing the Theramex License Agreement, we provided Theramex the regulatory materials and clinical data that were necessary for Theramex to obtain marketing authorizations and other applicable regulatory approvals for commercializing BIJUVA and IMVEXXY. We recognized the revenue related to the upfront fee, which was a non-refundable payment, during the third quarter of 2019, at a point in time when Theramex was able to use and benefit from the license which was when the knowledge transfer of regulatory documents occurred. We are eligible to receive additional milestone payments comprised of (i) up to an aggregate of EUR 2 million in regulatory milestone payments based on regulatory approvals for BIJUVA and IMVEXXY in certain specified markets and (ii) up to an aggregate of EUR 27.5 million in sales milestone payments to be paid in escalating tranches based on Theramex first attaining certain aggregate annual net sales milestones of BIJUVA and IMVEXXY in the Theramex Territory ranging from EUR 25 million to EUR 100 million. We are also entitled to receive quarterly royalty payments at a rate of 5% on net sales of BIJUVA and IMVEXXY in the Theramex Territory. Theramex is responsible for all regulatory and commercial activities for BIJUVA and IMVEXXY in the Theramex Territory. Theramex may sublicense its rights to commercialize BIJUVA and IMVEXXY in the Theramex Territory, except for certain specified markets. We may terminate the Theramex License Agreement if Theramex does not submit all regulatory applications, submissions and/or registrations required for regulatory approval to use and commercialize BIJUVA and IMVEXXY within certain specified time periods. We also may terminate the Theramex License Agreement if Theramex challenges our patents. Either party may terminate the Theramex 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.

Disaggregation of revenue

The following table provides information about disaggregated revenue by product mix for the years ended December 31, 2019, 2018, and 2017:

	For the Years Ended December 31,		
	2019	2018	2017
Prescription vitamins	\$ 9,885,493	\$ 15,041,259	\$ 16,744,831
IMVEXXY	16,252,045	1,058,201	—
BIJUVA	1,836,443	—	—
ANNOVERA	6,166,556	—	—
License revenue	15,506,400	—	—
OTC products	—	—	32,882
Net revenue	\$ 49,646,937	\$ 16,099,460	\$ 16,777,713

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.

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.

Cost of Sales

Cost of sales includes the cost of inventory, manufacturing, manufacturing overhead and supply chain costs, and product shipping and handling costs. The Population Council License Agreement requires payment of royalties based on the sale of future products. Such royalties are recorded as a component of cost of sales. Additionally, the amortization of license fees or milestone payments related to licensed products are classified as components of cost of sales to the extent such payments become due in the future.

Advertising Costs

We expense advertising costs when incurred. Advertising costs were \$9,045,571, \$1,682,746 and \$448,288 during the years ended December 31, 2019, 2018, and 2017, 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 other 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. These consulting 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 expenses 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,		
	2019	2018	2017
Stock options	25,030,234	20,872,824	23,365,225
Warrants	1,832,571	3,007,571	3,115,905
Restricted stock awards	1,240,000	1,040,000	—
	28,102,805	24,920,395	26,481,130

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 our 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 do not expect that the adoption of this standard will have a material effect on our disclosures.

In June 2018, the FASB issued ASU 2018-07 to simplify the accounting for share-based payments to non-employees 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 non-employees 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 adopted this standard on January 1, 2019 and the adoption of this standard did not have a material effect on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases. This guidance requires lessees to record most leases on their balance sheets while recognizing 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 was effective for public business entities for annual periods beginning after December 15, 2018, and interim periods within those years. 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 adopted ASU 2016-02 on January 1, 2019 utilizing the alternative transition method allowed for under ASU 2018-11 and we recorded a \$3.8 million right of use asset and a \$4.1 million liability related to adoption of this standard. In addition, upon commencement of additional leased space in the third quarter of 2019 (as disclosed in Note 13), we recorded an additional \$7.4 million right of use asset and an additional \$7.2 million liability related to our new leased space. Comparative financial information was not 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 did 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 elected not to separate lease components from non-lease components for our specified asset classes. Additionally, the adoption of the new standard resulted in increased disclosure requirements in our quarterly and annual filings.

