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, 2020

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	**87-0233535**
(State or Other Jurisdiction of Incorporation or Organization)	*(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.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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 (246,062,968 shares) based on the closing price of the registrant's common stock as reported on the Nasdaq Global Select Market on June 30, 2020, which was the last business day of the registrant's most recently completed second fiscal quarter, was $307,578,710.

As of March 1, 2021, there were outstanding 387,825,545 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 2021 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, 2020.

THERAPEUTICSMD, INC.
ANNUAL REPORT ON FORM 10-K
Fiscal Year Ended December 31, 2020
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Throughout this Annual Report, the terms “we,” “us,” “our,” “TherapeuticsMD,” or “our company” refer to TherapeuticsMD, Inc., a Nevada corporation, and unless specified otherwise, include our wholly owned subsidiaries, vitaMedMD, LLC, a Delaware limited liability company, or VitaMed; BocaGreenMD, Inc., a Nevada corporation, or BocaGreen; and VitaCare Prescription Services, Inc., a Florida corporation, or VitaCare.

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

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 novel patient-controlled, procedure free, long-lasting contraceptive to advanced U.S. Food and Drug Administration, or FDA, approved bio-identical hormone therapy pharmaceutical products for the treatment of vasomotor symptoms and dyspareunia 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 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, 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 bioidentical 17ß-estradiol and bio-identical progesterone in a single, oral softgel capsule, for the treatment of moderate-to-severe vasomotor symptoms, or VMS, due to menopause in women with a uterus, which was approved by the FDA in October 2018.
- In October 2019, we began a "test and learn" market introduction for our FDA-approved product ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system), the first and only annual 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 paused the full commercial launch of ANNOVERA in March 2020 due to the impact of the COVID-19 pandemic and resumed this initiative in July 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. Knight received the first regulatory approval in Canada for IMVEXXY and BIJUVA in the third quarter of 2020.
- 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 IMVEXXY and BIJUVA outside of the U.S., excluding Canada and Israel.

Impact of COVID-19 on our Business

Our business has been, and we anticipate that it will continue to be, impacted by the coronavirus (COVID-19) pandemic. Despite the ongoing COVID-19 pandemic, we remain committed to the execution of our corporate goals, demonstrated in part by the increase in product revenue throughout 2020. We resumed the full launch of ANNOVERA in July 2020 and launched the new consumer marketing campaign for IMVEXXY in August 2020.

At this time, the length and extent of the impact of the COVID-19 pandemic on our business continues to be highly uncertain and difficult to predict. We developed a comprehensive COVID-19 contingency plan designed to preserve the value of our investments in our sales and marketing infrastructure, protect our balance sheet during this period of market disruption, and meet the needs of our patients and prescribers. This contingency plan was designed to monitor the COVID-19 pandemic and adapt to the length of time that COVID-19 may impact our business, which is intended to allow us to conserve our financial resources during the COVID-19 pandemic.

COVID-19 has accelerated telehealth, online pharmacies, and retail pharmacies utilizing home delivery options. These are areas where we have been developing relationships with industry leaders and emerging technology companies and we believe we are well positioned to capitalize on these trends. For example, contraception is an important category within telehealth and since 2019 we have been working with leading online telehealth platforms that focus on directly prescribing and filling birth control to patients.

Cost Containment and Spending Cuts

We reduced our operating expenses at the beginning of COVID-19 pandemic, and we continue to identify areas in which we can further reduce operating expenses in the future. These cost cuts and reductions included permanent cost savings, as well as the interim cessation of certain spending that may be restarted in future quarters. These cost cuts included:

- Negotiating lower fees or suspending services from third party vendors;
- Implementing certain hiring restrictions;
- Delaying or cancelling non-critical information technology projects;
- Eliminating travel, entertainment, meeting, and event expenses; and
- Reducing the size of our sales force and eliminating certain staff positions.

Employees and Sales Force

We continue to monitor the COVID-19 pandemic and adapt to the impacts it has on our business. As interactions with HCPs continue to be challenged during the fourth quarter of 2020, we continue to utilize digital engagement tools and tactics and virtual detailing to remain engaged with prescribers and distribution channels to supplement live interactions.

- Our sales force continues to support HCPs remotely, when it is necessary, including the sales forces' ability to continue to provide HCPs with access to patient product samples, product marketing information, and information regarding patient affordability programs and support services.
- Our sales force is in regular interaction with HCPs, including conducting live and "virtual" educational programs with providers.
- Our sales force also continues product training, including sharing best practices, in how to operate and create impact in both live and virtual world.

Remote Pharmacy and At-Home Delivery Options

As of the date of this Annual Report on Form 10-K, we are providing continued access to our products for patients.

- Our products have broad distribution at all major retail pharmacy chains across the country.
- Our vitaCare patient model assists patients in obtaining easy and convenient access to their prescriptions for products at a retail pharmacy of their choice, including via home delivery retail pharmacy options. We anticipate that home delivery pharmacy options will continue to be attractive to patients during the COVID-19 pandemic.
- We anticipate that vitaCare will continue to support patient access to our products during the COVID-19 pandemic and will help sustain refill trends for our products given vitaCare's broad use by our patients.
- We have also engaged with independent community pharmacies and multiple third-party online pharmacies to help ensure patients have real-time access to both diagnosis and treatment.
- We have developed relationships with industry leaders and emerging technology companies in the telehealth channel, a channel that has seen accelerated growth because of COVID-19. Recognizing the importance of telehealth particularly in the contraception category, we began developing various telehealth relationships in 2019 to ensure access to our products. We provide information and links on both Annovera.com and Imvexxy.com for patients to connect with these telehealth providers. Among those relationships are leading online telehealth platforms that focus on prescribing and filling birth control directly to patients.

Supply of Products

As of the date of this Annual Report on Form 10-K, we do not anticipate a shortage of our products due to the COVID-19 pandemic.

- We currently have sufficient inventory of finished product in our contracted warehouses to meet anticipated demand for IMVEXXY and BIJUVA through the next six months and ANNOVERA through the next three months.
- We currently do not foresee any interruption in our contract manufacturers' abilities to continue to manufacture additional products to be used. Our contract manufacturers have sufficient active pharmaceutical ingredients on hand for the continued manufacture of our products and there is currently no interruption in the supply chain for the active pharmaceutical ingredients for our products.
- We currently have uninterrupted wholesale and retail distribution of our products and are actively working to ensure that there continues to be an adequate supply of our products at pharmacies for sales to patients.

While we currently believe that our COVID-19 contingency plan has the ability to mitigate the effect of the COVID-19 pandemic on our business, the severity of the impact of the COVID-19 pandemic on our business will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic, the effectiveness of, and ability to widely distribute, the COVID-19 vaccine, the duration of “stay at home,” quarantine or “social distancing” orders, the ability of our sales force to access HCPs to promote our products, increases in unemployment, which could reduce access to commercial health insurance for our patients, thus limiting payer coverage for our products, and the impact of the pandemic on our global supply chain, all of which are uncertain and cannot be predicted. Our future results of operations and liquidity could be materially adversely affected by delays in payments of outstanding receivable amounts beyond normal payment terms, supply chain disruptions, uncertain demand, and the impact of any initiatives or programs that we may undertake to address financial and operations challenges that we may face.

Our business may also be affected by negative impacts of the COVID-19 pandemic on capital markets and economies worldwide, and it is possible that the pandemic could cause a local and/or global economic recession. While policymakers globally have responded with fiscal policy actions to support the healthcare industry and economy as a whole, the magnitude and overall effectiveness of these actions remains uncertain.

Our Business Model

At TherapeuticsMD, our purposeful and continuous partnership with HCPs 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 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 healthcare providers, payers, pharmacists, and patients through the following means:

- We offer HCPs a comprehensive product line of women’s healthcare products across a woman’s reproductive lifecycle.
- Our hormone therapy pharmaceutical products are designed to respond to both healthcare professional and patient needs in the marketplace – low dose, FDA-approved 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 high-quality products with differentiating ingredients. 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 healthcare providers 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 HCPs, 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 efficiently commercialize our FDA-approved pharmaceutical products: ANNOVERA, IMVEXXY, and BIJUVA and our VitaMedMD and BocaGreenMD line of prenatal vitamins. In addition to our focus on direct selling from our sales organization, which currently targets approximately 128 territories, 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 in specialty segments of the birth control markets and in non-U.S. markets.

As of December 31, 2020, we marketed and sold ANNOVERA, IMVEXXY, and BIJUVA 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 brand name.

Our Growth Strategy

We believe that the relationships our national sales force has developed with OB/GYNs, 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 of FDA-approved 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 and supported by professional societies. 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, IMVEXXY and ANNOVERA as appropriate treatment alternatives is economically practical for independent and community-based pharmacies. A dedicated team of Key Account Management, or KAM, is focusing their efforts on growing BIJUVA through our higher writing BIJUVA prescribers and our BIO-IGNITE partners. As of December 31, 2020, there were approximately 260 BIO-IGNITE compounding pharmacies that were dispensing BIJUVA, IMVEXXY, and ANNOVERA.

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 in non-U.S. markets. In our U.S. markets, we have broadened our channels that allow for wide patient access. 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, and other direct-to-consumer telehealth platforms. Subject to state telehealth and prescribing laws, prescribers affiliated with 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 continue to adjust our marketing footprint in the United States and sales team, which currently targets approximately 128 territories, as we continue to commercialize ANNOVERA, IMVEXXY, and BIJUVA.

Industry and Market

Women's Healthcare Market

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.

According to the BBC Research report "Pharmaceuticals for Women's Health: Global markets" 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. Women's health therapeutics established a very strong presence in the global pharmaceutical market over the last few decades. The market is expected to grow moderately, mainly due to patent expirations of blockbuster drugs such as Evista, the Premarin family, Forteo, Mirena, Boniva, Actonel, Gonal-F and several other. However, the launch of new drugs in the market, and novel drugs under research and development in the late-stage pipeline, has the strong potential to drive the market during the forecast period. The global market for women's health therapeutics is projected to grow from $31.5 billion in 2019 to $41.2 billion by 2025, at a compound annual growth rate (CAGR) of 4.7% for the period of 2019-2025. The menopause market is projected to grow from $5.7 billion in 2019 to $7.7 billion by 2025 at a CAGR of 5.4% through 2025.

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 range 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.

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 ethinyl estradiol (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 2017 to 2019 from the Centers for Disease Control and Prevention, or CDC, indicate that approximately 65.3% of women aged 15 to 49 were using some type of contraceptive method with approximately half of these women in this age group using reversable prescription contraception. 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 $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® and Skyla®. The remainder of the market is dominated by oral contraceptives, which is represented by one major brand, Lo Loestrin® Fe by AbbVie and a variety of generics led by generic manufacturers such as Teva Pharmaceuticals, Mylan and Lupin Pharma.

Prenatal Vitamin Market

According to the CDC, 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, 2020, approximately 4.9 million prescriptions for prenatal vitamins were issued in the U.S. resulting in total sales of approximately $290 million.

Our Contraceptive Product

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. In October 2019, we began a “test and learn” market introduction phase of launch for ANNOVERA. We paused the planned full commercial launch of ANNOVERA in March 2020 due to the impact of the COVID-19 pandemic and resumed this initiative in July 2020.

The segesterone acetate component of ANNOVERA was classified by the FDA as a “new chemical entity,” or NCE, and thus ANNOVERA 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 (13 cycles) 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 ethinyl estradiol, or EE. EE is an approved active ingredient in many marketed hormonal contraceptive products. Segesterone acetate, an NCE, is a potent progestin that, based on pharmacological 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 µg/day 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.

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.

We believe that the strong initial commercial net revenue per unit of ANNOVERA and commercial insurance adoption provide us with an opportunity to deploy additional financial resources to maximize ANNOVERA's consumer-focused commercialization strategy and leverage the ability of doctor/patient choice of contraceptive to override insurance company formularies when necessary. As part of this strategy, we are pursuing distribution opportunities for ANNOVERA to provide women with additional access to ANNOVERA, particularly during the COVID-19 pandemic, with multiple direct-to-consumer telehealth platforms that extend the reach of ANNOVERA.

Our Menopause Portfolio

IMVEXXY

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

IMVEXXY is a small, digitally inserted, softgel vaginal insert that dissolves when inserted into the vagina. 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 is comfortable for patients, with no patient education required for dose application or applicators. Additionally, the dose packaging for IMVEXXY is designed to optimize compliance and convenience for users. 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.

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 6.0 million prescriptions for the 12 months ended December 31, 2020. Approximately $436 million in gross sales were generated by PREMARIN® cream (Pfizer), the leading brand in the market. ESTRACE® cream and Vagifem® are now mostly generics which generated approximately $ 1.1 billion in gross sales for the 12 months ended December 31, 2020. These three products are localized estrogen therapy which is the most commonly used method for the treatment of VVA.

BIJUVA

In October 2018, the FDA approved BIJUVA (estradiol and progesterone) capsules, 1 mg/100 mg, the first and only FDA-approved bio-identical hormone therapy combination of estradiol and progesterone in a single, oral capsule for the treatment of moderate-to-severe VMS (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 does not contain peanut oil unlike other FDA-approved progesterone products. 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, or in coagulation or lipid parameters, and while providing clinically meaningful improvements in quality of life and sleep disturbance.

In January 2020, we submitted a New Drug Application, or NDA, efficacy supplement for the 0.5 mg/100 mg dose of BIJUVA to the FDA for review and potential approval. The NDA efficacy supplement used existing data from our Phase 3 REPLENISH trial for BIJUVA, for which we announced results in December 2016, together with additional information and analyses. On November 5, 2020, we withdrew the NDA efficacy supplement. We currently intend to file a Formal Dispute Resolution Request, or FDRR, with the FDA that disputes the FDA's requirement that the efficacy supplement meet approval standards that have not been required of other approved drugs in BIJUVA's therapeutic class. There can be no assurance that we will prevail with respect to the FDRR, if filed, or that the 0.5 mg/100 mg dose of BIJUVA will be approved.

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 a uterus 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 23.4 million prescriptions for the 12 months ended December 31, 2020. The three primary hormone therapy products are estrogen, progestin, and a 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, 2020, 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 13.7 million prescriptions. For the 12 months ended December 31, 2020, gross sales in the U.S. of FDA-approved branded and generic products for progestins-only amounted to an aggregate of approximately $389.2 million on approximately 7.8 million prescriptions. For the 12 months ended December 31, 2020, gross sales in the U.S. of FDA approved branded and generic products for estrogens/progestins combined amounted to an aggregate of approximately $431.7 million on approximately 1.9 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, 2020. 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.

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, with sales of PREMPRO and Premarin constituting the largest branded products. The remainder of the market is represented almost exclusively by generic products (estradiol, the generic version of Estrace oral, and generic micronized progesterone). The leading generic manufacturers of these products are Teva, Mylan, Sandoz Inc, and Amneal Pharmaceuticals. 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.

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, 2020, 2019, and 2018, approximately 16%, 20%, and 93%, respectively, of our consolidated product 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 on 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 supplemented by non-personal promotion. Our sales force currently has approximately 128 territories targeting approximately 20,000 physicians, which includes the most significant part of the addressable markets across our product portfolio. As of December 31, 2020, more than 5,200 HCPs had written at least one prescription for ANNOVERA, more than 21,500 HCPs had written at least one prescription for IMVEXXY and more than 7,100 HCPs had written at least one prescription for BIJUVA, the majority of whom are also IMVEXXY writers, thereby demonstrating the value of portfolio and focus. In addition to our sales organization, we leverage non-personal promotion (multi-channel advertising) to HCPs designed to drive awareness, education, and action. These efforts are designed to allow for pull through of the sales organization's 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 to 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 existing BIO-IGNITE pharmacy partners and additional pharmacies that wish to enroll in the BIO-IGNITE program. Additionally, KAMs are focusing on supporting current prescribers of BIJUVA. As of December 31, 2020, there were approximately 260 BIO-IGNITE compounding pharmacies that were dispensing our products.

Payer Access - With the ever-changing payer environment, we believe 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. As of December 31, 2020, we have obtained coverage for the majority of commercial payers by commercial payer lives for IMVEXXY and BIJUVA 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 the top ten commercial payers of VVA products by commercial payer lives and we continue to sign new agreements with other payers to cover IMVEXXY. In addition, as of December 31, 2020, four of the top eight Medicare Part D payers of VVA products, based on covered lives, were adjudicating IMVEXXY. For BIJUVA, through December 31, 2020, we have achieved unrestricted coverage with nine 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, 2020, two of the top six Medicare Part D payers of VMS products, based on covered lives, 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, 2020, and we continue to pursue discussions with several of the country's largest commercial insurers to further expand coverage. As of December 31, 2020, approximately 62% of the commercial payer market covered ANNOVERA with unrestricted access under pharmacy benefits and approximately 74% 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 17 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 2021, 29 states require insurers that cover prescription drugs to provide coverage of FDA-approved prescription contraceptive drugs and devices. However, the Trump administration implemented new policies that permit certain employers to claim a religious or moral objection to the birth control coverage mandate under the ACA. Originally, the religious exemption applied only to churches, but the Department of Health and Human Services extended that privilege in 2017 to family-owned, non-publicly traded corporations whose owners state that paying for birth control would violate their religious beliefs. Exempted entities no longer need to certify their objection or otherwise notify the federal government of their decision to stop providing coverage. Health plans sponsored by certain exempt religious employers and non-profit religious organizations that have religious objections do not need to offer contraception coverage through their health benefit plans. In July 2020, the U.S. Supreme Court issued a ruling in the case styled *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania et al*., upholding the legality of the Trump Administration's religious exemption to the contraceptive mandate. As of January 2021, 21 states allow certain employers and insurers to refuse to comply with the ACA's contraceptive coverage mandate. Prior to his election, President Biden stated that he would undo the religious exemption expansion if he were elected. To date, the Biden Administration has not issued any Executive Order, regulation, or other policy change to reverse the Trump Administration religious exemption policy, but such action may be forthcoming. We anticipate that any impact on contraception coverage due to religious exemption will be low; however, healthcare reform 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. Department of Veteran's Affairs, 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 take active steps 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 online pharmacies. 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. For IMVEXXY and BIJUVA, enrolled patients paid as little as $35 for a prescription with commercial insurance coverage and as of January 1, 2021 pay as little as $75 for a prescription 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. 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 all of our products.

Consumer Communication - Another critical level in the commercial model is consumer outreach. 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 motivated 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 a second milestone payment of $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 additional 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 paid us $2 million in milestone fees upon the first regulatory approval in Canada for IMVEXXY and BIJUVA in the third quarter of 2020, and is also required to pay us 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 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. As part of the Knight License Agreement, Knight is prohibited from exporting IMVEXXY and BIJUVA to the United States.

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 currently have placed on hold our 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 also placed on hold our 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 pharmaceutical products and prenatal vitamin products to wholesale distributors and retail pharmacy distributors. See Note 13 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 for the U.S. market 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 within the U.S. 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 are 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 along with online 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. 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 vitamin and supplement products 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.

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

Historically, our product development programs have been concentrated in advanced hormone therapy pharmaceutical products. We have engaged, and may continue to engage, in programs to provide alternatives to the FDA and non-FDA-approved compounded bio-identical market for hormone therapy. Our programs have sought 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, 2020, we had 38 issued domestic patents and 39 issued foreign patents, including:

- 15 domestic patents and nine 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;
- 12 domestic patents (ten utility and two design) and 18 foreign patents (eight 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;
- One domestic utility patent and eight 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 a pending patent application with respect to our transdermal-patch candidates in Brazil;
- 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;
- 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 formulations containing progesterone in the U.S., Australia, Canada, Europe, and Mexico; and
- One domestic utility patent that relates to our OPERA information-technology platform, which is owned by us and will expire in 2031.

As of December 31, 2020, we have a license to three Orange Book listed patents relating to ANNOVERA. These patents will expire in 2039 and establish an important intellectual property foundation. In addition, we have a license to six U.S. pending applications relating to ANNOVERA.

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, 2020, we had filed over 138 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 193 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 governing the financial relationships between manufacturers and HCPs or other referral sources and industry stakeholders, laws protecting the privacy of health-related information, laws restricting items and services of value provided to patients, and laws prohibiting unfair and deceptive acts and trade practices. See also *Item 1A. Risk Factors – Risks Related to Our Business* for a discussion, among other things, of the extensive and costly governmental regulation we are subject to.

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. The INDs for TX-002HR and TX-003HR were withdrawn in December 2019, the IND for TX006-HR was made inactive in October 2020 and the INDs for TX-009HR was made inactive in December 2020. The INDs for TX-004HR, TX-001HR, 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 a 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 certain clinical trials and clinical trial results to public registry and results databases.

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 assesses interim data to make recommendations regarding the feasibility and appropriateness for a trial to move forward or continue to completion. 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 certain uses or in patient populations that are not described in the product's approved indications or that are not otherwise consistent with the approved, 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 and following a prior history in which states were primarily responsible for the regulation of compounding pharmacies, in light of industry changes to large-scale compounding operations and concerns regarding product quality and patient safety, Congress enacted and President Obama signed into law the Drug Quality and Security Act of 2013 which, among other things, formalized the relationship between the FDA and large-scale compounding pharmacies allowing for certain compounding pharmacy products to be offered without FDA approval requirements (e.g., an NDA or ANDA) and the requirement to label products with adequate directions for use, but requiring that the facilities and products meet FDA 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 IMVEXXY 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 IMVEXXY 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 IMVEXXY Notice Letter expire in 2032 or 2033. On April 1, 2020, we filed a complaint against Teva in the U.S. District Court for the District of New Jersey asserting infringement of the IMVEXXY patents, arising from Teva's ANDA filing with the FDA. We are seeking, among other relief, an order that the effective date of any FDA approval of Teva's ANDA would be a date no earlier than the expiration of the IMVEXXY Patents and equitable relief enjoining Teva from infringing the IMVEXXY Patents. Teva has filed its answer and counterclaim to the complaint, alleging that the IMVEXXY Patents are invalid and not infringed. A trial date has not been set. The complaint which we filed automatically precludes 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 intend to vigorously enforce our above-described intellectual property rights relating to IMVEXXY.

On March 17, 2020, we received a Paragraph IV certification notice letter, or the BIJUVA Notice Letter, regarding an ANDA submitted to the FDA by Amneal Pharmaceuticals, or Amneal. The ANDA seeks approval from the FDA to commercially manufacture, use, or sell a generic version of the 1 mg estradiol /100 mg progesterone dose of BIJUVA. In the BIJUVA Notice Letter, Amneal alleges that TherapeuticsMD patents listed in the FDA's Orange Book that claim compositions and methods of BIJUVA, or the BIJUVA Patents, are invalid, unenforceable, and/or will not be infringed by Amneal's commercial manufacture, use, or sale of its proposed generic drug product. The BIJUVA Patents identified in the Notice Letter expire in 2032. On April 29, 2020, we filed a complaint against Amneal in the U.S. District Court for the District of New Jersey asserting infringement of the BIJUVA Patents, arising from Amneal's ANDA filing with the FDA. We are seeking, among other relief, an order that the effective date of any FDA approval of Amneal's ANDA would be a date no earlier than the expiration of the BIJUVA Patents and equitable relief enjoining Amneal from infringing the BIJUVA Patents. Amneal has filed its answer and counterclaim to the complaint, alleging that the BIJUVA Patents are invalid and not infringed. A trial date has not been set. The complaint which we filed automatically precludes the FDA from approving Amneal's ANDA until the earlier of 30 months or entry of a district court decision finding the BIJUVA Patents invalid, unenforceable, or not infringed ("the 30-month"). On February 25, 2021, the District Court entered an order temporarily staying all proceedings in the BIJUVA litigation. The District Court stay also extends the 30-month stay for the period in which the BIJUVA litigation has been stayed. We intend to vigorously enforce our above-described intellectual property rights relating to BIJUVA.

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, or the arranging for, 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 or even self-pay; 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; state laws requiring a license, registration or permit to engage in manufacturing and distribution of prescription products or to engage in the practice of pharmacy; 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.

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. 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 not be 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 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. Following on this initiative, the Department of Health and Human Services announced a drug payment model through the Center for Medicare and Medicaid Innovation at CMS to lower Medicare Part B payments for certain drugs to the lowest price for similar countries. Beginning January 1, 2021, the model, known as the Most Favored Nation (MFN) Model, will test a new model of drug payments whereby Medicare will pay no more for high cost, physician-administered Medicare Part B drugs than the lowest price charged in other similar countries. The MFN Model may be subject to industry challenges but we expect that drug pricing will remain a priority under the Biden Administration. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical 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. We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare.

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.

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.

Human Capital Resources

We believe the growth of our employees drives the growth of our company. Therefore, to ensure the continued growth of our employees, our human capital strategy is measured around four key pillars; attracting talent, engaging the workforce, developing leaders, and promoting our culture. To attract key talent, we offer a competitive benefit package, 401(k) match, paid time off, referral bonus, and an employee stock purchase program (ESPP). To engage our workforce, in 2020 we refined our compensation approach to match our company's size and stage of growth. We introduced a new framework as a foundation to our talent and reward programs, to clarify career paths, to promote pay equity and pay for performance, and to ensure pay is competitive to attract and retain talent. To develop leaders, we provide self-directed learning and company leadership training. Such leadership and self-development progress is measured through our learning management system, and we evaluate our leaders according to their achievement against goals and company values. To promote our culture, we actively seek feedback from our employees to create a culture where they feel engaged, appreciated, and fulfilled. The feedback from our employees has earned us recognition as a "Top Workplace" according to the Sun Sentinel.

Employees

As of December 31, 2020, we had 400 employees, six of whom are executive officers. Our sales force currently consists mainly of employees with a limited number of contract sales agents who call on 340B entities, the Department of Defense, and Puerto Rico, 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.

Our business is subject to a number of risks and uncertainties. The following is a summary of the principal risk factors described in this section:

- Our financial condition and results of operations for fiscal year 2020 were, and our financial condition and results of operations for fiscal year 2021 and beyond may be, adversely affected by the ongoing COVID-19 (coronavirus) pandemic.
- We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future.
- Our level of indebtedness and the terms of the Financing Agreement, dated as of April 24, 2019, as amended, with Sixth Street 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, could adversely affect our operations and limit our ability to plan for or respond to changes in our business. If we are unable to comply with certain net revenue and minimum unrestricted cash covenants and other restrictions in the Financing Agreement, the repayment of our existing indebtedness could be accelerated.
- We may not recognize the anticipated benefits of the proposed disposition of vitaCare Prescription Services or any other divestitures we may pursue in the future.
- 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 an adverse effect on our business, financial condition, results of operations, and growth prospects.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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 products face significant competition from branded and generic products, and our operating results will suffer if we fail to compete effectively.
- Our success is tied to our distribution channels.
- We will need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

Risks Related to Our Business

Our financial condition and results of operations for fiscal year 2020 were, and our financial condition and results of operations for fiscal year 2021 and beyond may be, adversely affected by the ongoing COVID-19 (coronavirus) pandemic.

Our business has been, and we anticipate that it will continue to be, impacted by the COVID-19 pandemic. During the fourth quarter of 2020, all of our products remained affected by the COVID-19 pandemic, primarily due to our sales force having limited access to healthcare professionals and our patients deferring visits to healthcare professionals in certain areas. While we have developed a comprehensive COVID-19 contingency plan designed to preserve the value of our investments in our sales and marketing infrastructure, protect our balance sheet during this period of market disruption, and meet the needs of our patients and prescribers, the severity of the impact of the COVID-19 pandemic on our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted.

Stay at home, quarantine and social distancing orders and closures and restrictions on travel have negatively affected the ability of our sales force to access healthcare providers to promote our products and the ability of patients to visit their healthcare professionals for non-emergent matters. Our sales force is continuing to use a hybrid model of office visits when necessary and digital engagement tools and tactics and virtual detailing, which may be less effective than our ordinary course sales and marketing programs. Increases in unemployment could reduce access to commercial health insurance for our patients, thus limiting payer coverage for our products, which could lead to increased use of our co-pay assistance programs and negatively affect our results of operations.

Our future results of operations and liquidity could be adversely affected by, and we may require an increased level of working capital as a result of, extended billing and collection cycles as a result of displaced employees at our company, payers, revenue cycle management contractors, or otherwise; delays in payments of outstanding receivable amounts beyond normal payment terms; supply chain disruptions; uncertain demand; and the impact of any initiatives or programs that we may undertake to address financial and operations challenges that we may face.

Additionally, although we currently continue to have uninterrupted wholesale and retail distribution of our products and we do not anticipate a shortage of our products due to COVID-19 at this time, disruptions may occur for our customers or suppliers that may affect our ability to obtain supplies or other components for our products, manufacture additional products or deliver inventory in a timely manner. This would result in lost sales, additional costs, or penalties, or damage to our reputation.

Our business may also be affected by negative impacts of the COVID-19 pandemic on capital markets and economies worldwide, and it is possible that the pandemic could cause a local and/or global economic recession. While policymakers globally have responded with fiscal policy actions to support the healthcare industry and economy as a whole, the magnitude and overall effectiveness of these actions remains uncertain.

We may also experience other unknown impacts from COVID-19 that cannot be predicted. Accordingly, disruptions to our business as a result of COVID-19 could continue to result in an adverse effect on our business, results of operations, financial condition and prospects in the near-term and beyond 2021.

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 $184 million, $176 million, and $133 million for the years ended December 31, 2020, 2019, and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of approximately $879 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.

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 comply with certain net revenue covenants and other 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. On March 1, 2021, we entered into Amendment No. 8 to the Financing Agreement, or Amendment No. 8, pursuant to which we, among other things, repaid $15.0 million in principal under the Financing Agreement on such date and agreed to repay an additional $35.0 million in principal by no later than March 31, 2021, in each case plus a 5.0% prepayment fee. 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.

The Financing Agreement requires us to make certain payments of principal and interest over time and contains certain minimum quarterly net product revenue requirements and several other restrictive covenants. We are required to achieve total minimum net revenue for ANNOVERA, IMVEXXY, and BIJUVA equal to at least (i) $17.0 million, $20.0 million, $23.0 million, and $26.5 million for the first, second, third, and fourth quarters of 2021, respectively, (ii) $30.0 million, $35.0 million, $40.0 million and $45.0 million for the first, second, third, and fourth quarters of 2022, respectively, (iii) $50.0 million, $55.0 million, $60.0 million and $65.5 million for the first, second, third, and fourth quarters of 2023, and (iv) $70.0 million for the first quarter of 2024. Among other requirements of the Financing Agreement, we and our subsidiaries party to the Financing Agreement must maintain a minimum unrestricted cash balance of $60.0 million, less the amount of certain payables. 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. In order to maintain compliance with the minimum unrestricted cash balance requirement of the Financing Agreement, we anticipate that we may need to raise additional capital. We cannot guarantee that future financing sufficient to maintain or exceed the minimum unrestricted cash balance will be available in sufficient amounts, in a timely fashion, or on terms acceptable to us, if at all. If we are unable to maintain the minimum unrestricted cash balance, achieve any of the total minimum net revenue requirements or otherwise comply with any other covenant of the Financing Agreement, all or a portion of our obligations under the Financing Agreement may be declared immediately due and payable, which would have an adverse effect on our business, results of operations and financial condition.

Our business may not generate cash flow from operations in the future sufficient to service our debt and support our growth strategies, especially in light of the COVID-19 pandemic. 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.

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, 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 may not recognize any anticipated benefits of the proposed disposition of vitaCare Prescription Services or any other divestitures we may pursue in the future.

We have commenced a process for the divestiture of vitaCare Prescription Services. Additionally, we may evaluate other potential divestiture opportunities with respect to portions of our business from time to time, and may determine to proceed with a divestiture opportunity if and when we believe such opportunity is consistent with our business strategy and we would be able to realize value for our stockholders in so doing. There can be no assurance that we will be able to sell vitaCare Prescription Services. Any divestiture or disposition, including the potential disposition of vitaCare Prescription Services, could expose us to significant risks, including, without limitation, fees for legal and transaction-related services, diversion of management resources, transaction execution risks (including risks resulting from buyer financing and due diligence contingencies and other closing conditions), loss of key personnel and reduction in revenue. Further, we may be required to retain or indemnify a buyer against certain liabilities and obligations in connection with any such divestiture, and we may also become subject to third-party claims arising out of such divestiture. In addition, we may not achieve the expected price in a divestiture transaction, including the potential sale of vitaCare Prescription Services. A divesture of vitaCare Prescription Services may be subject to various third-party consents. There can be no assurances that we will obtain any necessary consents of governmental authorities or other third parties that might be required in order for us to sell vitaCare Prescription Services or effectuate any other divesture. If we are unable to consummate the divestiture of vitaCare Prescription Services or do not realize the expected strategic, economic, or other benefits of that or any other divestiture transaction, it could adversely affect our business and financial position.

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 an adverse effect on our business, financial condition, results of operations, and growth prospects.

In 2020, 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 an 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, including any access barriers such as prior authorizations and step-edits;
- 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, because the FDA applies a heightened level of scrutiny to comparative claims when applying its statutory standards for advertising and promotion, including with regard to its requirements for supporting data and that promotional labeling be truthful and not misleading, and there is potential for differing interpretations of whether certain communications are consistent with a product’s FDA-required labeling. 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.

We are subject to extensive and costly government regulation.

The products we are 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 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, or arrangement for the referral of, an individual for, or the purchase, lease, order, or recommendation of, any good or service reimbursable, in whole or in part, by 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 safe harbors are subject to change through legislative and regulatory action, and we may decide to adjust our business practices or be subject to heightened scrutiny as a result. For example, under a final rule issued in 2020 and to take effect January 1, 2022, OIG revised the AKS’s Discount Safe Harbor to explicitly exclude reductions in price offered by drug manufacturers to pharmacy benefit managers and Part D plans from the safe harbor’s definition of a “discount,” meaning AKS immunity would not be available for such arrangements, and as a result potential AKS risks would increase unless arraignments were restructured. 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 under the AKS may be established without proving actual knowledge of the statute or specific intent to violate it. In addition, federal law provides that the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act, or FCA, described below. Violations of the AKS carry potentially significant civil, criminal, and administrative penalties, including imprisonment, fines, civil monetary penalties, and exclusion from participation in government healthcare programs. The compliance and enforcement landscape, and related risk, is informed by government precedent, Advisory Opinions, and Special Fraud Alerts. For example, on November 16, 2020 the OIG published a Special Fraud Alert addressing manufacturer speaker programs signaling that such programs will be subject to an even higher degree of government scrutiny for potential AKS compliance concerns. Our approach to compliance may evolve over time in light of these types of developments. For example, we are currently evaluating the impact of the November 16, 2020 Special Fraud Alert on our speaker programs; if we are required to materially change our speaker programs to comply with the Special Fraud Alert, our speaker programs may be less effective, which may have an adverse effect on our business, financial condition, results of operations, and growth prospects.
- The FCA prohibits entities and individuals from intentionally (or with reckless disregard or deliberate ignorance) presenting or causing to be presented false or fraudulent claims to Medicare, Medicaid, and other federal healthcare programs, or improperly retaining known overpayments;

  - Violations of the FCA carry penalties of up to three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim. Suits filed under the federal FCA can be brought directly by the government or be brought by an individual (known as a “relator” or, more commonly, as a “whistleblower”) on behalf of the government, known as “qui tam” actions. Relators bringing qui tam actions under the FCA receive a share of any amounts paid by the entity to the government in fines or settlement. Qui tam actions have increased significantly in recent years, causing greater numbers of entities, including manufacturers, to have to defend a false claim action, even before the validity of the claim is established and even if the government decides not to intervene in the lawsuit. Companies may decide to agree to large settlements with the government and/or whistleblowers to avoid the cost and negative publicity associated with litigation. Criminal prosecution is possible for knowingly making or presenting a false or fictitious or fraudulent claim to the federal government. In addition to the FCA, many states have enacted their own false claims act statutes that address similar conduct and that may apply to claims for items or services submitted to any payor source, not just government-funded programs.

