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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

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 Road, Suite 220 Boca Raton, Florida	**33431**
(Address of principal executive offices)	(Zip Code)

561-961-1900

(Registrant's telephone number, including area code)

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 an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

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 Exchange Act). Yes ☐ No ☒

As of June 30, 2021, the registrant's most recently completed second fiscal quarter, the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the market price at which the common equity was last sold was $444,995,626.

As of March 17, 2022, there were outstanding 433,427,878 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 2022 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, 2021.

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Part I

Item 1. Business

Overview

Throughout this Annual Report on Form 10-K ("2021 10-K Report"), the terms "we," "us," "our," "TherapeuticsMD," "the Company," 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 ("vitaMed"), BocaGreenMD, Inc., a Nevada corporation ("BocaGreen"), and vitaCare Prescription Services, Inc., a Florida corporation ("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®, vitaCare™, ANNOVERA®, BIJUVA®, and IMVEXXY®, which are protected under applicable intellectual property laws and are the property of, or licensed to, the Company. This 2021 10-K 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 2021 10-K 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 2021 10-K 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 2021 10-K Report, this information could prove to be inaccurate as a result of a variety of matters.

Forward-looking statements

This 2021 10-K Report 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 ("R&D"), marketing, expenses and sales are all forward-looking statements. These statements may be found in the items of this 2021 10-K Report entitled "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as in this 2021 10-K 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 2021 10-K 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, our liquidity requirements, competition from other businesses, market and general economic factors, and the other risks discussed in Item 1A of this 2021 10-K Report. This discussion should be read in conjunction with the consolidated financial statements and notes thereto included in this 2021 10-K 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 2021 10-K 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 2021 10-K 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.

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 ("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. Beginning in 2018, the FDA approval of our pharmaceutical products transitioned our company from predominately focused on conducting R&D 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 (the "Population Council License Agreement") with the Population Council, Inc. (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 (the "Knight License Agreement") with Knight Therapeutics Inc. ("Knight") pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY and BIJUVA in Canada and Israel.
- In June 2019, we entered into an exclusive license and supply agreement (the "Theramex License Agreement") with Theramex HQ UK Limited ("Theramex") to commercialize IMVEXXY and BIJUVA outside of the U.S., excluding Canada and Israel. In 2021, Theramex secured regulatory approval for BIJUVA in certain European countries and began commercialization efforts in those countries.

vitaCare divestiture

On March 6, 2022, we entered into a stock purchase agreement (the "Purchase Agreement") with GoodRx, Inc. ("GoodRx"), a Delaware corporation and wholly-owned subsidiary of GoodRx Holdings, Inc. ("GoodRx Holdings"), which provides for the sale of all of the issued and outstanding capital stock of vitaCare to GoodRx (the "vitaCare Divestiture"). Under the terms of the Purchase Agreement, upon the closing of the vitaCare Divestiture (the "Closing"), we will receive a cash payment of $150.0 million, subject to adjustment as provided in the Purchase Agreement and customary holdbacks. In addition, we may receive up to an additional of $7.0 million in earn-out consideration, contingent upon vitaCare's financial performance through 2023 as determined in accordance with the terms of the Purchase Agreement.

The Purchase Agreement contains customary representations and warranties, covenants and indemnities of the parties thereto. In addition, the Purchase Agreement provides that at the Closing: (i) we will enter into a long-term services agreement with vitaCare to continue utilization of the vitaCare platform with respect to our products; (ii) we and vitaCare will enter into a transition services agreement for us to provide certain transition services to vitaCare for up to 12 months following the Closing; and (iii) certain employees of ours and/or vitaCare will enter into employment agreements with GoodRx,

The vitaCare Divestiture is expected to close in the second quarter of 2022, subject to the satisfaction or waiver of certain customary conditions, including the receipt of certain regulatory approvals.

The impact of COVID-19 on our business

With multiple variant strains of the SARS-Cov-2 virus and the COVID-19 disease that it causes (collectively, "COVID-19") still circulating, we continue to be subject to risks and uncertainties in connection with 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. The ultimate global recovery

from the pandemic will be dependent on, among other things, actions taken by governments and businesses to contain and combat the virus, including any variant strains, the speed and effectiveness of vaccine production and global distribution, as well as how quickly, and to what extent, normal economic and operating conditions can resume on a sustainable basis globally.

Since the early phase of the COVID-19 pandemic, we have been using substantial virtual options to ensure business continuity. We have also worked with independent community pharmacies and multiple third-party online pharmacies and telemedicine providers that focus on contraception or menopause which provide patients 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.

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 2021. 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 of 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 many of the negative effects 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 remain 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.

Our business model

At TherapeuticsMD, our purposeful and continuous partnership with healthcare professionals ("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 HCPs 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 HCP and patient needs in the marketplace – low dose, FDA-approved bio-identical and convenience.
- 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 HCPs 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 HCPs 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 in 103 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.

Currently, we market and sell 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 woman'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 aspects of a women's reproductive lifecycle. With the acquisition and launch of ANNOVERA, we demonstrated 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. BIJUVA provides a proven alternative to non-FDA approved compounded bio-identical hormone therapy products at potentially a lower price to patients since most insurance companies do not provide coverage for compounded hormone products, which are not FDA-approved and the safety of which has been questioned 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.

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 territories. We continue to adjust our marketing footprint in the United States (U.S.) and sales team, which currently totals 103 territories, as we continue to commercialize ANNOVERA, IMVEXXY, and BIJUVA.

Industry and market

Women's healthcare market

According to BBC Research's September 2020 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 R&D 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.

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, 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. As per the National Center for Health Statistics ("NCHS') Data Brief No. 388 from the Centers for Disease Control and Prevention ("CDC"), the latest data, for 2017 to 2019, indicate that 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 $9.9 billion by 2027, expanding at a CAGR of 4.3% from 2020 to 2027 according to Grand View Research, Inc. Increasing awareness about long-acting reversible contraceptives ("LARCs") is expected to augment the product demand, thereby driving the market over the next few years. According to the NCHS, the use of LARCs in the U.S. was 10.4% in 2017-2019 among women aged 15 to 49. We believe that the increasing awareness about LARCs will grow incremental product demand, thereby driving market growth over the coming years. This is currently led by IUDs. 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.