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,	
	2019	2018
Finished products	\$ 4,976,910	\$ 2,908,958
Work in process	1,182,059	339,312
Raw materials	5,701,747	19,400
TOTAL INVENTORY	\$ 11,860,716	\$ 3,267,670

NOTE 4 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	December 31,	
	2019	2018
Prepaid sales and marketing costs	\$ 1,583,698	\$ 5,148,789
Debt financing fees on undrawn tranches (Note 8)	550,757	1,898,074
Prepaid insurance	1,812,135	790,465

Prepaid manufacturing	2,595,721	—
Other prepaid costs	4,787,482	2,997,365
TOTAL OTHER CURRENT ASSETS	<u>\$ 11,329,793</u>	<u>\$ 10,834,693</u>

NOTE 5 – FIXED ASSETS, NET

Fixed assets, net consist of the following:

	December 31,	
	2019	2018
Accounting system	\$ 301,096	\$ 301,096
Equipment	1,619,646	490,576
Furniture and fixtures	1,406,858	116,542
Computer hardware	80,211	80,211
Leasehold improvements	68,788	37,888
TOTAL FIXED ASSETS	<u>3,476,599</u>	<u>1,026,313</u>
Accumulated depreciation	(968,824)	(553,630)
TOTAL FIXED ASSETS, NET	<u>\$ 2,507,775</u>	<u>\$ 472,683</u>

Depreciation expense for the years ended December 31, 2019, 2018, and 2017 was \$415,193, \$181,412, and \$141,601, 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, 2019 and 2018:

	December 31, 2019			Weighted-Average Remaining Amortization Period (yrs.)
	Gross Carrying Amount	Accumulated Amortization	Net Amount	
Amortizable intangible assets:				
Approved hormone therapy drug candidate patents	\$ 3,463,082	\$ (478,983)	\$ 2,984,099	13
Hormone therapy drug candidate patents (pending)	1,979,299	—	1,979,299	n/a
Non-amortizable intangible assets:				
Multiple trademarks	294,813	—	294,813	indefinite
TOTAL	<u>\$ 5,737,194</u>	<u>\$ (478,983)</u>	<u>\$ 5,258,211</u>	

December 31, 2018

	<u>Gross Carrying Amount</u>	<u>Accumulated Amortization</u>	<u>Net Amount</u>	<u>Weighted- Average Remaining Amortization Period (yrs.)</u>
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	

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 year ended December 31, 2019, we wrote off \$78,864 in costs related to trademarks and patents, including the net carrying amount of the OPERA patent.

As of December 31, 2019, we had 29 issued domestic patents and 30 issued foreign patents, including:

- 12 domestic patents and six foreign patents that relate to BIJUVA as well as three domestic patents that relate to estradiol and progesterone product candidates. These patents establish an important intellectual property foundation 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, China, Europe, Israel, Japan, Mexico, New Zealand, Russia, South Africa, and South Korea;
- Six domestic patents (five utility and one design) and 13 foreign patents (three utility and ten 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 countries, 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 seven 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., Brazil, Canada, Mexico, and South Africa;
- Three domestic utility patents that relate to TX-009HR, a progesterone and estradiol product candidate, which are 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.
- Two domestic and four foreign patents that relate to formulations containing progesterone, which are owned by us. The domestic patents will expire between 2032 and 2036. The foreign patents will expire no earlier than 2033. In addition, we have pending patent applications with respect to formulations containing progesterone in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;
- One domestic utility patent that relates to our OPERA information-technology platform, which is owned by us and will expire in 2031;

Amortization expense was \$197,593, \$112,474, and \$71,516 for the years ended December 31, 2019, 2018, and 2017, 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
2020	\$229,546
2021	\$229,546
2022	\$229,546
2023	\$229,546
2024	\$229,546

License Agreement with the Population Council

On July 30, 2018, we entered into the Population Council License Agreement to commercialize ANNOVERA in the U.S. ANNOVERA became commercially available in the third quarter of 2019 and we expect the full commercial launch of ANNOVERA in the first quarter of 2020.

Under the terms of the Population Council License Agreement, we paid the Population Council a milestone payment of \$20,000,000 within 30 days following the approval by the FDA of the new drug application, or NDA, for ANNOVERA and \$20,000,000 within 30 days following the first commercial batch release of ANNOVERA. Both milestone payments of \$20,000,000 were recorded as license rights in the consolidated balance sheets. We started amortizing the license rights in the third quarter of 2019 once ANNOVERA became commercially available for use. The cost is amortized over the remaining useful life over which the license rights will contribute directly or indirectly to our cash flows, which is estimated to be the remaining patent life of the product, which expires in December 2032. The cost is amortized using the straight-line method as the pattern of economic benefit cannot be reliably determined. During the year ended December 31, 2019, we recorded \$778,692 in amortization expense related to the license fee which was recorded as a component of cost of sales.