  - Although we do not submit claims directly to payers, manufacturers can be held liable under the FCA 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 the FCA. 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 Civil Monetary Penalties Law, or CMPL, imposes substantial civil monetary penalties against an entity that engages in prohibited activities, including but not limited to violations of the AKS, knowing submission of a false or fraudulent claim, employment of an excluded individual and the provision or offer of anything of value to a Medicare or Medicaid beneficiary that the transferring party knows or should know is likely to influence beneficiary selection of a particular provider for which payment may be made in whole or in part by Medicare or Medicaid;

  - "Remuneration" is defined under the CMPL as any transfer of items or services for free or for less than fair market value. There are certain exceptions to the definition of remuneration for offerings that meet the Financial Need, Preventative Care, or Promoting Access to Care exceptions. Sanctions for violations of the CMPL include civil monetary penalties and administrative penalties up to and including exclusion from participation in federal health care programs.

- 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. 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, also imposes obligations, including mandatory contractual terms, on certain covered entities and their business associates with respect to safeguarding the privacy, security, and transmission of individually identifiable health information. Our vitaCare Prescription Services subsidiary is a covered entity under HIPAA. HITECH also 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 deceptive 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 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. Transfers of value to certain other providers such as nurse practitioners and physician assistants will also need to be tracked and reported under the Sunshine Act beginning in 2022.

- 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 CCPA was recently amended by the California Privacy Rights Act, expanding certain consumer rights such as the right to know. It remains unclear what, if any, additional modifications will be made to these laws by the California legislature or how these laws will be interpreted and enforced. The potential effects of the CCPA and CPRA are significant and may cause us to incur substantial costs and expenses to comply.

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. 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. 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. We cannot guarantee that a government agency will agree with our interpretations and it is possible that an enforcement authority may find that one or more of our business practices may not comply. 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, 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 issued by federal or state agencies. Federal and state elections in 2020 have changed which persons and parties occupy the presidency of the United States and control both chambers of Congress and many states' governors and legislatures. These changes will likely result in new agency priorities, rulemakings, and legislation. We anticipate that the new Biden administration will issue a number of Executive Orders, which may alter the policies of the previous administration. Additionally, certain agency rules and policy statements of the prior administration may be rescinded. Further, the Biden administration may propose substantial changes to the U.S. healthcare system, including expanding government-funded health insurance options. We are uncertain of the impact or outcome of these potential Executive Orders, rescission of rules and policy statements, or new legislation, especially any relative impact on the healthcare regulatory and policy landscape, or the impact they may have on our business. 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 an 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. Payment or reimbursement of prescription drugs by Medicaid or Medicare requires manufacturers of the drugs to submit pricing information to CMS. The Medicaid Drug Rebate statute requires manufacturers to calculate and report price points, which are used to determine Medicaid rebate payments shared between the states and the federal government and Medicaid payment rates for the drug. For drugs paid under Medicare Part B, manufacturers must also calculate and report their Average Sales Price, or ASP, which is used to determine the Medicare Part B payment rate for the drug. The federal government sets general guidelines for Medicaid and requires rebates on outpatient drugs. Each state creates specific regulations that govern its individual program, including supplemental rebate programs that prioritize coverage for drugs on the state Preferred Drug List. In the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government provides reimbursement through the Medicare or Medicaid programs for such products and services. In addition, government programs like Medicaid include substantial penalties for increasing commercial prices over the rate of inflation which can affect realization and return on investment. The cost of pharmaceuticals continues to generate substantial governmental and third-party payor interest and states have begun to take action to increase transparency in drug pricing through mandatory reporting requirements. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations, and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, any such 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. A 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.

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. 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. The prior administration implemented policies that permit certain employers to claim a religious or moral objection to the birth control coverage mandate under the ACA. On July 8, 2020, the Supreme Court held in *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania, et. al.* that 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. This exemption could be overturned by the new Biden administration through an Executive Order or other policy or regulatory action. Further, despite our progress with commercial payers, there is no guarantee that we will be able to retain our 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 an 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. 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.

There have been efforts by government officials and legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation. On May 11, 2018, the prior administration issued its "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. Following on this initiative, HHS announced a drug payment model through the Center for Medicare and Medicaid Innovation at CMS to lower Medicare Part B payments for certain drugs to the lowest price for similar countries. Beginning January 1, 2021, the model, known as the Most Favored Nation (MFN) Model, will test a new model of drug payments whereby Medicare will pay no more for high cost, physician-administered Medicare Part B drugs than the lowest price charged in other similar countries.

While drug pricing was a priority for the prior administration, we expect that it will continue to be a focus of the Biden administration in 2021 and beyond. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical 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.

We are unable to predict the future course of federal or state healthcare legislation in the United States 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 an adverse effect on our business, financial condition and results of operations.

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 is 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. After generally suspending in-person inspections due to COVID-19, the FDA announced it would resume domestic facility inspections, although the agency continues its general suspension of foreign facility inspections (although "mission-critical" inspections may be considered on a case-by-case basis). Because of the global pandemic, decision-making around facility inspections by the FDA (including preapproval inspections) continues to evolve. 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 an 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 an adverse impact on our business. 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. Finally, we could experience manufacturing delays or interruptions as a result of the ongoing COVID-19 pandemic.

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 and reporting, 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 requirement. 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. Product identifier information (an aspect of the product tracing scheme) is also now required. The DSCSA requirements, development of standards, and the system for product tracing have been and will continue to be phased in over a period of years, with FDA indicating enforcement discretion on certain aspects due to the COVID-19 pandemic. The distribution of product samples continues to be regulated under the PDMA, and some states also impose regulations on drug sample distribution.

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.

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 exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions 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 exception 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 certain educational and research grants or patient assistance programs. The safe harbors are subject to change through legislative and regulatory action, and we may decide to adjust our business practices or be subject to heightened scrutiny as a result.

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 consistent with the FDA-required, 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 have shown and continue to show 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 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 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 a virtual health platform, such as PlushCare, a direct-to-consumer telehealth platform offering primary care medical services, subject to state telehealth 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 telehealth 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 provide patient access to our products via virtual care offerings. There have been recent waivers of telehealth restrictions, including many of those pertaining to electronic prescribing based on a telehealth encounter, in order to assist in expanding access to care during the COVID-19 pandemic. Many of these waivers are tied to the federal public health emergency declaration but some state laws have different expiration dates. 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; 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.

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.

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 IMVEXXY 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 IMVEXXY 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 IMVEXXY Notice Letter expire in 2032 or 2033. On April 1, 2020, we filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey arising from Teva's ANDA filing with the FDA. We are seeking, among other relief, an order that the effective date of any FDA approval of Teva's ANDA would be a date no earlier than the expiration of the IMVEXXY Patents and equitable relief enjoining Teva from infringing the IMVEXXY Patents. Teva has filed its answer and counterclaim to the complaint, alleging that the IMVEXXY Patents are invalid and not infringed. A trial date has not been set. The complaint which we filed automatically precludes 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 the complaint filed on April 1, 2020 or any other 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.

On March 17, 2020, we received the BIJUVA Notice Letter regarding an ANDA submitted to the FDA by Amneal. The ANDA seeks approval from the FDA to commercially manufacture, use, or sell a generic version of BIJUVA. In the BIJUVA Notice Letter, Amneal alleges that the BIJUVA Patents are invalid, unenforceable, and/or will not be infringed by Amneal's commercial manufacture, use, or sale of its proposed generic drug product. The BIJUVA Patents identified in the BIJUVA Notice Letter expire in 2032. On April 29, 2020, we filed a complaint for patent infringement against Amneal in the United States District Court for the District of New Jersey arising from Amneal's ANDA filing with the FDA. We are seeking, among other relief, an order that the effective date of any FDA approval of Amneal's ANDA would be a date no earlier than the expiration of the BIJUVA Patents and equitable relief enjoining Amneal from infringing the BIJUVA Patents. Amneal has filed its answer and counterclaim to the complaint, alleging that the BIJUVA Patents are invalid and not infringed. A trial date has not been set. The complaint which we filed automatically precludes the FDA from approving Amneal's ANDA until the earlier of 30 months or entry of a district court decision finding the BIJUVA Patents invalid, unenforceable, or not infringed. On February 25, 2021, the District Court entered an order temporarily staying all proceedings in the BIJUVA litigation. The District Court stay also extends the 30-month stay for the period in which the BIJUVA litigation has been stayed. We cannot assure you that the complaint filed on April 29, 2020 or any other patent infringement lawsuit that we may file will prevent the introduction of a generic version of BIJUVA for any particular length of time, or at all. If Amneal's ANDA is approved, and a generic version of BIJUVA is introduced, our sales of BIJUVA could be adversely affected.

In addition, we cannot predict what additional ANDAs could be filed by Teva, Amneal 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 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 an 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 an 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.

Our success is tied to our distribution channels.

We sell our products to wholesale distributors and retail pharmacy distributors. During 2020, three customers each generated more than 10% of our total revenues; revenue generated from these three customers combined accounted for approximately 63% of our total revenue during 2020. 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.

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 only have oversight of 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. Our reliance on the CROs does not relieve us of our regulatory responsibilities as sponsor. 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 current 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, CROs, 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 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 an 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, 2020, we had federal net operating loss carryforwards, or NOLs, of approximately $761.7 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 reduced 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. Additionally, in order to address the impact of the COVID-19 pandemic, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted into law on March 27, 2020. The CARES Act includes several significant business tax provisions that, among other things, includes further statutory amendments to the rules governing NOLs, as amended by The Tax Act. The CARES Act limits the NOL carryover deduction in taxable years beginning after December 31, 2020, to the lesser of the NOL carryforward or 80 percent of the taxpayer's taxable income (after considering the deduction for NOLs arising in tax years beginning before January 1, 2018), which may restrict our ability to offset future taxable income with NOLs and increase our future federal income taxes otherwise payable.

Our operations are concentrated in Boca Raton, Florida and interruptions affecting us or our suppliers due to natural disasters, the COVID-19 pandemic, or other unforeseen events could adversely affect our operations.

Our current operations are concentrated in Boca Raton, Florida. A hurricane, the COVID-19 pandemic, or other disaster or unforeseen event resulting in significant damage to our facilities, or causing illness in the personnel operating 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, or engage or hire new personnel due to the COVID-19 pandemic. 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 is otherwise impacted by the COVID-19 pandemic 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 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. 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 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, 2020, we had 400 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.

Risks Related to our Intellectual Property

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 IMVEXXY Notice Letter regarding an ANDA submitted to the FDA by Teva, and on March 17, 2020 we received the BIJUVA Notice Letter regarding an ANDA submitted to the FDA by Amneal. The ANDA submitted by Teva seeks approval from the FDA to commercially manufacture, use, or sell a generic version of the 4 mcg and 10 mcg doses of IMVEXXY, and the ANDA submitted by Amneal seeks approval from the FDA to commercially manufacture, use, or sell a generic version of BIJUVA.

In the IMVEXXY 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 IMVEXXY Notice Letter expire in 2032 or 2033. On April 1, 2020, we filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey arising from Teva’s ANDA filing with the FDA. We are seeking, among other relief, an order that the effective date of any FDA approval of Teva’s ANDA would be a date no earlier than the expiration of the IMVEXXY Patents and equitable relief enjoining Teva from infringing the IMVEXXY Patents. Teva has filed its answer and counterclaim to the complaint, alleging that the IMVEXXY Patents are invalid and not infringed. A trial date has not been set. The complaint which we filed automatically precludes 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.

In the BIJUVA Notice Letter, Amneal alleges that BIJUVA Patents listed in the FDA’s Orange Book that claim compositions and methods of BIJUVA are invalid, unenforceable, and/or will not be infringed by Amneal’s commercial manufacture, use, or sale of its proposed generic drug product. The BIJUVA Patents identified in the BIJUVA Notice Letter expire in 2032. On April 29, 2020, we filed a complaint for patent infringement against Amneal in the United States District Court for the District of New Jersey arising from Amneal’s ANDA filing with the FDA. We are seeking, among other relief, an order that the effective date of any FDA approval of Amneal’s ANDA would be a date no earlier than the expiration of the BIJUVA Patents and equitable relief enjoining Amneal from infringing the BIJUVA Patents. Amneal has filed its answer and counterclaim to the complaint, alleging that the BIJUVA Patents are invalid and not infringed. A trial date has not been set. The complaint which we filed automatically precludes the FDA from approving Amneal’s ANDA until the earlier of 30 months or entry of a district court decision finding the BIJUVA Patents invalid, unenforceable, or not infringed. On February 25, 2021, the District Court entered an order temporarily staying all proceedings in the BIJUVA litigation. The District Court stay also extends the 30-month stay for the period in which the BIJUVA litigation has been stayed.

We cannot assure you that any patent infringement lawsuit that we may file will prevent the introduction of a generic version of IMVEXXY or BIJUVA for any particular length of time, or at all. If Teva’s ANDA or Amneal’s ANDA are approved, and a generic version of IMVEXXY or BIJUVA is introduced, our sales of IMVEXXY or BIJUVA could be adversely affected. In addition, we cannot predict what additional ANDAs could be filed by Teva, Amneal 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 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.

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 BIJUVA Notice Letter, and Amneal’s ANDA and IMVEXXY 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.

Risks Related to Ownership of our Common Stock

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, 2020, our executive officers, directors, holders of 5% or more of our common stock, and their affiliates beneficially owned approximately 25% of our common stock, inclusive of vested options and warrants to acquire shares of our common stock. These stockholders may be able to largely determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to largely 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. Due to our current filing status, we are not required to have our independent registered public accounting firm 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 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, or voluntarily followed under, 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.

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.

General Risks Related to our Business

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 an 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 an 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 adversely affected.

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

We may be subject to product recalls, withdrawals, or seizures if any of the products we formulate, manufacture, or sell are believed to cause injury or illness or if we are alleged to have violated governmental regulations in the manufacture, labeling, promotion, sale, or distribution of any of our products. A recall, withdrawal, or seizure of any of our products could 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 adversely affect our business, financial condition, and results of operations.

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.

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 an 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 data and results 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 an 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.

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 impact our business, results of operations, and financial condition.

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. During the COVID-19 pandemic, in particular, cyber-attacks increased as companies shifted to remote work environments, including several high-profile, sophisticated attacks impacting government agencies and security firms alike, the impacts of which are still being uncovered. 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 an 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.

On July 16, 2020, the Court of Justice of the European Union issued its long-awaited decision in the case Data Protection Commission v. Facebook Ireland, Schrems, or the Schrems II Decision. The Schrems II decision invalidates the European Commission's adequacy decision for the EU-U.S. Privacy Shield Framework, calling into question personal data transfers from the EU to the U.S. While we have yet to determine the full impact of the invalidation of the EU-US Privacy Framework on our business, we anticipate increased legal and technological costs as we evaluate any trans-Atlantic transfers as well as the impact on any business that we may conduct in the EU.

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 an 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.

General 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 adversely affect our business, financial condition, and results of operations.

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 an 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.

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

General 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.

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.

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 commenced in May 2020.

Item 3. Legal Proceedings

From time to time, we are involved in litigation and proceedings in the ordinary course of our business.

On February 20, 2020, we received a Paragraph IV certification notice letter, or the IMVEXXY 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 IMVEXXY 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 IMVEXXY Notice Letter expire in 2032 or 2033. On April 1, 2020, we filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey arising from Teva's ANDA filing with the FDA. We are seeking, among other relief, an order that the effective date of any FDA approval of Teva's ANDA would be a date no earlier than the expiration of the IMVEXXY Patents and equitable relief enjoining Teva from infringing the IMVEXXY Patents. Teva has filed its answer and counterclaim to the complaint, alleging that the IMVEXXY Patents are invalid and not infringed. A trial date has not been set.

On March 17, 2020, we received a Paragraph IV certification notice letter, or the BIJUVA Notice Letter, regarding an ANDA submitted to the FDA by Amneal Pharmaceuticals, or Amneal. The ANDA seeks approval from the FDA to commercially manufacture, use, or sell a generic version of BIJUVA. In the BIJUVA Notice Letter, Amneal alleges that TherapeuticsMD patents listed in the FDA's Orange Book that claim compositions and methods of BIJUVA, or the BIJUVA Patents, are invalid, unenforceable, and/or will not be infringed by Amneal's commercial manufacture, use, or sale of its proposed generic drug product. The BIJUVA Patents identified in the BIJUVA Notice Letter expire in 2032. On April 29, 2020, we filed a complaint for patent infringement against Amneal in the United States District Court for the District of New Jersey arising from Amneal's ANDA filing with the FDA. We are seeking, among other relief, an order that the effective date of any FDA approval of Amneal's ANDA would be a date no earlier than the expiration of the BIJUVA Patents and equitable relief enjoining Amneal from infringing the BIJUVA Patents. Amneal has filed its answer and counterclaim to the complaint, alleging that the BIJUVA Patents are invalid and not infringed. A trial date has not been set. On February 25, 2021, the District Court entered an order temporarily staying all proceedings in the BIJUVA litigation. The District Court stay also extends the 30-month stay for the period in which the BIJUVA litigation has been stayed.

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.

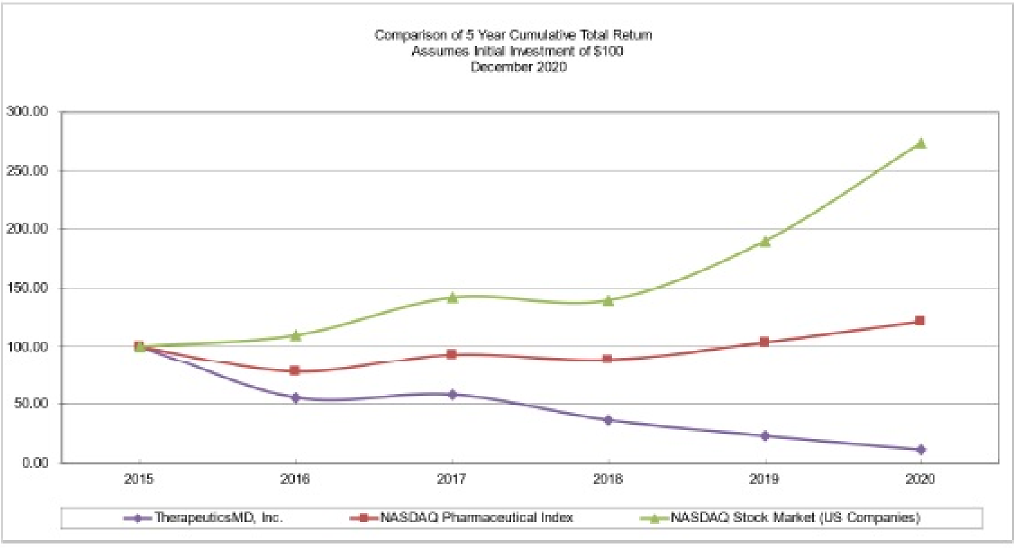
As of February 1, 2021, there were approximately 171 record holders and 28,853 beneficial owners of our common stock.

Dividends

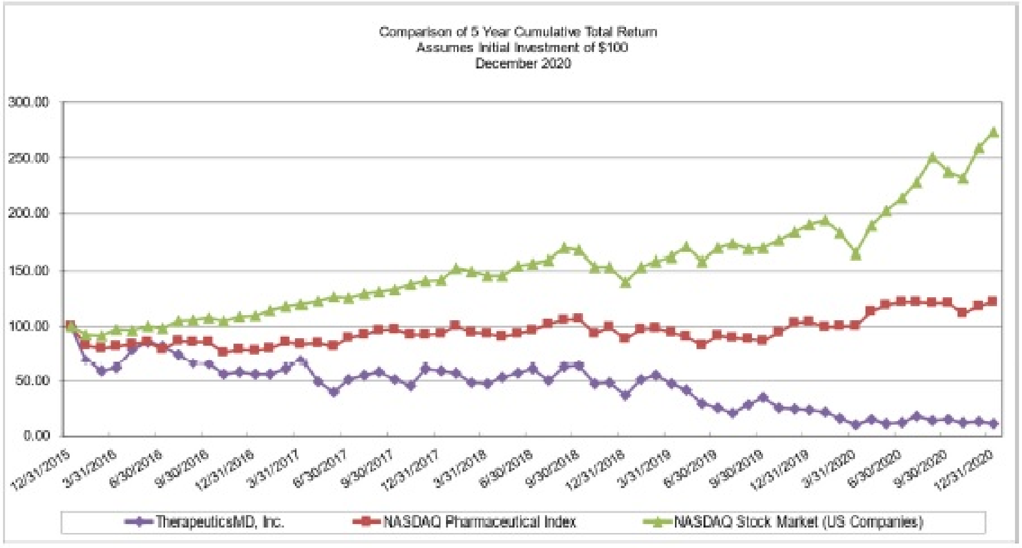
Historically, we have not paid dividends on our common stock, and we currently do not intend to pay any dividends on our common stock in the foreseeable future. We currently plan to retain any earnings to finance the growth of our business rather than to pay cash dividends. Payments of any cash dividends 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 Financing 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, 2020 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, 2015 and includes reinvestment of dividends. Measurement points are at December 31, 2015 and the last trading day of the fiscal years ended December 31, 2016, 2017, 2018, 2019, and 2020. 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, 2020 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, 2015 and includes reinvestment of dividends. Measurement points are December 31, 2015 and the last trading day of the fiscal years ended December 31, 2020, 2019, 2018, 2017, and 2016, 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.

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, 2020, 2019, and 2018 and the consolidated balance sheet data as of December 31, 2020 and 2019 are derived from our audited consolidated financial statements included in this Annual Report. The consolidated statements of operations for the years ended December 31, 2017 and 2016, and the consolidated balance sheet data as of December 31, 2018, 2017, and 2016 are derived from our audited consolidated financial statements not included in this Annual Report.

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

	Year Ended December 31,				
Consolidated Statements of Operations Data	**2020**	**2019**	**2018**	**2017**	**2016**
Product revenue, net	$ 62,872	$ 34,141	$ 16,099	$ 16,778	$ 19,356
License revenue	2,000	15,506	—	—	—
Cost of goods sold	15,975	6,335	2,737	2,637	4,185
Gross profit	48,897	43,312	13,362	14,141	15,171
Operating expenses:					
Sales, general, and administrative	192,964	174,113	115,989	57,703	51,348
Research and development	10,432	19,792	27,299	33,853	53,943
Depreciation and amortization	1,042	613	294	213	133
Total operating expenses	204,438	194,518	143,582	91,769	105,424
Operating loss	(155,541)	(151,206)	(130,220)	(77,628)	(90,253)
Other (expense) income, net	(27,983)	(24,939)	(2,397)	703	378
Net loss	$ (183,524)	$ (176,145)	$ (132,617)	$ (76,925)	$ (89,875)
Net loss per share, basic and diluted	$ (0.67)	$ (0.72)	$ (0.59)	$ (0.37)	$ (0.46)
Weighted average number of common shares outstanding, basic and diluted	275,649	246,353	225,026	205,523	196,088
Consolidated Balance Sheet Date (at end of period)					
Total assets	$ 181,610	$ 265,986	$ 211,984	$ 143,230	$ 142,472
Total debt	$ 237,698	$ 194,635	$ 73,381	—	—
Total operating lease liability	$ 10,929	$ 10,647	—	—	—
Total liabilities	$ 305,611	$ 256,785	$ 114,460	$ 13,321	$ 14,983
Total stockholders' (deficit) equity	$ (124,001)	$ 9,201	$ 97,524	$ 129,909	$ 127,489
Other Data:					
Capital expenditures (for the period)	$ 1,598	$ 3,892	$ 1,322	$ 827	$ 1,241
Working capital (at the end of the period)	$ 69,166	$ 155,411	$ 145,700	$ 126,233	$ 124,428

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 17ß-estradiol and bio-identical progesterone in a single, oral softgel capsule, for the treatment of moderate-to-severe vasomotor symptoms, or VMS, due to menopause in women with a uterus, which was approved by the FDA in October 2018.
- In October 2019, we began a "test and learn" market introduction for our FDA-approved product ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system), the first and only annual 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 paused the planned full commercial launch of ANNOVERA in March 2020 due to the impact of the COVID-19 pandemic and resumed this initiative in July 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. Knight received the first regulatory approval in Canada for IMVEXXY and BIJUVA in the third quarter of 2020.
- 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 IMVEXXY and BIJUVA 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.

In late January 2020, we submitted a New Drug Application, or NDA, efficacy supplement for the 0.5/100 mg dose of BIJUVA to the FDA for review and potential approval. The NDA efficacy supplement used existing data from our Phase 3 REPLENISH trial for BIJUVA, for which we announced results in December 2016, together with additional information and analyses. In November 2020, we withdrew the NDA efficacy supplement. We currently intend to file a Formal Dispute Resolution Request, or FDRR, with the FDA that disputes the FDA's requirement that the efficacy supplement meet approval standard that have not been required of other approved drugs in BIJUVA's therapeutic class. There can be no assurance that we will prevail with respect to the FDRR, if filed, or that the 0.5/100 mg dose of BIJUVA will be approved.

IMVEXXY

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

IMVEXXY is a small, digitally inserted, softgel vaginal insert that dissolves when inserted into the vagina. 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 is 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. 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.

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 annual 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 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 $20,000,000, 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. We paused the planned full commercial launch of ANNOVERA in March 2020 due to the impact of the COVID-19 pandemic and resumed this initiative in July 2020.

We believe that the strong initial commercial net revenue per unit of ANNOVERA and commercial insurance adoption provide us with an opportunity to deploy additional financial resources to maximize ANNOVERA's consumer-focused commercialization strategy and leverage the ability of doctor/patient choice of contraceptive to override insurance company formularies when necessary. As part of this strategy, we are pursuing distribution opportunities for ANNOVERA to provide women with additional access to ANNOVERA, particularly during the COVID-19 pandemic, with multiple direct-to-consumer contraceptive platforms that extend the reach of our products.

License Agreement with the Population Council

In July 2018, we entered into the Population Council License Agreement to commercialize ANNOVERA in the U.S. We began selling ANNOVERA in a "test and learn" market introduction in the third quarter of 2019. As a result of the uncertainty surrounding the COVID-19 pandemic, we paused the commercial launch of ANNOVERA in the first quarter of 2020 and deferred sales and marketing initiatives into subsequent quarters. We resumed the launch of ANNOVERA in July 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 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 a second milestone payment of $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 additional milestone payments of $40 million upon cumulative net sales of ANNOVERA in the U.S. by us and our affiliated and permitted sublicensees of each of $200 million, $400 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 paid us $2,000,000 in milestone fees upon the first regulatory approval in Canada for IMVEXXY and BIJUVA in the third quarter of 2020, and is required to pay us 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. 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. As part of the Knight License Agreement, Knight is prohibited from exporting IMVEXXY and BIJUVA to the United States.

License Agreement with Theramex

In June 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 in August 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.

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 development, support and maintenance 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,		
	2020	2019	2018
		(000s)	
TX 001-HR (BIJUVA)	$ 2,085	$ 3,848	$ 11,790
TX 004-HR (IMVEXXY)	1,311	2,522	4,890
ANNOVERA	1,990	2,637	—
Other research and development	5,046	10,785	10,619
Total	$ 10,432	$ 19,792	$ 27,299

Research and development expenditures have been reduced as we refocused our resources towards the commercialization of our approved pharmaceutical products. We will continue to deploy limited resources as we develop our drug pipeline, continue stability testing and validation on our pharmaceutical products, develop and validate secondary manufacturers, 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 a variety of factors. 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, 2020, 2019, and 2018:

Year ended December 31, 2020 compared with year ended December 31, 2019

	Years Ended December 31,		
	2020	2019	Change
		(000s)	
Product revenue, net	$ 62,872	$ 34,141	$ 28,731
License revenue	2,000	15,506	(13,506)
Cost of goods sold	15,975	6,335	9,640
Operating expenses	204,438	194,518	9,920
Operating loss	(155,541)	(151,206)	(4,335)
Other expense, net	(27,983)	(24,939)	(3,044)
Net loss	$ (183,524)	$ (176,145)	$ (7,379)

Revenue

Product revenue is recorded net of sales discounts, chargebacks, wholesaler fees, customer rebates, coupons and estimated returns. 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. We paused the planned full commercial launch of ANNOVERA in March 2020 due to the impact of the COVID-19 pandemic and resumed this initiative on July 1, 2020. Product revenue for the year ended December 31, 2020 increased approximately $28,731,000, or 84%, to approximately $62,872,000, compared with approximately $34,141,000 for the year ended December 31, 2019. Despite slower than anticipated growth of our product revenue due to the impact of the COVID-19 pandemic, product revenue increased primarily due to continued ramping of sales of IMVEXXY, BIJUVA and ANNOVERA during the year ended December 31, 2020, as compared to the prior period, partially offset by a decrease in prenatal vitamins sales.

Sales of IMVEXXY increased approximately $10,887,000 as compared to the prior year and sales of BIJUVA increased approximately $4,517,000 as compared to the prior year due to a higher number of units sold and increased net product revenue per unit. Sales of ANNOVERA increased approximately $13,445,000 as compared to the prior year primarily due to a higher number of units sold, partially offset by slightly lower net revenue per unit. In addition, during the year ended December 31, 2020, our prenatal vitamin sales decreased approximately $118,000 due to decreased number of units sold partially offset by an increased net product revenue per unit as compared to the prior year. In addition to our product revenue, during the year ended December 31, 2020, we recognized aggregate license revenue of $2,000,000 from two non-refundable milestone payments from Knight under the terms of the Knight License Agreement, which we recognized at the point in time upon the first regulatory approvals in Canada of each of IMVEXXY and BIJUVA. 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, payable 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.

During the launches of IMVEXXY and BIJUVA we introduced co-pay assistance programs which allow eligible enrolled patients to access the products at a reasonable cost regardless of insurance coverage. We expect that our product revenue will improve in the long term as commercial and Medicare payer coverage increases, and plans complete the process needed to adjudicate IMVEXXY, BIJUVA, and ANNOVERA prescriptions at pharmacies.

Cost of Goods Sold

Cost of goods sold increased approximately $9,640,000, or 152%, to approximately $15,975,000 for the year ended December 31, 2020, compared with approximately $6,335,000 for the year ended December 31, 2019. This increase is attributable to a 84% increase in product revenue as compared to the prior year, an increase in royalty fees of approximately $672,000, and an increase in amortization of our license fee related to ANNOVERA of approximately $2,246,000 as well as an increase of $4,085,000 inventory charge, primarily related to BIJUVA, as compared to the prior year. Our gross margin related to prescription products was approximately 75% and 81% for the years ended December 31, 2020 and 2019, respectively. The change in our gross margin between the two periods is primarily related to the change in product mix and its related costs including inventory charge, amortization of license fee and royalty fees described above.

Operating Expenses

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

	Years Ended December 31,	
	2020	2019
Sales and marketing costs, excluding human resource costs	44%	45%
Human resource related costs	33%	28%
Product research and development costs	5%	10%
Professional fees and consulting costs	6%	7%
Other operating expenses	12%	10%

Operating expenses increased by approximately $9,920,000, or 5%, to approximately $204,438,000 for the year ended December 31, 2020, compared with approximately $194,518,000 for the year ended December 31, 2019, as a result of the following items:

	Years Ended December 31,		
	2020	2019	Change
	(000s)		
Sales and marketing, excluding human resources costs	$ 89,286	$ 86,459	$ 2,827
Human resources related costs	66,969	54,120	12,849
Research and development costs	10,432	19,792	(9,360)
Professional and consulting costs	13,260	13,913	(653)
Other operating expenses	24,491	20,234	4,257
Total operating expenses	$ 204,438	$ 194,518	$ 9,920

Sales and marketing costs, excluding human resources costs, for the year ended December 31, 2020 increased by approximately $2,827,000, or 3%, to approximately $89,286,000, compared with approximately $86,459,000 for the year ended December 31, 2019. This increase was primarily due to higher expenses associated with advertising efforts to support the significant initiative related to the launch of ANNOVERA in March 2020, which was subsequently paused as a result of the COVID-19 pandemic and relaunched in July 2020, as well as continuing to support the commercialization of BIJUVA and IMVEXXY, which was partially offset by cost cutting initiatives put in place at the beginning of the COVID-19 pandemic, including reducing consulting and agency fees. In addition, we recorded product samples expense of approximately $7,100,000, during the year ended December 31, 2020, primarily related to BIJUVA. Sales and marketing costs, excluding human resources costs, also increased as compared to the prior year as a result of higher sales incentives due to the increase in product revenue, which was partially offset by lower physician education, training and travel expenses caused by restrictions on in-person speaker programs due to the COVID-19 pandemic. In addition, during the third quarter of 2020, we onboarded our outsourced sales personnel which decreased sales and marketing costs, excluding human resources costs.

Human resources costs, including salaries, benefits and taxes, for the year ended December 31, 2020 increased by approximately $12,849,000, or 24%, to approximately $66,969,000, compared with approximately $54,120,000 for the year ended December 31, 2019, as a result of an increase of approximately $11,964,000 primarily related to higher employee count which increased from 348 in 2019 to 400 in 2020 mostly in sales, marketing and regulatory areas to support commercialization of our pharmaceutical products which included onboarding our outsourced sales personnel and an increase of approximately $885,000 in non-cash compensation expense included in this category related to employee stock-based compensation during 2020 as compared to 2019, partially offset by cost cutting measures implemented due to the COVID-19 pandemic.

Product research and development costs for the year ended December 31, 2020 decreased by approximately $9,360,000, or 47%, to approximately $10,432,000, compared with approximately $19,792,000 for the year ended December 31, 2019. Product 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. Product research and development expenditures have been reduced as we refocused our resources towards the commercialization of our approved pharmaceutical products. We continue to deploy limited resources as we develop our drug pipeline, continue stability testing and validation on our pharmaceutical products, develop and validate secondary manufacturers, prepare regulatory submissions and work with regulatory authorities on existing submissions.