Menopause market

Menopause is the spontaneous and permanent cessation of menstruation, which naturally occurs in most women. The average age of menopause in the U.S. is 52. The range for women is usually between 45 and 58. Per the National Institutes of Health, in the U.S., approximately 1.3 million women become menopausal each year, typically beginning between the ages of 51 and 52. However, about 5.0% of women experience early menopause between the ages of 40 and 45. Additionally, 1.0% of women experience premature menopause before the age of 40, due to permanent ovarian failure that may be associated with sex chromosome abnormalities.

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 U.S. and Canada for relief of menopausal symptoms according to the North American Menopause Society ("NAMS"). Approved FDA prescriptions for menopausal hormone therapy in the U.S. dropped significantly following the Women's Health Initiative ("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.

Prenatal vitamin market

According to the CDC, there are approximately four million births per year in the U.S. 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.

Our contraceptive product

ANNOVERA

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 $20.0 million, half of such excess will offset against royalties or other payments owed by us 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 competes across all the contraception options for women, especially for those women seeking a long-lasting option without a procedure.

Additionally, we previously submitted a supplemental new drug application ("NDA") to FDA to revise certain manufacturing testing limits for ANNOVERA to allow for normal commercial manufacturing variation. In December 2021, FDA determined that it could not approve the supplemental NDA without additional information. In its complete response letter ("CRL"), FDA provided recommendations and requested additional information that could support approval of revisions to certain testing specifications. In January 2022, we responded to the CRL, and provided the requested additional information to the FDA and modified the request for the manufacturing testing limits based on the FDA recommendations. We expect a response from the FDA by the end of second quarter of 2022. We will continue to manufacture and supply ANNOVERA under the existing specification. In the meantime, our third-party

contract manufacturer may not be able to supply us with sufficient ANNOVERA to adequately supply the market, which would have an adverse effect on our business, results of operations and financial condition.

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 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.

Based on prescription data from Symphony Health Solutions, the FDA-approved prescription market in the U.S. for contraceptive products during 2021 amounted to more than 69 million prescriptions, generating $5.4 billion in gross sales.

For 2021, 2020, and 2019, 44.2%, 31.2% and 18.1%, respectively, of our consolidated product revenue was generated by ANNOVERA.

Our menopause portfolio

IMVEXXY

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) generated an aggregate of $1.9 billion in gross sales on 6.5 million prescriptions for 2021. Of the total gross sales, $371 million were generated by PREMARIN® cream (Pfizer), the leading brand in the market. In addition, ESTRACE® cream and Vagifem® are now mostly generic which generated $1.2 billion in gross sales for 2021. These three products are localized estrogen therapy which is the most commonly used method for the treatment of VVA.

For 2021, 2020, and 2019, 36.8%, 43.2% and 47.6%, respectively, of our consolidated product revenue was generated by IMVEXXY.

BIJUVA

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 do 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 December 2021, the FDA approved the supplemental NDA for the 0.5 mg/100 mg dose of BIJUVA®. We are currently evaluating plans for commercialization of the low dosage BIJUVA® product.

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 $2.1 billion of gross sales on 23.5 million prescriptions for 2021. 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 2021, gross sales in the U.S. of FDA-approved branded and generic products for estrogen-only amounted to an aggregate of $1.3 billion on 13.2 million prescriptions. For 2021, gross sales in the U.S. of FDA-approved branded and generic products for progestins-only amounted to an aggregate of $372 million on 8.4 million prescriptions. For 2021, gross sales in the U.S. of FDA approved branded and generic products for estrogens/progestins combined amounted to an aggregate of $435 million on 1.7 million prescriptions.

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). 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. 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 FDA approved.

For 2021, 2020, and 2019, 12.3%, 10.1% and 5.4%, respectively, of our consolidated product revenue was generated by BIJUVA.

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*

According to Symphony Health Solutions, for 2021, 4.2 million prescriptions for prenatal vitamins were issued in the U.S. resulting in total sales of $188 million.

For 2021, 2020, and 2019, 6.7%, 15.5% and 29.0%, 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 103 territories, which includes the most significant part of the addressable markets across our product portfolio. As of December 31, 2021, 10,700 HCPs had written at least one prescription for ANNOVERA, 28,900 HCPs had written at least one prescription for IMVEXXY, and 9,800 HCPs had written at least one prescription for BIJUVA. 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.

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. For IMVEXXY, through December 31, 2021, we achieved unrestricted coverage with the majority of the top nine commercial payers of VVA products by commercial payer lives, and as of December 31, 2021, 62% of the commercial payer market covered IMVEXXY with unrestricted access under pharmacy benefits. For BIJUVA, through December 31, 2021, we achieved unrestricted coverage with the majority of the top nine commercial payers of VMS products by commercial payer lives, and as of December 31, 2021, 66% of the commercial payer market covered BIJUVA with unrestricted access under pharmacy benefits. 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, and we continue to pursue discussions with several of the country's largest commercial insurers to further expand coverage. As of December 31, 2021, 66% of the commercial payer market covered ANNOVERA with unrestricted access under pharmacy benefits and 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 (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 ("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. 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. However, the Trump administration implemented 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. 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. 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 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, and online pharmacies.