The Population Council is also eligible to receive milestone payments and royalties from commercial sales of ANNOVERA. We are responsible for marketing expenses related to the commercialization 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. 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 million, \$400 million and \$1 billion. 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 Population Council License Agreement. We and the Population Council have agreed to form a joint product committee responsible for overseeing activities under the Population 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 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.

NOTE 7 – OTHER CURRENT LIABILITIES

Other current liabilities consist of the following:

	December 31,	
	2019	2018
Accrued payroll, bonuses and commission costs	\$ 8,040,278	\$ 6,854,002
Allowance for coupons and returns	10,316,298	5,294,120
Accrued sales and marketing costs	3,285,662	2,288,028
Accrued compensated absences	1,463,878	1,178,110
Allowance for wholesale distributor fees	2,347,122	792,891
Accrued legal and accounting expense	422,336	385,824
Accrued research and development	1,049,603	388,675
Accrued rent	—	365,155
Operating lease liability	1,501,539	—
Accrued rebates	3,916,672	412,570
Other accrued expenses	1,480,225	375,573
TOTAL OTHER CURRENT LIABILITIES	\$ 33,823,613	\$ 18,334,948

NOTE 8 – DEBT

On April 24, 2019, we entered into a Financing Agreement, as amended on December 27, 2019, or the Financing Agreement, with TPG Specialty Lending, Inc., as administrative agent, or the Administrative Agent, various lenders from time to time party thereto, and certain of our subsidiaries party thereto from time to time as guarantors, which provides us with a \$300,000,000 first lien secured term loan credit facility, or the Facility. The Facility provides for availability to us in three tranches: (i) \$200,000,000 was drawn upon entering into the Financing Agreement; (ii) \$50,000,000 will be available to us in the Administrative Agent's sole and absolute discretion either contemporaneously with the delivery of our financial statements for the fiscal quarter ending June 30, 2020 or at such earlier date as the Administrative Agent shall have consented to; and (iii) \$50,000,000 was drawn on February 18, 2020 following our achievement of more than \$11,000,000 in net revenues from IMVEXXY, BIJUVA and ANNOVERA for the fourth quarter of 2019. Borrowings under the Facility accrue interest at either (i) 3-month LIBOR plus 7.75%, subject to a LIBOR floor of 2.70% or (ii) the prime rate plus 6.75%, subject to a prime rate floor of 5.2% as selected by us. Interest on amounts borrowed under the Facility is payable quarterly. The outstanding principal amount of the Facility is payable in four equal quarterly installments beginning on June 30, 2023, with the Facility maturing on March 31, 2024. We have the right to prepay borrowings under the Facility in whole or in part at any time, subject to a prepayment fee on the principal amount being prepaid of (i) 30.0% for the first two years following the initial funding date of the applicable borrowing, (ii) 5.0% for the third year following the initial funding date of the applicable borrowing, (iii) 3.0% for the fourth year following the initial funding date of the applicable borrowing and (iv) 1.0% for the fifth year following the initial funding date of the applicable borrowing but prior to March 31, 2024. In connection with the initial borrowing under the Facility, we paid, for the benefit of the lenders, a facility fee equal to 2.5% of the initial amount borrowed and will be required to pay such a facility fee in connection with any subsequent borrowings under the Facility. We are also required to pay the Administrative Agent and the lenders an annual administrative fee in addition to other fees and expenses. The Financing Agreement contains customary mandatory prepayments, restrictions and covenants applicable to us that are customary for financings of this type. Among other requirements, we are required to (i) maintain a minimum unrestricted cash balance of \$50,000,000, which will increase to \$60,000,000 if we draw either the second or third tranche of the Facility, and (ii) achieve certain minimum consolidated net revenue amounts attributable to commercial sales of our IMVEXXY, BIJUVA and ANNOVERA products beginning with the fiscal quarter ending December 31, 2020. The Financing Agreement also includes other representations, warranties, indemnities and events of default that are customary for financings of this type, including an event of default relating to a change of control of the Company. Upon or after an event of default, the Administrative Agent and the lenders may declare all or a portion of our obligations under the Financing Agreement to be immediately due and payable and exercise other rights and remedies provided for under the Financing Agreement. The obligations of our company and its subsidiaries under the Financing Agreement are secured, subject to customary permitted liens and other agreed upon exceptions, by a first priority perfected security interest in all existing and after acquired assets of our company and its subsidiaries. The obligations under the Financing Agreement will be guaranteed by each of our future direct and indirect subsidiaries, subject to certain exceptions.