● Since the project's inception in February 2013, we have incurred approximately $133,120,000 in research and development costs with respect to BIJUVA.

● Since the project's inception in August 2014, we have incurred approximately $49,572,000 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 fees and consulting costs for the year ended December 31, 2020 decreased by approximately $653,000, or 5%, to approximately $13,260,000, compared with approximately $13,913,000 for the year ended December 31, 2019, primarily as a result of reduced recruiting and consulting fees, partially offset by increased legal, accounting and other professional fees.

All other operating expenses for the year ended December 31, 2020 increased by approximately $4,257,000, or 21%, to approximately $24,491,000, compared with approximately $20,234,000 for the year ended December 31, 2019, primarily as a result of increased insurance, dues and subscriptions, rent, depreciation and amortization expenses, and write off of intangible assets and patents, partially offset by lower other office and travel expenses due to travel restrictions caused by the COVID-19 pandemic.

Operating Loss

As a result of the foregoing, our operating loss increased approximately $4,335,000, or 3%, to approximately $155,541,000 for the year ended December 31, 2020, compared with approximately $151,206,000 for the year ended December 31, 2019, primarily as a result of an increase in total operating expenses to support commercialization and launch efforts related to our pharmaceutical products, a decrease in our license revenue as well as write off of inventory and product samples due to the COVID-19 pandemic, as described above, partially offset by increased total net product 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, net

Other non-operating expense, net increased by approximately $3,044,000, or 12%, to an expense of approximately $27,983,000 for the year ended December 31, 2020, compared with an expense of approximately $24,939,000 for the year ended December 31, 2019, primarily as a result of increased interest expense related to our Financing Agreement partially offset by the loss on extinguishment of debt of $10,058,000 incurred during the year ended December 31, 2019. For more information regarding our Financing Agreement, see "Liquidity and Capital Resources" below.

Net Loss

Because of the net effects of the foregoing, net loss increased by approximately $7,379,000, or 4%, to approximately $183,524,000 for the year ended December 31, 2020, compared with approximately $176,145,000 for the year ended December 31, 2019. Net loss per share of Common Stock, basic and diluted, was ($0.67) and ($0.72) for the years ended December 31, 2020 and 2019, respectively.

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

	Years Ended December 31, 2019	Years Ended December 31, 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, 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. 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	Years Ended December 31, 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	Years Ended December 31, 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.

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.

Other expense, net

Other non-operating expense, 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 approximately $10,058,000 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.

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 ended December 31, 2020, we received approximately $198,642,000 in net proceeds from the issuance of shares of our common stock, par value $0.001 per share, or Common Stock. As of December 31, 2020, we had a cash balance of approximately $80,486,000. Subsequent to December 31, 2020, we received approximately $47,300,000 in net proceeds from sales of our Common Stock in January and February 2021 pursuant to a Controlled Equity Offering℠ Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, and approximately $97,100,000 in net proceeds from sales of our Common Stock pursuant to an underwritten public offering of our common stock in February 2021, each as described below.

On November 10, 2020, we entered into an underwriting agreement with Cantor Fitzgerald relating to an underwritten public offering of 23,437,500 shares of our Common Stock. We granted to the underwriter an option, exercisable for a period of 30 days, to purchase up to 3,515,625 additional shares of Common Stock, which was exercised in full. The net proceeds the offering were approximately $31,703,000, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. The offering closed on November 13, 2020.

On November 27, 2020, we entered into the Sales Agreement with Cantor Fitzgerald relating to shares of our Common Stock. In accordance with the terms of the sales agreement, in January and February 2021 we offered and sold an aggregate of 28,600,689 shares of our Common Stock having an aggregate offering price of $50 million, resulting in estimated net proceeds to us of approximately $47.3 million. Sales of our Common Stock under the Sales Agreement were made in sales deemed to be “at the market offering” as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, or the Securities Act. Cantor Fitzgerald was entitled to compensation at a fixed commission rate of 3.0% of the aggregate gross sales price per share sold.

On February 11, 2021, we entered into an underwriting agreement with Cantor Fitzgerald, as underwriter, relating to an underwritten public offering of 59,459,460 shares of our Common Stock. Pursuant to the underwriting agreement, we granted to the underwriter an option, exercisable for a period of 30 days, to purchase up to 8,918,919 additional shares of Common Stock. The net proceeds to us from the offering, excluding any proceeds that may be received from the exercise of the underwriter’s option to purchase additional shares, were approximately $97.1 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. The offering closed on February 16, 2021.

On April 24, 2019, we entered into a Financing Agreement, as amended, or the Financing Agreement, with Sixth Street 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 provided us with up to a $300,000,000 first lien secured term loan credit facility, or the Facility. The Facility provided for fund availability in multiple tranches: $200,000,000 was drawn upon entering into the Financing Agreement while an additional $50,000,000 was drawn on February 18, 2020. An additional $50,000,000 was previously available to us in the Administrative Agent’s sole and absolute discretion either contemporaneously with the delivery of our financial statements for the quarter ended June 30, 2020 or at such earlier date as the Administrative Agent may have consented to. Subsequent to the pause in the full launch of ANNOVERA caused by the COVID-19 pandemic, the undrawn $50,000,000 tranche under the Financing Agreement is no longer available.

On August 5, 2020, we and our subsidiaries entered into Amendment No. 5 to the Financing Agreement, or Amendment No. 5, with the Administrative Agent and the lenders party thereto, pursuant to which we modified the minimum consolidated net product revenue requirements attributable to commercial sales of our IMVEXXY, BIJUVA, and ANNOVERA products, which requirements are effective beginning with the fiscal quarter ending December 31, 2020. In lieu of a cash amendment fee, to induce the lenders to enter into Amendment No. 5, on August 5, 2020, we issued warrants, or the Lender Warrants, to the lenders under the Financing Agreement to purchase an aggregate of 4,752,116 shares of Common Stock, pursuant to a subscription agreement among the parties, or the Subscription Agreement. The Warrants have an exercise price of $1.58 per share of Common Stock and an expiration date of August 5, 2030. The Warrants may also be exercised via cashless exercise pursuant to the terms thereof. No registration rights were issued pursuant to the Warrants or Subscription Agreement. On November 8, 2020, in connection with entering into Amendment No. 6 to the Financing Agreement, or Amendment No. 6, we amended the Lender Warrants to provide for an adjustment to the exercise price if we conducted certain dilutive issuances prior to December 31, 2020, or if the volume-weighted average price of our Common Stock for the fifteen trading days ending December 31, 2020 was lower than the then-current exercise price. The issuance of the shares of Common Stock in our November 2020 underwritten public offering at a price per share equal to $1.1856 triggered the automatic reduction in the exercise price of the Lender Warrants from $1.58 to $1.1856. On January 13, 2021, in connection with entering into Amendment No. 7 to the Financing Agreement, or Amendment No. 7, the Lender Warrants were further amended to provide for an additional adjustment to the exercise price if we conduct certain dilutive issuances prior to March 31, 2021. In connection with entering into Amendment No. 7, we paid the Administrative Agent an amendment fee of $5.0 million.

As of the filing date of this Annual Report on Form 10-K, our cash balance was above the required balance by the Financing Agreement. Based on our current projections, and recent equity financing, we anticipate that we will remain in compliance with the minimum cash balance covenant for the next twelve months from the issuance of these financial statements. In addition, we have reviewed numerous potential scenarios in connection with the impact of COVID-19 pandemic on our business and we believe that our existing cash reserves are sufficient to meet our cash needs arising in the ordinary course of business for the next twelve months from the issuance of these financial statements. However, if we are unsuccessful with the commercialization of IMVEXXY, BIJUVA, or ANNOVERA, if such commercialization is delayed, or if the continued impact of the COVID-19 pandemic on our business is worse than we anticipate, among other circumstances, we may consume funds significantly faster than we currently anticipate and our existing cash reserves would be insufficient to maintain compliance with the Financing Agreement covenants or satisfy our liquidity requirements until we are able to successfully commercialize IMVEXXY, BIJUVA, and ANNOVERA.

The Financing Agreement requires us to maintain certain minimum quarterly product net revenue requirements and several other restrictive covenants. On March 1, 2021, we entered into Amendment No. 8, pursuant to which, among other amendments, the minimum quarterly product net revenue requirements attributable to commercial sales of IMVEXXY, BIJUVA, and ANNOVERA were revised to (i) $17.0 million, $20.0 million, $23.0 million, and $26.5 million for the first, second, third, and fourth quarters of 2021, respectively, (ii) $30.0 million, $35.0 million, $40.0 million and $45.0 million for the first, second, third, and fourth quarters of 2022, respectively, (iii) $50.0 million, $55.0 million, $60.0 million and $65.5 million for the first, second, third, and fourth quarters of 2023, and (iv) $70.0 million for the first quarter of 2024. In connection with entering into Amendment No. 8, we repaid $15.0 million in principal under the Financing Agreement on such date and agreed to repay an additional $35.0 million in principal by no later than March 31, 2021, in each case plus a 5.0% prepayment fee. Additionally, we have agreed to make quarterly repayments under the Financing Agreement commencing with the fiscal quarter ending March 31, 2022. See Note 8 – Debt for information regarding our debt maturity.

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. If we are unable to maintain the minimum unrestricted cash balance, achieve any of the total minimum net revenue requirements or otherwise comply with any other covenant of the Financing Agreement, all or a portion of our obligations under the Financing Agreement may be declared immediately due and payable, which would have an adverse effect on our business, results of operations and financial condition.

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 by the average daily net product revenue during the quarter. We also disclose gross DSO, which includes the calculation of gross accounts receivable divided by the average daily gross product revenue to distributors during the quarter. For the three months ended December 31, 2020, our gross DSO was 61 days compared to 55 days for the three months ended December 31, 2019 and our net DSO was 132 days for the three months ended December 31, 2020 compared to 141 days for the three months ended December 31, 2019. We anticipate that our DSO will fluctuate in the future based upon a variety of factors, including longer payment terms associated with the launches of IMVEXXY, BIJUVA, and ANNOVERA and changes in the healthcare industry. Our exposure to credit losses may increase if our customers are adversely affected by changes in healthcare laws, coverage, and reimbursement, economic pressures or uncertainty associated with local or global economic recessions, disruption associated with the COVID-19 pandemic, or other customer-specific factors. Although we have historically not experienced significant credit losses, it is possible that there could be a material adverse impact from potential adjustments of the carrying amount of trade receivables in the future.

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,		
	2020	**2019**	**2018**
Net cash used in operating activities	$ (159,470,335)	$ (165,697,595)	$ (106,811,781)
Net cash used in investing activities	$ (1,597,907)	$ (23,912,694)	$ (21,497,857)
Net cash provided by financing activities	$ 80,724,313	$ 188,826,925	$ 162,787,087

Operating Activities

The principal use of cash in operating activities for the year ended December 31, 2020 and 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 decrease of approximately $6,227,000 in cash used in operating activities for the year ended December 31, 2020 in comparison to the year ended December 31, 2019 was primarily due to changes in the components of working capital partially offset by an increase in non-cash items and an increase in our net loss.

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 primarily due 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.

Investing Activities

During the year ended December 31, 2020, a decrease in spending on fixed assets, patents and trademarks resulted in a decrease in cash used in investing activities for the year ended December 31, 2020 compared with the same period in 2019. In addition, 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.

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.

Financing Activities

Financing activities currently represent the principal source of our cash flow.

Our financing activities for the year ended December 31, 2020 provided net cash of approximately $80,724,000 which consisted of the funding from our Financing Agreement of $50,000,000, approximately $31,703,000 in proceeds from the sale of our common stock and the exercise of options to purchase common stock of approximately $271,000, partially offset by the payment of deferred financing fees of $1,250,000.

On November 10, 2020, we entered into an underwriting agreement with Cantor Fitzgerald, as underwriter, relating to an underwritten public offering of 23,437,500 shares of our common stock. We granted to the underwriter an option, exercisable for a period of 30 days, to purchase up to 3,515,625 additional shares of common stock, which was exercised in full. The net proceeds the offering were approximately $31,703,000, after deducting the underwriting discounts and commissions and offering expenses paid by us. The offering of 23,437,500 shares closed on November 13, 2020 and the offering of 3,515,625 shares closed on November 20, 2020.

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 $77,031,000, after deducting underwriting discounts and commissions and offering expenses paid by us.

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. As of December 31, 2020, our products consisted primarily of prescription vitamins and our FDA-approved products: IMVEXXY, which we began selling during the third quarter of 2018, BIJUVA, which we began selling in the second quarter of 2019, and ANNOVERA, which we began selling in the third quarter of 2019. As a result of the uncertainty surrounding the COVID-19 pandemic, we paused the commercial launch of ANNOVERA in the first quarter of 2020 and deferred sales and marketing initiatives into subsequent quarters. We resumed the launch of ANNOVERA in July 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 distributor, 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 product 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 product 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 product revenue would be subject to a significant reversal. We consider all the facts and circumstances associated with both the risk of a product 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 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. On January 1, 2020, we began calculating the expected term of our stock-based awards, which represents the period that the stock-based awards are expected to be outstanding. Prior to January 1, 2020, the average expected life of options was 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. The assumptions used in calculating the fair value of stock-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.

We grant performance-based stock units and restricted stock units for shares of common stock to employees. We value our restricted stock units and our performance-based stock units by reference to our stock price on the date of grant. We recognize compensation expense for restricted stock units based on a straight-line basis over the requisite service period of the entire award. We recognize performance-based restricted stock as compensation expense based on the most likely probability of attaining the prescribed performance and over the requisite service period beginning at its grant date and through the date the restricted stock vests. The number of target shares that vest are determined based on the level of attainment of the targets. If a minimum level of performance is attained for the awards, restricted stock is issued based on the level of attainment.

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, 2020 and 2019, 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.

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 executive leadership team that is chaired by the Chief Executive Officer of our Company, who oversees all operations. 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 March 2020, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, 2020-04: Reference Rate Reform (Topic 848) Facilitation of the Effects of Reference Rate Reform on Financial Reporting. This update provides optional guidance for a limited period of time to ease potential accounting impacts associated with transitioning away from reference rates that are expected to be discontinued, such as London Interbank Offered Rate (LIBOR). This ASU includes practical expedients for contract modifications due to reference rate reform. Generally, contract modifications related to reference rate reform may be considered an event that does not require remeasurement or reassessment of a previous accounting determination at the modification date. This ASU is effective March 12, 2020 through December 31, 2022. Our Financing Agreement currently include the use of alternate rates when LIBOR is not available. We do not expect the change from LIBOR to an alternate rate will have a material impact on our financial statements and, to the extent we enter into modifications of agreements that are impacted by the LIBOR phase-out, we will apply such guidance to those contract modifications.

In August 2018, the FASB issued 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 adopted this standard on January 1, 2020, and the adoption did not have a material effect on our disclosures.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments. The amendments in this update require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected based on historical experience, current conditions, and reasonable supportable forecasts. The amendments in this update are effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted no sooner than the first quarter of 2019. A modified retrospective approach is required for all investments, except debt securities for which an other-than-temporary impairment had been recognized prior to the effective date, which will require a prospective transition approach and should be applied either prospectively or retrospectively depending on the nature of the disclosure. The adoption of ASU 2016-13 requires expanded quantitative and qualitative disclosures about the Company’s expected credit losses. Effective January 1, 2020, we adopted ASU 2016-13 under a modified retrospective approach for all financial assets measured at amortized cost. There was no adjustment recorded for the cumulative effect of adopting ASU 2016-13. The adoption expanded disclosures about our credit losses.

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, 2020, 2019, and 2018, 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, 2020, 2019, and 2018.

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, 2020, 2019, and 2018, our business and operations have not been materially affected by inflation.

Contractual Obligations

A summary of contractual obligations as of December 31, 2020 is as follows:

		Payments Due by Period			
	Total	Less than 1 Year	2-3 Years	4-5 Years	More than 5 Years
Operating lease obligations	$ 15,615,418	$ 2,334,582	$ 2,856,432	$ 2,989,992	$ 7,434,412
Long-term debt obligation (1)	250,000,000	—	187,500,000	62,500,000	—
Interest payments (2)	76,034,635	26,487,847	47,913,975	1,632,813	—
Purchase obligations (3)	32,923,559	4,984,374	5,141,093	7,133,647	15,664,445
Total	$ 374,573,612	$ 33,806,803	$ 243,411,500	$ 74,256,452	$ 23,098,857

(1) Reflects amounts payable under the Financing Agreement as of December 31, 2020, which provided for the outstanding principal amount to be paid in four equal quarterly installments beginning on June 30, 2023, with the Financing Agreement maturing on March 31, 2024. In connection with Amendment No. 8 to the Financing Agreement, entered into on March 1, 2021, we agreed to make quarterly repayments under the Financing Agreement commencing with the fiscal quarter ending March 31, 2022. See Note 8 – Debt for information regarding our debt maturity.

(2) Interest calculation is based on interest rates in place on December 31, 2020.

(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 or softgels after the first contract year. If the minimum order quantities of specific products are not met, we are required to pay Catalent 50% of the difference between the total amount we would have paid to Catalent if the minimum requirement had been fulfilled and the sum of all purchases of our products from Catalent during the contract year. 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, 2020, we have met our minimum purchase commitments with our manufacturers related to fiscal year 2020.

Legal Proceedings

See Item 3 “Legal Proceedings” for more information.

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 $80,486,000 as of December 31, 2020. 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.

Amounts borrowed under the Financing Agreement 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 $250,000,000 at December 31, 2020, a 1.0% change in interest rates would result in an impact to loss before income taxes of $2,500,000 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, 2020, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is (i) recorded, processed, summarized, and reported within the time periods specified in the SEC rules and forms, and (ii) is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

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

Inherent Limitations on Effectiveness of Controls

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

Management's Annual Report on Internal Control over Financial Reporting

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2020. 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, 2020.

This Annual Report on Form 10-K does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to the rules of the SEC that permit the Company to provide only management's report in this Annual Report on Form 10-K.

Item 9B. Other Information

Amendment No. 8 to Financing Agreement

On March 1, 2021, we entered into Amendment No. 8, pursuant to which, among other amendments, the minimum quarterly product net revenue requirements attributable to commercial sales of IMVEXXY, BIJUVA, and ANNOVERA were revised, the amortization and prepayment terms of the borrowings under the Financing Agreement were revised, and the Administrative Agent consented to a framework for our potential disposition of our vitaCare prescription services business. The minimum quarterly product net revenue requirements attributable to commercial sales of IMVEXXY, BIJUVA, and ANNOVERA were revised pursuant to Amendment No. 8 to (i) $17.0 million, $20.0 million, $23.0 million, and $26.5 million for the first, second, third, and fourth quarters of 2021, respectively, (ii) $30.0 million, $35.0 million, $40.0 million and $45.0 million for the first, second, third, and fourth quarters of 2022, respectively, (iii) $50.0 million, $55.0 million, $60.0 million and $65.5 million for the first, second, third, and fourth quarters of 2023, and (iv) $70.0 million for the first quarter of 2024. With respect to amortization and prepayment terms of the borrowings under the Financing Agreement, in connection with Amendment No. 8, we (i) repaid $15.0 million in principal under the Financing Agreement on such date, plus a 5.0% prepayment fee, (ii) agreed to repay an additional $35.0 million in principal by no later than March 31, 2021, plus a 5.0% prepayment fee, and (iii) agreed to make additional principal repayments as follows: (x) $5.0 million on each of March 31, 2022, June 30, 2022 and September 30, 2022; (y) $10.0 million on each of December 31, 2022 and March 31, 2023; and (z) $41.25 million on each of June 30, 2023, September 30, 2023, December 31, 2023 and March 31, 2024, plus the prepayment fees described in the following sentence. In connection with Amendment No. 8, the prepayment fees on principal amounts being prepaid under the Financing Agreement were revised as follows: (i) 30.0% of the principal amount being repaid through March 31, 2022 (excluding the scheduled $5.0 million principal repayment on such date, which is subject to a 5.0% prepayment fee); (ii) 5.0% of the principal amount being repaid from April 1, 2022 through March 31, 2023; (iii) 3.0% of the principal amount being repaid from April 1, 2023 through March 31, 2024; and (iv) thereafter, none, in each case subject to certain limited exceptions, including with respect to a repayment in full of the obligations under the Financing Agreement. The foregoing summary of Amendment No. 8 does not purport to be complete and is subject to, and qualified in its entirety by, the full text of Amendment No. 8, a copy of which is filed as Exhibit 10.25 to this Annual Report on Form 10-K and is incorporated herein by reference.

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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 2021 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 2021 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 2021 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 2021 Annual Meeting of Stockholders.

Item 14. Principal Accountant 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 2021 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
2.1	July 6, 2009	Agreement and Plan of Reorganization among Croff Enterprises, Inc., AMHN Acquisition Corp., America's Minority Health Network, Inc., and the Major Shareholders [1]
2.2	June 11, 2010	Agreement and Plan of Reorganization among AMHN, Inc., SHN Acquisition Corp., Spectrum Health Network, Inc., and the Sole Shareholder of Spectrum Health Network, Inc. [2]
2.3	October 25, 2007	Croff Enterprises, Inc. Plan of Corporate Division and Reorganization [3]
2.4	July 18, 2011	Agreement and Plan of Merger among VitaMedMD, LLC, AMHN, Inc., and VitaMed Acquisition, LLC [4]
3.1	July 20, 2010	Articles of Conversion of AMHN, Inc. filed in the State of Nevada[5]
3.2	July 20, 2010	Articles of Incorporation of AMHN, Inc. filed in the State of Nevada[5]
3.3	n/a	Composite Amended and Restated Articles of Incorporation of the Company, as amended [6]
3.4	n/a	Bylaws of AMHN, Inc. [7]
3.5	December 17, 2015	First Amendment to Bylaws of the Company [8]
4.1	n/a	Form of Certificate of Common Stock [9]
4.2	n/a	Description of Securities of the Company [10]
10.1	n/a	Form of Common Stock Purchase Warrant [11]
10.2*	n/a	Form of Non-Qualified Stock Option Agreement [11]
10.3*	n/a	TherapeuticsMD, Inc. 2019 Stock Incentive Plan [12]
10.4*	n/a	Amended and Restated 2012 Stock Incentive Plan [13]
10.5*	n/a	2009 Long Term Incentive Compensation Plan, as amended [14]
10.6*	n/a	TherapeuticsMD, Inc. 2020 Employee Stock Purchase Plan [15]
10.7	October 23, 2011	Common Stock Purchase Warrant to Lang Naturals, Inc. [16]
10.8	February 24, 2012	Form of Common Stock Purchase Warrant [17]
10.9	January 31, 2013	Common Stock Purchase Warrant, issued to Plato & Associates, LLC [18]
10.10	August 5, 2020	Form of Warrant to Purchase Common Stock [6]
10.11	November 8, 2020	Amendment to Company Warrant issued by the Company to the Subscribers party to that certain Subscription Agreement, dated as of August 5, 2020 [19]
10.12†	January 13, 2021	Second Amendment to Company Warrant issued by the Company to the Subscribers party to that certain Subscription Agreement, dated as of August 5, 2020
10.13†	October 4, 2011	Warrant issued by the Company to Robert Finizio
10.14†	February 18, 2021	Amendment to Warrant issued by the Company to Robert Finizio
10.15†	October 4, 2011	Warrant issued by the Company to John C.K. Milligan, IV
10.16†	February 20, 2021	Amendment to Warrant issued by the Company to John C.K. Milligan, IV
10.17***	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 [20]
10.18	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[6]
10.19	April 17, 2020	Amendment No. 2 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[6]
10.20	May 1, 2020	Amendment No. 3 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[6]
10.21	May 13, 2020	Amendment No. 4 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[6]
10.22	August 5, 2020	Amendment No. 5 to the Financing Agreement, by and among TherapeuticsMD, Inc., VitaMedMD, LLC, BocagreenMD, Inc., VitaCare Prescription Services, Inc., Sixth Street Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC[6]
10.23	November 8, 2020	Amendment No. 6 to the Financing Agreement, by and among TherapeuticsMD, Inc., VitaMedMD, LLC, BocagreenMD, Inc., VitaCare Prescription Services, Inc., Sixth Street Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC[19]
10.24†	January 13, 2021	Amendment No. 7 to the Financing Agreement, by and among TherapeuticsMD, Inc., VitaMedMD, LLC, BocagreenMD, Inc., VitaCare Prescription Services, Inc., Sixth Street Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC
10.25***†	March 1, 2021	Amendment No. 8 to the Financing Agreement, by and among TherapeuticsMD, Inc., VitaMedMD, LLC, BocagreenMD, Inc., VitaCare Prescription Services, Inc., Sixth Street Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC
10.26	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. [20]

10.27	August 5, 2020	Subscription Agreement, by and among TherapeuticsMD, Inc. and the Subscribers identified on the Schedule of Subscribers attached thereto [(6)]
10.28***	September 28, 2018	Commercial Supply Agreement by and between TherapeuticsMD, Inc. and QPharma AB [(21)]
10.29**	April 20, 2016	Commercial Supply Agreement by and between TherapeuticsMD, Inc. and Catalent Pharma Solutions, LLC [(22)]
10.30***	September 29, 2020	Amendment No. 2 to the Commercial Supply Agreement, between TherapeuticsMD, Inc. and Catalent Pharma Solutions, LLC [(19)]
10.31**	June 24, 2016	Softgel Commercial Supply Agreement by and between TherapeuticsMD, Inc. and Catalent Pharma Solutions, LLC [(23)]
10.32***	December 1, 2017	Amendment No. 1 to the Softgel Commercial Supply Agreement, between TherapeuticsMD, Inc. and Catalent Pharma Solutions, LLC [(19)]
10.33***	September 29, 2020	Amendment No. 2 to the Softgel Commercial Supply Agreement, between TherapeuticsMD, Inc. and Catalent Pharma Solutions, LLC [(19)]
10.34**	July 30, 2018	Population Council License Agreement by and between TherapeuticsMD, Inc. and The Population Council, Inc. [(24)]
10.35*	May 8, 2013	Agreement to Forfeit Non-Qualified Stock Options between the Company and Robert G. Finizio [(25)]
10.36***	October 5, 2018	Lease by and between 951 Yamato Acquisition Company, LLC and TherapeuticsMD, Inc. [(26)]
10.37*	November 24, 2020	Amended and Restated Employment Agreement between the Company and Robert G. Finizio [(27)]
10.38*	November 24, 2020	Amended and Restated Employment Agreement between the Company and Michael Donegan [(27)]
10.39*	November 24, 2020	Amended and Restated Employment Agreement between the Company and John C.K. Milligan, IV [(27)]
10.40*	June 1, 2020	Employment Agreement between the Company and James C. D'Arecca [(6)]
10.41*†	October 30, 2019	Employment Agreement between the Company and Edward J. Borkowski
10.42*†	November 22, 2019	Amendment to Employment Agreement between the Company and Edward J. Borkowski
10.43***	June 6, 2019	License and Supply Agreement, by and between TherapeuticsMD, Inc. and Theramex HQ UK Limited [(20)]
10.44*	n/a	Form of Indemnification Agreement between TherapeuticsMD, Inc. and each of its executive officers and directors. [(19)]
10.45	November 27, 2020	Controlled Equity Offering[SM] Sales Agreement, dated November 27, 2020, by and between TherapeuticsMD, Inc. and Cantor Fitzgerald & Co. [(27)]
21.1	n/a	Subsidiaries of the Company[(10)]
23.1††	March 3, 2021	Consent of Grant Thornton LLP
31.1††	March 3, 2021	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities Exchange Act of 1934, as amended
31.2††	March 3, 2021	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities Exchange Act of 1934, as amended
32.1††	March 3, 2021	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2††	March 3, 2021	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS†	n/a	XBRL Instance Document – 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, 2020 filed with the Commission on August 7, 2020 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 10-K for the year ended December 31, 2019 filed with the Commission on February 24, 2020 and incorporated herein by reference (SEC File No. 001-00100).
(11) 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).
(12) 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).
(13) 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).
(14) 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).
(15) Filed as an appendix to the Definitive Proxy Statement filed with the Commission on May 4, 2020 and incorporated herein by reference (SEC File No. 000-00100).
(16) 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).
(17) 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).
(18) 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).
(19) Filed as an exhibit to Form 10-Q filed with the Commission on November 9, 2020 and incorporated herein by reference (SEC File No. 000-00100).
(20) 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).
(21) 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).
(22) 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).
(23) 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).
(24) 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).
(25) 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).
(26) 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).
(27) Filed as an exhibit to Form 8-K filed with the Commission on November 27, 2020 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: March 3, 2021

THERAPEUTICSMD, INC.

/s/ Robert G. Finizio
Robert G. Finizio
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated.

Signature	Capacity	Date
/s/ Robert G. Finizio Robert G. Finizio	Chief Executive Officer, Director (Principal Executive Officer)	March 3, 2021
/s/ John C.K. Milligan, IV John C.K. Milligan, IV	President and Secretary	March 3, 2021
/s/ James C. D'Arecca James C. D'Arecca	Chief Financial Officer (Principal Financial Officer)	March 3, 2021
/s/ Michael Donegan Michael Donegan	Chief Accounting Officer (Principal Accounting Officer)	March 3, 2021
/s/ Tommy G. Thompson Tommy G. Thompson	Chairman	March 3, 2021
/s/ Paul M. Bisaro Paul M. Bisaro	Director	March 3, 2021
/s/ J. Martin Carroll J. Martin Carroll	Director	March 3, 2021
/s/ Cooper C. Collins Cooper C. Collins	Director	March 3, 2021
/s/ Karen L. Ling Karen L. Ling	Director	March 3, 2021
/s/ Jules A. Musing Jules A. Musing	Director	March 3, 2021
/s/ Gail K. Naughton, Ph.D. Gail K. Naughton, Ph.D.	Director	March 3, 2021
/s/ Angus C. Russell Angus C. Russell	Director	March 3, 2021

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

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, 2020 and 2019, the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical audit matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

<u>Calculation of variable consideration related to sales deductions</u>

As described further in Note 2 to the 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 was 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 level 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 evaluated the design and tested the operating effectiveness of controls over 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 calculation.

- 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 information related to coupon and rebate settlements. We used historical sales and return data in developing our independent expectations and in 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 vouching a sample of transactions settled during the year to source documentation.

<u>Forecasted debt covenant compliance and going concern</u>

As described further in Note 2 to the consolidated financial statements, the Company's Financing Agreement contains covenants that, among other items, require the Company to maintain a minimum cash balance and meet certain minimum quarterly product revenue requirements. The principal assumptions used in management's cash flow and product net revenue analyses used to estimate future covenant compliance consisted of the forecasts related to revenue growth, gross profit margins, and sales and marketing expenses. We identified the evaluation of management's forecasted debt covenant compliance and going concern analysis as a critical audit matter.

The principal considerations for our determination that the evaluation of management's forecasted debt covenant compliance and going concern analysis was a critical audit matter are the significant judgment by management when evaluating the uncertainty related to the Company's forecasts and a high degree of auditor judgment in evaluating management's forecasts for at least the next twelve months.

Our audit procedures related to the evaluation of management's forecasted debt covenant compliance and going concern analysis included the following, among others, (i) testing management's process for forecasting financial results for one year after the date the financial statements are issued; and (ii) testing the completeness and accuracy of underlying data used in the forecast; and (iii) evaluation of management's covenant compliance assessment and their disclosure in the consolidated financial statements regarding having the ability of the Company to continue to maintain liquidity and meet the Company's financial covenants for at least the next twelve months.