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 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 for the product and subsequently led to reduced utilization of the product. For IMVEXXY and BIJUVA, enrolled patients paid as little as $35.00 for a prescription with commercial insurance coverage and pay as little as $75.00 for a prescription without commercial insurance coverage. For ANNOVERA, for commercially insured patients, we offer patients assistance for as low as $60.00 for an annual prescription. However, 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

Population Council license agreement

Under the terms of the Population Council License Agreement, we paid the Population Council a milestone payment of $20.0 million in 2018, which was within 30 days following the approval by the FDA of the NDA for ANNOVERA, and $20.0 million in 2019 following the first commercial batch release of ANNOVERA. The aggregate $40.0 million of milestone payments were recorded as license rights. For additional information, see "Note 6. License rights and other intangible assets" to the consolidated financial statements included in this 2021 10-K Report. The Population Council is also eligible to receive future payments upon the achievement of certain commercial sales milestones of ANNOVERA. We are required to pay the Population Council additional milestone payments of $40.0 million upon cumulative net sales of ANNOVERA in the U.S. by us and our affiliated and permitted sublicensees of each of $200.0 million, $400.0 million and $1.0 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 $20.0 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. To the extent that the Population Council does not fulfil these studies to FDA's satisfaction, FDA may impose additional requirements and penalties against us, as we hold the NDA for ANNOVERA. In July 2021, we received a letter from FDA indicating that the post-marketing commitment study being conducted by the Population Council for ANNOVERA to characterize the in vivo release rate of ANNOVERA was not fulfilled to FDA's satisfaction. In addition, the final reports for the two post-marketing requirement studies being performed by the Population Council for ANNOVERA were not submitted by the initial listed submission deadline, which deadlines have since been extended by FDA. We are working with Population Council to complete the post-marketing commitment study to FDA's satisfaction and reduce the delay in submitting the post-marketing requirement final reports. To the extent that the Population Council does not fulfil these studies to FDA's satisfaction, FDA may impose additional requirements and penalties against us, as we hold the NDA for ANNOVERA.

We and the Population Council have agreed to form a joint product committee responsible for overseeing activities under the Population Council License Agreement. We are responsible for all aspects of marketing, 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.

We are also required to pay the Population Council, on a quarterly basis, step-based royalty payments based on our annual net sales of ANNOVERA as follows: (i) if annual net sales are less than or equal to $50.0 million, a royalty of 5% of net sales; (ii) for annual net sales greater than $50.0 million and less than or equal to $150.0 million, a royalty of 10% of such net sales; and (iii) for net sales greater than $150.0 million, 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.

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.

Knight license agreement

Pursuant to the terms of the Knight License Agreement, Knight paid us $2.0 million in milestone fees upon the first regulatory approval in Canada for IMVEXXY and BIJUVA in 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 U.S.

Theramex license agreement

Under the terms of the Theramex License Agreement, Theramex paid us EUR 14 million, or $15.5 million, 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. In 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 recognized the revenue related to the upfront fee, which was a non-refundable payment.

In 2021, we received additional milestone payments comprised of an aggregate of EUR 1.0 million, or $1.2 million, in regulatory milestone payments based on regulatory approvals for BIJUVA in certain specified markets. Additionally, in December 2021, we received EUR 0.5 million, or $0.6 million, in additional upfront payments for the license grants of IMVEXXY in Brazil and Mexico. The additional upfront payment for the license grants of IMVEXXY in Brazil and Mexico may be returned to Theramex under certain conditions if IMVEXXY fails to obtain marketing authorization in one of Brazil or Mexico within a prespecified period.

We are eligible to receive additional sales milestone payments 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 outside of the U.S., excluding Canada and Israel (collectively 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.

Preclinical development

As our current focus is the commercialization of our three FDA-approved pharmaceutical products, we have placed on hold our five preclinical projects: (i) a progesterone-alone transdermal cream (TX-005HR), (ii) a combination estradiol and progesterone transdermal cream (TX-006HR), (iii) a pair of transdermal patch product candidates (TX-007HR and TX-008HR), and (iv) an oral progesterone and estradiol formulation (TX-009HR). "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. TX-009HR previously showed improved bioavailability in animals, and in 2019, TX-009HR was tested in a Phase 1 study of healthy postmenopausal women and was well-tolerated in that study. We may, in the future, engage with a financing partner to advance one or more of these product candidates.

Sales concentration

We sell our prescription pharmaceutical products and prenatal vitamin products to wholesale distributors and retail pharmacy distributors. For information on the concentration of sales of our products, see "Note 11. Revenue" to the consolidated financial statements included in this 2021 10-K Report.

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 ("CMOs"), for the commercial supply of our products. The regulations for manufacturing of approved drug products are significantly more extensive than the standards for manufacturing supplements or drug product for early-stage 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 ("Catalent") for the commercial supply of our IMVEXXY and BIJUVA, and Sever Pharma Solution (formerly QPharma AB), both of which have their establishments registered with FDA, 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. See also Item 1A. Risk Factors – "Our dependence upon third parties for the manufacture and supply of our existing women's healthcare products may cause delays in, or prevent us from, successfully commercializing, and marketing our products" below for further discussion related to our dependence on third-party CMOs.

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, evaluation of adherence to Good Manufacturing Practices through audits, a review of their business continuity plans, management of finished product inventory and safety stock, and the initiation of projects to qualify second sourcing as appropriate.

We have also sourced and qualified manufacturers of the active pharmaceutical ingredient ("APIs") to be used in our drugs and drug candidates. We follow a risk management approach for our API manufacturers similar to that followed for the commercial supply of the finished drug products.

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 ("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 product packaging. 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 material 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 established and reliable, 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 Sever Pharma Solutions 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, Sever 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). Our quality assurance team is responsible for the final release of the packaged drug product (ANNOVERA, IMVEXXY and BIJUVA) into commercial distribution.

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 (the "DSCSA") and the Prescription Drug Marketing Act ("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, BIJUVA and IMVEXXY 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.

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 FDA approved products 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

Patents and trademarks

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, 2021, we have 46 issued domestic patents and 47 issued foreign patents as well as 86 pending patent applications (66 foreign and 20 domestic), including:

- 20 issued domestic patents and 14 issued foreign patents that relate to BIJUVA. These patents establish an important intellectual property foundation for BIJUVA and are owned by us. The domestic patents will expire in 2032. The foreign patents will expire no earlier than 2032. In addition, we have pending patent applications relating to BIJUVA in the U.S., Argentina, Australia, Brazil, Canada, China, Europe, Israel, Japan, Mexico, New Zealand, Russia, South Africa, and South Korea;
- 16 issued domestic patents (14 utility and two design) and 23 foreign patents (13 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 issued domestic utility patent that relates to our topical-cream candidates, which is owned by us and will expire in 2035;
- One issued domestic utility patent and six 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;
- Two issued domestic utility patents that relate to estradiol and progesterone product candidates, which are owned by us and will expire in 2032;
- Three issued domestic utility patents that relate to TX-009HR, a progesterone and estradiol product candidate, which are owned by us and will expire in 2037; and
- Three issued domestic and four issued 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., Canada, Europe, and Mexico.