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), as amended. The Credit Agreement provided 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 was available to be made in three separate tranches, with each tranche to be made available to us, at our option, upon our achievement of certain milestones. Amounts borrowed under the Term Loan bore 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.

On April 24, 2019, we terminated the Credit Agreement. A portion of the initial tranche of borrowing under the Financing Agreement in the amount of approximately \$81,661,000 was used to repay all amounts outstanding under the Credit Agreement, which included a prepayment fee of 4%, a repayment fee of 4% and other fees and expenses payable to the lenders under the Credit Agreement. As a result of the termination of the Credit Agreement, we recorded \$10,057,632 in loss on extinguishment of debt in the accompanying consolidated financial statements. Interest on amounts borrowed under the Term Loan was due and payable monthly in arrears. Interest expense for the year ending December 31, 2019 related to the Credit Agreement was \$1,816,747. During the year ended December 31, 2019, and prior to the repayment of the Credit Agreement, we amortized \$120,146 of deferred financing fees as interest expense in our accompanying consolidated financial statements and during the year ended December 31, 2018, we amortized \$269,859, of debt issuance costs as interest expense in our accompanying consolidated financial statements.

As of December 31, 2019, we had \$200,000,000 in borrowings outstanding under the Financing Agreement, which are classified as long-term debt in the accompanying consolidated financial statements. During the year ended December 31, 2019, we incurred \$6,652,270 in deferred financing fees related to the Financing Agreement. Deferred financing fees related to the entire Financing Agreement have been allocated pro rata between the funded and unfunded portions of each tranche. Allocated deferred financing fees related to the first tranche of borrowings of \$6,101,513 have been reflected as a debt discount and are accreted to interest expense using the effective interest method. Deferred financing fees associated with unfunded tranches were deferred as assets until the respective tranche has been drawn. As of December 31, 2019, deferred financing fees related to the unfunded tranches were included in other current assets in the accompanying consolidated financial statements. During the year ended December 31, 2019, we amortized \$736,156 of deferred financing fees related to the first tranche as interest expense in the accompanying consolidated financial statements. Interest on amounts borrowed under the Financing Agreement is due and payable quarterly in arrears. Interest expense for the year ended December 31, 2019 was \$14,709,166. The overall effective interest rate under the Financing Agreement was approximately 11% as of December 31, 2019.

As of December 31, 2019 and 2018, the carrying value of our debt consisted of the following:

	As of December 31,	
	2019	2018
Financing Agreement	\$ 200,000,000	\$ —
Credit Agreement	—	75,000,000
Debt discount and financing fees	(5,365,357)	(1,618,986)
TOTAL LONG-TERM DEBT	\$ 194,634,643	\$ 73,381,014

NOTE 9 – STOCKHOLDERS’ EQUITY

Preferred Stock

At December 31, 2019, 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, 2019, we had 350,000,000 shares of Common Stock authorized for issuance, of which 271,177,076 shares of Common Stock were issued and outstanding.

Issuances During 2019

On October 24, 2019, we entered into an underwriting agreement with J.P. Morgan Securities LLC, as representative of the underwriters, relating to an underwritten public offering of 26,000,000 shares of our Common Stock at a public offering price of \$2.75 per share. We granted the underwriters an option, exercisable for a period of 30 days, to purchase up to 3,900,000 additional shares of Common Stock, which was exercised in full. The net proceeds to us from the offering were approximately \$77,031,000, after deducting the underwriting discount and offering expenses payable by us. The offering closed on October 29, 2019.

During the year ended December 31, 2019, certain individuals exercised stock options to purchase an aggregate of 331,619 shares of Common Stock for \$108,656 in cash. Also, during the year ended December 31, 2019, stock options to purchase an aggregate of 12,097 shares of Common Stock were exercised pursuant to the options’ cashless exercise provisions, which resulted in 11,834 shares of Common Stock being issued.