/s/ GRANT THORNTON LLP

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

Miami, Florida
March 3, 2021

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2020	December 31, 2019
ASSETS		
Current Assets:		
Cash	$ 80,485,784	$ 160,829,713
Accounts receivable, net of allowance for doubtful accounts of $1,117,854 and $904,040, respectively	32,381,701	24,395,958
Inventory	7,993,087	11,860,716
Other current assets	7,543,397	11,329,793
Total current assets	128,403,969	208,416,180
Fixed assets, net	1,942,224	2,507,775
Other Assets:		
License rights, net	36,196,916	39,221,308
Intangible assets, net	5,247,723	5,258,211
Right of use assets	9,565,700	10,109,154
Other assets	253,121	473,009
Total other assets	51,263,460	55,061,682
Total assets	$ 181,609,653	$ 265,985,637
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current Liabilities:		
Accounts payable	$ 21,068,327	$ 19,181,212
Other current liabilities	38,169,869	33,823,613
Total current liabilities	59,238,196	53,004,825
Long-Term Liabilities:		
Long-term debt	237,697,531	194,634,643
Operating lease liability	8,675,477	9,145,049
Total long-term liabilities	246,373,008	203,779,692
Total liabilities	305,611,204	256,784,517
Commitments and Contingencies - See Note 14		
Stockholders' (Deficit) Equity:		
Preferred stock - par value $0.001; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock - par value $0.001; 600,000,000 and 350,000,000 shares authorized: 299,765,396 and 271,177,076 issued and outstanding, respectively	299,765	271,177
Additional paid-in capital	754,644,100	704,351,222
Accumulated deficit	(878,945,416)	(695,421,279)
Total stockholders' (deficit) equity	(124,001,551)	9,201,120
Total liabilities and stockholders' (deficit) equity	$ 181,609,653	$ 265,985,637

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2020	2019	2018
Product revenues, net	$ 62,872,280	$ 34,140,537	$ 16,099,460
License revenue	2,000,000	15,506,400	—
Total revenue, net	64,872,280	49,646,937	16,099,460
Cost of goods sold	15,974,977	6,334,585	2,737,652
Gross profit	48,897,303	43,312,352	13,361,808
Operating expenses:			
Sales, general, and administrative	192,963,967	174,112,612	115,988,954
Research and development	10,431,907	19,792,212	27,299,138
Depreciation and amortization	1,042,170	612,786	293,886
Total operating expenses	204,438,044	194,517,610	143,581,978
Operating loss	(155,540,741)	(151,205,258)	(130,220,170)
Other (expense) income			
Loss on extinguishment of debt	—	(10,057,632)	—
Miscellaneous income	597,647	2,500,106	2,280,844
Interest expense	(28,581,043)	(17,382,215)	(4,677,834)
Total other expense	(27,983,396)	(24,939,741)	(2,396,990)
Loss before income taxes	(183,524,137)	(176,144,999)	(132,617,160)
Provision for income taxes	—	—	—
Net loss	$ (183,524,137)	$ (176,144,999)	$ (132,617,160)
Loss per share, basic and diluted:			
Net loss per share, basic and diluted	$ (0.67)	$ (0.72)	$ (0.59)
Weighted average number of common shares outstanding, basic and diluted	275,648,552	246,353,318	225,026,300

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2020, 2019 AND 2018

	Common Stock		Additional Paid in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
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 and warrants, 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	271,177,076	271,177	704,351,222	(695,421,279)	9,201,120
Shares issued in offerings, net of cost	26,953,125	26,953	31,675,682	—	31,702,635
Shares issued for exercise of options and warrants, net	1,182,195	1,182	270,496	—	271,678
Issuance of shares from release of restricted stock	453,000	453	(453)	—	—
Warrant granted in relation to Financing Agreement	—	—	7,668,161	—	7,668,161
Share-based compensation	—	—	10,678,992	—	10,678,992
Net loss	—	—	—	(183,524,137)	(183,524,137)
Balance, December 31, 2020	299,765,396	$ 299,765	$ 754,644,100	$ (878,945,416)	$ (124,001,551)

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,		
	2020	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (183,524,137)	$ (176,144,999)	$ (132,617,160)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of fixed assets	772,624	415,193	181,412
Amortization of intangible assets	269,546	197,593	112,474
Write off of patent and trademark cost	1,131,776	78,864	—
Write off of deferred financing fees	275,379	—	—
Non-cash operating lease expense	1,405,443	1,062,318	—
Provision for doubtful accounts	213,814	307,438	216,022
Lease impairment	136,832	—	—
Inventory charge	7,204,818	—	—
Loss of extinguishment of debt	—	10,057,632	—
Share-based compensation	10,678,992	10,693,662	8,661,967
Amortization of intellectual property license fee	3,024,391	778,692	—
Amortization of deferred financing costs	2,256,429	856,302	269,859
Changes in operating assets and liabilities:			
Accounts receivable	(8,199,558)	(13,639,575)	(6,951,041)
Inventory	(3,337,189)	(8,593,046)	(1,782,312)
Other assets	3,429,443	(1,880,048)	(2,657,190)
Accounts payable	1,887,115	(3,562,629)	18,646,241
Accrued expenses and other liabilities	2,903,947	13,675,008	9,107,947
Net cash used in operating activities	(159,470,335)	(165,697,595)	(106,811,781)
CASH FLOWS FROM INVESTING ACTIVITIES			
Payment for intellectual property license	—	(20,000,000)	(20,000,000)
Patent costs	(1,390,834)	(1,441,989)	(1,105,407)
Purchase of fixed assets	(207,073)	(2,450,285)	(217,040)
Payment of security deposit	—	(20,420)	(175,410)
Net cash used in investing activities	(1,597,907)	(23,912,694)	(21,497,857)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from exercise of options and warrants	271,678	108,656	1,666,208
Proceeds from sale of common stock, net of costs	31,702,635	77,031,258	89,907,797
Proceeds from Financing Agreement	50,000,000	200,000,000	—
Proceeds from Credit Agreement	—	—	75,000,000
Payment of deferred financing fees	(1,250,000)	(6,652,270)	(3,786,918)
Repayment of Credit Agreement	—	(81,660,719)	—
Net cash provided by financing activities	80,724,313	188,826,925	162,787,087
(Decrease) increase in cash	(80,343,929)	(783,364)	34,477,449
Cash, beginning of period	160,829,713	161,613,077	127,135,628
Cash, end of period	$ 80,485,784	$ 160,829,713	$ 161,613,077
Supplemental disclosure of cash flow information			
Interest paid	$ 25,849,236	$ 17,787,903	$ 1,890,166
Non-cash investing activity			
Warrant granted in relation to Financing Agreement	$ 7,668,161	$ —	$ —

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

NOTE 1 – THE COMPANY

TherapeuticsMD, Inc., a Nevada corporation, or TherapeuticsMD or the Company, has three wholly owned subsidiaries, vitaMedMD, LLC, a Delaware limited liability company, or vitaMed; BocaGreenMD, Inc., a Nevada corporation, or BocaGreen; and VitaCare Prescription Services, Inc., a Florida corporation, or VitaCare. Unless the context otherwise requires, TherapeuticsMD, vitaMed, BocaGreen, and VitaCare collectively are sometimes referred to as “our company,” “we,” “our,” or “us.” TherapeuticsMD®, vitaMedMD®, BocaGreenMD®, IMVEXXY®, BIJUVA® and ANNOVERA® are registered trademarks 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 17ß-estradiol and bio-identical progesterone in a single, oral softgel capsule, for the treatment of moderate-to-severe vasomotor symptoms, or VMS, due to menopause in women with a uterus. In October 2019, we began a test and learn market introduction for our FDA-approved product ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system), the first and only annual patient-controlled, procedure-free, reversible prescription contraceptive option for women. Although we expected to commence the full commercial launch of ANNOVERA in the first quarter of 2020, as a result of the uncertainty surrounding the COVID-19 pandemic, we paused the commercial launch of ANNOVERA and deferred sales and marketing initiatives into subsequent quarters as the pandemic began to negatively affect our revenue growth. We resumed the commercial launch of ANNOVERA on July 1, 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.

Risks and Uncertainties

We continue to be subject to risks and uncertainties as a result of the COVID-19 pandemic. The extent of the future impact of the COVID-19 pandemic on our business continues to be highly uncertain and difficult to predict. We continue to provide an uninterrupted supply of our portfolio of products for patients. We have sufficient inventory of finished product to meet anticipated demand in the near future. Additionally, we currently do not foresee any interruption in our ability to continue to manufacture additional product to be used beyond this period and have sufficient active pharmaceutical ingredients on hand for the continued manufacture of our products. During the year ended December 31, 2020, we recorded an inventory charge of $7,204,818 which was primarily related to BIJUVA and resulted from the impact of the COVID-19 pandemic on our business, which decreased demand for our products.

Since the early phase of the COVID-19 pandemic, we have been using substantial virtual options to ensure business continuity. Our VitaCare Prescription Services patient model assists patients in obtaining easy and convenient access to their prescriptions for products at a retail pharmacy of their choice, including via home delivery retail pharmacy options. We have also partnered with independent community pharmacies and multiple third-party online pharmacies and telemedicine providers that focus on contraception or menopause to ensure patients have real-time access to both diagnosis and treatment. We continue to support prescribers’ needs with samples and product materials through our sales force. If access is restricted, we have mailing options in place for these materials. We also have business continuity plans and infrastructure in place that allows for live virtual e-detailing of our products.

As part of our response to the COVID-19 pandemic, we implemented measures to reduce marketing expenses for 2020. We also implemented cost saving measures, which included negotiating lower fees or suspending services from third party vendors; implementing a company-wide hiring restriction; delaying or cancelling non-critical information technology projects; and eliminating non-essential travel, entertainment, meeting, and event expenses.

The full impact of the COVID-19 pandemic continues to evolve. However, we remain committed to the execution of our corporate goals, despite the ongoing COVID-19 pandemic, as demonstrated in part by the increase in product revenue throughout 2020. As of the date of issuance of these consolidated financial statements, the future extent to which the COVID-19 pandemic may continue to materially impact our financial condition, liquidity, or results of operations remains uncertain. We are continuing to assess the effect the COVID-19 pandemic on our operations by monitoring the spread of COVID-19 and the various actions implemented to combat the pandemic throughout the world. Even after the COVID-19 pandemic has subsided, we may continue to experience adverse impacts to our business as a result of any economic recession or depression that has occurred or may occur in the future.

While we currently believe that our COVID-19 contingency plan has the ability to mitigate the effect of the COVID-19 pandemic on our business, the severity of the impact of the COVID-19 pandemic on our business will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic, the duration of "social distancing" orders, the ability of our sales force to access healthcare providers to promote our products, increases in unemployment, which could reduce access to commercial health insurance for our patients, thus limiting payer coverage for our products, and the impact of the pandemic on our global supply chain, all of which are uncertain. Our future results of operations and liquidity could be materially adversely affected by delays in payments of outstanding receivable amounts beyond normal payment terms, supply chain disruptions, uncertain demand, and the impact of any initiatives or programs that we may undertake to address financial and operations challenges that we may face.

Liquidity

As of the filing date of this Annual Report on Form 10-K, our cash balance was above the required balance by the Financing Agreement (as defined in Note 8 - Debt). On November 8, 2020, we and our subsidiaries entered into Amendment No. 6 to the Financing Agreement, or Amendment No. 6, with the Administrative Agent (as defined in Note 8 - Debt) and the lenders party thereto, pursuant to which we temporarily lowered the minimum required cash balance from $60 million to $45 million through December 31, 2020. After December 31, 2020, the minimum cash balance reverted to $60 million. Based on our current projections, and recent equity financings, we anticipate that we will remain in compliance with the minimum cash balance covenant for the next twelve months from the issuance of these financial statements. In addition, we have reviewed numerous potential scenarios in connection with the impact of COVID-19 pandemic on our business and we believe that our existing cash reserves are sufficient to meet our cash needs arising in the ordinary course of business for the next twelve months from the issuance of these financial statements.

However, if we are unsuccessful with the commercialization of IMVEXXY, BIJUVA, or ANNOVERA, if commercialization is delayed, or if the continued impact of the COVID-19 pandemic on our business is worse than we anticipate, our existing cash reserves may be insufficient to maintain compliance with the Financing Agreement covenants or satisfy our liquidity requirements until we are able to successfully commercialize IMVEXXY, BIJUVA, and ANNOVERA. The Financing Agreement also requires us to maintain certain minimum quarterly product net revenue requirements and several other restrictive covenants. On March 1, 2021, we entered into Amendment No. 8 to the Financing Agreement, or Amendment No. 8, pursuant to which, among other amendments, the minimum consolidated net revenue requirements attributable to commercial sales of IMVEXXY, BIJUVA, and ANNOVERA were revised. See Note 8 – Debt – for a description of these covenants. 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. If we are unable to maintain the minimum unrestricted cash balance, achieve any of the total minimum net revenue requirements, or otherwise comply with the covenants of the Financing Agreement, all or a portion of our obligations under the Financing Agreement may be declared immediately due and payable, which would have a material adverse effect on our business, results of operations and financial condition.

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, reasonable supportable forecasts, and existing economic conditions and we record an allowance that presents the net amount expected to be collected. We evaluate trade accounts receivable 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. Our exposure to credit losses may increase if our customers are adversely affected by changes in healthcare laws, coverage, and reimbursement, economic pressures or uncertainty associated with local or global economic recessions, disruption associated with the current COVID-19 pandemic, or other customer-specific factors. Although we have historically not experienced significant credit losses, it is possible that there could be a material adverse impact from potential adjustments of the carrying amount of trade receivables in the future. At December 31, 2020, four different customers represented 25%, 19%, 17% and 11% of our gross accounts receivable. At December 31, 2019, four different customers represented 36%, 21%,16% and 11% of our gross accounts receivable.

The opening balance of the allowance for doubtful accounts is reconciled to the closing balance for expected credit losses as follows:

Allowance for Doubtful Accounts		
Balance - January 1, 2020	$	904,040
Increase in allowance		422,137
Recoveries		(181,514)
Write-offs		(26,809)
Balance - December 31, 2020	$	1,117,854

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, product improvements rendering previous versions obsolete, or decreases in demand for our products.

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.

Inventory Write-Off

We evaluate inventory quarterly for short dated and excess inventory. During the years ended December 31, 2020 and December 31, 2019, we recorded an inventory charge of $7,204,818 and $0, respectively. The charge recorded during the year ended December 31, 2020 was primarily related to BIJUVA and resulted from the impact of the COVID-19 pandemic on our business, which decreased demand for our products.

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.

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, 2020, we had 38 issued domestic, or U.S., patents and 39 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. 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.

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.

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 years ended December 31, 2020 and 2019, we wrote off $1,131,776 and $78,864, respectively, in costs related to trademarks and patents. There was no impairment of intangible assets during the year ended December 31, 2018.

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, 2020 and 2019 (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, 2020 and 2019, we had no assets or liabilities that were valued at fair value on a recurring basis.

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, 2020 and 2019, 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. On January 1, 2020, we began calculating the expected term of our stock-based awards, which represents the period that the stock-based awards are expected to be outstanding. Prior to January 1, 2020, the average expected life of options was 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. In addition, the terms of the Financing Agreement (See Note 8) preclude us from paying dividends, and any future debt agreements may also preclude us from paying dividends. The assumptions used in calculating the fair value of stock-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.

We grant restricted stock units and performance-based stock units for shares of common stock, par value $0.001 per share, or Common Stock, to employees. We value our restricted stock units and our performance-based stock units by reference to our stock price on the date of grant. We recognize compensation expense for restricted stock units based on a straight-line basis over the requisite service period of the entire award. We recognize performance-based restricted stock as compensation expense based on the most likely probability of attaining the prescribed performance and over the requisite service period beginning at its grant date and through the date the performance restricted stock vests. The number of target shares that vest are determined based on the level of attainment of the targets. If a minimum level of performance is attained for the awards, restricted stock is issued based on the level of attainment.

Revenue Recognition

In accordance with ASC 606, *Revenue from Contracts with Customers*, or 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, 2020, our products consisted primarily of prescription vitamins and our FDA-approved products: IMVEXXY, which we began selling during the third quarter of 2018, BIJUVA, which we began selling in the second quarter of 2019, and ANNOVERA, which we began selling in the third quarter of 2019. As a result of the uncertainty surrounding the COVID-19 pandemic, we paused the commercial launch of ANNOVERA in the first quarter of 2020 and deferred sales and marketing initiatives into subsequent quarters. We resumed the commercial launch of ANNOVERA on July 1, 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 product 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 product 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 product revenue would be subject to a significant reversal. We consider all the facts and circumstances associated with both the risk of a product 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. ANNOVERA cannot be returned before the expiration date and expired ANNOVERA can be returned up to 12 months past the expiration date. Our prescription vitamins, IMVEXXY and BIJUVA currently have a shelf life of 24 months from the date of manufacture and ANNOVERA currently has 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 product 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 product 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 product revenue is deferred due to the anticipated return). Return estimates are recorded in 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 revenue at the time the product revenue is recognized. We record distributor fees based on amounts stated in contracts. Rebate and coupon estimates and distributor fees are recorded in other current liabilities on the consolidated balance sheet. We estimate chargebacks based on number of units sold during the period taking into account prices stated in contracts and our historical experience. Estimates related to distributors fees, rebates, coupons and returns are disclosed in Note 7. We provide invoice discounts to our customers for prompt payment. Estimates relating to invoice discounts and chargebacks are deducted from gross product revenue at the time the product revenue is 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. 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 product 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.

Disaggregation of revenue

The following table provides information about disaggregated revenue, net by product mix for the years ended December 31, 2020, 2019, and 2018:

	For the Years Ended December 31,		
	2020	2019	2018
Prescription vitamins	$ 9,767,644	$ 9,885,493	$ 15,041,259
IMVEXXY	27,139,387	16,252,045	1,058,201
BIJUVA	6,353,963	1,836,443	—
ANNOVERA	19,611,286	6,166,556	—
License revenue	2,000,000	15,506,400	—
Net revenue	$ 64,872,280	$ 49,646,937	$ 16,099,460

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 intellectual property is transferred to the customer.

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. We began selling ANNOVERA in a “test and learn” market introduction in the third quarter of 2019. As a result of the uncertainty surrounding the COVID-19 pandemic, we paused the commercial launch of ANNOVERA in the first quarter of 2020 and deferred sales and marketing initiatives into subsequent quarters. We resumed the commercial launch of ANNOVERA on July 1, 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 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 as early as December 2032. The cost is amortized using the straight-line method as the pattern of economic benefit cannot be reliably determined. During the years ended December 31, 2020 and 2019 we recorded $3,024,391 and $778,692, respectively, 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.

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.

License Agreement with Knight Therapeutics Inc.

In July 2018, we entered into the Knight License Agreement 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 paid us $2,000,000 in milestone fees upon the first regulatory approval in Canada for IMVEXXY and BIJUVA in the third quarter of 2020, and is required to pay us 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. 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. As part of the Knight License Agreement, Knight is prohibited from exporting IMVEXXY and BIJUVA to the United States.

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.

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 executive leadership team that is led by the Chief Executive Officer of our Company, who oversees all operations. We do not operate separate lines of business with respect to any of our products and we do not prepare discrete financial information with respect to separate products. All product sales are derived from sales in the United States. Accordingly, we view our business as one reportable operating segment.

Shipping and Handling Costs

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

Advertising Costs

We expense advertising costs when incurred. Advertising costs were $35,799,313, $9,045,571 and $1,682,746 during the years ended December 31, 2020, 2019, and 2018, 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 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 units 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,		
	2020	2019	2018
Stock options	23,781,930	25,030,234	20,872,824
Warrants	6,534,687	1,832,571	3,007,571
Performance stock units	2,403,951	—	—
Restricted stock units	7,061,024	1,240,000	1,040,000
	39,781,592	28,102,805	24,920,395

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 March 2020, the FASB issued Accounting Standards Update, or ASU, 2020-04: Reference Rate Reform (Topic 848) Facilitation of the Effects of Reference Rate Reform on Financial Reporting. This update provides optional guidance for a limited period of time to ease potential accounting impacts associated with transitioning away from reference rates that are expected to be discontinued, such as London Interbank Offered Rate (LIBOR). This ASU includes practical expedients for contract modifications due to reference rate reform. Generally, contract modifications related to reference rate reform may be considered an event that does not require remeasurement or reassessment of a previous accounting determination at the modification date. This ASU is effective March 12, 2020 through December 31, 2022. Our debt agreements currently include the use of alternate rates when LIBOR is not available. We do not expect the change from LIBOR to an alternate rate will have a material impact to our financial statements and, to the extent we enter into modifications of agreements that are impacted by the LIBOR phase-out, we will apply such guidance to those contract modifications.

In August 2018, the FASB issued 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 adopted this standard on January 1, 2020, and the adoption did not have a material effect on our disclosures.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments. The amendments in this update require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected based on historical experience, current conditions, and reasonable supportable forecasts. The amendments in this update are effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted no sooner than the first quarter of 2019. A modified retrospective approach is required for all investments, except debt securities for which an other-than-temporary impairment had been recognized prior to the effective date, which will require a prospective transition approach and should be applied either prospectively or retrospectively depending on the nature of the disclosure. The adoption of ASU 2016-13 requires expanded quantitative and qualitative disclosures about the Company’s expected credit losses. Effective January 1, 2020, we adopted ASU 2016-13 under a modified retrospective approach for all financial assets measured at amortized cost. There was no adjustment recorded for the cumulative effect of adopting ASU 2016-13. The adoption expanded disclosures about our credit losses.

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, 2020	December 31, 2019
Finished products	$3,350,580	$ 4,976,910
Work in process	219,918	1,182,059
Raw materials	4,422,589	5,701,747
TOTAL INVENTORY	$7,993,087	$11,860,716

NOTE 4 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	December 31, 2020	December 31, 2019
Prepaid sales and marketing costs	$ 4,308	$ 1,583,698
Debt financing fees on undrawn tranches (Note 8)	—	550,757
Prepaid insurance	2,568,269	1,812,135
Prepaid manufacturing	1,331,100	2,595,721
Other prepaid costs	3,639,720	4,787,482
TOTAL OTHER CURRENT ASSETS	$ 7,543,397	$ 11,329,793

NOTE 5 – FIXED ASSETS, NET

Fixed assets, net consist of the following:

	December 31, 2020	December 31, 2019
Accounting system	$ 411,550	$ 301,096
Equipment	1,704,931	1,619,646
Furniture and fixtures	1,406,858	1,406,858
Computer hardware	80,211	80,211
Leasehold improvements	80,121	68,788
TOTAL FIXED ASSETS	3,683,671	3,476,599
Accumulated depreciation	(1,741,447)	(968,824)
TOTAL FIXED ASSETS, NET	$ 1,942,224	$ 2,507,775

Depreciation expense for the years ended December 31, 2020, 2019, and 2018 was $772,624, $415,193, and $181,412, 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, 2020 and 2019:

	December 31, 2020			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizable intangible assets:				
Approved hormone therapy drug candidate patents	$ 4,044,552	$ (748,627)	$ 3,295,925	12
Hormone therapy drug candidate patents (pending)	1,628,457	—	1,628,457	n/a
Non-amortizable intangible assets:				
Multiple trademarks	323,341	—	323,341	indefinite
TOTAL	$ 5,996,350	$ (748,627)	$ 5,247,723	

	December 31, 2019			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
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	$ 5,737,194	$ (478,983)	$ 5,258,211	

We capitalize external costs, consisting primarily of legal costs, related to securing our patents and trademarks. Once a patent is granted, we amortize the approved hormone therapy drug candidate patents using the straight-line method over the estimated useful life of approximately 20 years, which is the life of intellectual property patents. If the patent is not granted, we write-off any capitalized patent costs at that time. Trademarks are perpetual and are not amortized. During the years ended December 31, 2020 and 2019, we wrote off $1,131,776 and $78,864, respectively, in costs related to trademarks and patents. There was no impairment of intangible assets during the year ended December 31, 2018.

As of December 31, 2020, we had 38 issued domestic patents and 39 issued foreign patents, including:

- 15 domestic patents and nine 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;
- 12 domestic patents (ten utility and two design) and 18 foreign patents (eight 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;
- One domestic utility patent and eight 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 a pending patent application with respect to our transdermal-patch candidates in Brazil;
- 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;
- 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 formulations containing progesterone in the U.S., Australia, Canada, Europe, and Mexico; and
- 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 $269,546, $197,593, and $112,474 for the years ended December 31, 2020, 2019, and 2018, 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	
2021	$	274,669
2022	$	274,669
2023	$	274,669
2024	$	274,669
2025	$	274,669

NOTE 7– OTHER CURRENT LIABILITIES

Other current liabilities consist of the following:

	December 31,			
	2020		2019	
Accrued payroll, bonuses and commission costs	$	8,758,073	$	8,040,278
Allowance for coupons and returns		6,770,206		10,316,298
Accrued sales and marketing costs		227,500		3,285,662
Accrued compensated absences		2,353,996		1,463,878
Allowance for wholesale distributor fees		2,632,432		2,347,122
Accrued legal and accounting expense		898,568		422,336
Accrued research and development		925,314		1,049,603
Operating lease liability		2,253,994		1,501,539
Accrued rebates		11,010,588		3,916,672
Other accrued expenses		2,339,198		1,480,225
TOTAL OTHER CURRENT LIABILITIES	$	38,169,869	$	33,823,613

NOTE 8 – DEBT

On April 24, 2019, we entered into a Financing Agreement, as amended, or the Financing Agreement, with Sixth Street 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 provided us with up to a $300,000,000 first lien secured term loan credit facility, or the Facility. The Facility provided 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 following our achievement of more than $11,000,000 in net revenues from IMVEXXY, BIJUVA, and ANNOVERA for the fourth quarter of 2019 and (iii) $50,000,000 was previously available to us in the Administrative Agent's sole and absolute discretion either contemporaneously with the delivery of our financial statements for the quarter ended June 30, 2020 or at such earlier date as the Administrative Agent may have consented to. Subsequent to the pause in the successful full launch of ANNOVERA caused by the COVID-19 pandemic, the undrawn $50,000,000 tranche under the Financing Agreement is no longer available. 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. Prior to entering into Amendment No. 8, the outstanding principal amount of the Facility was payable in four equal quarterly installments beginning on June 30, 2023, with the Facility maturing on March 31, 2024. In connection with Amendment No. 8 we, among other things, (i) repaid $15.0 million in principal under the Financing Agreement on such date, plus a 5.0% prepayment fee, (ii) agreed to repay an additional $35.0 million in principal by no later than March 31, 2021, plus a 5.0% prepayment fee, and (iii) agreed to make additional principal repayments as follows: (x) $5.0 million on each of March 31, 2022, June 30, 2022 and September 30, 2022; (y) $10.0 million on each of December 31, 2022 and March 31, 2023; and (z) $41.25 million on each of June 30, 2023, September 30, 2023, December 31, 2023 and March 31, 2024, plus the prepayment fees described in the following sentence. 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, which was revised in connection with Amendment No. 8, of (i) 30.0% of the principal amount being repaid through March 31, 2022 (excluding the scheduled $5.0 million principal repayment on such date, which is subject to a 5.0% prepayment fee); (ii) 5.0% of the principal amount being repaid from April 1, 2022 through March 31, 2023; (iii) 3.0% of the principal amount being repaid from April 1, 2023 through March 31, 2024; and (iv) thereafter, none, in each case subject to certain limited exceptions, including with respect to a repayment in full of the obligations under the Financing Agreement. 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 were required to pay such a facility fee in connection with 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 $60,000,000, 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 ended December 31, 2020. Pursuant to Amendment No. 8, the minimum consolidated net revenue requirements attributable to commercial sales of IMVEXXY, BIJUVA, and ANNOVERA were revised to (i) $17.0 million, $20.0 million, $23.0 million, and $26.5 million for the first, second, third, and fourth quarters of 2021, respectively, (ii) $30.0 million, $35.0 million, $40.0 million and $45.0 million for the first, second, third, and fourth quarters of 2022, respectively, (iii) $50.0 million, $55.0 million, $60.0 million and $65.5 million for the first, second, third, and fourth quarters of 2023, respectively, and (iv) $70.0 million for the first quarter of 2024. Pursuant to Amendment No. 6 (as defined below), the minimum required cash balance was lowered to $45 million from November 8, 2020 through December 31, 2020. As of December 31, 2020, we were in compliance with all covenants under the Financing Agreement. The Financing Agreement also includes other representations, warranties, indemnities, restrictions on the payment of dividends, 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. Also pursuant to Amendment No. 8, the Administrative Agent consented to a framework for our potential disposition of our vitaCare prescription services business.

On August 5, 2020, we entered into Amendment No. 5 to the Financing Agreement, or Amendment No. 5. Amendment No. 5 adjusted the covenant in the Financing Agreement regarding our achievement of minimum consolidated net revenue attributable to commercial sales of our IMVEXXY, BIJUVA, and ANNOVERA products to reflect the impact of COVID-19 on our business. The covenant was effective beginning with the fiscal quarter ending December 31, 2020. In connection with Amendment No. 5 and in lieu of a cash amendment fee, we issued to the Administrative Agent and the lenders under the Financing Agreement warrants to purchase an aggregate of 4,752,116 shares of Common Stock with an exercise price of $1.58 per share and a ten-year term, or the Lender Warrants. The Lender Warrants were issued pursuant to an exemption from registration under the Securities Act of 1933, as amended, and no registration rights were issued. The Company concluded that the modification accounting model is applicable to this transaction and recognized the fair value of the warrants as a debt discount.

On November 8, 2020, in connection with entering into Amendment No. 6 to the Financing Agreement, or Amendment No. 6, we amended the Lender Warrants to provide for an adjustment to the exercise price if we conduct certain dilutive issuances prior to December 31, 2020, or if the volume-weighted average price of our Common Stock for the fifteen trading days ending December 31, 2020 is lower than the then-current exercise price. Pursuant to Amendment No. 6, the issuance of Common Stock by the Company in the underwritten public offering at a price per share equal to $1.1856 triggered the automatic reduction in the exercise price of the Lender Warrants from $1.58 to $1.1856.

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 second quarter of 2019. Interest expense for the years ended December 31, 2019 and 2018 related to the Credit Agreement was $1,816,747 and $4,407,975, respectively. 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 the accompanying consolidated financial statements. During the year ended December 31, 2018, we amortized $269,859 of deferred financing fees as interest expense in the accompanying consolidated financial statements.

As of December 31, 2020, we had $250,000,000 in borrowings outstanding under the Financing Agreement, which are classified as long-term debt in the accompanying consolidated financial statements. Since the inception of the Financing Agreement, we have incurred $7,902,270 in deferred financing fees related to the Financing Agreement. Deferred financing fees related to the entire Financing Agreement were allocated pro rata between the funded and unfunded tranches. Allocated deferred financing fees related to the two tranches of borrowings that we received of $7,626,891 have been reflected as debt discount upon each draw and are amortized to interest expense using the effective interest method. In addition, during the third quarter of 2020, we recorded the fair value of the Lender Warrants based on Amendment No. 5 of $7,428,178 as a debt discount, which is being amortized to interest expense using the effective interest method over the term of the Financing Agreement. Based on Amendment No. 6 to the Financing Agreement, we recognized additional value to the debt discount of $239,983, which is being amortized to interest expense using the effective interest method over the term of the Financing Agreement. The public offering in November 2020 triggered the down round provision underlying the warrants granted in August 2020, as modified in November 2020, which was immaterial.

During the third quarter of 2020, we concluded that the undrawn $50,000,000 tranche under the Financing Agreement is no longer available to us. As such, we wrote off $275,379 of deferred financing fees associated with the unfunded tranche, which were previously deferred as assets until such tranche had been drawn.

During the years ended December 31, 2020 and 2019, we amortized $2,256,428 and $736,156, respectively, of deferred financing fees related to the Financing Agreement 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 years ended December 31, 2020 and 2019 was $26,049,236 and $14,709,166, respectively. The overall effective interest rate under the Financing Agreement was approximately 12.5% as of December 31, 2020.

As of December 31, 2020 and 2019, the carrying value of our debt consisted of the following:

	As of December 31,	
	2020	2019
Financing Agreement	$ 250,000,000	$ 200,000,000
Debt discount and financing fees	(12,302,469)	(5,365,357)
TOTAL LONG-TERM DEBT	$ 237,697,531	$ 194,634,643

The following table reflects our aggregate future principal payments under the Financing Agreement for the next five years, as amended by Amendment No. 8:

Year Ending December 31,		
2021	$	50,000,000
2022	$	25,000,000
2023	$	133,750,000
2024	$	41,250,000
2025	$	—

NOTE 9 – STOCKHOLDERS' EQUITY

Preferred Stock

At December 31, 2020, we had 10,000,000 shares of preferred stock, par value $0.001 per share, or Preferred Stock, authorized for issuance, of which no shares of Preferred Stock were issued or outstanding.

Common Stock

At December 31, 2020, we had 600,000,000 shares of Common Stock authorized for issuance, of which 299,765,396 shares of Common Stock were issued and outstanding.

Issuances During 2020

During the year ended December 31, 2020, stock options to purchase an aggregate of 1,182,195 shares of Common Stock were exercised for $271,678 in cash.

On November 10, 2020, we entered into an underwriting agreement with Cantor Fitzgerald & Co., or Cantor Fitzgerald, as underwriter, relating to an underwritten public offering of 23,437,500 shares of Common Stock at a public offering price of $1.1856 per share. We granted to the underwriter an option, exercisable for a period of 30 days, to purchase up to 3,515,625 additional shares of Common Stock, which was exercised in full. The net proceeds the offering were approximately $31,703,000, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. The offering of 23,437,500 shares closed on November 13, 2020 and the offering of 3,515,625 shares closed on November 20, 2020.

In November 2020, we entered into a Controlled Equity Offering[SM] Sales Agreement, or sales agreement, with Cantor Fitzgerald relating to shares of our Common Stock. In accordance with the terms of the sales agreement, we were permitted to offer and sell shares of our Common Stock having an aggregate offering price of up to $50 million from time to time through or to Cantor Fitzgerald, acting as sales agent. Cantor Fitzgerald was entitled to compensation at a fixed commission rate of 3.0% of the aggregate gross sales price per share sold. No shares of Common Stock were sold under the sales agreement during the year ended December 31, 2020. As further described in Note 16 - Subsequent Events, on February 8, 2021, our "at the market" offering with Cantor Fitzgerald terminated following the sale of the maximum $50 million of shares of Common Stock in January 2021 and February 2021 pursuant to the sales agreement.

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.

Warrants to Purchase Common Stock

As of December 31, 2020, we had warrants outstanding to purchase an aggregate of 6,534,687 shares of Common Stock with a weighted-average contractual remaining life of approximately 7.25 years, and exercise prices ranging from $0.24 to $8.20 per share, resulting in a weighted average exercise price of $1.55 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.

In connection with Amendment No. 5 and in lieu of a cash amendment fee, we issued to the Administrative Agent and the lenders under the Financing Agreement the Lender Warrants. The fair value for the Lender Warrants was determined by using the Black-Scholes Model on the date of the grant using a term of ten years, volatility of 68.8%, risk-free interest rate of 0.34% and dividend yield of 0%. The grant date fair value of the warrants was $1.56 per share. The warrants vested upon issuance. We concluded that the modification accounting model is applicable to this warrant issuance and recognized the fair value of the warrants as a debt discount. As a result, the fair value of the Lender Warrants is being amortized to interest expense over the term of the Financing Agreement.

On November 8, 2020, in connection with entering into Amendment No. 6, we amended the Lender Warrants to provide for an adjustment to the exercise price if we conducted certain dilutive issuances prior to December 31, 2020, or if the volume-weighted average price of our Common Stock for the fifteen trading days ending December 31, 2020 was lower than the then-current exercise price. Pursuant to Amendment No. 6, the issuance of the shares of Common Stock in the November 2020 underwritten public offering triggered the automatic reduction in the exercise price of the Warrants from $1.58 to $1.1856. Based on Amendment No. 6 to the Financing Agreement, we recognized additional value to the debt discount of $239,983.

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.

We recorded share-based compensation expense related to warrants previously issued of $26,446, $254,970, and $494,136 for the years ended December 31, 2020, 2019 and 2018, respectively, in the accompanying consolidated financial statements. At December 31, 2020, there was no unrecognized compensation expense remaining related to unvested warrants.

Summary of our Warrant activity during the year ended December 31, 2020:

	Number of Shares Under Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2019	1,832,571	$ 2.62	1.95	$ 2,447,929
Granted	4,752,116	$ 1.19		
Exercised	—	—		—
Expired	—	—		
Cancelled/Forfeited	(50,000)	$ 6.35		
Balance at December 31, 2020	6,534,687	$ 1.55	7.25	$ 1,041,219
Vested and Exercisable at December 31, 2020	6,534,687	$ 1.55	7.25	$ 1,041,219
Unvested at December 31, 2020	—	—	—	—

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, 2020, 2019, and 2018 are set forth in the table below.

	2020	2019	2018
Weighted average exercise price	$ 1.19	$ 5.63	$ 5.16
Weighted average grant date fair value	$ 1.56	$ 3.00	$ 2.79
Risk-free interest rate	0.34%	2.52%	2.36%
Volatility	68.8%	60.8%	62.12%
Term (in years)	10	5	5
Dividend yield	0.00%	0.00%	0.00%

Warrant exercises

During the year ended December 31, 2020, no warrants were exercised.

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.

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, 2020, there were non-qualified stock options to purchase an aggregate of 13,285,205 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, 2020, there were non-qualified stock options to purchase an aggregate of 6,305,974 shares of Common Stock outstanding and an aggregate of 890,000 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, 2020, there were 2,583,565 shares of Common Stock available for issuance under the 2019 Plan, consisting of (i) new shares, (ii) 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) 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, 2020, there were non-qualified stock options to purchase 4,190,751 shares of Common Stock outstanding under the 2019 Plan and an aggregate of 6,171,024 restricted stock units and 2,403,951 performance stock units 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, 2020, 2019, and 2018 are set forth in the table below.