Also, as of December 31, 2021, we have a license to six U.S. Orange Book listed patents and one design patent relating to ANNOVERA. The Orange Book patents will expire in 2039. The design patent will expire in 2036. These licensed patents establish an important intellectual property foundation for ANNOVERA. In addition, we have a license to six U.S. pending patent applications relating to ANNOVERA.

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 U.S., the FDA regulates pharmaceuticals, biologics, medical devices, dietary supplements, and cosmetics under the Federal Food, Drug, and Cosmetic Act (“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 U.S. 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 ("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. Currently, we have three active INDs for our FDA-approved pharmaceutical products of ANNOVERA, IMVEXXY and BIJUVA.

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. In certain circumstances, FDA may deviations from the conventional three-Phase model for clinical, pursuant to modeling that FDA terms "adaptive clinical trial design."

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 a new molecular entity NDA, or within 10 months of receipt for non-NME drug. 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

We are required to comply with several post-approval requirements for our currently approved drug products. 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 related to our BIJUVA product were identified in Catalent’s response to the Form FDA. 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 non-FDA approved hormone therapy products supplied by compounding pharmacies. Pharmacy compounding is a practice in which a licensed medical practitioner or 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 (“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 meeting FDA approval requirements (e.g., an NDA or ANDA) and without complying with

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. Thus, overall, 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

There are two types of NDAs available under Section 505(b) the FDCA. Section 505(b)(1) of the FDCA provides a marketing approval pathway that is known as the "traditional" or "full" NDA process. Sponsors use 505(b)(1) applications to obtain marketing approval of a new drug with active ingredients that have not previously been approved by FDA. The data package necessary for approval of this new drug requires demonstration of safety and efficacy based on adequate and well controlled human clinical trials conducted by or for the sponsor, without allowance for reference to third party data. In contrast, Section 505(b)(2) of the FDCA provides an alternative NDA process for approving a new drug that contains the same active ingredient as a previously approved product but allows sponsors to rely on clinical trials not conducted by or for the sponsor, as well as other clinical data or literature produced by other parties. In addition, Section 505(j) of the FDCA provides for a significantly shortened regulatory pathway for approval of a "generic" version of a new drug, by way of an Abbreviated New Drug Application or ANDA. Rather than demonstrating safety and effectiveness as required for an NDA, the ANDA requires proof that the generic drug is the "same" as or "bioequivalent" to the new drug under the standard of "bioequivalence," often using pharmacokinetic, pharmacodynamic, and/or in vitro studies.

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 ("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.

In February 2020, we received a Paragraph IV certification notice letter (the "IMVEXXY Notice Letter") regarding an ANDA submitted to FDA by Teva Pharmaceuticals USA, Inc. ("Teva"). See Legal Proceedings in Item 4 of this 2021 10-K Report for additional information.

In March 2020, we received a Paragraph IV certification notice letter (the "BIJUVA Notice Letter") regarding an ANDA submitted to FDA by Amneal Pharmaceuticals ("Amneal"). In April 2020, we filed a complaint for patent infringement against Amneal in the U.S. District Court for the District of New Jersey arising from Amneal's ANDA filing with FDA. In December 2021, we entered into a settlement agreement (the "Settlement Agreement") with Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York LLC (collectively "Amneal") to resolve the litigation over our patents listed in FDA's Orange Book that claim compositions and methods of BIJUVA (the "BIJUVA Patents"). Under the terms of the Settlement Agreement, the parties agreed

filed a consent judgment with the U.S. District Court for the District of New Jersey that enjoins Amneal from marketing a generic version of BIJUVA (1 mg estradiol and 100 mg progesterone) before the expiration of the patents-in-suit, except as provided in the Settlement Agreement, and the Company granted Amneal a non-exclusive, non-transferable, royalty-free license to commercialize Amneal's generic formulation of BIJUVA in the U.S. commencing in May 2032 (180 days before the current expiration date in November 2032 for the last to expire of our BIJUVA Patents), or earlier under certain circumstances customary for settlement agreements of this nature.

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 (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 ("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 U.S. before October 1994 may be used in dietary supplements without notifying the FDA. "New" dietary ingredients (*i.e.*, dietary ingredients that were "not marketed in the U.S. before October 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 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 ("FSMA"), which was enacted in January 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 ("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 has been 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, in November 2021, the Biden Administration announced several prescription drug pricing proposals as part of the Build Back Better legislation. In particular, the plan would allow for Medicare to negotiate prices for high-cost prescription drugs, including for both Part D and Part B drugs, after the drugs have been on the market for a fixed number of years: 9 years for small molecule drugs and 12 years for biologics. Medicare will negotiate up to 10 drugs per year during 2023, with the negotiated prices taking effect in 2025, increasing up to 20 drugs per year. Further, the plan imposes a tax penalty if drug manufacturers increase their prices faster than inflation. Finally, the plan places a $2,000 per year cap on out-of-pocket drug costs under Medicare Part D. 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 U.S. 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 ("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 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 are 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” for 2020 according to the Sun Sentinel.

Employees

As of December 31, 2021, we had 416 employees, five of whom were 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.

Available information

We are a Nevada corporation, and 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 2021 10-K Report or in any other report or document we file with the SEC.

Item 1A. Risk factors

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, together with all of the information included in this 2021 10-K 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 2020 and 2021 were, and our financial condition and results of operations for 2022 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, as amended (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, which matures in June 2022, raises substantial doubt about our ability to continue as a going concern.
- We may not recognize the anticipated benefits of the proposed disposition of vitaCare or any other divestitures we may pursue in the future.
- We may not be able to realize the expected savings from our cost savings initiatives.
- We could be affected by transitions in our senior management team.
- 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 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.
- 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 2020 and 2021 were, and our financial condition and results of operations for 2022 and beyond may be, adversely affected by the ongoing COVID-19 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 2021, 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 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.

Disruptions have occurred and may occur in the future that 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 2022.