Issuances During 2018

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 to us 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 to us of \$20,000,000.

During the year ended December 31, 2018, certain individuals exercised stock options to purchase an aggregate of 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 an aggregate of 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 an aggregate of 102,546 shares of Common Stock for \$212,615 in cash.

Warrants to Purchase Common Stock

As of December 31, 2019, we had warrants outstanding to purchase an aggregate of 1,832,571 shares of Common Stock with a weighted-average contractual remaining life of approximately 1.95 years, and exercise prices ranging from \$0.24 to \$8.20 per share, resulting in a weighted average exercise price of \$2.62 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, 2019, we granted warrants to purchase an aggregate of 75,000 shares of Common Stock to outside consultants which vest ratably over a 12-month period and have an expiration date of February 13, 2024. During the year ended December 31, 2018, we granted warrants to purchase an aggregate of 175,000 shares of Common Stock to outside consultants which 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 an aggregate of 125,000 shares of Common Stock to outside consultants which vest ratably over a 12-month period and have an expiration date of March 15, 2022.

We recorded share-based compensation expense related to warrants previously issued of \$254,970, \$494,136, and \$313,271 for the years ended December 31, 2019, 2018 and 2017, respectively, in the accompanying consolidated financial statements. At December 31, 2019, total unrecognized estimated compensation expense related to unvested warrants was approximately \$26,446 which is expected to be recognized over weighted-average period of 0.1 years.

Summary of our Warrant activity during the year ended December 31, 2019:

	Number of Shares Under Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2018	3,007,571	\$ 2.78	1.58	\$ 4,826,403
Granted	75,000	\$ 5.63		
Exercised	(1,250,000)	\$ 3.20		\$ 2,420,000
Expired	—	—		—
Cancelled/Forfeited	—	—		—
Balance at December 31, 2019	1,832,571	\$ 2.62	1.95	\$ 2,447,929
Vested and Exercisable at December 31, 2019	1,820,071	\$ 2.60	1.90	\$ 2,447,929
Unvested at December 31, 2019	12,500	\$ 5.63	9.13	—

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, 2019, 2018, and 2017 are set forth in the table below.

	2019	2018	2017
Weighted average exercise price	\$ 5.63	\$ 5.16	\$ 6.83
Weighted average grant date fair value	\$ 3.00	\$ 2.79	\$ 3.67
Risk-free interest rate	2.52%	2.36%	1.47%
Volatility	60.8%	62.12%	63.24%
Term (in years)	5	5	5
Dividend yield	0.00%	0.00%	0.00%

Warrant exercises

During the year ended December 31, 2019, warrants to purchase an aggregate of 1,250,000 shares of Common Stock were exercised pursuant to the warrants' cashless exercise provisions, which resulted in 471,184 shares of Common Stock being issued. During the year ended December 31, 2018, no warrants were exercised.

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

Options to Purchase Common Stock of the Company

In 2009, we adopted the 2009 Long Term Incentive Compensation Plan, or the 2009 Plan, to provide financial incentives to employees, directors, advisers, and consultants of our company who are able to contribute towards the creation of or who have created stockholder value by providing them stock options and other stock and cash incentives, or the Awards. As of December 31, 2019, there were non-qualified stock options to purchase an aggregate of 15,017,759 shares of Common Stock outstanding under the 2009 Plan. Effective upon our adoption of the TherapeuticsMD, Inc. 2019 Stock Incentive Plan, or the 2019 Plan, on June 20, 2019, no future awards may be made under the 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. As of December 31, 2019, there were non-qualified stock options to purchase an aggregate of 6,316,474 shares of Common Stock outstanding and an aggregate of 1,040,000 restricted stock awards under the 2012 Plan. Effective upon our adoption of the 2019 Plan, no future awards may be made under the 2012 Plan.

On June 20, 2019, we adopted the 2019 Plan 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 2019 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 2019 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.