	2020	2019	2018
Weighted average exercise price	$ 1.58	$ 3.10	$ 5.45
Weighted average grant date fair value	$ 0.95	$ 1.82	$ 3.24
Risk-free interest rate	0.34-1.68%	1.64-2.54%	2.38-2.89%
Volatility	63.53-67.92%	61.25-64.49%	59.45-64.04%
Term (in years)	6-6.8	5.5-6.5	5.1-6.25
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, 2020 is as follows:

	Number of Shares Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2019	25,030,234	$ 4.65	5.84	$ 3,668,171
Granted	736,500	$ 1.58		
Exercised	(1,182,195)	$ 0.23		$ 1,738,740
Expired	(386,609)	$ 3.76		
Cancelled/Forfeited	(416,000)	$ 3.80		
Balance at December 31, 2020	23,781,930	$ 4.80	5.20	$ 152,253
Vested and Exercisable at December 31, 2020	19,862,681	$ 5.06	4.59	$ 117,443
Unvested at December 31, 2020	3,919,249	$ 3.53	8.29	$ 34,810

At December 31, 2020, our outstanding options had exercise prices ranging from $0.38 to $8.92 per share. Share-based compensation expense related to options recognized in our results of operations for the years ended December 31, 2020, 2019, and 2018 was approximately $5,235,585, $8,798,707, and $8,091,294, respectively, and it is based on awards vested. At December 31, 2020, total unrecognized estimated compensation expense related to unvested options was approximately $5,238,000, which may be adjusted for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 1.9 years. No tax benefit was realized due to a continued pattern of operating losses.

Restricted Stock

Restricted stock units 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.

Performance stock units will vest if certain performance targets are achieved. If minimum performance thresholds are achieved, each award will convert into Common Stock at a defined ratio depending on the degree of achievement of the performance target designated by each individual award. If minimum performance thresholds are not achieved, then no shares will be issued. We recognize performance-based restricted stock as compensation expense based on the most likely probability of attaining the prescribed performance and over the requisite service period beginning at its grant date and through the date the restricted stock vests. The expected levels of achievement are reassessed over the requisite service periods and, to the extent that the expected levels of achievement change, stock-based compensation is adjusted and recorded on the consolidated statements of income and the remaining unrecognized stock-based compensation is recognized over the remaining requisite service period.

During the years ended December 31, 2020, 2019 and 2018 we recorded $5,399,472, $1,628,407 and $73,132, respectively, in share-based compensation expense related to restricted stock units and performance stock units. As of December 31, 2020, we recognized performance-based compensation expense using our assessment of the most likely probability of attaining quarterly EBITDA break-even which would result in vesting 1.5 times the base number of performance stock units. At December 31, 2020, total unrecognized estimated compensation expense related to unvested restricted stock units and performance stock units was approximately $9,989,000, which may be adjusted if certain performance targets are achieved or for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 1.6 years.

Schedule of restricted stock units and performance stock units

	Restricted Stock Units		Performance Stock Units	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Balance at December 31, 2019	1,240,000	$ 3.56	—	$ —
Granted	6,152,818	$ 1.39	2,585,745	$ 1.08
Vested/Released	(301,500)	$ 1.78	(151,500)	$ 1.14
Forfeited	(30,294)	$ 1.07	(30,294)	$ 1.07
Balance at December 31, 2020	7,061,024	$ 1.76	2,403,951*	$ 1.08

* The number of performance stock units (PSUs) represents the base number of PSUs that may vest. The actual number of PSUs that will vest will be between zero and two times the base number of PSUs depending on the Company’s achievement of break-even quarterly EBITDA.

Employee Stock Purchase Plan

On June 18, 2020, our stockholders approved the TherapeuticsMD, Inc. 2020 Employee Stock Purchase Plan, or the ESPP, which reserved 5,400,000 shares of Common Stock for purchase. The ESPP permits eligible employee participants to purchase Common Stock at a price per share which is equal to 85% of the lesser of (a) the fair market value of the shares on the offering date of the offering period or (b) the fair market value of the shares on the purchase date. During the year ended December 31, 2020, no shares were issued under the ESPP. We recorded $17,489 of non-cash compensation expense related to the ESPP during the year ended December 31, 2020.

NOTE 10 – EMPLOYEE BENEFIT PLAN

The Company maintains a voluntary defined contribution 401(k) plan covering all eligible employees as defined in the plan documents. The plan provides for discretionary matching contribution, which is equal to up to four percent of each eligible contributing participant’s elective deferral not to exceed $2,000 per year. Employees who elect to participate in the plan are generally fully vested in any existing matching contribution after five years of service with the Company. Contributions by the Company under the plan amounted to approximately $487,000 and $403,000 for the years ended December 31, 2020 and 2019, respectively.

NOTE 11 – INCOME TAXES

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

	2020	2019	2018
United States	$ (183,524,137)	$ (176,144,999)	$ (132,617,160)
Total	$ (183,524,137)	$ (177,144,999)	$ (132,617,160)

For the years ended December 31, 2020, 2019, and 2018, there was no provision for income taxes, current or deferred. At December 31, 2020, we had a federal net operating loss carry forward of approximately $761,701,546 available to offset future taxable income through 2038. 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 $422,926,214 can be carried forward indefinitely.

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

	2020	2019	2018
Federal statutory tax rate	21.0%	21.0%	21.0%
State tax rate, net of federal tax benefit	5.1%	4.0%	5.2%
Adjustment in valuation allowances	(27.0)%	(22.5)%	(31.2)%
Excess stock benefits	0.1%	0.2%	5.3%
Federal income tax rate change	0%	0%	-%
Permanent and other differences	0.8%	(2.7)%	(0.3)%
Provision (benefit) for income taxes	—	—	—

Deferred income taxes result from temporary differences between the amount of assets and liabilities recognized for financial reporting and tax purposes.

The components of the net deferred income tax asset as of December 31, 2020, 2019, and 2018 are as follows:

	2020	2019	2018
Deferred Income Tax Assets:			
Net operating losses	$ 195,008,131	$ 157,555,975	$ 126,419,113
Share based compensation	17,251,900	13,913,568	11,640,464
Interest expense limitation	12,991,716	5,389,129	1,173,614
Other, net	4,818,935	3,662,037	1,658,573
R&D credit	186,347	186,347	186,347
Total deferred income tax asset	230,257,029	180,707,056	141,078,111
Valuation allowance	(230,257,029)	(180,707,056)	(141,078,111)
Deferred income tax assets, net	$ —	$ —	$ —

We believe that it is more likely than not that we will not generate sufficient future taxable income to realize the tax benefits related to the deferred tax assets on our balance sheet and as such, a valuation allowance has been established against the deferred tax assets for the period ended December 31, 2020.

The change in valuation allowance was $49,549,973, $39,628,945, and $41,295,443 for the years ended December 31, 2020, 2019, and 2018, respectively.

Unrecognized Tax Benefits

As of December 31, 2020 and 2019, we have no unrecognized tax benefits.

NOTE 12 – 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, 2020, 2019 and 2018, we were billed by Catalent approximately $3,036,000, $6,101,000 and $4,111,000, respectively, for manufacturing activities related to our clinical trials, scale-up, registration batches, stability and validation testing. As of December 31, 2020 and 2019, there were amounts due to Catalent of approximately $0 and $35,000, respectively. In addition, we have minimum purchase requirements in place with Catalent as disclosed in Note 14, Commitments and Contingencies.

In April 2020, Karen L. Ling, Executive Vice President and Chief Human Resources Officer of American International Group, Inc., or AIG, was appointed to our board of directors. From time to time, we have entered into agreements with AIG in the normal course of business. Agreements with AIG have been reviewed by independent directors of our Company, or a committee consisting of independent directors of our Company, since April 2020. During the year ended December 31, 2020, we were billed by AIG approximately $209,000 for various insurance coverage for our Company.

NOTE 13 - BUSINESS CONCENTRATIONS

We purchase our prescription products from several suppliers with approximately 36%, 30% and 25% of our purchases supplied by three vendors each, respectively, during the year ended December 31, 2020, 24%, 27% and 35% of our purchases supplied by three vendors each, respectively, during the year ended December 31, 2019, and 43%, 33% and 24% of our purchases supplied by three vendors each, respectively, during the year ended December 31, 2018.

We sell our prescription products to wholesale distributors, specialty pharmacies, specialty distributors, and chain drug stores that generally sell products to retail pharmacies, hospitals, and other institutional customers. During the year ended December 31, 2020, three customers each accounted for more than 10% of our total product revenue. During each of the years ended December 31, 2019 and 2018, four customers each accounted for more than 10% of our total product revenue. Product revenue from the three customers combined accounted for approximately 63% of our product revenue for the year ended December 31, 2020. Product revenue from the four customers combined accounted for approximately 73% and 76% of our product revenue for the years ended December 31, 2019 and 2018, respectively.

During the year ended December 31, 2020, Cardinal Health accounted for approximately $17,489,000 of our product revenue, Pillpack, Inc. accounted for approximately $13,228,000 of our product revenue, and McKesson Corporation accounted for approximately $9,862,000 of our product revenue. During the year ended December 31, 2019, Pillpack, Inc. accounted for approximately $12,676,000 of our product revenue, Cardinal Health accounted for approximately $4,551,000 of our product revenue, AmerisourceBergen accounted for approximately $3,927,000 of our product revenue and McKesson Corporation accounted for approximately $3,911,000 of our product revenue. During the year ended December 31, 2018, Pillpack, Inc. accounted for approximately $5,075,000 of our product revenue, AmerisourceBergen accounted for approximately $3,246,000 of our product revenue and Cardinal Health accounted for approximately $2,308,000 of our product revenue, and McKesson Corporation accounted for approximately $1,610,000 of our product revenue.

NOTE 14 – COMMITMENTS AND CONTINGENCIES

Operating Leases

We adopted ASC 842, Leases, 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 commenced in May 2020.

Supplemental lease information as of:	December 31, 2020	December 31, 2019
Right-of-use asset	$ 9,565,700	$ 10,109,154
Short-term operating lease liability (included in Other current liabilities)	$ 2,253,994	$ 1,501,539
Long-term operating lease liability	$ 8,675,477	$ 9,145,049
Weighted average remaining term	8.9 years	9 years
Weighted average discount rate	8.30%	8.25%

Supplemental cash flow information for the year ended:	December 31, 2020	December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities for operating lease	$ 1,617,645	$ 1,164,234
Right-of-use assets obtained in exchange for lease obligation	$ 998,821	$ 11,171,471

The following table reconciles the undiscounted cash flows for all operating leases at December 31, 2020 to the operating lease liabilities recorded on the balance sheet:

Years Ending December 31,	
2021	$ 2,334,582
2022	1,413,289
2023	1,443,143
2024	1,476,534
2025	1,513,458
Thereafter	7,434,412
Total undiscounted lease payments	15,615,418
Less: imputed interest	(4,685,947)
Present value of lease payments	$ 10,929,471

During the year ended December 31, 2020, operating lease expense related to our real estate leases was $2,325,844, and variable lease expense was $423,578. 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 year ended December 31, 2018 was $1,068,275.

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 2, Summary of Significant Accounting Policies 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. The minimum purchase commitments for Catalent for the next five years are as follows: 2021 - $3,458,000, 2022 - $2,150,000, 2023 - $2,991,000, 2024 - $3,347,000, and 2025 - $3,786,000. 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 2021 is approximately $1,526,000. As of December 31, 2020, we have met our minimum purchase commitments with our manufacturers.

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, 2020, 2019, and 2018, 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 15 – SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

Summarized quarterly financial data for fiscal years 2020 and 2019 is as follows:

	2020			
(In thousands, except per share)	First Quarter	Second Quarter	Third Quarter (1)(2)(3)(4)	Fourth Quarter (5)
Revenues	$ 12,251	$ 10,701	$ 19,343	$ 22,577
Gross profit	$ 9,536	$ 6,301	$ 16,064	$ 16,996
Net loss	$ (56,849)	$ (51,976)	$ (32,611)	$ (42,088)
Loss per common share, basic and diluted	$ (0.21)	$ (0.19)	$ (0.12)	$ (0.15)

	2019			
(In thousands, except per share)	First Quarter	Second Quarter (6)	Third Quarter (7)	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)

(1) During the third quarter of 2020, we recorded $2 million in license revenue related to the Knight License Agreement. Refer to discussion in Note 2-Summary of Significant Accounting Policies.
(2) During the third quarter of 2020, we recorded the fair value of the Lender Warrants based on Amendment No. 5 of approximately $7.4 million as a debt discount, which is being amortized to interest expense using the effective interest method over the term of the Financing Agreement. Refer to discussion in Note 8-Debt.
(3) During the third quarter of 2020, we wrote off approximately $0.6 million in costs related to trademarks and patents. Refer to discussion in Note 6-Intangible Assets, Net.
(4) During the third quarter of 2020, we recorded approximately $5.7 million in inventory charge, primarily related to BIJUVA. Refer to discussion in Note 2-Summary of Significant Accounting Policies.
(5) During the fourth quarter of 2020, we wrote off approximately $0.5 million in costs related to trademarks and patents. Refer to discussion in Note 6-Intangible Assets, Net.
(6) During the second quarter of 2019, we recorded approximately $10.1 million in loss on extinguishment of debt related to the repayment of the Credit Agreement. Refer to discussion in Note 8-Debt.
(7) During the third quarter of 2019, we recorded approximately $15. 5 million in license revenue related to the Theramex License Agreement. Refer to discussion in Note 2-Summary of Significant Accounting Policies.

NOTE 16 – SUBSEQUENT EVENTS

During the period from January 1, 2021 through February 8, 2021 in accordance with the terms of the sales agreement described in Note 9- Stockholders' Equity, we sold 28,600,689 shares of Common Stock for net proceeds of approximately $47.3 million through Cantor Fitzgerald who acted as our sales agent.

On January 13, 2021, we entered into Amendment No. 7 to the Financing Agreement, or Amendment No. 7, pursuant to which, among other amendments, the minimum consolidated net revenue requirements attributable to commercial sales of IMVEXXY, BIJUVA, and ANNOVERA for the fiscal quarters ending March 31, 2021 and June 30, 2021 were reduced to $18.0 million and $22.0 million, respectively. On January 13, 2021, in connection with entering into Amendment No. 7 to the Financing Agreement, the Lender Warrants were further amended to provide for an additional adjustment to the exercise price if we conduct certain dilutive issuances prior to March 31, 2021.

On March 1, 2021, we entered into Amendment No. 8, pursuant to which, among other amendments, the minimum consolidated net revenue requirements attributable to commercial sales of IMVEXXY, BIJUVA, and ANNOVERA. See Note 8 – Debt for information regarding Amendment No. 8.

On February 11, 2021, we entered into an underwriting agreement with Cantor Fitzgerald, as underwriter, relating to an underwritten public offering of 59,459,460 shares of Common Stock. Pursuant to the underwriting agreement, we granted to the underwriter an option, exercisable for a period of 30 days, to purchase up to 8,918,919 additional shares of Common Stock. The net proceeds to us from the offering, excluding any proceeds that may be received from the exercise of the underwriter's option to purchase additional shares, are expected to be approximately $97.1 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. The offering closed on February 16, 2021.

Exhibit 10.12

SECOND AMENDMENT TO COMPANY WARRANT

This SECOND AMENDMENT TO THE COMPANY WARRANT (this "**Amendment**"), dated as of January 13, 2021, is by and among TherapeuticsMD, Inc., a Nevada corporation (the "**Company**"), Tao Finance 1, LLC, a Delaware limited liability company ("**Tao Finance**"), Redwood IV Finance 1, LLC, a Delaware limited liability company ("**Redwood IV**") and Sixth Street Specialty Lending, Inc., a Delaware corporation ("**Sixth Street**" and together with Tao Finance and Redwood IV, collectively the "**Holders**").

WHEREAS, the Company issued Warrant No. 1 to Sixth Street on August 5, 2020 convertible into 712,817 shares of Company Common Stock (the "**Sixth Street Warrant**");

WHEREAS, the Company issued Warrant No. 2 to Redwood IV on August 5, 2020 convertible into 1,188,029 shares of Company Common Stock (the "**Redwood IV Warrant**");

WHEREAS, the Company issued Warrant No. 3 to Tao Finance on August 5, 2020 convertible into 2,851,270 shares of Company Common Stock (the "**Tao Finance Warrant**" and together with the Sixth Street Warrant and Redwood IV Warrant collectively, the "**Warrants**");

WHEREAS, the Company and the Holders amended the terms and conditions of the Warrants pursuant to that certain Amendment to the Company Warrant, dated as of November 8, 2020, by and among the Company and the Holders;

WHEREAS, on November 13, 2020, the Company sold 23,437,500 shares of Common Stock at a price per share equal to $1.1856, and, pursuant to Section 3(b) of each of the Warrants, adjusted the Exercise Price of the Warrants to $1.1856; and

WHEREAS, the Company and the Holders wish to further amend the Warrants on the terms set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the Holders agree as follows:

1. <u>Amendment to Warrant: Adjustment to Exercise Price For Subsequent Issuances</u>. Section 3(b) of each Warrant is hereby amended to add the following language at the end of such section:

> "If the Company shall, at any time or from time to time after January 13, 2021 (the "**Second Adjustment Date**") and on or prior to March 31, 2021, issue or sell, or in accordance with Section 3(e) is deemed to have issued or sold, any shares of Common Stock for consideration per share less than the Exercise Price in effect immediately prior to such issuance or sale (or deemed issuance or sale) ("**Second Adjustment Trigger Shares**"), then immediately upon such issuance or sale (or deemed issuance or sale), the Exercise Price shall be reduced to the weighted average per share consideration received by the Company for all Second Adjustment Trigger Shares so issued or sold (or deemed issued or sold) from and after the Second Adjustment Date and on or prior to March 31, 2021, as determined in good faith by the Board.

2. Governing Law. This Amendment shall be governed by and construed in accordance with the laws of the State of New York, without regard to principles of conflict of laws.

3. No Other Amendments. Except as expressly amended herein, each of the Warrants remains in full force and effect in accordance with its terms.

4. Counterparts. This Amendment may be executed in any number of counterparts, each of which shall be an original, but all of which taken together shall constitute one and the same agreement. Delivery of an executed counterpart of this Amendment by telefacsimile or other electronic means (including email with a “pdf”) shall have the same force and effect as the delivery of an original executed counterpart of this Amendment.

[*Signature Page to Follow*]

IN WITNESS WHEREOF, each of the undersigned has duly executed this Amendment as of the day and year first above written.

COMPANY:

TherapeuticsMD, Inc.

By: /s/ James C. D'Arecca
Name: James C. D'Arecca
Title: Chief Financial Officer

HOLDERS:

Tao Finance 1, LLC

By: /s/ Joshua Peck
Name: Joshua Peck
Title: Vice President

Redwood IV Finance 1, LLC

b

By: /s/ Joshua Peck
Name: Joshua Peck
Title: Vice President

Sixth Street Specialty Lending, Inc.

By: /s/ Joshua Easterly
Name Joshua Easterly
Title: Chief Executive Officer

Exhibit 10.13

THIS COMMON STOCK PURCHASE WARRANT IS ISSUED PURSUANT TO THE AGREEMENT AND PLAN OF MERGER BETWEEN AMHN, INC. AND VITAMEDMD, LLC WHICH CLOSED ON OCTOBER 4, 2011. THIS WARRANT REPLACES IN ITS ENTIRETY THAT CERTAIN WARRANT ISSUED BY VITAMEDMD, LLC TO THE WARRANTHOLDER DATED MARCH 6, 2011.

THIS WARRANT AND THE SECURITIES ISSUABLE UPON EXERCISE HEREOF HAVE BEEN ACQUIRED FOR INVESTMENT PURPOSES ONLY AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR UNDER ANY APPLICABLE STATE SECURITIES LAWS. THIS WARRANT MAY NOT BE SOLD OR OTHERWISE TRANSFERRED OR PLEDGED, EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR SUCH APPLICABLE STATE SECURITIES LAWS, OR IF THE PROPOSED TRANSFER MAY BE EFFECTED WITHOUT REGISTRATION UNDER THE SECURITIES ACT OR REGISTRATION OR QUALIFICATION UNDER APPLICABLE STATE SECURITIES LAWS.

THERAPEUTICSMD, INC.

WARRANT

(ISSUED IN CONNECTION WITH THE GUARANTY OF A LINE OF CREDIT ISSUED BY 1ST UNITED BANK)

Warrant No.: 1
Date of Issuance: October 4, 2011
Initial Units: 204,571

THERAPEUTICSMD, INC., a Nevada corporation, (the "***Company***"), for value received, hereby grants to **Robert G. Finizio**, or his registered permitted assigns (the "***Holder***") the right to purchase from the Company Two Hundred Four Thousand Five Hundred Seventy-One (204,571) shares of the Company's Common Stock, $0.0001 par value per share (the "***Shares***") at a per Share price of $0.2444 (the "***Purchase Price***"), all as subject to adjustment and upon the terms and conditions hereinafter provided. To the extent not exercised, the Holder's rights under this Warrant shall become void at 5:00 p.m. on the Expiration Date. This Warrant (the "***Warrant***") was issued in conjunction with the guaranty (the "***Guaranty***") by the Holder of a line of credit provided to the Company's subsidiary, vitaMedMD, LLC, a Delaware limited liability company ("VitaMed"), by 1st United Bank (1st United Bank together with its successors and assigns the "***Lender***") pursuant to the Guaranty Agreement dated March 6, 2011 by and among VitaMed, the Holder and the other persons issuing guarantees to the Lender with respect to the line of credit (the "***Guaranty Agreement***").

This Warrant is subject to the following provisions:

1. **Vesting.** Provided that the Guaranty is still in effect, this Warrant shall be exercisable as it vests as follows:

Warrants to purchase 20,833 Units shall vest on June 30, 2011
Warrants to purchase an additional 20,833 Units shall vest on September 30, 2011
Warrants to purchase an additional 20,833 Units shall vest on December 31, 2011
Warrants to purchase an additional 20,834 Units shall vest on March 31, 2012
Warrants to purchase an additional 20,833 Units shall vest on June 30, 2012
Warrants to purchase an additional 20,833 Units shall vest on September 30, 2012
Warrants to purchase an additional 20,833 Units shall vest on December 31, 2012
Warrants to purchase the remaining 20,834 Units shall vest on March 31, 2013

THIS COMMON STOCK PURCHASE WARRANT IS ISSUED PURSUANT TO THE AGREEMENT AND PLAN OF MERGER BETWEEN AMHN, INC. AND VITAMEDMD, LLC WHICH CLOSED ON OCTOBER 4, 2011. THIS WARRANT REPLACES IN ITS ENTIRETY THAT CERTAIN WARRANT ISSUED BY VITAMEDMD, LLC TO THE WARRANTHOLDER DATED MARCH 6, 2011.

2. **Exercise of Warrant.**

(a) This Warrant may be exercised by the Holder, to the extent vested, in whole or in part at any time and from time to time during the Exercise Period (as hereinafter defined) by the surrender of this Warrant, together with the completed Exercise Agreement substantially in the form set forth in Exhibit I, executed by the Holder accompanied by payment in full in cash or by a check payable to the Company in an amount equal to the product of the Purchase Price multiplied by the number of Shares being purchased upon such exercise.

(b) If the Lender exercises its rights under the Holder's Guaranty and the Holder pays to the Lender all or a portion of the amounts due and owing to the Lender, this Warrant shall be exercised, without any further action on the part of the Holder or the Company, for such number of Shares (whether or not vested) as equals (x) the amount paid by or on behalf of the Holder to the Lender under the Guaranty divided by (y) $0.30. Upon exercise of this Warrant pursuant to this Section 2(b) any and all amounts due and payable by the Company to the Holder under the Guaranty Agreement shall be deemed paid in full.

(c) The Shares issuable upon the exercise of this Warrant shall be deemed to have been issued to the Purchaser immediately prior to the close of business on the date of its surrender for exercise, and the Purchaser shall be deemed for all purposes to have become the record holder of such Stock at such time.

(d) As soon as practicable after the exercise of this Warrant in whole or in part, and in any event within ten (10) days thereafter, the Company at its expense will cause to be issued in the name of, and delivered to, the Holder a certificate or certificates for the number of Shares to which the Holder shall be entitled, together with a new warrant certificate for any unexercised warrants.

3. **Adjustments.**

(a) **Splits and Dividends.** If the outstanding Company Shares are subdivided into a greater number of Shares or a dividend in Company Shares is paid in respect of Company Shares, the Purchase Price in effect immediately prior to such subdivision or at the record date of such dividend shall simultaneously with the effectiveness of such subdivision or immediately after the record date of such dividend be proportionately reduced. If outstanding Company Shares are combined into a smaller number of Shares, the Purchase Price in effect immediately prior to such combination shall, simultaneously with the effectiveness of such combination, be proportionately increased. When any adjustment is required to be made in the Purchase Price, the number of Warrant Shares purchasable upon the exercise of this Warrant shall be changed to the number determined by dividing (i) an amount equal to the number of Shares issuable upon the exercise of this Warrant immediately prior to such adjustment, multiplied by the Purchase Price in effect immediately prior to such adjustment, by (ii) the Purchase Price in effect immediately after such adjustment.

(b) **Reclassification, Etc.** In case there occurs any reclassification or change of the outstanding securities of the Company or any Reorganization on or after the date hereof, then and in each such case the Registered Holder, upon the exercise hereof at any time after the consummation of such reclassification, change, or Reorganization shall be entitled to receive, in lieu of the Shares or other securities and property receivable upon the exercise hereof prior to such consummation, the Shares or other securities or property to which such Registered Holder would have been entitled upon such consummation if such Registered Holder had exercised this Warrant immediately prior thereto, all subject to further adjustment pursuant to the provisions of this Section 3.

(c) **Adjustment Certificate.** When any adjustment is required to be made in the type or number of Shares or the Purchase Price pursuant to this Section 3, the Company shall promptly mail to the Holder a certificate setting forth (i) a brief statement of the facts requiring such adjustment, (ii) the Purchase

Price after such adjustment and (iii) the kind and amount of Shares or other securities or property into which this Warrant shall be exercisable after such adjustment.

4. Transfers.

(a) **Unregistered Security.** The Holder acknowledges that this Warrant, and the Shares of the Company issuable pursuant to this Warrant have not been registered under the Securities Act of 1933, as amended (the "***Securities Act***"), and agrees not to sell, pledge, distribute, offer for sale, transfer or otherwise dispose of this Warrant or any Shares issued upon its exercise in the absence of (i) an effective registration statement under the Securities Act as to this Warrant or such Shares and registration or qualification of this Warrant or such Shares under any applicable U.S. federal or state securities law then in effect, or (ii) an opinion of counsel, satisfactory to the Company, that such registration and qualification are not required. Each certificate or other instrument for Shares issued upon the exercise of this Warrant shall bear a legend substantially to the foregoing effect.

(b) **Transferability.** This Warrant and the Shares shall be subject to the restrictions on transferability set forth herein. Subject to the restrictions of Section 4(a), this Warrant and all rights hereunder are transferable, in whole or in part, upon surrender of the Warrant with a properly executed assignment (in the form of Exhibit A hereto) at the principal office of the Company. This Warrant (or any portion hereof) may only be transferred in connection with a proportional transfer of the Guaranty.

5. **No Impairment.** The Company will not, by amendment of the Articles of organization or through reorganization, consolidation, merger, dissolution, sale of assets or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such action as may be necessary or appropriate in order to protect the rights of the Holder of this Warrant against impairment. The foregoing shall not, in any circumstances, prevent the Holder from taking any action permitted by this Warrant.

6. **Term and Termination.** The right to exercise this Warrant and the right to purchase securities upon exercise hereof shall commence on the date hereof and shall terminate on the 10th anniversary of the date of issuance of the original Warrant issued by VitaMed on March 6, 2011 (the "***Expiration Date***" and the period commencing on the Date of Issuance and ending on the Expiration Date, the "***Exercise Period***").

7. **Reservation of Units.** The Company will at all times reserve and keep available, solely for the issuance and delivery upon the exercise of this Warrant, such Shares as from time to time shall be issuable upon the exercise and conversion of this Warrant.

8. **Replacement of Warrants.** Upon receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and (in the case of loss, theft or destruction) upon delivery of an indemnity agreement (with surety if reasonably required) in an amount reasonably satisfactory to the Company, or (in the case of mutilation) upon surrender and cancellation of this Warrant, the Company will issue, in lieu thereof, a new Warrant of like tenor.

9. **Mailing of Notices.** Unless otherwise provided, any notice required or permitted under this Warrant shall be given in writing.

10. **No Fractional Units.** No fractional Shares will be issued in connection with any exercise hereunder. In lieu of any fractional shares which would otherwise be issuable, the Company shall pay cash equal to the product of such fraction multiplied by the fair market value of one Share (or other share or security issuable upon exercise hereof) on the date of exercise, as determined in good faith by the Board of Directors of the Company.

THIS COMMON STOCK PURCHASE WARRANT IS ISSUED PURSUANT TO THE AGREEMENT AND PLAN OF MERGER BETWEEN AMHN, INC. AND VITAMEDMD, LLC WHICH CLOSED ON OCTOBER 4, 2011. THIS WARRANT REPLACES IN ITS ENTIRETY THAT CERTAIN WARRANT ISSUED BY VITAMEDMD, LLC TO THE WARRANTHOLDER DATED MARCH 6, 2011.

11. **Amendment or Waiver.** Neither this Warrant nor any term hereof may be changed, waived, discharged or terminated without the prior written consent of (a) the Company and (b) the Holder.

12. **Headings.** The headings in this Warrant are for purposes of reference only and shall not limit or otherwise affect the meaning of any provision of this Warrant.

13. **Governing Law.** This Warrant shall be governed, construed and interpreted in accordance with the laws of the State of Delaware, without giving effect to principles of conflicts of law.

{Signature page follows.}

THIS COMMON STOCK PURCHASE WARRANT IS ISSUED PURSUANT TO THE AGREEMENT AND PLAN OF MERGER BETWEEN AMHN, INC. AND VITAMEDMD, LLC WHICH CLOSED ON OCTOBER 4, 2011. THIS WARRANT REPLACES IN ITS ENTIRETY THAT CERTAIN WARRANT ISSUED BY VITAMEDMD, LLC TO THE WARRANTHOLDER DATED MARCH 6, 2011.

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its duly authorized officer as of the first date written above.

THERAPEUTICSMD, INC.

By: ______________________
John C.K. Milligan, President

{Signature Page to Warrant}

EXHIBIT A

ASSIGNMENT FORM

FOR VALUE RECEIVED, ____ hereby sells, assigns and transfers all of the rights of the undersigned under the attached Warrant with respect to the number of Warrant Shares covered thereby set forth below, unto:

Name of Assignee	**Address/Facsimile Number**	**No. of Shares**

Dated:_____________, 20__

Signature:______________________________

____

Witness: ______________________________

Exhibit 10.14

AMENDMENT TO WARRANT

This Amendment to Warrant (this "***Amendment***") is dated as of February 18, 2021 by and between Robert G. Finizio ("***Holder***") and TherapeuticsMD, Inc. ("***Company***").

Recitals

WHEREAS, in connection with the guaranty by Holder of a line of credit issued by 1st United Bank to vitaMedMD, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company on March 6, 2011, Company issued to Holder that certain Warrant No. 1 dated as of October 4, 2011 granting Holder the right to purchase 204,571 shares of common stock, $0.001 par value per share, of the Company ("***Shares***") at a per Share price of $0.2444 (the "***Warrant***").

WHEREAS, pursuant to Section 11 of the Warrant, neither the Warrant nor any term thereof may be changed, waived, discharged or terminated without the prior written consent of Holder and the Company.

WHEREAS, Company and Holder wish to amend the Warrant in order to allow for a cashless exercise of the Warrant.

NOW, THEREFORE, Company and Holder agree as follows:

1. The Warrant is hereby amended to add Sections 2(e) and 2(f), to read in their entirety as follows:

(e) In lieu of, or in addition to, exercising this Warrant as specified in subsection (a) above, Holder may from time to time convert this Warrant, in whole or in part, into a number of Shares determined by dividing (a) the aggregate fair market value of the Shares or other securities otherwise issuable upon exercise of this Warrant minus the aggregate Purchase Price of such Shares by (b) the fair market value of one Share. The fair market value of the Shares shall be determined pursuant to subsection (f) of this Section.

(f) If the Shares are traded regularly in a public market, the fair market value of the Shares shall be the closing price of the Shares reported for the business day immediately before Holder delivers its completed Exercise Agreement to the Company. If the Shares are not regularly traded in a public market, the Board of Directors of the Company shall determine fair market value in its reasonable good faith judgment.

2. Except as amended hereby, the Warrant remains in full force and effect. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, and both of which shall constitute one instrument.

THERAPEUTICSMD, INC.	**ROBERT G. FINIZIO**
By: /s/ James C. D'Arecca	By: /s/ Robert G. Finizio
James C. D'Arecca	
Chief Financial Officer	

Exhibit 10.15

THIS COMMON STOCK PURCHASE WARRANT IS ISSUED PURSUANT TO THE AGREEMENT AND PLAN OF MERGER BETWEEN AMHN, INC. AND VITAMEDMD, LLC WHICH CLOSED ON OCTOBER 4, 2011. THIS WARRANT REPLACES IN ITS ENTIRETY THAT CERTAIN WARRANT ISSUED BY VITAMEDMD, LLC TO THE WARRANTHOLDER DATED MARCH 6, 2011.

THIS WARRANT AND THE SECURITIES ISSUABLE UPON EXERCISE HEREOF HAVE BEEN ACQUIRED FOR INVESTMENT PURPOSES ONLY AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR UNDER ANY APPLICABLE STATE SECURITIES LAWS. THIS WARRANT MAY NOT BE SOLD OR OTHERWISE TRANSFERRED OR PLEDGED, EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR SUCH APPLICABLE STATE SECURITIES LAWS, OR IF THE PROPOSED TRANSFER MAY BE EFFECTED WITHOUT REGISTRATION UNDER THE SECURITIES ACT OR REGISTRATION OR QUALIFICATION UNDER APPLICABLE STATE SECURITIES LAWS.

THERAPEUTICSMD, INC.

WARRANT

(ISSUED IN CONNECTION WITH THE GUARANTY OF A LINE OF CREDIT ISSUED BY 1ST UNITED BANK)

Warrant No.: 2
Date of Issuance: October 4, 2011
Initial Units: 204,571

THERAPEUTICSMD, INC., a Nevada corporation, (the "***Company***"), for value received, hereby grants to **John C.K. Milligan, IV**, or his registered permitted assigns (the "***Holder***") the right to purchase from the Company Two Hundred Four Thousand Five Hundred Seventy-One (204,571) shares of the Company's Common Stock, $0.0001 par value per share (the "***Shares***") at a per Share price of $0.2444 (the "***Purchase Price***"), all as subject to adjustment and upon the terms and conditions hereinafter provided. To the extent not exercised, the Holder's rights under this Warrant shall become void at 5:00 p.m. on the Expiration Date. This Warrant (the "***Warrant***") was issued in conjunction with the guaranty (the "***Guaranty***") by the Holder of a line of credit provided to the Company's subsidiary, vitaMedMD, LLC, a Delaware limited liability company ("VitaMed"), by 1st United Bank (1st United Bank together with its successors and assigns the "***Lender***") pursuant to the Guaranty Agreement dated March 6, 2011 by and among VitaMed, the Holder and the other persons issuing guarantees to the Lender with respect to the line of credit (the "***Guaranty Agreement***").