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 $172.4 million, $183.5 million and $176.1 million for 2021, 2020 and 2019, respectively. As of December 31, 2021, we had an accumulated deficit of $1.1 billion. We 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, which matures in June 2022, raises substantial doubt about our ability to continue as a going concern.

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. In March 2021, in connection with Amendment No. 8 to the Financing Agreement, we repaid $50.0 million in principal under the Financing Agreement 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 following the first quarter of 2022, will contains certain minimum quarterly net product revenue requirements and several other restrictive covenants. Among other requirements of the Financing Agreement, we and our subsidiaries party to the Financing Agreement must maintain a minimum unrestricted cash balance 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, and (vii) 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. 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.

In addition, in March 2022, we entered into Amendment No. 9 to the Financing Agreement ("Amendment No. 9"). Pursuant to Amendment No. 9, the Financing Agreement matures on June 1, 2022, and the entire principal balance under the Financing Agreement is due and payable as of such date. Our current cash on hand is not sufficient to pay the amounts due under the Financing Agreement. This raises substantial doubt about our ability to continue as a going concern. We agreed to use the first $120.0 million of net proceeds from the divestiture of vitaCare and all net proceeds of the divestiture of vitaCare in excess of $135.0 million to prepay the loans under the Financing Agreement. However, we will need to raise additional capital to repay the entire principal balance of the Financing Agreement in June 2022. The report of our independent registered public accounting firm on our audited financial statements contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern. Our audited financial statements do not include any adjustments that might result from the outcome of the uncertainty regarding our ability to continue as a going concern. This going concern opinion could materially limit our ability to raise additional funds through the issuance of equity or debt securities or otherwise. Additionally, we are currently not in compliance with the continued listing requirements of the Nasdaq Global Select Market ("Nasdaq"), and in the event we are delisted from Nasdaq, our ability to raise additional funds through the issuance of equity or debt securities could be significantly affected. See "Our failure to maintain compliance with the continued listing requirements of could result in the delisting of our common stock" below for further information on our compliance with Nasdaq's continuing listing requirements. If we cannot continue as a going concern, our investors may lose their entire investment in our securities. Until we can generate significant cash flows, we expect to satisfy our future cash needs through debt or equity financing; however, there can be no assurance that such capital will be available, or if available, that it will be on terms acceptable to us.

If we are unable raise additional capital or to generate cash flow through operations, 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 the Financing Agreement.

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

We have signed a definitive agreement for the vitaCare Divestiture of vitaCare. 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 close the vitaCare Divestiture. Any divestiture or disposition, including the vitaCare Divestiture, 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 (and will be upon the closing of the vitaCare Divestiture) 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. Additionally, there can be no assurances that we will obtain any necessary consents of governmental authorities or other third parties that might be required for the vitaCare Divestiture or effectuate any other divesture. If we are unable to consummate the vitaCare Divestiture 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 may not be able to realize the expected savings from our cost savings initiatives.

We have implemented a significant cost savings initiative that is designed to reduce our annual costs in 2022 by at least $40.0 million, excluding the estimated annualized cost savings of approximately $20.0 million, or any costs associated with, the vitaCare Divestiture. There can be no assurance that the anticipated cost saving initiatives will be achieved, or that they will not be significantly and materially less than anticipated, or that the completion of such cost savings initiatives will be effectively accomplished. In addition, our ability to realize the anticipated cost savings are subject to significant business, economic and competitive uncertainties and contingencies, many of which are beyond our control, such as changes to government regulation governing or otherwise impacting drug products, operating

difficulties, supply chain issues or other issues related to third-parties and general economic or industry condition. If we fail to realize the anticipated cost savings it could have a negative impact on our financial position.

We have experienced significant turnover in our top executives, and our business could be adversely affected by these and other transitions in our senior management team.

We have experienced turnover in our top executives and the replacement of these positions with new officers. During 2021, our Board of Directors appointed a new Chief Executive Officer, who had previously served as our President since August of 2021. Our existing Chief Financial Officer has also resigned, effective of April 1, 2022.

Management transition is often difficult and inherently causes some loss of institutional knowledge, which could negatively affect our results of operations and financial condition. Our ability to execute our business strategies may be adversely affected by the uncertainty associated with these transitions and the time and attention of the board and management dedicated to management transitions could disrupt our business. Further, we cannot guarantee that we will not face similar turnover in the future. Although we generally enter into employment agreements with our executives, our executive officers may terminate their employment relationship with us at any time, and we cannot ensure that we will be able to retain the services of any of them. Our senior management's knowledge of our business and industry could be difficult to replace, and management turnover could negatively affect our business, growth, financial conditions, results of operations and cash flows.

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. 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 the FDA's current Good Manufacturing Practice ("cGMPs"). We have entered into long-term supply agreements with Catalent Pharma Solutions, LLC 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, now known as Sever Pharma Solutions, for ANNOVERA. Under the terms of the QPharma AB 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 ("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 because of the ongoing COVID-19 pandemic.

One of our third-party contract manufacturers has recently experienced an increase in difficulties with manufacturing of ANNOVERA, resulting in intermittent supply of ANNOVERA for commercial distribution. The challenges are multifactorial and include variability in raw material supply and normal manufacturing variation due to a semi-manual process. This has recently resulted in challenges to supply ANNOVERA consistently within the approved specification at a rate that meets the projected demand for ANNOVERA. To mitigate the manufacturing challenges, in August 2021 we filed a supplemental NDA with the FDA to modify the testing specifications for ANNOVERA to allow for increased consistency of manufacturing and supply of ANNOVERA. In December 2021, FDA determined that it could not approve supplemental NDA without additional information. In its complete response letter, the FDA provided recommendations and requested additional information that could support approval of revisions to certain testing specifications. In January 2022, we responded to the CRL, and provided the requested additional information to the FDA and modified the request for the manufacturing testing limits based on the FDA recommendations. We expect a response from the FDA by the end of second quarter of 2022. We will continue to manufacture and supply ANNOVERA under the existing specifications. In the meantime, our third-party contract manufacturer may not be able to supply us with sufficient ANNOVERA to adequately supply the market, which would have an adverse effect on our business, results of operations and financial condition. Additionally, we may incur increased write-offs of ANNOVERA products manufactured in 2022 that do not meet existing specifications.