As of December 31, 2019, there were 13,599,382 shares of Common Stock available for issuance under the 2019 Plan, consisting of (i) 11,103,999 new shares, (ii) 2,395,333 unallocated shares previously available for issuance under the 2012 Plan that were not then subject to outstanding "Awards" (as defined in the 2012 Plan), and (iii) 100,050 unallocated shares previously available for issuance under the 2009 Plan that were not then subject to outstanding "Awards" (as defined in the 2009 Plan). Any shares subject to outstanding options or other equity "Awards" under the 2019 Plan, the 2012 Plan and the 2009 Plan that are forfeited, expire or otherwise terminate without issuance of the underlying shares, or if any such Award is settled for cash or otherwise does not result in the issuance of all or a portion of the shares subject to such Award (other than shares tendered or withheld in connection with the exercise of an Award or the satisfaction of withholding tax liabilities), the shares to which those Awards were subject, shall, to the extent of such forfeiture, expiration, termination, cash settlement or non-issuance, again be available for delivery with respect to Awards under the 2019 Plan. As of December 31, 2019, there were non-qualified stock options to purchase 3,696,001 shares of Common Stock outstanding under the 2019 Plan and 200,000 restricted stock awards outstanding under the 2019 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, 2019, 2018, and 2017 are set forth in the table below.

	2019	2018	2017
Weighted average exercise price	\$ 3.10	\$ 5.45	\$ 6.60
Weighted average grant date fair value	\$ 1.82	\$ 3.24	\$ 3.82
Risk-free interest rate	1.64-2.54%	2.38-2.89%	1.84-2.05%
Volatility	61.25-64.49%	59.45-64.04%	61.56-64.25%
Term (in years)	5.5-6.5	5.1-6.25	5.5-6.25
Dividend yield	0.00%	0.00%	0.00%

A summary of activity under the 2009, 2012 and 2019 Plans and related information during the year ended December 31, 2019 is as follows:

	Number of Shares Under Options	Weighted Average Exercise Price	Remaining Contractual Life in Years	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2018	20,872,824	\$ 4.93	5.94	\$ 12,239,876	
Granted	4,620,501	\$ 3.10			
Exercised	(343,716)	\$ 0.32			\$ 1,426,828
Expired	(26,375)	\$ 5.57			
Cancelled/Forfeited	(93,000)	\$ 5.16			
Balance at December 31, 2019	25,030,234	\$ 4.65	5.84	\$ 3,668,171	
Vested and Exercisable at December 31, 2019	18,025,819	\$ 4.88	4.62	\$ 3,319,621	
Unvested at December 31, 2019	7,004,415	\$ 4.05	8.96	\$ 348,550	

At December 31, 2019, our outstanding options had exercise prices ranging from \$0.19 to \$8.92 per share. Share-based compensation expense related to options recognized in our results of operations for the years ended December 31, 2019, 2018, and 2017 was approximately \$8,798,707, \$8,091,294, and \$6,447,154, respectively, and it is based on awards vested. At December 31, 2019, total unrecognized estimated compensation expense related to unvested options was approximately \$11,460,000, which may be adjusted for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 2.4 years. No tax benefit was realized due to a continued pattern of operating losses.

Restricted Stock

Restricted stock awards granted under our 2009, 2012 and 2019 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 an aggregate of 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. At December 31, 2019, 150,000 of those restricted stock units vested due to an employment termination. On July 30, 2019, we granted an aggregate of 200,000 restricted stock units to certain executive employees which will vest on January 31, 2022. The grant date fair value was \$2.18 per unit. During the year ended December 31, 2019 and 2018, we recorded \$1,628,407 and \$73,132, respectively, in share-based compensation expense related to restricted stock units. At December 31, 2019, total unrecognized estimated compensation expense related to unvested restricted stock units was approximately \$2,711,000, which may be adjusted for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 2.0 years. At December 31, 2019, we had 1,240,000 restricted stock awards 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 began on July 1, 2018 and ended on or immediately following June 30, 2019. SARs were 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 provided 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 were recorded in our consolidated balance sheets as a liability until the date of exercise. The fair value of each SAR award was estimated using the Black-Scholes valuation model. In accordance with ASC Topic 718, *Stock Compensation*, the fair value of each SAR award was 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 June 30, 2019, the fair market value of our Common Stock was lower than the grant price of the SARs and, as a result, the recorded liability was reversed and no cash payment was made.