This Warrant is subject to the following provisions:

1. **Vesting**. Provided that the Guaranty is still in effect, this Warrant shall be exercisable as it vests as follows:

Warrants to purchase 20,833 Units shall vest on June 30, 2011
Warrants to purchase an additional 20,833 Units shall vest on September 30, 2011
Warrants to purchase an additional 20,833 Units shall vest on December 31, 2011
Warrants to purchase an additional 20,834 Units shall vest on March 31, 2012
Warrants to purchase an additional 20,833 Units shall vest on June 30, 2012
Warrants to purchase an additional 20,833 Units shall vest on September 30, 2012
Warrants to purchase an additional 20,833 Units shall vest on December 31, 2012
Warrants to purchase the remaining 20,834 Units shall vest on March 31, 2013

THIS COMMON STOCK PURCHASE WARRANT IS ISSUED PURSUANT TO THE AGREEMENT AND PLAN OF MERGER BETWEEN AMHN, INC. AND VITAMEDMD, LLC WHICH CLOSED ON OCTOBER 4, 2011. THIS WARRANT REPLACES IN ITS ENTIRETY THAT CERTAIN WARRANT ISSUED BY VITAMEDMD, LLC TO THE WARRANTHOLDER DATED MARCH 6, 2011.

2. **Exercise of Warrant.**

(a) This Warrant may be exercised by the Holder, to the extent vested, in whole or in part at any time and from time to time during the Exercise Period (as hereinafter defined) by the surrender of this Warrant, together with the completed Exercise Agreement substantially in the form set forth in Exhibit I, executed by the Holder accompanied by payment in full in cash or by a check payable to the Company in an amount equal to the product of the Purchase Price multiplied by the number of Shares being purchased upon such exercise.

(b) If the Lender exercises its rights under the Holder's Guaranty and the Holder pays to the Lender all or a portion of the amounts due and owing to the Lender, this Warrant shall be exercised, without any further action on the part of the Holder or the Company, for such number of Shares (whether or not vested) as equals (x) the amount paid by or on behalf of the Holder to the Lender under the Guaranty divided by (y) $0.30. Upon exercise of this Warrant pursuant to this Section 2(b) any and all amounts due and payable by the Company to the Holder under the Guaranty Agreement shall be deemed paid in full.

(c) The Shares issuable upon the exercise of this Warrant shall be deemed to have been issued to the Purchaser immediately prior to the close of business on the date of its surrender for exercise, and the Purchaser shall be deemed for all purposes to have become the record holder of such Stock at such time.

(d) As soon as practicable after the exercise of this Warrant in whole or in part, and in any event within ten (10) days thereafter, the Company at its expense will cause to be issued in the name of, and delivered to, the Holder a certificate or certificates for the number of Shares to which the Holder shall be entitled, together with a new warrant certificate for any unexercised warrants.

3. **Adjustments.**

(a) **<u>Splits and Dividends</u>.** If the outstanding Company Shares are subdivided into a greater number of Shares or a dividend in Company Shares is paid in respect of Company Shares, the Purchase Price in effect immediately prior to such subdivision or at the record date of such dividend shall simultaneously with the effectiveness of such subdivision or immediately after the record date of such dividend be proportionately reduced. If outstanding Company Shares are combined into a smaller number of Shares, the Purchase Price in effect immediately prior to such combination shall, simultaneously with the effectiveness of such combination, be proportionately increased. When any adjustment is required to be made in the Purchase Price, the number of Warrant Shares purchasable upon the exercise of this Warrant shall be changed to the number determined by dividing (i) an amount equal to the number of Shares issuable upon the exercise of this Warrant immediately prior to such adjustment, multiplied by the Purchase Price in effect immediately prior to such adjustment, by (ii) the Purchase Price in effect immediately after such adjustment.

(b) **<u>Reclassification, Etc.</u>** In case there occurs any reclassification or change of the outstanding securities of the Company or any Reorganization on or after the date hereof, then and in each such case the Registered Holder, upon the exercise hereof at any time after the consummation of such reclassification, change, or Reorganization shall be entitled to receive, in lieu of the Shares or other securities and property receivable upon the exercise hereof prior to such consummation, the Shares or other securities or property to which such Registered Holder would have been entitled upon such consummation if such Registered Holder had exercised this Warrant immediately prior thereto, all subject to further adjustment pursuant to the provisions of this Section 3.

(c) **<u>Adjustment Certificate</u>.** When any adjustment is required to be made in the type or number of Shares or the Purchase Price pursuant to this Section 3, the Company shall promptly mail to the Holder a certificate setting forth (i) a brief statement of the facts requiring such adjustment, (ii) the Purchase

Price after such adjustment and (iii) the kind and amount of Shares or other securities or property into which this Warrant shall be exercisable after such adjustment.

4. Transfers.

(a) **Unregistered Security.** The Holder acknowledges that this Warrant, and the Shares of the Company issuable pursuant to this Warrant have not been registered under the Securities Act of 1933, as amended (the "***Securities Act***"), and agrees not to sell, pledge, distribute, offer for sale, transfer or otherwise dispose of this Warrant or any Shares issued upon its exercise in the absence of (i) an effective registration statement under the Securities Act as to this Warrant or such Shares and registration or qualification of this Warrant or such Shares under any applicable U.S. federal or state securities law then in effect, or (ii) an opinion of counsel, satisfactory to the Company, that such registration and qualification are not required. Each certificate or other instrument for Shares issued upon the exercise of this Warrant shall bear a legend substantially to the foregoing effect.

(b) **Transferability.** This Warrant and the Shares shall be subject to the restrictions on transferability set forth herein. Subject to the restrictions of Section 4(a), this Warrant and all rights hereunder are transferable, in whole or in part, upon surrender of the Warrant with a properly executed assignment (in the form of Exhibit A hereto) at the principal office of the Company. This Warrant (or any portion hereof) may only be transferred in connection with a proportional transfer of the Guaranty.

5. No Impairment. The Company will not, by amendment of the Articles of organization or through reorganization, consolidation, merger, dissolution, sale of assets or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such action as may be necessary or appropriate in order to protect the rights of the Holder of this Warrant against impairment. The foregoing shall not, in any circumstances, prevent the Holder from taking any action permitted by this Warrant.

6. Term and Termination. The right to exercise this Warrant and the right to purchase securities upon exercise hereof shall commence on the date hereof and shall terminate on the 10th anniversary of the date of issuance of the original Warrant issued by VitaMed on March 6, 2011 (the "***Expiration Date***" and the period commencing on the Date of Issuance and ending on the Expiration Date, the "***Exercise Period***").

7. Reservation of Units. The Company will at all times reserve and keep available, solely for the issuance and delivery upon the exercise of this Warrant, such Shares as from time to time shall be issuable upon the exercise and conversion of this Warrant.

8. Replacement of Warrants. Upon receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and (in the case of loss, theft or destruction) upon delivery of an indemnity agreement (with surety if reasonably required) in an amount reasonably satisfactory to the Company, or (in the case of mutilation) upon surrender and cancellation of this Warrant, the Company will issue, in lieu thereof, a new Warrant of like tenor.

9. Mailing of Notices. Unless otherwise provided, any notice required or permitted under this Warrant shall be given in writing.

10. No Fractional Units. No fractional Shares will be issued in connection with any exercise hereunder. In lieu of any fractional shares which would otherwise be issuable, the Company shall pay cash equal to the product of such fraction multiplied by the fair market value of one Share (or other share or security issuable upon exercise hereof) on the date of exercise, as determined in good faith by the Board of Directors of the Company.

THIS COMMON STOCK PURCHASE WARRANT IS ISSUED PURSUANT TO THE AGREEMENT AND PLAN OF MERGER BETWEEN AMHN, INC. AND VITAMEDMD, LLC WHICH CLOSED ON OCTOBER 4, 2011. THIS WARRANT REPLACES IN ITS ENTIRETY THAT CERTAIN WARRANT ISSUED BY VITAMEDMD, LLC TO THE WARRANTHOLDER DATED MARCH 6, 2011.

11. **Amendment or Waiver.** Neither this Warrant nor any term hereof may be changed, waived, discharged or terminated without the prior written consent of (a) the Company and (b) the Holder.

12. **Headings.** The headings in this Warrant are for purposes of reference only and shall not limit or otherwise affect the meaning of any provision of this Warrant.

13. **Governing Law.** This Warrant shall be governed, construed and interpreted in accordance with the laws of the State of Delaware, without giving effect to principles of conflicts of law.

{Signature page follows.}

THIS COMMON STOCK PURCHASE WARRANT IS ISSUED PURSUANT TO THE AGREEMENT AND PLAN OF MERGER BETWEEN AMHN, INC. AND VITAMEDMD, LLC WHICH CLOSED ON OCTOBER 4, 2011. THIS WARRANT REPLACES IN ITS ENTIRETY THAT CERTAIN WARRANT ISSUED BY VITAMEDMD, LLC TO THE WARRANTHOLDER DATED MARCH 6, 2011.

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its duly authorized officer as of the first date written above.

THERAPEUTICSMD, INC.

By: ____________________________

Robert G. Finizio, Chief Executive Officer

{Signature Page to Warrant}

EXHIBIT A

ASSIGNMENT FORM

FOR VALUE RECEIVED, ____ hereby sells, assigns and transfers all of the rights of the undersigned under the attached Warrant with respect to the number of Warrant Shares covered thereby set forth below, unto:

Name of Assignee	**Address/Facsimile Number**	**No. of Shares**

Dated:______________, 20__

Signature:______________________________

____

Witness: ______________________________

Exhibit 10.16

AMENDMENT TO WARRANT

This Amendment to Warrant (this "***Amendment***") is dated as of February 20, 2021 by and between John C.K. Milligan, IV ("***Holder***") and TherapeuticsMD, Inc. ("***Company***").

Recitals

WHEREAS, in connection with the guaranty by Holder of a line of credit issued by 1st United Bank to vitaMedMD, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company on March 6, 2011, Company issued to Holder that certain Warrant No. 2 dated as of October 4, 2011 granting Holder the right to purchase 204,571 shares of common stock, $0.001 par value per share, of the Company ("***Shares***") at a per Share price of $0.2444 (the "***Warrant***").

WHEREAS, pursuant to Section 11 of the Warrant, neither the Warrant nor any term thereof may be changed, waived, discharged or terminated without the prior written consent of Holder and the Company.

WHEREAS, Company and Holder wish to amend the Warrant in order to allow for a cashless exercise of the Warrant.

NOW, THEREFORE, Company and Holder agree as follows:

1. The Warrant is hereby amended to add Sections 2(e) and 2(f), to read in their entirety as follows:

(e) In lieu of, or in addition to, exercising this Warrant as specified in subsection (a) above, Holder may from time to time convert this Warrant, in whole or in part, into a number of Shares determined by dividing (a) the aggregate fair market value of the Shares or other securities otherwise issuable upon exercise of this Warrant minus the aggregate Purchase Price of such Shares by (b) the fair market value of one Share. The fair market value of the Shares shall be determined pursuant to subsection (f) of this Section.

(f) If the Shares are traded regularly in a public market, the fair market value of the Shares shall be the closing price of the Shares reported for the business day immediately before Holder delivers its completed Exercise Agreement to the Company. If the Shares are not regularly traded in a public market, the Board of Directors of the Company shall determine fair market value in its reasonable good faith judgment.

2. Except as amended hereby, the Warrant remains in full force and effect. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, and both of which shall constitute one instrument.

THERAPEUTICSMD, INC.	**JOHN C.K. MILLIGAN, IV**
By: /s/ James C. D'Arecca James C. D'Arecca Chief Financial Officer	By: John C.K. Milligan, IV

Exhibit 10.24

AMENDMENT NO. 7
TO FINANCING AGREEMENT

AMENDMENT NO. 7 TO FINANCING AGREEMENT, dated as of January 13, 2021 (this "Amendment"), to the Financing Agreement, dated as of April 24, 2019 (as amended, restated, supplemented or otherwise modified from time to time, the "Financing Agreement"), by and among THERAPEUTICSMD, INC., a Nevada corporation ("Company" or "Borrower"), certain Subsidiaries of Borrower, as Guarantors, the Lenders from time to time party thereto, and SIXTH STREET SPECIALTY LENDING, INC., a Delaware corporation ("Sixth Street"), as administrative agent for the Lenders (in such capacity, together with its successors and assigns in such capacity, the "Administrative Agent").

WHEREAS, the Loan Parties have requested that the Administrative Agent and the Lenders amend certain terms and conditions of the Financing Agreement; and

WHEREAS, the Administrative Agent and the Lenders are willing to amend such terms and conditions of the Financing Agreement on the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the premises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. Definitions. All terms used herein that are defined in the Financing Agreement and not otherwise defined herein shall have the meanings assigned to them in the Financing Agreement.

2. Amendments.

(a) New Definitions. Section 1.01 of the Financing Agreement is hereby amended by adding the following definitions, in appropriate alphabetical order:

(i) ""Amendment No. 7" means Amendment No. 7 to Financing Agreement, dated as of January 13, 2021, by and among the Loan Parties, the Administrative Agent and the Lenders."

(ii) ""Amendment No. 7 Effective Date" means the "Amendment Effective Date" as set forth in Amendment No. 7."

(iii) ""Cash Collateral Account" means that certain Deposit Account with Bank of America, N.A. identified by account number 4451020473."

(iv) ""Specified Payables" means the aggregate amount of all trade payables aged in excess of 60 days past the applicable invoice date and all book overdrafts, in each case as reasonably determined by Administrative Agent."

(b) Existing Definitions. Section 1.01 of the Financing Agreement is hereby amended as follows:

(i) The definition of Excluded Account is hereby amended and restated to read as follows:

"“Excluded Account” means (i) Deposit Accounts and Securities Accounts the balance of which consists exclusively of (a) withheld income Taxes and federal, state or local employment Taxes in such amounts as are required to be paid to the Internal Revenue Service or state or local government agencies within the following two months with respect to employees of the Company or any of its Subsidiaries, and (b) any payroll accounts, health care reimbursement accounts and employee benefits accounts, including any accounts containing amounts required to be paid over to an employee benefit plan pursuant to DOL Reg. Sec. 2510.3-102 on behalf of or for the benefit of employees of the Company or any of its Subsidiaries, (ii) all segregated Deposit Accounts constituting (and the balance of which consists solely of funds set aside in connection with) tax accounts, fiduciary accounts and trust accounts and (iii) any Deposit Accounts and Securities Accounts, amounts on deposit in which do not exceed $100,000 individually or $500,000 in the aggregate at any one time, (iv) any Deposit Accounts that contain accounts receivable arising from any Governmental Payor where Administrative Agent may not under applicable Law obtain a security interest in or lien on such Deposit Account receiving the proceeds of such accounts receivable; provided, that amounts in such Deposit Account referred to in this subclause (iv) are automatically transferred on each Business Day into a Deposit Account that is not an Excluded Account, (v) the Cash Collateral Account, or (vi) the Deposit Account with Bank of America, N.A. identified by account number 4451288202."

(ii) The definition of Permitted Indebtedness is hereby amended by deleting "and" at the end of clause (m), deleting the "." at the end of clause (n) and inserting a ";" in place thereof, and inserting a new clause (o) as follows:

"(o) Indebtedness of the Loan Parties in respect of credit card programs in the ordinary course of business in an aggregate amount not to exceed $200,000 at any time outstanding."

(iii) The definition of Permitted Liens is hereby amended by deleting "and" at the end of clause (p), deleting the "." at the end of clause (q) and inserting a ";" in place thereof, and inserting a new clause (r) as follows:

"(r) Liens on the Cash Collateral Account securing Permitted Indebtedness described under clause (o) of the definition thereof."

(c) Section 5.1(a) (Cash Reports). Section 5.1(a) of the Financing Agreement is hereby amended and restated in its entirety to read as follows:

"(a) Cash Reports. Promptly, but in any event within 5 Business Days, after the end of each week commencing with the week ending January 15, 2021, a report (which report may consist of bank statements) of the current Cash and Cash Equivalent balances (including the balances in each Deposit Account of each Loan Party) of the Company and its Subsidiaries, which report shall identify (i) unrestricted (other than restrictions created by the Collateral Documents) and restricted Cash and Cash Equivalents and (ii) those accounts that constitute Qualified Cash; provided, that at any time the current Cash and Cash Equivalent balances of the Company and its Subsidiaries is less than (A) $75,000,000, the Company shall either (1) on each Business Day provide a report of at least 95% of the current Cash and Cash Equivalent balances of the Company and its Subsidiaries (the "Specified Cash"), which report shall identify unrestricted (other than restrictions created by the Collateral Documents) and restricted Cash and Cash Equivalents (or, if greater, all Cash and Cash Equivalent balances required to satisfy the covenant set forth in Section 6.8) or (2) provide Administrative Agent with electronic, read only access to such Deposit Accounts of the Company and its Subsidiaries which contain the Specified Cash and (B) $60,000,000, the Company shall immediately notify Administrative Agent in writing of the current Cash and Cash Equivalent balances (including the balances in each Deposit Account of each Loan Party) of the Company and its Subsidiaries."

(d) Section 6.8(a) (Minimum Qualified Cash). Section 6.8(a) of the Financing Agreement is hereby amended and restated in its entirety to read as follows:

"(a) Minimum Qualified Cash. At all times, Borrower shall not permit Qualified Cash to be less than $60,000,000 *minus* the Specified Payables."

(e) Section 6.8(b) (Minimum Revenue). Section 6.8(b) of the Financing Agreement is hereby amended by amending the table set forth therein for the Fiscal Quarters ending March 31, 2021 and June 30, 2021 such that the minimum Product Revenue for the Fiscal Quarter ending (i) March 31, 2021 shall be $18,000,000 and (ii) June 30, 2021 shall be $22,000,000.

3. Waiver.

(a) Pursuant to the request of the Loan Parties and in reliance upon the representations and warranties of the Loan Parties described herein, Administrative Agent and the Lenders hereby waive any Event of Default under Section 8.1(c) of the Financing Agreement arising out of the Loan Parties' failure to comply with Section 6.16 of the Financing Agreement solely as a result of the failure of the Loan Parties to cause the Cash Collateral Account to be subject to a Control Agreement (the "Specified Event of Default").

(b) The waiver in this Section 3 shall be effective only in this specific instance and for the specific purpose set forth herein and does not allow for any other or further departure from the terms and conditions of the Financing Agreement or any other Loan Document, which terms and conditions shall continue in full force and effect.

4. Conditions to Effectiveness. This Amendment shall become effective only upon satisfaction in full, in a manner satisfactory to the Administrative Agent, of the following conditions precedent (the first date upon which all such conditions shall have been satisfied being hereinafter referred to as the "Amendment Effective Date"):

(a) Payment of Fees, Etc. The Borrowers shall have paid on or before the Amendment Effective Date (i) an amendment fee equal to $5,000,000, which fee shall be fully earned, due and payable to Administrative Agent on the Amendment Effective Date, and (ii) all fees, costs, expenses and taxes then payable, if any, pursuant to Section 2.7 or 10.2 of the Financing Agreement.

(b) Representations and Warranties. The representations and warranties contained in this Amendment and in Article IV of the Financing Agreement and in each other Loan Document shall be true and correct in all material respects (except that such materiality qualifier shall not be applicable to any representations or warranties that already are qualified or modified as to "materiality" or "Material Adverse Effect" in the text thereof, which representations and warranties shall be true and correct in all respects subject to such qualification) on and as the Amendment Effective Date to the same extent as though made on and as of that date, except to the extent such representations and warranties specifically relate to an earlier date, in which case such representations and warranties shall have been true and correct in all material respects (except that such materiality qualifier shall not be applicable to any representations or warranties that already are qualified or modified as to "materiality" or "Material Adverse Effect" in the text thereof, which representations and warranties shall be true and correct in all respects subject to such qualification) on and as of such earlier date.

(c) No Default; Event of Default. No Default or Event of Default (other than the Specified Event of Default) shall have occurred and be continuing on the Amendment Effective Date or result from this Amendment becoming effective in accordance with its terms.

(d) Delivery of Documents. The Administrative Agent shall have received on or before the Amendment Effective Date:

(i) this Amendment, duly executed by the Loan Parties, the Administrative Agent and the Lenders; and

(ii) an amendment to each Warrant to Purchase Common Stock dated August 5, 2020 issued by the Borrower to Sixth Street, Redwood IV Finance 1, LLC and TAO Finance 1, LLC, in each case in form and substance satisfactory to the Administrative Agent and duly executed by the Borrower.

(e) Material Adverse Effect. The Administrative Agent shall have determined, in its reasonable judgment, that no event or development shall have occurred since December 31, 2019, which could reasonably be expected to have a Material Adverse Effect.

(f) Liens; Priority. The Administrative Agent shall be satisfied that the Administrative Agent has been granted, and holds, for the benefit of the Administrative Agent and the Lenders, a perfected, first priority Lien on and security interest in all of the Collateral, subject only to Permitted Liens, to the extent such Liens and security interests are required pursuant to the Loan Documents to be granted or perfected on or before the Amendment Effective Date.

(g) Approvals. All consents, authorizations and approvals of, and filings and registrations with, and all other actions in respect of, any Governmental Authority or other Person required in connection with any Loan Document or the transactions contemplated thereby or the conduct of the Loan Parties' business shall have been obtained or made and shall be in full force and effect. There shall exist no claim, action, suit, investigation, litigation or proceeding (including, without limitation, shareholder or derivative litigation) pending or, to the knowledge of any Loan Party, threatened in any court or before any arbitrator or Governmental Authority which (i) relates to the Loan Documents or the transactions contemplated thereby or (ii) could reasonably be expected to have a Material Adverse Effect.

5. Conditions Subsequent to Effectiveness. As an accommodation to the Loan Parties, Administrative Agent and the Lenders have agreed to execute this Amendment notwithstanding the failure by the Loan Parties to satisfy the conditions set forth below on or before the Amendment Effective Date. In consideration of such accommodation, the Loan Parties agree that, in addition to all other terms, conditions and provisions set forth herein and in the Financing Agreement and the other Loan Documents, including, without limitation, those conditions set forth in Section 4 hereof, the Loan Parties shall satisfy each of the conditions subsequent set forth below on or before the date applicable thereto (it being understood that (a) the failure by the Loan Parties to perform or cause to be performed any such condition subsequent on or before the date applicable thereto shall constitute an Event of Default and (b) to the extent that the existence of any such condition subsequent would otherwise cause any representation, warranty or covenant in this Amendment, the Financing Agreement or any other Loan Document to be breached, the Required Lenders hereby waive such breach for the period from the Amendment Effective Date until the date on which such condition subsequent is required to be fulfilled pursuant to this Section 5):

(a) On or prior to the date that is 30 days following the Amendment Effective Date (or such later date as agreed to in writing by Administrative Agent in its sole discretion), the Loan Parties shall deliver to Administrative Agent (x) Control Agreements for (i) each Deposit Account identified on Exhibit A hereto and (ii) any other Deposit Account with respect to which a Control Agreement is required to be delivered under the Loan Documents, in each case duly executed by, in addition to the applicable Loan Party, the applicable financial institution, (y) evidence that the Deposit Account identified by account number 898049551890 has been closed; and

(b) On or prior to the date that is 5 Business Days following the Amendment Effective Date (or such later date as agreed to in writing by Administrative Agent in its sole discretion), the Loan Parties shall deliver to Administrative Agent Collateral Assignments for Security in respect of the trademarks, patents and patent applications identified on Exhibit B hereto.

6. Continued Effectiveness of the Financing Agreement and Other Loan Documents. Each Loan Party hereby (a) acknowledges and consents to this Amendment, (b) confirms and agrees that the Financing Agreement and each other Loan Document to which it is a party is, and shall continue to be, in full force and effect and is hereby ratified and confirmed in all respects, except that on and after the Amendment Effective Date, all references in any such Loan Document to "the Financing Agreement", the "Agreement", "thereto", "thereof", "thereunder" or words of like import referring to the Financing Agreement shall mean the Financing Agreement as amended by this Amendment, and (c) confirms and agrees that, to the extent that any such Loan Document purports to assign or pledge to the Administrative Agent, for the benefit of the Administrative Agent and the Lenders, or to grant to the Administrative Agent, for the benefit of the Administrative Agent and the Lenders, a security interest in or Lien on any Collateral as security for the Obligations of the Loan Parties from time to time existing in respect of the Financing Agreement (as amended hereby) and the other Loan Documents, such pledge, assignment and/or grant of the security interest or Lien is hereby ratified and confirmed in all respects. This Amendment does not and shall not affect any of the obligations of the Loan Parties, other than as expressly provided herein, including, without limitation, the Loan Parties' obligations to repay the Loans in accordance with the terms of Financing Agreement or the obligations of the Loan Parties under any Loan Document to which they are a party, all of which obligations shall remain in full force and effect. Except as expressly provided herein, the execution, delivery and effectiveness of this Amendment shall not operate as a waiver of any right, power or remedy of Administrative Agent or any Lender under the Financing Agreement or any other Loan Document nor constitute a waiver of any provision of the Financing Agreement or any other Loan Document.

7. No Novation. Nothing herein contained shall be construed as a substitution or novation of the Obligations outstanding under the Financing Agreement or instruments securing the same, which shall remain in full force and effect, except as modified hereby.

8. No Representations by Administrative Agent or Lenders. Each Loan Party hereby acknowledges that it has not relied on any representation, written or oral, express or implied, by Administrative Agent or any Lender, other than those expressly contained herein, in entering into this Amendment.

9. Release. Each Loan Party hereby acknowledges and agrees that: (a) neither it nor any of its Subsidiaries has any claim or cause of action against Administrative Agent or any Lender (or any of the directors, officers, employees, agents, attorneys or consultants of any of the foregoing) and (b) the Administrative Agent and the Lenders have heretofore properly performed and satisfied in a timely manner all of their obligations to the Loan Parties, and all of their Subsidiaries and Affiliates. Notwithstanding the foregoing, the Administrative Agent and the Lenders wish (and the Loan Parties agree) to eliminate any possibility that any past conditions, acts, omissions, events or circumstances would impair or otherwise adversely affect any of their rights, interests, security and/or remedies. Accordingly, for and in consideration of the agreements contained in this Amendment and other good and valuable consideration, each Loan Party (for itself and its Subsidiaries and Affiliates and the successors, assigns, heirs and representatives of each of the foregoing) (collectively, the "Releasors") does hereby fully, finally, unconditionally and irrevocably release, waive and forever discharge the Administrative Agent and the Lenders, together with their respective Affiliates and Related Funds, and each of the directors, officers, employees, agents, attorneys and consultants of each of the foregoing (collectively, the "Released Parties"), from any and all debts, claims, allegations, obligations, damages, costs, attorneys' fees, suits, demands, liabilities, actions, proceedings and causes of action, in each case, whether known or unknown, contingent or fixed, direct or indirect, and of whatever nature or description, and whether in law or in equity, under contract, tort, statute or otherwise, which any Releasor has heretofore had or now or hereafter can, shall or may have against any Released Party by reason of any act, omission or thing whatsoever done or omitted to be done, in each case, on or prior to the Amendment Effective Date directly arising out of, connected with or related to this Amendment, the Financing Agreement or any other Loan Document, or any act, event or transaction related or attendant thereto, or the agreements of Administrative Agent or any Lender contained therein, or the possession, use, operation or control of any of the assets of any Loan Party, or the making of any Loans or other advances, or the management of such Loans or other advances or the Collateral. Each Loan Party represents and warrants that it has no knowledge of any claim by any Releasor against any Released Party or of any facts or acts or omissions of any Released Party which on the date hereof would be the basis of a claim by any Releasor against any Released Party which would not be released hereby.

10. Further Assurances. The Loan Parties shall execute any and all further documents, agreements and instruments, and take all further actions, as may be required under applicable law or as Administrative Agent may reasonably request, in order to effect the purposes of this Amendment.

11. Miscellaneous.

(a) This Amendment may be executed in any number of counterparts and by different parties hereto in separate counterparts, each of which shall be deemed to be an original but all of which taken together shall constitute one and the same agreement. Delivery of an executed counterpart of this Amendment by facsimile or electronic mail shall be equally effective as delivery of an original executed counterpart of this Amendment.

(b) Section and paragraph headings herein are included for convenience of reference only and shall not constitute a part of this Amendment for any other purpose.

(c) This Amendment shall be governed by, and construed in accordance with, the laws of the State of New York.

(d) Each Loan Party hereby acknowledges and agrees that this Amendment constitutes a "Loan Document" under the Financing Agreement. Accordingly, it shall be an immediate Event of Default under the Financing Agreement if (i) any representation or warranty made by any Loan Party under or in connection with this Amendment shall have been incorrect in any respect when made or deemed made, or (ii) any Loan Party shall fail to perform or observe any term, covenant or agreement contained in this Amendment.

(e) Any provision of this Amendment that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining portions hereof or affecting the validity or enforceability of such provision in any other jurisdiction.

[*Remainder of page intentionally left blank.*]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed and delivered as of the date set forth on the first page hereof.

BORROWER:

THERAPEUTICSMD, INC.

By: /s/ James C. D'Arecca
Name: James C. D'Arecca
Title: Chief Financial Officer

GUARANTORS:

VITAMEDMD, LLC

By: /s/ James C. D'Arecca
Name: James C. D'Arecca
Title: Chief Financial Officer

BOCAGREENMD, INC.

By: /s/ James C. D'Arecca
Name: James C. D'Arecca
Title: Chief Financial Officer

VITACARE PRESCRIPTION SERVICES, INC.

By: /s/ John C.K. Milligan, IV
Name: John C.K. Milligan, IV
Title: President

SIXTH STREET SPECIALTY LENDING, INC.,
as Administrative Agent and Lender

By: /s/ Joshua Easterly
Name: Joshua Easterly
Title: Chief Executive Officer

TOP IV TALENTS, LLC, as Lender

By: /s/ Joshua Peck
Name: Joshua Peck
Title: Vice President

TAO TALENTS, LLC, as Lender

By: /s/ Joshua Peck
Name: Joshua Peck
Title: Vice President

Exhibit 10.25

Execution Version

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. [***] INDICATES THAT INFORMATION HAS BEEN REDACTED.

AMENDMENT NO. 8
TO FINANCING AGREEMENT

AMENDMENT NO. 8 TO FINANCING AGREEMENT, dated as of March 1, 2021 (this "Amendment"), to the Financing Agreement, dated as of April 24, 2019 (as amended, restated, supplemented or otherwise modified from time to time, the "Financing Agreement"), by and among THERAPEUTICSMD, INC., a Nevada corporation ("Company" or "Borrower"), certain Subsidiaries of Borrower, as Guarantors, the Lenders from time to time party thereto, and SIXTH STREET SPECIALTY LENDING, INC., a Delaware corporation ("Sixth Street"), as administrative agent for the Lenders (in such capacity, together with its successors and assigns in such capacity, the "Administrative Agent").

WHEREAS, the Loan Parties have requested that the Administrative Agent and the Lenders amend certain terms and conditions of the Financing Agreement; and

WHEREAS, the Administrative Agent and the Lenders are willing to amend such terms and conditions of the Financing Agreement on the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the premises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. Definitions. All terms used herein that are defined in the Financing Agreement and not otherwise defined herein shall have the meanings assigned to them in the Financing Agreement.

2. Amendments.

(a) New Definitions. Section 1.01 of the Financing Agreement is hereby amended by adding the following definitions, in appropriate alphabetical order:

(i) ""Amendment No. 8" means Amendment No. 8 to Financing Agreement, dated as of March 1, 2021, by and among the Loan Parties, the Administrative Agent and the Lenders."

(ii) ""Amendment No. 8 Effective Date" means the "Amendment Effective Date" as set forth in Amendment No. 8."

(iii) ""VitaCare" means VitaCare Prescription Services, Inc., a Florida corporation."

(i) ""VitaCare Business Assets" means the assets and property (other than cash or Cash Equivalents) that are part of the Loan Parties' VitaCare prescription services business as of the Amendment No. 8 Effective Date or are acquired by such business after such date in the ordinary course of business."

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(ii) "“VitaCare Business Asset Excess Amount” means an amount equal to the excess, if any, of (i) the aggregate amount paid by the Loan Parties to acquire VitaCare Business Assets after the Amendment No. 8 Effective Date over (ii) $[***].”

(iii) "“VitaCare Sale” has the meaning set forth in Section 6.9(b)(i).”

(b) Amended Definitions. Section 1.01 of the Financing Agreement is hereby amended by amending the following definitions as follows:

(i) The definition of Affiliate is hereby amending by adding the following sentence at the end of such definition:

“Notwithstanding anything herein to the contrary, in no event shall VitaCare (following the VitaCare Sale) or the acquiring entity in the VitaCare Sale (or any direct or indirect parent or Subsidiary thereof) be considered an “Affiliate” of any Loan Party.”

(ii) The definition of Permitted Indebtedness is hereby amended by deleting the “and” at the end of clause (l), deleting the “.” at the end of clause (m) and substituting “and” therefor, and inserting the following new clause (n) as follows:

“(n) Indebtedness incurred by a Loan Party or any of its Subsidiaries arising from (i) customary indemnification obligations or (ii) revenue guarantees or other similar obligations, in each case as (A) provided under the definitive documentation related to the VitaCare Sale and (B) consented to by the Administrative Agent in writing (such consent not to be unreasonably withheld, delayed or conditioned (it being understood and agreed by the Administrative Agent and the Lenders that such consent shall not require any economic consideration, other consideration or any repayment of the Obligations (other than any payment required by either Section 2.8(y) or Section 2.10(a)(ii)(A), as applicable) as a condition thereof)), except that no consent will be required in the case of clause (ii) above if such obligations are satisfied solely in Capital Stock.”

(iii) The definition of Permitted Investments is hereby amended by deleting the “and” at the end of clause (h), deleting the “.” at the end of clause (i) and substituting “and” therefor, and inserting the following new clause (j) as follows:

“(j) any contribution of VitaCare Business Assets by a Loan Party to VitaCare in connection with the VitaCare Sale.”

(c) Section 2.8 (Repayment of the Loans). Section 2.8 of the Financing Agreement is hereby amended and restated in its entirety to read as follows:

“Section 2.8 Repayment of Term Loans. (x) On the Amendment No. 8 Effective Date the Borrower shall repay $15,000,000 in principal amount of the Term Loan, (y) on March 31, 2021 the Borrower shall repay $35,000,000 in principal amount of the Term Loan so long as the Borrower shall not have made a mandatory prepayment in accordance with Section 2.10(a)(ii)(A) prior to such date, and (z) commencing on March 31, 2022 and on the last day of each Fiscal Quarter ending thereafter, the Borrower shall repay the principal amount of the Term Loan in the aggregate amounts set forth below, in each case which payments shall be applied as follows: (a) first, the principal of the Initial Term Loan until paid in full, (b) second, the principal of the Delayed Draw A-1 Term Loan until paid in full and (c) third, the principal of the Delayed Draw A-2 Term Loan until paid in full.