We have also experienced a greater than expected amount of raw materials for ANNOVERA being out of specification. If any of our third-party CMOs or any suppliers of raw materials or API experience further difficulties, do not comply with the terms of an agreement between us, or do not devote sufficient time, energy, and care to providing our manufacturing needs, or if the manufacturing specification modifications that we have requested are not approved by the FDA, we could experience additional interruptions in the supply of our products, which may have a material adverse impact on our revenue, results of operations and financial position.

We also do not have long-term contracts for the supply of all the API used in 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.

We currently derive all 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.

We derived all 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 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.

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 ("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 or maintained 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. In July 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. Healthcare reform implementation, additional legislation or regulations, and other changes in government policy or regulation may 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.

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 ("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 ("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 several 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. 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 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 ("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 considering 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 or the making of false statements material to a claim 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 ("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 or supplier for the provision of items or service 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 ("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 ("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 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 (the "OCR") has increased its focus on compliance and continues to train state attorneys general for enforcement purposes.
- According to 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 considering 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 to CMS for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under certain government healthcare programs (with certain exceptions) of information related to certain payments or other "transfers of value" made or provided to HCPs and teaching hospitals, or to other entities or individuals at the request of, or designated on behalf of, the HCPs and teaching hospitals. Numerous state laws may also require disclosure of transfers of value to HCPs, pharmaceutical pricing information and marketing expenditures.
- 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 ("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 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, all of which are subject to influence resulting from changes in political party control. For instance, 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 new legislation, regulation, Executive Orders, rescission of rules and policy statements, or new agency priorities, 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.

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. For example, in November 2021, the Biden Administration announced several prescription drug pricing proposals as part of the Build Back Better legislation. In particular, the plan would allow for Medicare to negotiate prices for high-cost prescription drugs, including for both Part D and Part B drugs, after the drugs have been on the market for a fixed number of years: 9 years for small molecule drugs and 12 years for biologics. Medicare will negotiate up to 10 drugs per year during 2023, with the negotiated prices taking effect in 2025, increasing up to 20 drugs per year. Further, the plan imposes a tax penalty if drug manufacturers increase their prices faster than inflation. Finally, the plan places a $2,000 per year cap on out-of-pocket drug costs under Medicare Part D. 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.

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 ("FDAAA) gives the FDA enhanced post-market authority, including the imposition of a Risk Evaluation and Mitigation Strategy ("REMS") as well as 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. Foreign regulatory agencies often have similar authority and may impose comparable requirement.

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 four non-closed post-marketing studies, including both post-marketing reviews and post-marketing commitments. Each study has a timeline for completion and submission of a final report to the FDA. If a post-approval study is not fulfilled according to FDA requirements, the FDA may impose certain further requirements and/or penalties against the holder of the new drug application ("NDA"). For ANNOVERA, certain of the studies are being performed by the Population Council. To the extent that the Population Council does not fulfil these studies to the FDA's satisfaction, FDA may impose additional requirements and penalties against us, as we hold the NDA for ANNOVERA. In July 2021, we received a letter from the FDA indicating that the post-marketing commitment study being conducted by the Population Council for ANNOVERA to characterize the in vivo release rate of ANNOVERA was not fulfilled to FDA's satisfaction. In addition, the final reports for the two post-marketing requirement studies being performed by the Population Council for ANNOVERA were not submitted by the initial listed submission deadline, which deadlines have since been extended by FDA. We are working with Population Council to complete the post-marketing commitment study to the FDA's satisfaction and reduce the delay in submitting the post-marketing requirement final reports. To the extent that the Population Council does not fulfil these studies to the FDA's satisfaction, the FDA may impose additional requirements and penalties against us, as we hold the NDA for ANNOVERA.

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.

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 ("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 ("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 HCPs, 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 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, 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's 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. Following the closing of the

vitaCare Divestiture, we may still be required to indemnify the buyer of vitaCare in the event any enforcement related to activities prior to the vitaCare Divestiture. 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, 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 the Population Council License Agreement 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 R&D 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.

In February 2020, we received a Paragraph IV certification notice letter (the “IMVEXXY Notice Letter”) regarding an ANDA submitted to the FDA by Teva Pharmaceuticals USA, Inc. (“Teva”). See “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” below for more information regarding the IMVEXXY Notice Letter. Additionally, on March 2020, we received a Paragraph IV certification notice letter (the “BIJUVA Notice Letter”) regarding an ANDA submitted to FDA by Amneal Pharmaceuticals. See Item 1. Business – Pharmaceutical Regulation – Regulatory Exclusivity for more information on the BIJUVA Notice Letter.

In addition, we cannot predict what additional ANDAs could be filed by Teva or other potential generic competitors requesting approval to market generic forms of our products, which could require us to incur significant additional expense and result in distraction for our management team, and if approved, result in significant decreases in the revenue derived from sales of our marketed products and thereby 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 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. In 2021, four customers each generated more than 10% of our total revenues; the combined revenue generated from these four customers aggregated to 55% of our total revenue. 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 R&D 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 R&D activities. Therefore, we have relied, and plan to continue to rely, on various third-party contract research organizations ("CROs") to conduct our R&D 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 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 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, 2021, we had federal net operating loss (“NOL”) carryforwards of $885.1 million. Subject to applicable limitations, our NOL 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 NOL carryforwards 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 NOL carryforwards 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 NOL carryforwards, or a portion thereof, against our future taxable income may be subject to an annual limitation under Section 382.

In 2017, the U.S. federal government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the “2017 Tax Act”). The 2017 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 NOL carryforwards. The 2017 Tax Act reduced the corporate tax rate to 21 percent, effective January 1, 2018. Management assessed the valuation allowance analyses with respect to our NOL carryforwards as affected by various aspects of the 2017 Tax Act and determined that a full valuation allowance continues to be appropriate. Additionally, 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 in March 2020. The CARES Act includes several significant business tax provisions that, among other things, includes further statutory amendments to the rules governing NOL carryforwards, as amended by the 2017 Tax Act. The CARES Act limits the NOL deduction in taxable years beginning in 2021 to the lesser of the NOL carryforwards or 80% of the taxpayer's taxable income (after considering the deduction for NOL arising in tax years beginning before January 1, 2018), which may restrict our ability to offset future taxable income with NOL carryforwards 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 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.