NOTE 10 – INCOME TAXES

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

	2019	2018	2017
United States	\$ (176,144,999)	\$ (132,617,160)	\$ (76,925,380)
Total	<u>\$ (176,144,999)</u>	<u>\$ (132,617,160)</u>	<u>\$ (76,925,380)</u>

For the years ended December 31, 2019, 2018, and 2017, there was no provision for income taxes, current or deferred. At December 31, 2019, we had a federal net operating loss carry forward of approximately \$620,354,163. Approximately \$338,775,332 of the federal net operating loss carry forward can be carried forward for 20 years and will begin to expire in 2031. The remaining \$281,578,831 can be carried forward indefinitely.

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

	2019	2018	2017
Federal statutory tax rate	21.0%	21.0%	34.0%
State tax rate, net of federal tax benefit	4.0%	5.2%	5.0%
Adjustment in valuation allowances	(22.5)%	(31.2)%	22.6%
Excess stock benefits	0.2%	5.3%	—%
Federal income tax rate change	0%	—%	(60.8)%
Permanent and other differences	(2.7)%	(0.3)%	(0.8)%
Provision (benefit) for income taxes	<u>—</u>	<u>—</u>	<u>—</u>

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, 2019, 2018, and 2017 are as follows:

	2019	2018	2017
Deferred Income Tax Assets:			
Net operating losses	\$ 180,520,709	\$ 140,891,764	\$ 99,596,321
R&D Credit	186,347	186,347	186,347
Total deferred income tax asset	<u>180,707,056</u>	<u>141,078,111</u>	<u>99,782,668</u>
Valuation allowance	(180,707,056)	(141,078,111)	(99,782,668)
Deferred income tax assets, net	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

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, 2019.

Unrecognized Tax Benefits

As of the period ended December 31, 2019, 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, 2019, 2018 and 2017, we were billed by Catalent approximately \$6,101,000, \$4,111,000 and \$3,646,000, respectively, for manufacturing activities related to our clinical trials, scale-up, registration batches, stability and validation testing. As of December 31, 2019 and 2018, there were amounts due to Catalent of approximately \$35,000 and \$88,000, 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 24%, 27% and 35% of our purchases supplied by three vendors each, respectively, during the year ended December 31, 2019, 43%, 33% and 24% of our purchases supplied by three vendors each, respectively, during the year ended December 31, 2018, and 100% of our purchases supplied by one vendor for the year ended December 31, 2017.

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 each of the years ended December 31, 2019, 2018 and 2017, four customers each accounted for more than 10% of our total prescription revenues. Prescription revenue from the four customers combined accounted for approximately 73%, 76%, and 59% of our prescription revenue for the years ended December 31, 2019, 2018 and 2017, respectively.

During the year ended December 31, 2019, McKesson Corporation accounted for approximately \$3,911,000 of our prescription revenue, Pillpack, Inc. accounted for approximately \$12,676,000 of our prescription revenue, AmerisourceBergen accounted for approximately \$3,927,000 of our prescription revenue and Cardinal Health accounted for approximately \$4,551,000 of our prescription revenue. During the year ended December 31, 2018, McKesson Corporation accounted for approximately \$1,610,000 of our prescription revenue, Pillpack, Inc. accounted for approximately \$5,075,000 of our prescription revenue, AmerisourceBergen accounted for approximately \$3,246,000 of our prescription revenue and Cardinal Health accounted for approximately \$2,308,000 of our prescription revenue. During the year ended December 31, 2017, AmerisourceBergen accounted for approximately \$2,667,000 of our prescription revenue; McKesson Corporation accounted for approximately \$1,959,000 of our prescription revenue; Cardinal Health accounted for approximately \$2,559,000 of our prescription revenue and Pharmacy Innovations PA accounted for approximately \$2,715,000 of our prescription revenue.

NOTE 13 – COMMITMENTS AND CONTINGENCIES

Operating Leases

We adopted ASC 842 effective January 1, 2019. Substantially all our operating lease right-of-use assets and operating lease liabilities represent leases for office space used to conduct our business. Upon adoption, we recognized a right-of-use asset and a lease liability for all leases that have commenced as of January 1, 2019. The right-of-use assets represent the right to use the leased asset for the lease term. The lease liabilities represent the present value of the lease payments under the lease. The right-of-use asset is initially measured at cost, which primarily comprises the initial amount of the lease liability, plus any initial direct costs incurred, less any lease incentives received. All right-of-use assets are reviewed for impairment. The lease liability is initially measured at the present value of the lease payments, discounted using our secured incremental borrowing rate for the same term as the underlying lease because the rates are not implicit in the leases. Some of our leases contain variable lease payments, including payments based on an index or rate. Variable lease payments based on an index or rate are initially measured using the index or rate in effect at lease commencement. Additional payments based on the change in an index or rate, or payments based on a change in our portion of the operating expenses are recorded as a period expense when incurred. Lease modifications result in remeasurement of the lease liability. Included in lease expense are any variable lease payments incurred in the period that were not included in the initial lease liability.