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Fiscal Quarter Ending	**Term Loan Repayment**
March 31, 2022	$5,000,000
June 30, 2022	$5,000,000
September 30, 2022	$5,000,000
December 31, 2022	$10,000,000
March 31, 2023	$10,000,000
June 30, 2023	$41,250,000
September 30, 2023	$41,250,000
December 31, 2023	$41,250,000
March 31, 2024	$41,250,000

Notwithstanding the foregoing, the Term Loan, together with all other amounts owed hereunder with respect thereto, shall be paid in full no later than the Term Loan Maturity Date."

(d) Section 2.10(a)(ii) (Asset Sales). Section 2.10(a)(ii) of the Financing Agreement is hereby amended and restated in its entirety to read as follows:

"(ii) (A) On the same Business Day of the receipt by any Loan Party of the proceeds of the VitaCare Sale, Company shall prepay the principal amount of the Term Loans as set forth in Section 2.11(a)(ii) in an aggregate amount equal to $35,000,000; and

(B) No later than the fifth Business Day following the date of receipt by any Loan Party of any Net Proceeds from any other Asset Sales (which, for the avoidance of doubt, shall not include the VitaCare Sale) in excess of $5,000,000 in the aggregate in any Fiscal Year that do not constitute a Permitted Product Transaction, Company shall prepay the Term Loans as set forth in Section 2.11(a)(i) in an aggregate amount equal to such Net Proceeds in excess of $5,000,000 in such Fiscal Year; provided, solely in the case of this clause (B), so long as (i) no Default or Event of Default shall have occurred and be continuing, (ii) Company has delivered Administrative Agent prior written notice of Company's intention to apply such monies (the "Reinvestment Amounts") to reinvest in or to the costs of purchase of other assets used or useful in the business of the Loan Parties including capital expenditures, (iii) the monies are held in a Deposit Account subject to a Control Agreement, and (iv) the Loan Parties complete such reinvestment or purchase within 365 days after the initial receipt of such monies, the Loan Parties shall have the option to apply such monies to the reinvestment in or the costs of purchase of other assets used or useful in the business of the Loan Parties (including capital expenditures) unless and to the extent that such applicable period shall have expired without such reinvestment or purchase being made or completed, in which case, any such amounts not so used to reinvest or purchase shall be paid to Administrative Agent and applied in accordance with Section 2.11(a)(i)."

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(e) Section 2.11(a) (Application of Prepayments of Term Loans). Section 2.11(a) of the Financing Agreement is hereby amended and restated in its entirety to read as follows:

"(a) Application of Prepayments of Term Loans. Except in connection with any Waivable Mandatory Prepayment provided for in Section 2.11(b), so long as no Application Event has occurred and is continuing:

(i) any mandatory prepayment of any Loan pursuant to Section 2.10 (other than Section 2.10(a)(ii)(A)), in each case, shall be applied as follows:

first, to prepay accrued and unpaid interest on the Term Loan;

second, to pay any Prepayment Premium payable thereon; and

third, to prepay (A) first, the principal of the Initial Term Loan to the installments thereof on a pro rata basis until paid in full, (B) second, the principal of the Delayed Draw A-1 Term Loan to the installments thereof on a pro rata basis until paid in full and (C) third, the principal of the Delayed Draw A-2 Term Loan to the installments thereof on a pro rata basis until paid in full; and

(ii) any mandatory prepayment of any Loan pursuant to Section 2.10(a)(ii)(A) shall be applied as follows:

first, to prepay (A) first, the principal of the Initial Term Loan to the installments thereof on a pro rata basis until paid in full, (B) second, the principal of the Delayed Draw A-1 Term Loan to the installments thereof on a pro rata basis until paid in full and (C) third, the principal of the Delayed Draw A-2 Term Loan to the installments thereof on a pro rata basis until paid in full

second, to prepay accrued and unpaid interest on the Term Loan; and

third, to pay any Prepayment Premium payable thereon."

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(f) Section 6.8(b) (Minimum Revenue). The table set forth in Section 6.8(b) of the Financing Agreement is hereby amended and restated in its entirety to read as follows:

"Fiscal Quarter Ending	**Product Revenue**
December 31, 2020	$20,000,000
March 31, 2021	$17,000,000
June 30, 2021	$20,000,000
September 30, 2021	$23,000,000
December 31, 2021	$26,500,000
March 31, 2022	$30,000,000
June 30, 2022	$35,000,000
September 30, 2022	$40,000,000
December 31, 2022	$45,000,000
March 31, 2023	$50,000,000
June 30, 2023	$55,000,000
September 30, 2023	$60,000,000
December 31, 2023	$65,500,000
March 31, 2024	$70,000,000"

(g) Section 6.9(b) (Fundamental Changes; Dispositions of Assets; Acquisitions). Section 6.9(b) of the Financing Agreement is hereby amended and restated in its entirety to read as follows:

"(b) (i) any Asset Sale of VitaCare (which shall include any VitaCare Business Assets sold or transferred by a Loan Party in connection therewith to the extent such VitaCare Business Assets are not contributed by such Loan Party to VitaCare in connection therewith) so long as (A) the proceeds thereof are not less than the sum of (y) $[***] plus (z) the VitaCare Business Assets Excess Amount (of which not less than the sum of (y) $[***] plus (z) the VitaCare Business Assets Excess Amount shall be in Cash) and (B) such proceeds shall be applied as required by Section 2.10(a)(ii) (a "VitaCare Sale") (it being understood and agreed that it is intended that the assets and other property to be sold pursuant to the VitaCare Sale shall be sold free and clear of the Administrative Agent's and the Lenders' security interest, subject to the execution and delivery by the Administrative Agent (at the Loan Parties' expense) of such release documentation as may be reasonably requested by the Loan Parties and reasonably acceptable to the Administrative Agent); provided that, if following any VitaCare Sale the Loan Parties retain any interest, directly or indirectly, in the VitaCare Business Assets pursuant to which any Loan Party has any primary or contingent obligations payable in cash or Cash Equivalents, any obligations of the Loan Parties with respect to such retained interest shall be consented to by the Administrative Agent in writing (such consent not to be unreasonably withheld, delayed or conditioned (it being understood and agreed by the Administrative Agent and the Lenders that such consent shall not require any economic consideration, other consideration or any repayment of the Obligations (other than any payment required by either Section 2.8(y) or Section 2.10(a)(ii)(A), as applicable) as a condition thereof));

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(ii) any merger or other reorganization of VitaCare pursuant to an "F reorganization" in connection with the VitaCare Sale, as consented to by the Administrative Agent in writing (such consent not to be unreasonably withheld, delayed or conditioned (it being understood and agreed by the Administrative Agent and the Lenders that such consent shall not require any economic consideration, other consideration or any repayment of the Obligations (other than any payment required by either Section 2.8(y) or Section 2.10(a)(ii)(A), as applicable) as a condition thereof)); and

(iii) any other Asset Sales (other than (A) subject to Section 6.9(d), those constituting Permitted Product Transactions and (B) any other Asset Sale in respect of the Products or the Product Patents) in any Fiscal Year, the proceeds of which are less than $10,000,000 with respect to any single Asset Sale or series of related Asset Sales made within the same Fiscal Year; provided (1) the consideration received for such assets shall be in an amount at least equal to the fair market value thereof (determined in good faith by officers of Company or the Board of Directors of Company (or similar governing body)), (2) no less than 85% thereof shall be paid in Cash, and (3) if and to the extent required by Section 2.10(a)(ii), the proceeds thereof shall be applied as required by Section 2.10(a)(ii);".

3. Conditions to Effectiveness. This Amendment shall become effective only upon satisfaction in full, in a manner satisfactory to the Administrative Agent, of the following conditions precedent (the first date upon which all such conditions shall have been satisfied being hereinafter referred to as the "Amendment Effective Date"):

(a) Payment of Fees, Etc. The Borrowers shall have paid on or before the Amendment Effective Date all fees, costs, expenses and taxes then payable, if any, pursuant to Section 2.7 or 10.2 of the Financing Agreement.

(b) Representations and Warranties. The representations and warranties contained in this Amendment and in Article IV of the Financing Agreement and in each other Loan Document shall be true and correct in all material respects (except that such materiality qualifier shall not be applicable to any representations or warranties that already are qualified or modified as to "materiality" or "Material Adverse Effect" in the text thereof, which representations and warranties shall be true and correct in all respects subject to such qualification) on and as the Amendment Effective Date to the same extent as though made on and as of that date, except to the extent such representations and warranties specifically relate to an earlier date, in which case such representations and warranties shall have been true and correct in all material respects (except that such materiality qualifier shall not be applicable to any representations or warranties that already are qualified or modified as to "materiality" or "Material Adverse Effect" in the text thereof, which representations and warranties shall be true and correct in all respects subject to such qualification) on and as of such earlier date.

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(c) No Default; Event of Default. No Default or Event of Default shall have occurred and be continuing on the Amendment Effective Date or result from this Amendment becoming effective in accordance with its terms.

(d) Delivery of Documents. The Administrative Agent shall have received on or before the Amendment Effective Date (i) this Amendment, duly executed by the Loan Parties, the Administrative Agent and the Lenders and (ii) the Amended and Restated Fee Letter, dated as of the date hereof, duly executed by the Borrower and the Administrative Agent;

(e) Material Adverse Effect. The Administrative Agent shall have determined, in its reasonable judgment, that no event or development shall have occurred since December 31, 2019, which could reasonably be expected to have a Material Adverse Effect.

(f) Liens; Priority. The Administrative Agent shall be satisfied that the Administrative Agent has been granted, and holds, for the benefit of the Administrative Agent and the Lenders, a perfected, first priority Lien on and security interest in all of the Collateral, subject only to Permitted Liens, to the extent such Liens and security interests are required pursuant to the Loan Documents to be granted or perfected on or before the Amendment Effective Date.

(g) Approvals. All consents, authorizations and approvals of, and filings and registrations with, and all other actions in respect of, any Governmental Authority or other Person required in connection with any Loan Document or the transactions contemplated thereby or the conduct of the Loan Parties' business shall have been obtained or made and shall be in full force and effect. There shall exist no claim, action, suit, investigation, litigation or proceeding (including, without limitation, shareholder or derivative litigation) pending or, to the knowledge of any Loan Party, threatened in any court or before any arbitrator or Governmental Authority which (i) relates to the Loan Documents or the transactions contemplated thereby or (ii) could reasonably be expected to have a Material Adverse Effect.

(h) Term Loan Prepayment. The Borrower shall have prepaid $15,000,000 in principal amount of the Term Loan.

4. Continued Effectiveness of the Financing Agreement and Other Loan Documents. Each Loan Party hereby (a) acknowledges and consents to this Amendment, (b) confirms and agrees that the Financing Agreement and each other Loan Document to which it is a party is, and shall continue to be, in full force and effect and is hereby ratified and confirmed in all respects, except that on and after the Amendment Effective Date, all references in any such Loan Document to "the Financing Agreement", the "Agreement", "thereto", "thereof", "thereunder" or words of like import referring to the Financing Agreement shall mean the Financing Agreement as amended by this Amendment, and (c) confirms and agrees that, to the extent that any such Loan Document purports to assign or pledge to the Administrative Agent, for the benefit of the Administrative Agent and the Lenders, or to grant to the Administrative Agent, for the benefit of the Administrative Agent and the Lenders, a security interest in or Lien on any Collateral as security for the Obligations of the Loan Parties from time to time existing in respect of the Financing Agreement (as amended hereby) and the other Loan Documents, such pledge, assignment and/or grant of the security interest or Lien is hereby ratified and confirmed in all respects. This Amendment does not and shall not affect any of the obligations of the Loan Parties, other than as expressly provided herein, including, without limitation, the Loan Parties' obligations to repay the Loans in accordance with the terms of Financing Agreement or the obligations of the Loan Parties under any Loan Document to which they are a party, all of which obligations shall remain in full force and effect. Except as expressly provided herein, the execution, delivery and effectiveness of this Amendment shall not operate as a waiver of any right, power or remedy of Administrative Agent or any Lender under the Financing Agreement or any other Loan Document nor constitute a waiver of any provision of the Financing Agreement or any other Loan Document.

5. No Novation. Nothing herein contained shall be construed as a substitution or novation of the Obligations outstanding under the Financing Agreement or instruments securing the same, which shall remain in full force and effect, except as modified hereby.

6. No Representations by Administrative Agent or Lenders. Each Loan Party hereby acknowledges that it has not relied on any representation, written or oral, express or implied, by Administrative Agent or any Lender, other than those expressly contained herein, in entering into this Amendment.

7. Release. Each Loan Party hereby acknowledges and agrees that: (a) neither it nor any of its Subsidiaries has any claim or cause of action against Administrative Agent or any Lender (or any of the directors, officers, employees, agents, attorneys or consultants of any of the foregoing) and (b) the Administrative Agent and the Lenders have heretofore properly performed and satisfied in a timely manner all of their obligations to the Loan Parties, and all of their Subsidiaries and Affiliates. Notwithstanding the foregoing, the Administrative Agent and the Lenders wish (and the Loan Parties agree) to eliminate any possibility that any past conditions, acts, omissions, events or circumstances would impair or otherwise adversely affect any of their rights, interests, security and/or remedies. Accordingly, for and in consideration of the agreements contained in this Amendment and other good and valuable consideration, each Loan Party (for itself and its Subsidiaries and Affiliates and the successors, assigns, heirs and representatives of each of the foregoing) (collectively, the "Releasors") does hereby fully, finally, unconditionally and irrevocably release, waive and forever discharge the Administrative Agent and the Lenders, together with their respective Affiliates and Related Funds, and each of the directors, officers, employees, agents, attorneys and consultants of each of the foregoing (collectively, the "Released Parties"), from any and all debts, claims, allegations, obligations, damages, costs, attorneys' fees, suits, demands, liabilities, actions, proceedings and causes of action, in each case, whether known or unknown, contingent or fixed, direct or indirect, and of whatever nature or description, and whether in law or in equity, under contract, tort, statute or otherwise, which any Releasor has heretofore had or now or hereafter can, shall or may have against any Released Party by reason of any act, omission or thing whatsoever done or omitted to be done, in each case, on or prior to the Amendment Effective Date directly arising out of, connected with or related to this Amendment, the Financing Agreement or any other Loan Document, or any act, event or transaction related or attendant thereto, or the agreements of Administrative Agent or any Lender contained therein, or the possession, use, operation or control of any of the assets of any Loan Party, or the making of any Loans or other advances, or the management of such Loans or other advances or the Collateral. Each Loan Party represents and warrants that it has no knowledge of any claim by any Releasor against any Released Party or of any facts or acts or omissions of any Released Party which on the date hereof would be the basis of a claim by any Releasor against any Released Party which would not be released hereby.

8. Further Assurances. The Loan Parties shall execute any and all further documents, agreements and instruments, and take all further actions, as may be required under applicable law or as Administrative Agent may reasonably request, in order to effect the purposes of this Amendment.

9. Miscellaneous.

(a) This Amendment may be executed in any number of counterparts and by different parties hereto in separate counterparts, each of which shall be deemed to be an original but all of which taken together shall constitute one and the same agreement. Delivery of an executed counterpart of this Amendment by facsimile or electronic mail shall be equally effective as delivery of an original executed counterpart of this Amendment.

(b) Section and paragraph headings herein are included for convenience of reference only and shall not constitute a part of this Amendment for any other purpose.

(c) This Amendment shall be governed by, and construed in accordance with, the laws of the State of New York.

(d) Each Loan Party hereby acknowledges and agrees that this Amendment constitutes a "Loan Document" under the Financing Agreement. Accordingly, it shall be an immediate Event of Default under the Financing Agreement if (i) any representation or warranty made by any Loan Party under or in connection with this Amendment shall have been incorrect in any respect when made or deemed made, or (ii) any Loan Party shall fail to perform or observe any term, covenant or agreement contained in this Amendment.

(e) Any provision of this Amendment that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining portions hereof or affecting the validity or enforceability of such provision in any other jurisdiction.

[*Remainder of page intentionally left blank.*]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed and delivered as of the date set forth on the first page hereof.

BORROWER:

THERAPEUTICSMD, INC.

By: /s/ Robert Finizio
Name: Robert Finizio
Title: CEO

GUARANTORS:

VITAMEDMD, LLC

By: /s/ Robert Finizio
Name: Robert Finizio
Title: CEO

BOCAGREENMD, INC.

By: /s/ Robert Finizio
Name: Robert Finizio
Title: CEO

VITACARE PRESCRIPTION SERVICES, INC.

By: /s/ John C.K. Milligan
Name: John C.K. Milligan
Title: President

SIXTH STREET SPECIALTY LENDING, INC., as Administrative Agent and Lender

By: /s/ Robert (Bo) Stanley
Name: Robert (Bo) Stanley
Title: President

TOP IV TALENTS, LLC, as Lender

By: /s/ Joshua Peck
Name: Joshua Peck
Title: Vice President

TAO TALENTS, LLC, as Lender

By: /s/ Joshua Peck
Name: Joshua Peck
Title: Vice President

Exhibit 10.41

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "Agreement"), by and between TherapeuticsMD, Inc., a Nevada corporation (the "Company"), and Edward J. Borkowski ("Executive") is entered into and effective as of the 30th day of October 2019 (the "Effective Date").

WHEREAS, the Company and Executive now wish to provide for terms and conditions of Executive's continued employment with the Company, pursuant to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the premises and of the mutual covenants set forth in this Agreement, the parties hereto agree as follows:

1. **Employment and Duties.**

(a) **Employment and Term**. The Company agrees to employ Executive, and Executive hereby agrees to serve the Company, in accordance with the terms and conditions set forth herein, for a period of three (3) years, commencing as of the Effective Date (such three (3) year period, as it may be extended pursuant to this Section 1(a), the "Term"), unless sooner terminated pursuant to Section 3 hereof. Commencing on the third anniversary of the Effective Date, and each anniversary thereafter, the Term shall automatically be extended for one (1) additional year, unless at least ninety (90) days prior to such anniversary, the Company or Executive shall have given notice in accordance with Section 8 that it or Executive does not wish to extend the Term.

(b) **Duties of Executive.** Executive shall serve as the Executive Vice President, Operations of the Company, shall diligently perform all services as may be reasonably assigned to Executive by the Company's Board of Directors (the "Board") or the Company's Chief Executive Officer and shall exercise such power and authority as may from time to time be delegated to Executive by the Board, the Chief Executive Officer of the Company, or the designee to whom Executive reports. During Executive's employment, Executive shall devote Executive's full business time, energy, and ability exclusively to the business and interests of the Company, shall be physically present at the Company's offices in Boca Raton, Florida during normal business hours each week (other than permitted periods of working remotely, paid time off ("PTO") and on appropriate business travel for the benefit of the Company and shall not, without the Company's prior written consent, be engaged in any other business activity pursued for gain, profit, or other pecuniary advantage if such activity interferes in any material respect with Executive's duties and responsibilities hereunder. In Executive's capacity as the Executive Vice President, Operations of the Company, Executive shall do and perform all services, acts, or things necessary or advisable to manage and conduct the business of the Company, subject to the policies and procedures set by the Company, including, but not limited to providing all services, acts, or things necessary or advisable as may be assigned by the Chief Executive Officer from time to time consistent with Executive's role, including, but not limited to: providing advice and recommendations to the executive officers of the Company and the Board of Directors to assist them in continuing to transition the Company from a development stage to a commercial pharmaceutical company over a variety of functions, including, but not limited to, human resources, finance, legal, research and development, and business development; interfacing with investors; providing advice and recommendations regarding potential transactions; providing advice related to functional planning, corporate processes and structure, and identification of corporate gaps and solutions to the same; and providing advice and potential solutions regarding Company risk. Except as otherwise agreed in writing by the Company, it shall not be a violation of this Agreement for Executive, and Executive shall be permitted, to (i) serve on any civic or charitable boards; (ii) deliver lectures, fulfill speaking engagements, or teach at educational institutions and other institutions; (iii) subject to any applicable Company policies, make personal investments in such form or manner as will neither require Executive's services in the operation or affairs of the companies or enterprises in which such investments are made nor subject Executive to any conflict of interest with respect to Executive's duties to the Company; and (iv) serve, with the written approval of the Board, as a director of one or more private or public companies, in each case so long as any such activities do not significantly interfere with the performance of Executive's responsibilities under this Agreement, create a conflict of interest, or create an adverse interest or position detrimental to Company.

(c) Policies. Executive shall faithfully adhere to, execute, and fulfill all lawful policies established by the Company as are communicated to Executive by the Company.

(d) **Place of Performance**. In connection with Executive's employment by the Company, Executive shall be based at the Company's principal executive offices in Boca Raton, Florida.

2. Compensation. For all services rendered by Executive, the Company shall compensate Executive as follows:

(a) **Base Salary**. Effective on the Effective Date, the base salary ("Base Salary") payable to Executive shall be Four hundred thirty thousand dollars ($430,000) per year, payable on a regular basis in accordance with the Company's standard payroll procedures, but not less than monthly. The Board or a committee of the Board shall review Executive's performance on at least an annual basis and may make increases to such Base Salary if, in its sole discretion, any such increase is warranted. The Board may reduce the Base Salary without Executive's consent only if such reduction applies in the same or greater percentage to all other executives of the Company at the Vice President level and above.

(b) **Annual Short-Term Incentive**. Executive shall be entitled to participate in the Company's annual short-term incentive compensation program, as such program may exist from time to time, at a level commensurate with that being offered to other executives of the Company at the Chief level. For calendar years beginning on or after January 1, 2018, the percentage of Base Salary targeted as annual cash short-term incentive compensation for each calendar year during the Term shall be eighty-five percent (85%) of Base Salary (the "Targeted Annual Bonus Award"). Executive acknowledges that the amount of annual short-term incentive compensation, if any, to be awarded shall be at the sole, good faith discretion of the Board or a committee of the Board, may be less or more than the Targeted Annual Bonus Award, and will be based on a number of factors determined by the Board or a committee of the Board for each calendar year, including the Company's performance in connection with, among other factors, the clinical program, regulatory filings, commercialization and/or sales, and Executive's individual performance. Any annual short-term incentive compensation earned for any calendar year shall be paid in the immediately following calendar year, as soon as practicable. Except as set forth in Sections 3(b)(ii), 3(b)(iii), and 3(b)(iv), Executive must be employed by the Company on the date on which short-term incentive compensation is paid in order to receive such short-term incentive compensation. The 2019 Targeted Annual Bonus Award will be paid to Executive as if Executed were employed for the full year and will be at target or higher.

(c) **Long-Term Incentive**. Executive shall be entitled to participate in the Company's long-term incentive compensation program, as such program may exist from time to time, at a level commensurate with that being offered to other executives of the Company at the Vice President level and above. Executive acknowledges that the amount of long-term incentive compensation, if any, to be awarded shall be at the sole, good faith discretion of the Board or a committee of the Board, and will be based on a number of factors determined by the Board or a committee of the Board for the applicable performance period, including the Company's performance in connection with, among other factors, the clinical program, regulatory filings, commercialization and/or sales, and Executive's individual performance. Any long-term incentive compensation earned for the applicable performance period shall be paid within the first 2 ½ months of the calendar year immediately following the calendar year in which the applicable performance period ends. Except as otherwise set forth herein, Executive must be employed by the Company on the date on which long-term incentive compensation is paid to receive such long-term incentive compensation.

(d) **Stock Options.** The Company will grant to Executive by the Board of Directors as soon as practicable, pursuant to the Company's 2009 Amended and Restated Stock Incentive Plan, as the same may be amended from time to time (the "2009 Plan"), and the Company's 2012 Amended and Restated Stock Incentive Plan, as the same may be amended from time to time (the "2012 Plan" and, together with the 2009 Plan, collectively, the "Plans"), stock options to purchase 250,000 shares of the Company's common stock (the "Previously Granted Stock Options"). The stock options are subject to the terms and conditions set forth in the applicable Plans and in the stock option agreement(s) previously executed by the Company and Executive. Additional options or other equity compensation may be granted at the Board's discretion.

(e) **Restricted Stock Units.** As soon as practicable following the Effective Date, the Company will grant to Executive one million (1,000,000) restricted stock units ("RSUs") under the 2012 Plan as consideration for Executive entering into this Agreement, which RSUs will not vest in whole or in part until three (3) years after the Effective Date, at which time the RSUs will fully and completely vest, subject to Executive' continued employment with the Company and the terms and conditions in the 2012 Plan and an award agreement to be entered into between the Company and Executive.

(f) **Executive Perquisites, Benefits, and Other Compensation**. Executive shall be entitled to receive additional benefits and compensation from the Company in such form and to such extent as specified below:

(i) **Insurance Coverage**. During the Term, and as otherwise provided within the provisions of each of the respective plans, the Company shall make available to Executive all employee benefits to which other executives of the Company are entitled to receive, subject to the eligibility requirements and other provisions of such arrangements as applicable to executives of the Company generally. Such benefits shall include, but shall not be limited to, comprehensive health and major medical insurance, dental and life insurance, and short-term and long-term disability.

(ii) **Reimbursement for Expenses**. Reimbursement for business travel and other out-of-pocket expenses reasonably incurred by Executive in the performance of Executive's services under this Agreement, including, but not limited to, industry appropriate seminars and subscriptions and applicable licensing and continuing education expenses. All reimbursable expenses shall be appropriately documented in reasonable detail by Executive upon submission of any request for reimbursement and shall be in a format and manner consistent with the Company's expense reporting policy. Company will provide for Executive reasonable (i) temporary hotel or rental housing, (ii) rental vehicle, and (iii) airfare for the period of time in which he commutes from his home in New Jersey. The Company will reimburse Executive for reasonable, actual expenses to relocate his household to Florida.

(iii) **Paid Time Off**. Executive shall be eligible to accrue PTO and utilize and carryover from year to year such PTO, consistent with the Company's policies and procedures in effect from time to time for officers of Executive's level.

(iv) **Other Executive Perquisites**. The Company shall provide Executive with other executive perquisites as may be made available to or deemed appropriate for Executive by the Board or a committee of the Board and participation in all other Company-wide employee benefits as are available to the Company's executives from time to time, including any plans, programs, or arrangements relating to retirement, deferred compensation, profit sharing, 401(k), and employee stock ownership.

(v) **Working Facilities**. During the Term, the Company shall furnish Executive with an office, staffing and administrative support and such other facilities and services suitable to Executive's position with the Company and adequate for the performance of Executive's duties hereunder, which will be reviewed and provided based on the Company's needs.

3. **Term of Employment**.

(a) **Termination Under Certain Circumstances**.

(i) **Death**. Executive's employment and the Term shall be automatically terminated, without notice, effective upon the date of Executive's death.

(ii) **Disability**. If, as a result of incapacity due to physical or mental illness or injury, Executive shall have been absent from Executive's full-time duties hereunder for six (6) consecutive months, then thirty (30) days after giving written notice to Executive (which notice may occur before or after the end of such six (6) month period, but which shall not be effective earlier than the last day of such six (6) month period), the Company may terminate Executive's employment and the Term, provided Executive is unable to resume Executive's full-time duties at the conclusion of such notice period.

(iii) **Termination by the Company for Good Cause**. The Company may terminate Executive's employment and the Term upon ten (10) days prior written notice to Executive for "Good Cause," which shall mean any one or more of the following: (A) Executive's material breach of this Agreement (continuing for thirty (30) days after receipt of written notice of need to cure, if, in the Company's determination, such breach is curable); (B) Executive's negligence in the performance or intentional nonperformance (continuing for thirty (30) days after receipt of written notice of need to cure, if, in the Company's determination, such breach is curable) of any of Executive's material duties and responsibilities; (C) Executive's willful dishonesty, fraud, or misconduct with respect to the business or affairs of the Company; (D) Executive's indictment for, charge of, conviction of, or guilty or *nolo contendre* plea to a felony crime involving dishonesty or moral turpitude whether or not relating to the Company; (E) a confirmed positive drug test result for an illegal drug; or (F) a material sanction is imposed on Executive by any applicable professional organization or professional governing body including, for the avoidance of doubt, an accounting regulatory board.

(iv) **Termination by the Company Without Good Cause**. The Company may terminate Executive's employment and the Term at any time without Good Cause.

(v) **Termination by Executive Without Good Reason**. Executive, at Executive's option and upon written notice to the Company, may terminate Executive's employment and the Term without Good Reason (as defined below) at any time, effective on the date of that notice.

(vi) **Termination by Executive With Good Reason**. At any time during the Term, Executive may terminate Executive's employment and the Term for Good Reason. For purposes of this Agreement, "Good Reason" shall mean (A) the assignment to Executive of material duties inconsistent with Executive's position as the Executive Vice President, Operations (including status, office, titles and reporting requirements), or any other action by the Company that results in a material diminution in such position, excluding for this purpose (i) any action not taken in bad faith and that is remedied by the Company promptly after receipt of a Notice of Termination for Good Reason (as defined below) thereof given by Executive and (ii) any change in status, office, titles and reporting requirements following a Change in Control of the Company in which the Company ceases to be a standalone public reporting company, provided that the material duties of Executive following such Change in Control are not inconsistent with those of Executive immediately prior to such Change in Control; or (B) any material failure by the Company to comply with any of the provisions of this Agreement, other than a failure not occurring in bad faith and that is remedied by the Company promptly after receipt of a Notice of Termination for Good Reason given thereof by Executive. A termination of employment by Executive for Good Reason shall be effected by Executive's giving the Board written notice ("Notice of Termination for Good Reason") of the termination, setting forth in reasonable detail the specific conduct of the Company that constitutes Good Reason and the specific provision(s) of this Agreement on which Executive relies, within ninety (90) days of the initial existence of one of the conditions constituting Good Reason. A termination of employment by Executive for Good Reason shall be effective on the thirty-first (31st) day following the date when the Notice of Termination for Good Reason is given to the Company; provided that such a termination of employment shall not become effective if the Company shall have substantially corrected the circumstance giving rise to the Notice of Termination for Good Reason within thirty (30) days after the Company's receipt of such Notice of Termination for Good Reason.

(b) **Result of Termination**.

(i) Except as otherwise set forth in this Agreement, in the event of the termination of Executive's employment and the Term pursuant to Sections 3(a)(iii) ("Termination by the Company for Good Cause") or 3(a)(v) ("Termination by Executive Without Good Reason") above, Executive shall receive no further compensation under this Agreement other than the payment of Base Salary as shall have accrued and remained unpaid as of the date of termination and accrued but unused PTO consistent with the Company's policies and procedures therefor in effect at the time of such termination for officers of Executive's level.

(ii) In the event of the termination of Executive's employment and the Term pursuant to Sections 3(a)(iv) ("Termination by the Company Without Good Cause") or 3(a)(vi) ("Termination by Executive With Good Reason") above and after the first ninety (90) days of employment, (a) Executive shall, for a period of twelve (12) months following the effective date of such termination, continue to receive Executive's then current annual Base Salary, as provided in Section 2(a), (b) Executive shall receive an amount equal to Executive's Targeted Annual Bonus Award for the calendar year in which the termination of Executive's employment occurs, which amount shall be paid to Executive in a single lump sum, which is unpaid on the effective date of Executive's termination, and which shall be paid to Executive when paid to other similarly situated executives of the Company in accordance with Section 2(b) hereof, (c) Executive shall receive, beginning on the first payroll date occurring on or after the thirtieth (30^{th}) day following the effective date of the termination of Executive's employment under this Agreement and for a period of twenty-four (24) months thereafter for a total of twenty-four (24) monthly payments, a monthly cash payment equal to the one (1) month cost of COBRA continuation of the health insurance benefits for Executive and Executive's immediate family as applicable, as the effective date of such termination, less, the one (1) month cost for the same health insurance benefits for Executive and Executive's immediate family as applicable that would have been incurred by Executive immediately prior to the effective date of such termination if Executive remained employed with the Company, (d) all unvested equity compensation of any kind (including, without limitation, stock options, restricted stock, or restricted stock units) held by Executive in Executive's capacity as an employee of the Company on the effective date of the termination shall vest as of the effective date of such termination, (e) Executive shall receive payment for accrued but unused PTO consistent with the Company's policies and procedures therefor in effect at the time of such termination for officers of Executive's level, and (f) Executive shall receive payment for any annual short-term incentive compensation earned pursuant to Section 2(b) hereof for the calendar year immediately preceding the calendar year in which the termination of Executive's employment occurs which is unpaid on the effective date of Executive's termination, which shall be paid to Executive when paid to other similarly situated executives of the Company in accordance with Section 2(b) hereof.

(iii) In the event of the termination of Executive's employment and the Term pursuant to Sections 3(a)(i) ("Death") or 3(a)(ii) ("Disability") above, (a) Executive shall receive an amount equal to Executive's Targeted Annual Bonus Award for the calendar year in which the termination of Executive's employment occurs, multiplied by a fraction, the numerator of which is the number of full months of such calendar year during which Executive was employed with the Company, and the denominator of which is twelve (12), which amount shall be paid to Executive in a single lump sum on the first payroll date occurring on or after the thirtieth (30th) day following the effective date of the termination of Executive's employment under this Agreement, (b) all unvested equity compensation of any kind (including, without limitation, stock options, restricted stock, or restricted stock units) held by Executive in Executive's capacity as an employee of the Company on the effective date of the termination shall vest as of the effective date of such termination, (c) Executive shall receive payment for accrued but unused PTO consistent with the Company's policies and procedures therefor in effect at the time of such termination for officers of Executive's level, and (d) Executive shall receive payment for any annual short-term incentive compensation earned pursuant to Section 2(b) hereof for the calendar year immediately preceding the calendar year in which the termination of Executive's employment occurs which is unpaid on the effective date of Executive's termination, which shall be paid to Executive when paid to other similarly situated executives of the Company in accordance with Section 2(b) hereof.