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 our development and commercialization plans and strategies evolve, we may 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. In February 2020, we received the IMVEXXY Notice Letter regarding an ANDA submitted to the FDA by Teva. 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.

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. In April 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. In September 2021, the District Court made available a public version of the order following the parties' agreement to a consent motion to redact information Teva contended was confidential. The order provides that the statutory stay that prevents FDA from granting final approval of the ANDA for 30 months from the date of the Notice Letter will be extended for the number of days that the stay of the IMVEXXY litigation is in place. The length of the stay of the IMVEXXY litigation is dependent on further action by Teva.

We cannot assure you that any patent infringement lawsuit that we may file will prevent the introduction of a generic version of IMVEXXY for any particular length of time, or at all. If Teva's ANDA is approved, and a generic version of IMVEXXY is introduced,

our sales of IMVEXXY could be adversely affected. In addition, we cannot predict what additional ANDAs could be filed by Teva, or other potential generic competitors requesting approval to market generic forms of our products, which could require us to incur significant additional expense and result in distraction for our management team, and if approved, result in significant decreases in the revenue derived from sales of our marketed products and thereby 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 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 failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock.

In September 2021, we received a deficiency letter (the "Notice") from the staff of the Nasdaq Stock Market LLC (the "Nasdaq Staff") notifying us that for the prior 30 consecutive business days, the bid price for our common stock had closed below $1.00 per share, which is the minimum closing price required to maintain continued listing on the Nasdaq under Nasdaq Listing Rule 5450(a)(1) (the "Minimum Bid Price Requirement"). The Notice had no immediate effect on the listing of our common stock. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had 180 calendar days to regain compliance (the "Compliance Period") with the Minimum Bid Price Requirement. In March 2022, we received a determination letter from the Nasdaq Staff stating that we have not regained compliance with the Minimum Bid Price Requirement because the closing bid price of our common stock had not been at least $1.00 per share for a minimum of ten consecutive trading days at any time during the Compliance Period.

We have requested a hearing before the Nasdaq Hearings Panel (the "Panel") to appeal the Nasdaq Staff's determination and present a plan to regain compliance with the Minimum Bid Price Requirement. If we had not requested a hearing, our common stock would have been subject to delisting and removal of registration from Nasdaq. While the appeal process is pending, the suspension of trading of our common stock on Nasdaq will be stayed and our common stock will continue to trade on Nasdaq until the hearing process concludes and the Panel issues its decision. We intend to monitor the closing bid price of our common stock and intend to conduct a reverse stock split, if necessary, to regain compliance with the Minimum Bid Price Requirement.

There can be no assurance that we will be able to regain compliance with the Minimum Bid Price Requirement or that we will otherwise remain in compliance with the other listing standards for the Nasdaq listing requirements. If we are unable to comply with the Nasdaq listing requirements, our common stock could be delisted from Nasdaq, which could have material adverse effects on our ability to finance our operations and our stockholders' ability to monetize the investment in our Company.

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, 2021, our executive officers, directors, holders of 5% or more of our common stock, and their affiliates beneficially owned 13% of our common stock, inclusive of exercisable options to acquire shares of our common stock and vested restricted and performance stock units which have not yet been settled with 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 because 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, considering 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 R&D 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. One of our third-party contract manufacturers has recently experienced an increase in difficulties with manufacturing of ANNOVERA, resulting in intermittent supply of ANNOVERA for commercial distribution. See "Our dependence upon third parties for the manufacture and supply of our existing women's healthcare products may cause delays in, or prevent us from, successfully commercializing, and marketing our products" above. 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 because 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 the ("GDPR") in May 2018. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the U.S., provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the non-compliant company, whichever is greater. The recent implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business.

In July 2020, the Court of Justice of the European Union issued its long-awaited decision in the case Data Protection Commission v. Facebook Ireland, Schrems. The decision on this case 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 entered 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

Our headquarters is 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. We believe that our facilities are sufficient for our present needs.

Item 3. Legal proceedings

In February 2020, we received a Paragraph IV certification notice letter (the "IMVEXXY Notice Letter") regarding an ANDA submitted to FDA by Teva Pharmaceuticals USA, Inc. ("Teva"). The ANDA seeks approval from 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 FDA's Orange Book that claim compositions and methods of IMVEXXY (the "IMVEXXY Patents"), are invalid, unenforceable, and/or will not be infringed by Teva's commercial manufacture, use, or sale of its proposed generic drug product. The IMVEXXY Patents identified in the IMVEXXY Notice Letter expire in 2032 or 2033. In April 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. In July 2021, following a proposal by Teva, the District Court entered an order temporarily staying all proceedings in the IMVEXXY litigation, which order was filed under seal. In September 2021, the District Court made available a public version of the order following the parties' agreement to a consent motion to redact information Teva contended was confidential. The order provides that the statutory stay that prevents FDA from granting final approval of the ANDA for 30 months from the date of the Notice Letter will be extended for the number of days that the stay of the IMVEXXY litigation is in place. The length of the stay of the IMVEXXY litigation is dependent on further action by Teva.

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

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 2017, our common stock has been listed on the Nasdaq Global Select Market ("Nasdaq") under the symbol "TXMD."

As of December 31, 2021, the closing price of our common stock on Nasdaq was $0.36 per share. As of March 17, 2022, there were 128 stockholders of record of our common stock.

Performance graph

As a "smaller reporting company," as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and pursuant to Instruction 6 to Item 201(e) of Regulation S-K, we are not required to provide this information.

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.

Item 6. Reserved

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 our consolidated financial statements and the notes to those financial statements included elsewhere in this 2021 10-K 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 2021 10-K Report.

Certain amounts in the Management's discussion and analysis of financial condition and results of operations may not add due to rounding, and all percentages have been calculated using unrounded amounts.

Business overview

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 have a portfolio of branded and generic prescription prenatal vitamins under the vitaMedMD and BocaGreenMD brands that furthers our women's healthcare focus.