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 became effective beginning November 1, 2016.

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 the full premises, of which the lease on 7,561 square feet commenced in 2018 and the lease on the remaining 48,651 square feet commenced in August 2019, or the full premises commencement date. The lease will expire 11 years after the 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 extension option is not included in the determination of the lease term as it is not reasonably certain to be exercised. 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 June 2019, we entered into an agreement with the same lessors to lease additional 6,536 square feet of administrative office space in the same location, pursuant to an addendum to such lease, which is expected to commence as soon as the first quarter of 2020.

Supplemental lease information at December 31, 2019

Right-of-use asset	\$ 10,109,154
Short-term operating lease liability (included in Other current liabilities)	\$ 1,501,539
Long-term operating lease liability	\$ 9,145,049
Weighted average remaining term	9 Years
Weighted average discount rate	8.25%

Supplemental cash flow information for the year ended

December 31, 2019

Cash paid for amounts included in the measurement of lease liabilities for operating lease	\$ 1,164,234
Right-of-use assets obtained in exchange for lease obligation	\$ 11,171,471

The following table reconciles the undiscounted cash flows for all operating leases at December 31, 2019 to the operating lease liabilities recorded on the balance sheet:

Years Ending December 31,	
2020	\$ 1,566,617
2021	2,198,541
2022	1,262,302
2023	1,293,859
2024	1,326,206
Thereafter	8,036,931
Total undiscounted lease payments	15,684,456
Less: imputed interest	(5,037,868)
Present value of lease payments	\$ 10,646,588

During the year ended December 31, 2019, operating lease expense related to our real estate leases was \$1,558,794, and variable lease expense was insignificant. The rental expense during the years ended December 31, 2018 and 2017 was \$1,068,275 and \$1,029,205, respectively.

Intellectual Property Licenses

The Population Council License Agreement provides for future milestone 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 manufacturing and supply agreements whereby we are required to purchase from Catalent a minimum number of softgels during the first contract year and a higher number of 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. Minimum purchase commitments for Catalent for the next five years are as follows: 2020 – \$5,650,853; 2021 – \$4,000,035; 2022 – \$5,643,291; 2023 – \$6,445,301 and 2024 – \$6,758,945. In addition, we have a manufacturing and supply agreement whereby we are required to purchase a minimum number of units of ANNOVERA during a contract year. The minimum purchase commitment for ANNOVERA for 2020 is approximately \$1,049,750. As of December 31, 2019, we have met our minimum purchase commitments with our manufacturers related to fiscal year 2019.

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, 2019, 2018, and 2017, 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 2019 and 2018 is as follows:

<i>(In thousands, except per share)</i>	2019			
	First Quarter	Second Quarter ⁽¹⁾	Third Quarter ⁽²⁾	Fourth Quarter
Revenues	\$ 3,947	\$ 6,079	\$ 23,719	\$ 15,902
Gross profit	\$ 3,184	\$ 4,830	\$ 22,275	\$ 13,023
Net loss	\$ (39,506)	\$ (55,237)	\$ (31,967)	\$ (49,435)
Loss per common share, basic and diluted	\$ (0.16)	\$ (0.23)	\$ (0.13)	\$ (0.19)

<i>(In thousands, except per share)</i>	2018			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
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)

- (1) During the second quarter of 2019, we recorded \$10.1 million in loss on extinguishment of debt related to the repayment of the Credit Agreement. Refer to discussion in Note 8-Debt.
- (2) During the third quarter of 2019, we recorded \$15.5 million in license revenue related to the Theramex License Agreement. Refer to discussion in Note 2-Summary of Significant Accounting Policies.

NOTE 15 – SUBSEQUENT EVENTS

On February 18, 2020, we received \$50,000,000 under the Financing Agreement following our achievement of more than \$11,000,000 in net revenues from IMVEXXY, BIJUVA and ANNOVERA for the fourth quarter of 2019 (refer to discussion in Note 8-Debt).