(iv) In the event of the termination of Executive's employment and the Term pursuant to Sections 3(a)(iv) ("Termination by the Company Without Good Cause") or 3(a)(vi) ("Termination by Executive With Good Reason") during the twelve (12) month period immediately following a Change in Control, then in lieu of any benefits or amounts otherwise payable under Section 3(b)(ii) hereof, (a) Executive shall, for a period of eighteen (18) months following the effective date of such termination, continue to receive Executive's then current annual Base Salary, as provided in Section 2(a), (b) Executive shall receive an amount equal to one and one half times (1.5x) Executive's Targeted Annual Bonus Award for the calendar year in which the termination of Executive's employment occurs, which amount shall be paid to Executive in a single lump sum on the first payroll date occurring on or after the thirtieth (30th) day following the effective date of the termination of Executive's employment under this Agreement, (c) Executive shall receive, beginning on the first payroll date occurring on or after the thirtieth (30th) day following the effective date of the termination of Executive's employment under this Agreement and for a period of eighteen (18) months thereafter for a total of eighteen (18) monthly payments, a monthly cash payment equal to the one (1) month cost of COBRA continuation of the health insurance benefits for Executive and Executive's immediate family as applicable, as the effective date of such termination, less, the one (1) month cost for the same health insurance benefits for Executive and Executive's immediate family as applicable that would have been incurred by Executive immediately prior to the effective date of such termination if Executive remained employed with the Company, (d) all unvested equity compensation of any kind (including, without limitation, stock options, restricted stock, or restricted stock units) held by Executive in Executive's capacity as an employee of the Company on the effective date of the termination shall vest as of the effective date of such termination, (e) Executive shall receive payment for accrued but unused PTO consistent with the Company's policies and procedures therefor in effect at the time of such termination for officers of Executive's level, and (f) Executive shall receive payment for any annual short-term incentive compensation earned pursuant to Section 2(b) hereof for the calendar year immediately preceding the calendar year in which the termination of Executive's employment occurs which is unpaid on the effective date of Executive's termination, which shall be paid to Executive when paid to other similarly situated executives of the Company in accordance with Section 2(b) hereof.

(c) **Release**. Notwithstanding any other provision in this Agreement to the contrary, as a condition precedent to receiving any post-termination payments or benefits identified in Sections 3(b)(ii), 3(b)(iii) and 3(b)(iv) of this Agreement, Executive agrees to execute (and not revoke) a full and complete release of all claims against the Company and its affiliates, in the form attached hereto as Exhibit A (subject to such modifications as the Company reasonably may request) (the "Release"). If Executive fails to execute and deliver to the Company the Release within twenty-one (21) days following the date of termination, or revokes the Release, within seven (7) days following the date Executive executes and delivers the Release, or materially breaches any term of this Agreement or any other agreement between Executive and the Company while receiving such post-termination payments or benefits, Executive agrees that Executive shall not be entitled to receive any such post-termination payments. For purposes of this Agreement, the Release shall be deemed to have been executed by Executive if it is signed by Executive's legal representative in the case of legal incompetence or on behalf of Executive's estate in the case of Executive's death. Payment of any post-termination payments or benefits identified in Sections 3(b)(ii), 3(b)(iii) and 3(b)(iv) of this Agreement shall be delayed until the first payroll date occurring on or after the thirtieth (30^{th}) day following the effective date of the termination of Executive's employment under this Agreement, and any payments that are so delayed shall be paid on the first payroll date occurring on or after the thirtieth (30^{th}) day following the effective date of the termination of Executive's employment under this Agreement.

(d) **Section 409A**. Any payments made by the Company pursuant to Sections 3(b)(ii), 3(b)(iii) and 3(b)(iv) of this Agreement (except for unpaid annual short-term incentive compensation earned in the calendar year immediately preceding the calendar year in which the termination of Executive's employment occurs, which shall be paid to Executive when paid to other similarly situated executives of the Company) shall be paid or commence on the first payroll date occurring on or after the thirtieth (30^{th}) day following the effective date of Executive's "separation from service" within the meaning of Section 409A ("Section 409A") of the Internal Revenue Code of 1986, as amended (the "Code"). For purposes of applying the provisions of Section 409A to this Agreement, each separately identified amount to which Executive is entitled under this Agreement shall be treated as a separate payment. In addition, to the extent permissible under Section 409A, any series of installment payments under this Agreement shall be treated as a right to a series of separate payments. Executive shall receive no additional compensation following any termination except as provided herein. In the event of any termination, Executive shall resign all positions with the Company and its subsidiaries. If Executive is a "specified employee" within the meaning of Section 409A, then payments identified in Section 3(b) of this Agreement shall not commence until six (6) months following "separation from service" within the meaning of Section 409A to the extent necessary to avoid the imposition of the additional twenty percent (20%) tax under Section 409A (and in the case of installment payments, the first payment shall include all installment payments required by this subsection that otherwise would have been made during such six-month period). If the payments described in Section 3(b) must be delayed for six (6) months pursuant to the preceding sentence, Executive shall not be entitled to additional compensation to compensate for such delay period. Upon the date such payment would otherwise commence, the Company shall reimburse Executive for such payments, to the extent that such payments otherwise would have been paid by the Company had such payments commenced upon Executive's "separation from service" within the meaning of Section 409A.

Any remaining payments shall be provided by the Company in accordance with the schedule and procedures specified herein. This Agreement is intended to satisfy the requirements of Section 409A with respect to amounts subject thereto, and shall be interpreted and construed consistent with such intent. Any reimbursements by the Company to Executive of any eligible expenses under this Agreement that are not excludable from Executive's income for Federal income tax purposes (the "Taxable Reimbursements") shall be made by no later than the last day of the taxable year of Executive following the year in which the expense was incurred. The amount of any Taxable Reimbursements, and the value of any in-kind benefits to be provided to Executive, during any taxable year of Executive shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year of Executive. The right to Taxable Reimbursement, or in-kind benefits, shall not be subject to liquidation or exchange for another benefit. Notwithstanding the foregoing, the Company does not make any representation to Executive that the payments or benefits provided under this Agreement are exempt from, or satisfy, the requirements of Section 409A, and the Company shall have no liability or other obligation to indemnify or hold harmless Executive or any beneficiary for any tax, additional tax, interest or penalties that Executive or any beneficiary may incur in the event that any provision of this Agreement, or any amendment or modification thereof, or any other action taken with respect thereto, is deemed to violate any of the requirements of Section 409A.

(e) **Section 280G**.

(i) **Certain Reductions in Agreement Payments**. Anything in this Agreement to the contrary notwithstanding, in the event a nationally recognized independent accounting firm designated by the Company and reasonably acceptable to Executive (the "Accounting Firm") shall determine that receipt of all payments or distributions by the Company and its affiliates in the nature of compensation to or for Executive's benefit, whether paid or payable pursuant to this Agreement or otherwise (a "Payment"), would subject Executive to the excise tax under Section 4999 of the Code, the Accounting Firm shall determine as required below in this Section 3(e) whether to reduce any of the Payments paid or payable pursuant to this Agreement (the "Agreement Payments") to the Reduced Amount (as defined below). The Agreement Payments shall be reduced to the Reduced Amount only if the Accounting Firm determines that Executive would have a greater Net After-Tax Receipt (as defined below) of aggregate Payments if Executive's Agreement Payments were so reduced. If the Accounting Firm determines that Executive would not have a greater Net After-Tax Receipt of aggregate Payments if Executive's Agreement Payments were so reduced, then Executive shall receive all Agreement Payments to which Executive is entitled.

(ii) Accounting Firm Determinations. If the Accounting Firm determines that aggregate Agreement Payments should be reduced to the Reduced Amount, then the Company shall promptly give Executive notice to that effect and a copy of the detailed calculation thereof. All determinations made by the Accounting Firm under this Section 3(e) shall be binding upon the Company and Executive and shall be made as soon as reasonably practicable and in no event later than twenty (20) days following the effective date of the termination of Executive's employment with the Company. For purposes of reducing the Agreement Payments to the Reduced Amount, only amounts payable under this Agreement (and no other Payments) shall be reduced. The reduction of the amounts payable hereunder, if applicable, shall be made (A) only from Payments that the Accounting Firm determines reasonably may be characterized as "parachute payments" under Section 280G of the Code; (B) only from Payments that are required to be made in cash, (C) only with respect to any amounts that are not payable pursuant to a "nonqualified deferred compensation plan" subject to Section 409A of the Code, until those payments have been reduced to zero, and (D) in reverse chronological order, to the extent that any Payments subject to reduction are made over time (e.g., in installments). In no event, however, shall any Payments be reduced if and to the extent such reduction would cause a violation of Section 409A of the Code or other applicable law. All fees and expenses of the Accounting Firm shall be borne solely by the Company.

(iii) Overpayments; Underpayments. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that amounts will have been paid or distributed by the Company to or for the benefit of Executive pursuant to this Agreement which should not have been so paid or distributed (an "Overpayment") or that additional amounts which will have not been paid or distributed by the Company to or for the benefit of Executive pursuant to this Agreement which should have been so paid or distributed (an "Underpayment"), in each case consistent with the calculation of the Reduced Amount hereunder. In the event that the Accounting Firm, based upon the assertion of a deficiency by the Internal Revenue Service against either the Company or Executive which the Accounting Firm believes has a high probability of success determines that an Overpayment has been made, Executive shall pay any such Overpayment to the Company together with interest at the applicable federal rate provided for in Section 7872(f)(2) of the Code; provided, however, that no amount shall be payable by Executive to the Company if and to the extent such payment would not either reduce the amount on which Executive is subject to tax under Section 1 and Section 4999 of the Code or generate a refund of such taxes. In the event that the Accounting Firm, based upon controlling precedent or other substantial authority, determines that an Underpayment has occurred, any such Underpayment shall be paid promptly (and in no event later than 60 days following the date on which the Underpayment is determined) by the Company to or for the benefit of Executive together with interest at the applicable federal rate provided for in Section 7872(f)(2) of the Code.

(iv) Definitions. The following terms shall have the following meanings for purposes of this Section 3:

(A) "Net After-Tax Receipt" shall mean the present value (as determined in accordance with Sections 280G(b)(2)(A)(ii) and 280G(d)(4) of the Code) of a Payment net of all taxes imposed on Executive with respect thereto under Sections 1 and 4999 of the Code and under applicable state and local laws, determined by applying the highest marginal rate under Section 1 of the Code and under state and local laws which applied to Executive's taxable income for the immediately preceding taxable year, or such other rate(s) as the Accounting Firm determined to be likely to apply to Executive in the relevant taxable year(s).

(B) "Reduced Amount" shall mean the greatest amount of Agreement Payments that can be paid that would not result in the imposition of the excise tax under Section 4999 of the Code if the Accounting Firm determines to reduce Agreement Payments pursuant to Section 3(e)(i).

4. **Competition and Non-Solicitation.**

(a) **Interests to be Protected**. The parties acknowledge that Executive will perform essential services for the Company, its employees, and its stockholders during the term of Executive's employment with the Company. Executive will be exposed to, have access to, and work with, a considerable amount of confidential information. The parties also expressly recognize and acknowledge that the personnel of the Company have been trained by, and are valuable to, the Company and that the Company will incur substantial recruiting and training expenses if the Company must hire new personnel or retrain existing personnel to fill vacancies. The parties expressly recognize that it could seriously impair the goodwill and diminish the value of the Company's business should Executive compete with the Company in any manner whatsoever. The parties acknowledge that this covenant has an extended duration; however, they agree that this covenant is reasonable and it is necessary for the protection of the Company, its stockholders, and employees. For these and other reasons, and the fact that there are many other employment opportunities available to Executive if Executive's employment is terminated, the parties are in full and complete agreement that the following restrictive covenants are fair and reasonable and are entered into freely, voluntarily, and knowingly. Furthermore, each party was given the opportunity to consult with independent legal counsel before entering into this Agreement.

(b) **Non-Competition**. During the term of Executive's employment with the Company and for eighteen (18) months after the termination of Executive's employment with the Company, which may be extended an additional twelve (12) months in the sole and absolute discretion of the Company for a total of thirty (30) months after termination of Executive's employment with the Company, regardless of the reason therefor, Executive shall not (whether directly or indirectly, as owner, principal, agent, stockholder, director, officer, manager, employee, partner, participant, or in any other capacity) engage or become substantially and directly financially interested in any Competitive Business Activities conducted within the Restricted Territory (as defined below). In the event of the termination of Executive's employment and the Term pursuant to Sections 3(a)(iv) ("Termination by the Company Without Good Cause") or 3(a)(vi) ("Termination by Executive With Good Reason"), if the Company exercises its right to extend this non-competition clause by the additional twelve (12) months, then Executive will, (a) for a period of twelve (12) additional months, continue to receive Executive's then current annual Base Salary, as provided in Section 2(a), and (b) Executive will receive for a period of an additional six (6), a monthly cash payment equal to the one (1) month cost of COBRA continuation of the health insurance benefits for Executive and Executive's immediate family as applicable. As used herein, the term "Competitive Business Activities" shall mean business activities that are competitive with the business of the Company, including but not limited to, business activities in the pharmaceutical industry related to products that compete with the Company's products, and the term "Restricted Territory" shall mean any state or other geographical area in which the Company has demonstrated an intent to develop, commercialize, and/or distribute products during Executive's employment with the Company. Executive hereby agrees that, as of the date hereof, during Executive's employment with the Company, the Company has demonstrated an intent to develop, commercialize, and/or distribute products throughout the United States of America, Canada, Mexico, Brazil, Argentina, Europe, Australia, South Africa, Russia, Israel, Japan, and South Korea.

(c) Non-Solicitation of Employees. During the term of Executive's employment and for a period of twenty-four (24) months after the termination of Executive's employment with the Company, regardless of the reason therefor, Executive shall not directly or indirectly, for the Company, or on behalf of or in conjunction with any other person, company, partnership, corporation, or governmental or other entity, solicit for employment, seek to hire, or hire any person who is employed by the Company, is a consultant of the Company, or is an independent contractor of the Company, within twenty-four (24) months of the termination of Executive's employment, and, as related solely to consultants, for the purpose of having any such consultant engage in services that are the same as, similar to, or related to the services that such consultant provided for the Company and that are competitive with the services provided by the consultant for the Company.

(d) **Non-Solicitation of Customers**. During the term of Executive's employment and for a period of twenty-four (24) months after the termination of Executive's employment with the Company, regardless of the reason therefor, Executive shall not directly or indirectly, for the Company, or on behalf of, or in conjunction with, any other person, company, partnership, corporation, or governmental entity, call on, solicit, or engage in business with, any of the actual or targeted prospective customers or clients of the Company on behalf of any person or entity in connection with any Competitive Business, nor shall Executive make known the names and addresses of such actual or targeted prospective customers or clients, or any information relating in any manner to the trade or business relationships of the Company with such customers or clients, other than in connection with the performance of Executive's duties under this Agreement, and/or persuade or encourage or attempt to persuade or encourage any persons or entities with whom the Company does business or has some business relationship to cease doing business or to terminate its business relationship with the Company or to engage in any Competitive Business Activities on its own or with any competitor of the Company. As used herein, the term "Competitive Business" shall mean business that is directly competitive with the business of the Company, including but not limited to, business in the pharmaceutical industry related to products that directly compete with the Company's products.

(e) **Employee Assignment, Invention and Confidentiality Agreement**. Executive hereby reaffirms, acknowledges, and agrees that Executive will be subject to the terms and conditions set forth in that certain Employee Assignment, Invention, and Confidentiality Agreement (the "EAICA") that must be entered into as a condition of employment between the Company and Executive, and that this Agreement does not modify or amend the EAICA.

(f) **Equitable Relief**. In the event a violation of any of the restrictions contained in this Section 4 occurs, the Company shall be entitled to preliminary and permanent injunctive relief (without being required to post bond), reasonable attorneys' fees, and damages and an equitable accounting of all earnings, profits, and other benefits arising from such violation, which right shall be cumulative and in addition to any other rights or remedies to which the Company may be entitled. In the event of a violation of any provision of Section 4(b), Section 4(c), or Section 4(d), the period for which those provisions would remain in effect shall be extended for a period of time equal to that period beginning when such violation commenced and ending when the activities constituting such violation shall have been finally terminated in good faith.

(g) **Restrictions Separable**. If the scope of any provision of this Agreement (whether in this Section 4 or otherwise) is found by a court to be too broad to permit enforcement to its full extent, then such provision shall be enforced to the maximum extent permitted by law. The parties agree that the scope of any provision of this Agreement may be modified by a judge in any proceeding to enforce this Agreement, so that such provision can be enforced to the maximum extent permitted by law. Each and every restriction set forth in this Section 4 is independent and severable from the others, and no such restriction shall be rendered unenforceable by virtue of the fact that, for any reason, any other or others of them may be unenforceable in whole or in part.

5**.** **Return of Company Property**. At any time as requested by the Company, or upon the termination of Executive's employment with the Company for any reason, Executive shall deliver promptly to the Company all files, lists, books, records, manuals, memoranda, drawings, and specifications; all other written or printed materials and computers, cell phones, and other equipment that are the property of the Company (and any copies of them); and all other materials that may contain confidential information relating to the business of the Company, which Executive may then have in Executive's possession or control, whether prepared by Executive or not.

6. **Cooperation**. Following the Term, Executive shall give assistance and cooperation willingly, upon reasonable advance notice with due consideration for Executive's other business or personal commitments, in any matter relating to Executive's position with the Company, or Executive's expertise or experience as the Company may reasonably request, including Executive's attendance and truthful testimony where deemed appropriate by the Company, with respect to any investigation or the Company's defense or prosecution of any existing or future claims or litigations or other proceedings relating to matters in which Executive was involved or potentially had knowledge by virtue of Executive's employment with the Company. The Company agrees that (a) it shall promptly reimburse Executive for Executive's reasonable and documented expenses in connection with rendering assistance and/or cooperation under this Section 6 upon Executive's presentation of documentation for such expenses and (b) Executive shall be reasonably compensated for any continued material services as required under this Section 6.

7. **No Prior Agreements**. Executive hereby represents and warrants to the Company that the execution of this Agreement by Executive and Executive's employment by the Company and the performance of Executive's duties hereunder will not violate or be a breach of any agreement with a former employer, client, or any other person or entity. Further, Executive agrees to indemnify the Company for any claim, including, but not limited to, attorneys' fees and expenses of investigation, by any such third party that such third party may now have or may hereafter come to have against the Company based upon or arising out of any non-competition, invention, or secrecy agreement between Executive and such third party that was in existence as of the date of this Agreement.

8. **Miscellaneous**.

(a) **Notice**. All notices, requests, demands, and other communications required or permitted under this Agreement shall be in writing and shall be deemed to have been duly given, made, and received (i) if personally delivered, on the date of delivery, (ii) if by e-mail transmission, upon receipt, (iii) if mailed United States mail, registered or certified, return receipt requested, postage prepaid, and addressed as provided below, upon receipt or refusal of delivery, or (iv) if by a courier delivery service providing overnight or "next-day" delivery, upon receipt or refusal of delivery, in each case addressed as follows:

To the Company:

TherapeuticsMD, Inc.
6800 Broken Sound Parkway NW, 3rd Floor
Boca Raton, Florida 33487
Attention: Chief Executive Officer
Phone: (561) 961-1900

With a copy, which shall not constitute notice, to:

TherapeuticsMD, Inc.
6800 Broken Sound Parkway NW, 3rd Floor
Boca Raton, Florida 33487
Attention: General Counsel
Phone: (561) 961-1900

To Executive: Edward J. Borkowski

Either party may alter the address to which communications or copies are to be sent by giving notice of such change of address in conformity with the provisions of this Section 8 for the giving of notice.

(b) **Indulgences; Waivers**. Neither any failure nor any delay on the part of either party to exercise any right, remedy, power, or privilege under this Agreement shall operate as a waiver thereof, nor shall any single or partial exercise of any right, remedy, power, or privilege preclude any other or further exercise of the same or of any other right, remedy, power, or privilege, nor shall any waiver of any right, remedy, power, or privilege with respect to any occurrence be construed as a waiver of such right, remedy, power, or privilege with respect to any other occurrence. No waiver shall be binding unless executed in writing by the party making the waiver.

(c) **Controlling Law**. This Agreement and all questions relating to its validity, interpretation, performance and enforcement, shall be governed by and construed in accordance with the laws of the State of Florida, notwithstanding any Florida or other conflict-of-interest provisions to the contrary. Venue for any action arising out of this Agreement or the employment relationship shall be brought only in courts of competent jurisdiction in or for Palm Beach County, Florida and each party hereby irrevocably waives, to the fullest extent permitted by law, any objection which they may now or hereafter have to the laying of venue in such courts and submits to the jurisdiction of such courts. THE PARTIES (BY THEIR ACCEPTANCE HEREOF) HEREBY KNOWINGLY, IRREVOCABLY, VOLUNTARILY, AND INTENTIONALLY WAIVE ANY RIGHT EACH MAY HAVE TO A TRIAL BY JURY WITH RESPECT TO ANY DISPUTES BASED UPON OR ARISING OUT OF THIS AGREEMENT.

(d) **Execution in Counterpart**. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original as against any party whose signature appears thereon, and all of which shall together constitute one and the same instrument. This Agreement shall become binding when one or more counterparts hereof, individually or taken together, shall bear the signatures of the parties reflected hereon as the signatories.

(e) **Entire Agreement**. Except as herein contained, this Agreement contains the entire understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior and contemporaneous agreements and understandings, inducements, and conditions, express or implied, oral or written, which shall no longer have any force or effect. The express terms hereof control and supersede any course of performance and/or usage of the trade inconsistent with any of the terms hereof. This Agreement may not be modified or amended other than by an agreement in writing.

(f) **Paragraph Headings**. The paragraph headings in this Agreement are for convenience only; they form no part of this Agreement and shall not affect its interpretation.

(g) **Number of Days**. In computing the number of days for purposes of this Agreement, all days shall be counted, including Saturdays, Sundays, and holidays; provided, however, that if the final day of any time period falls on a Saturday, Sunday, or holiday, then the final day shall be deemed to be the next day that is not a Saturday, Sunday, or holiday.

(h) **Successors and Assigns.** This Agreement shall inure to the benefit of and be binding upon the successors and assigns of the parties hereto; provided that because the obligations of Executive hereunder involve the performance of personal services, such obligations shall not be delegated by Executive. For purposes of this Agreement, successors and assigns shall include, but not be limited to, any individual, corporation, trust, partnership, or other entity that acquires a majority of the stock or assets of the Company by sale, merger, consolidation, liquidation, or other form of transfer. The Company will require any successor (whether direct or indirect, by purchase, merger, consolidation, or otherwise) to all or substantially all of the business and/or assets of the Company to expressly assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform it if no such succession had taken place.

(i) **Tax Withholding.** The Company may withhold from any benefits payable under this Agreement all federal, state, city, or other taxes as may be required pursuant to any law or governmental regulation or ruling.

(j) **Survival.** The respective rights and obligations of the parties hereunder shall survive any termination of Executive's employment hereunder, including without limitation, the Company's obligations under Section 3 and Executive's obligations under Section 4 above, and the expiration of the Term, to the extent necessary to the intended preservation of such rights and obligations.

(k) **Right to Consult with Counsel; No Drafting Party.** Executive acknowledges having read and considered all of the provisions of this Agreement carefully, and having had the opportunity to consult with counsel of Executive's own choosing, and, given this, Executive agrees that the obligations created hereby are not unreasonable. Executive acknowledges that Executive has had an opportunity to negotiate any and all of these provisions and no rule of construction shall be used that would interpret any provision in favor of or against a party on the basis of who drafted the Agreement.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

THERAPEUTICSMD, INC.

/s/ Robert Finizio
Robert Finizio

EXECUTIVE:

/s/ Edward J. Borkowski
Edward J. Borkowski

[Signature Page to Employment Agreement]

EXHIBIT A
FORM OF RELEASE

This Separation Agreement ("Agreement") is made between TherapeuticsMD, Inc. ("Company") and ____________________ ("Employee"), intending to be legally bound, and in consideration of the mutual covenants contained herein, and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Separation and Severance. Employee's final day of employment with Company was ____________________. Although the parties agree that Company does not owe Employee any further consideration, as severance, Company agrees to pay Employee as set forth in Employee's Employment Agreement dated __________________ (the "Employment Agreement"), provided Employee executes this Agreement, complies with its terms and the terms of Employee's Employment Agreement[[, and does not revoke this Agreement during the Revocation Period as defined in Section 8 below.]][1] Employee acknowledges that no other compensation of any kind remains outstanding, that the consideration provided herein is more than Employee would otherwise be entitled to receive, that Employee shall not be entitled to any other payments or benefits from Company, and that no other amounts are due or owing or shall become due or owing relating to any obligation, agreement, or otherwise.

1. Execution of Separation Agreement. Should employee wish to accept this Agreement, it must be signed and returned to ________________________________ by ______________.

2. EAICA. Employee acknowledges and agrees that Employee's obligations contained in the paragraphs 2, 3, 4, 6, 8, 9, 10 and 11 of the Employee Assignment, Invention, and Confidentiality Agreement ("EAICA") that Employee signed on _____________________, a copy of which is attached as Exhibit A, remain in full force and effect. The terms of this Agreement are in additional to and do not supersede the surviving terms of the EAICA.

3. Confidentiality of Agreement. Employee understands and agrees that the existence of this Agreement and the terms and conditions thereof, shall be considered confidential, and shall not be disclosed by Employee to any third party or entity except with the prior written approval of Company, to Employee's attorney, or upon the order of a court of competent jurisdiction. Notwithstanding anything in this Agreement to the contrary, nothing in this Agreement or any other agreement between the Company and Employee shall prevent Employee from sharing information and communicating in good faith, without prior notice to the Company, with any federal government agency having jurisdiction over the Company or its operations, and cooperating in any investigation by any such federal government agency; provided that Employee receives no monies for compensatory or other damages as a result of participating in any such communication or cooperation with the EEOC.

4. Non-Disparagement. At all time Employee will refrain from and will not directly or indirectly engage in any conversation that would tend to negatively impact Company or any of the Releasees as defined in Section 8 below.

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[1] Employee will be entitled to a revocation period only if over the age of 40 at the date of termination.

5. Return of Company Property. Employee agrees to immediately return to Company any and all property of Company in Employee's possession, custody, or control. No severance shall be paid pursuant to this Agreement until all Company property is returned.

6. Confidential Information. Employee acknowledges that Employee has had access to Company confidential and proprietary information and agrees that all such Confidential Information is and shall remain the exclusive property of Company. Employee further agrees that Employee shall not publish, disclose, or otherwise make available to any third party any such Confidential Information. Employee acknowledges and agrees that Employee has continuing confidentiality obligations under the EAICA. Employee warrants that Employee has no materials containing Confidential Information, but if Employee does, Employee shall return immediately to Company any and all materials containing any Confidential Information in Employee's possession, custody, or control. The terms of this Separation Agreement comprise confidential information of the Company.

7. Release. That the undersigned, ________________, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, intending to be legally bound, and Employee's past, present and future agents, representatives, attorneys, affiliates, heirs, executors, assigns and successors, and all other persons connected therewith, and on behalf of all successors and assigns, hereby releases and forever discharges TherapeuticsMD, Inc., vitaMedMD, LLC, BocaGreenMD, Inc., vitaCare Prescription Services and all of their past, present and future agents, representatives, principals, attorneys, affiliates, owners, parent corporations, subsidiaries, officers, directors, employees, assigns and successors, and all other persons, firms or corporations connected or affiliated therewith (collectively "Releasees"), of and from any and all legal, equitable or other claims, demands, setoffs, defenses, contracts, accounts, suits, debts, agreements, actions, causes of action, sums of money, judgments, findings, controversies, disputes, or past, present and future duties, responsibilities, obligations, or suits at law and/or equity of whatsoever kind, from the beginning of the world to the date hereof, in addition, without limitation, any and all actions, causes of action, claims, counterclaims, third party claims, and any and all other federal, state, local and/or municipality statutes, laws and/or regulations and any ordinance and/or common law pertaining to employment or otherwise and any and all other claims which have been or which could have been asserted against any party in any forum.

By signing this Agreement, Employee knowingly and voluntarily fully releases and forever discharges Releasees of and from all claims, demands and liability of any kind arising under any statute, law or ordinance, including, without limitation, Title VII of the Civil Rights Act of 1964, the Fair Labor Standards Act, the National Labor Relations Act, the Americans with Disabilities Act, any state Human Rights Act, Fla. Stat. 448, or any facts or claims arising under the Age Discrimination in Employment Act ("ADEA"). This release is intended to cover all actions, causes of action, claims and demands for damages, loss or injury arising from the beginning of time until the date of this Agreement, whether presently known or unknown to Employee. However, Employee does not waive Employee's rights to claims which may arise after this Agreement becomes effective.

In addition, Employee is hereby advised to consult with an attorney prior to executing this Agreement. Employee agrees that Employee has been given a reasonable time in which to consider the Agreement and seek such consultation. Employee further warrants that Employee has consulted with knowledgeable persons concerning the effect of this Agreement and all rights which Employee might have under any and all state and federal laws relating to employment and employment discrimination and otherwise. Employee fully understands these rights and that by signing this Agreement Employee forfeits all rights to sue Releasees for matters relating to or arising out of employment, separation, or otherwise.

In accordance with provisions of the ADEA, as amended, 29 U.S.C. §601-634, Employee is hereby provided a period of twenty-one (21) days from the date Employee receives this Agreement to review the waiver of rights under the ADEA and sign this Agreement. Furthermore, Employee has seven (7) days after the date Employee signs the Agreement ("Revocation Period") to revoke Employee's consent. This Agreement shall not become effective or enforceable until the Revocation Period has expired. If Employee does not deliver a written revocation to ____________________________ before the Revocation Period expires, this Agreement will become effective.

Notwithstanding anything in this Section 8 to the contrary, releases contained in this Agreement shall not apply to (i) any rights to receive any payments or benefits pursuant to Sections 3(b)(ii), 3(b)(iii) or 3(b)(iv) of the Employment Agreement, (ii) any rights or claims that may arise as a result of events occurring after the date this Agreement is executed, (iii) any indemnification rights Employee may have as a former officer or director of the Company or its subsidiaries or affiliated companies, (iv) any claims for benefits under any directors' and officers' liability policy maintained by the Company or its subsidiaries or affiliated companies in accordance with the terms of such policy, and (v) any rights as a holder of equity securities of the Company.

8. Opportunity to Seek Counsel. The parties represent that they have had an opportunity to retain legal counsel to represent them in connection with this matter, that they have been advised of the legal effect and consequences of this Agreement, that they have entered into this Agreement knowingly, freely and voluntarily of their own volition, and that they have not been coerced, forced, harassed, threatened or otherwise unduly pressured to enter into this Agreement.

9. Reporting of Known Issues. As a further condition to your receipt of the benefits described in this Agreement, you hereby represent and warrant that you have reported in writing to ____________________________ any unethical conduct or violations of laws, regulations, Company policies and procedures by the Company, a Company employee, or a Company officer of which you are aware.

10. No Admissions. This Agreement is not and shall not in any way be construed as an admission by either party of any wrongful act or omission, or any liability due and owing, or any violation of any federal, state or local law or regulation.

11. Miscellaneous. This Agreement may not be amended or modified except in writing signed by Employee and an authorized representative with actual authority to bind Company, specifically stating that it is an amendment to this Agreement. This Agreement shall be governed by and construed in accordance with Sections 4(g) (Restrictions Separable), 8(a) (Notice), 8(b) (Indulgences; Waivers), 8(c) (Controlling Law), 8(d) (Execution in Counterpart), 8(f) (Paragraph Headings), and 8(k) (Right to Consult with Counsel; No Drafting Party) of the Employment Agreement. This Agreement and the Employment Agreement constitute the entire Agreement between the parties hereto with respect to the subject matter hereof; provided, however, that Employee's continuing obligations to the Company under the terms of the EAICA are incorporated herein and shall remain in full force and effect as set forth herein.

IN WITNESS THEREOF, the parties hereto acknowledge, understand and agree to this Agreement and intend to be bound by all of the clauses contained in this document.

EMPLOYEE	THERAPEUTICSMD, INC.
______________________	By: ______________________
[Employee]	Its: ______________________
Date: ______________________	Date: ______________________

Exhibit 10.42

AMENDMENT TO EMPLOYMENT AGREEMENT

This Amendment ("Amendment") to the Employment Agreement ("Agreement"), effective 30th day of October 2019, by and between **TherapeuticsMD, Inc.** with a place of business at 6800 Broken Sound Parkway NW, 3rd Floor, Boca Raton, Florida 33487 ("TherapeuticsMD"); and Edward J. Borkowski ("Borkowski").

WHEREAS, the Agreement exists between TherapeuticsMD and Borkowski (collectively herein as the "Parties") relating to Borkowski's employment with TherapeuticsMD;

WHEREAS, Borkowski requested to postpone his starting date as an employee of TherapeuticsMD until January 1, 2020 and be brought in as a consultant for the remainder of 2019; and

WHEREAS, the Parties have agreed to amend the Agreement.

NOW, THEREFORE, in consideration of the mutual promises set forth herein and for other good and valuable consideration, the receipt and sufficiency of which the Parties hereby acknowledge, intending to be legally bound, the Parties hereby agree as follows:

1. To replace the Preamble of the Agreement with the following:

   THIS EMPLOYMENT AGREEMENT (this "Agreement"), by and between TherapeuticsMD, Inc., a Nevada corporation (the "Company"), and Edward J. Borkowski ("Executive") is entered into and effective as of the 1st day of January 2020 (the "Effective Date").

2. To delete the last sentence of paragraph 2(b) that reads:

   The 2019 Targeted Annual Bonus Award will be paid to Executive as if Executed were employed for the full year and will be at target or higher.

3. Except as specifically referenced herein, the Agreement shall remain unchanged and shall continue in full force and effect.

This Amendment may be executed in any number of counterparts, each of which shall be enforceable against the Parties actually executing such counterparts, and all of which shall constitute one instrument.

[Remainder of page left intentionally blank]

TherapeuticsMD, Inc.

/s/ Robert Finizio | Date: November 22, 2019

Signature

Robert Finizio, CEO

Printed Name and Title

Edward J. Borkowski

/s/ Edward J. Borkowski | Date: November 22, 2019

Signature

Edward J. Borkowski

Printed Name

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 3, 2021, with respect to the consolidated financial statements included in the Annual Report of TherapeuticsMD, Inc. on Form 10-K for the year ended December 31, 2020. We consent to the incorporation by reference of said report in the Registration Statements of TherapeuticsMD, Inc. on Form S-3 (File No. 333-226452) and on Forms S-8 (File No. 333-191730, File No. 333-232268 and File No. 333-242363).

/s/ GRANT THORNTON LLP

Miami, Florida
March 3, 2021

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Robert G. Finizio, certify that:

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

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

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

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

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

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

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

Date: March 3, 2021

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

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, James C. D’Arecca, certify that:

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

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

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

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

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

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

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

Date: March 3, 2021

/s/ James C. D’Arecca
James C. D’Arecca
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

SECTION 1350 CERTIFICATION OF CHIEF EXECUTIVE OFFICER

In connection with the annual report of TherapeuticsMD, Inc. (the “Company”) on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Robert G. Finizio, Chief Executive Officer of the Company, certify, to my best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

March 3, 2021

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

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

Exhibit 32.2

SECTION 1350 CERTIFICATION OF CHIEF FINANCIAL OFFICER

In connection with the annual report of TherapeuticsMD, Inc. (the “Company”) on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, James C. D’Arecca, Chief Financial Officer of the Company, certify, to my best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

March 3, 2021

/s/ James C. D’Arecca
James C. D’Arecca
Chief Financial Officer
(Principal Financial Officer)

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