During 2021, the recovery from the COVID-19 pandemic drove improved access to health-care providers for our sales force and increased consumer demand for our products, which had a positive impact on our net product revenue relating to ANNOVERA, IMVEXXY, and BIJUVA. We believe the growth in our net product revenue will continue to be affected by the pace of recovery from the COVID-19 pandemic.

vitaCare Divestiture

On March 6, 2022, we entered into a stock purchase agreement (the "Purchase Agreement") with GoodRx, Inc. ("GoodRx"), a Delaware corporation and wholly-owned subsidiary of GoodRx Holdings, Inc. ("GoodRx Holdings"), which provides for the sale of all of the issued and outstanding capital stock of our vitaCare Prescription Services subsidiary ("vitaCare") to GoodRx (the "vitaCare Divestiture"). Under the terms of the Purchase Agreement, upon the closing of the vitaCare Divestiture (the "Closing"), we will receive a cash payment of $150.0 million, subject to adjustment as provided in the Purchase Agreement and customary holdbacks. In addition,

we may receive up to an additional of $7.0 million in earn-out consideration, contingent upon vitaCare's financial performance through 2023 as determined in accordance with the terms of the Purchase Agreement.

The Purchase Agreement contains customary representations and warranties, covenants and indemnities of the parties thereto. In addition, the Purchase Agreement provides that at the Closing: (i) we will enter into a long-term services agreement with vitaCare to continue utilization of the vitaCare platform with respect to our products; (ii) we and vitaCare will enter into a transition services agreement for us to provide certain transition services to vitaCare for up to 12 months following the Closing; and (iii) certain employees of ours and/or vitaCare will enter into employment agreements with GoodRx,

The vitaCare Divestiture is expected to close in the second quarter of 2022, subject to the satisfaction or waiver of certain customary conditions, including the receipt of certain regulatory approvals.

COVID-19

With multiple variant strains of the SARS-Cov-2 virus and the COVID-19 disease that it causes (collectively, "COVID-19") still circulating, we continue to be subject to risks and uncertainties in connection with 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. The ultimate global recovery from the pandemic will be dependent on, among other things, actions taken by governments and businesses to contain and combat the virus, including any variant strains, the speed and effectiveness of vaccine production and global distribution, as well as how quickly, and to what extent, normal economic and operating conditions can resume on a sustainable basis globally.

As part of our response to the COVID-19 pandemic, we implemented measures to reduce marketing expenses for 2020 and we also implemented cost saving measures in 2020 and 2021, 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. In addition, we have implemented a significant cost savings initiative that is designed to reduce our annual costs in 2022 by at least $40.0 million. This figure does not include estimated annualized cost savings of approximately $20.0 million from, or the costs associated with the vitaCare Divestiture.

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 2021. 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 of 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 many of the negative effects 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 any "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 remain 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.

Product portfolio

Our portfolio of products focused on women's health allows us to efficiently leverage our sales and marketing plans to grow our pharmaceutical products. We are focused on activities necessary for the continued commercialization of IMVEXXY, commercially launched in the third quarter of 2018; BIJUVA, commercially launched in the third quarter of 2019; and ANNOVERA, which we started selling in the third quarter of 2019 and commercially launched in March 2020, which was subsequently paused because of the COVID-19 pandemic and relaunched in July 2020. 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.

IMVEXXY (estradiol vaginal inserts), 4-µg and 10-µg

This pharmaceutical product is for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy due to menopause. 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.

We market and sell IMVEXXY in the U.S. and have entered into licensing agreements with third parties to market and sell IMVEXXY outside of the U.S. We have entered into a license and supply agreement (the "Knight License Agreement"), with Knight Therapeutics, Inc. ("Knight") pursuant to which, we granted Knight an exclusive license to commercialize IMVEXXY in Canada and Israel. We have entered into a licensing and supply agreement (the "Theramex License Agreement") with Theramex HQ UK Limited ("Theramex") pursuant to which we granted Theramex an exclusive license to commercialize IMVEXXY for human use outside of the U.S., except for Canada and Israel. As of December 31, 2021, no IMVEXXY sales have been made through these licensing agreements.

BIJUVA (estradiol and progesterone) capsules, 1 mg/100 mg

This pharmaceutical product is 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 vasomotor symptoms (commonly known as hot flashes or flushes) due to menopause in women with a uterus. We market and sell BIJUVA in the U.S. and have entered into licensing agreements with third parties to market and sell BIJUVA outside of the U.S. We have entered into the Knight License Agreement with Knight pursuant to which we granted Knight an exclusive license to commercialize BIJUVA in Canada and Israel. We have entered into the Theramex License Agreement with Theramex pursuant to which we granted Theramex an exclusive license to commercialize BIJUVA for human use outside of the U.S., except for Canada and Israel. During 2021, we had BIJUVA sales of $1.4 million made through the Theramex License Agreement, and such sales were included as product revenue in the statements of operations. As of December 31, 2021, no BIJUVA sales have been made through the Knight License Agreement.

ANNOVERA (segesterone acetate ("SA") and ethinyl estradiol ("EE") vaginal system)

This pharmaceutical product is a one-year ring-shaped contraceptive vaginal system ("CVS") and 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). ANNOVERA is commercially sold by us in the U.S. pursuant to the terms of the Population Council License Agreement. 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. 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 $20.0 million, half of such excess will offset against royalties or other payments owed by us 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 the strong 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 telehealth platforms that extend the reach of ANNOVERA.

Prenatal vitamin products

We 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.

Results of operations

2021 compared to 2020

Revenue. Our total revenue 2021 was $87.0 million, an increase of $22.1 million, or 34.0%, compared to 2020.

The following table sets forth our revenue during these periods (in thousands):

	2021	2020
Product revenue:		
ANNOVERA	$ 37,943	$ 19,611
IMVEXXY	31,533	27,139
BIJUVA	10,579	6,354
Prescription vitamin	5,725	9,768
Product revenue, net	85,780	62,872
License revenue	1,171	2,000
Total revenue, net	$ 86,951	$ 64,872

Our sales of ANNOVERA were $37.9 million for 2021, an increase of $18.3 million, or 93.5%, compared to 2020. This increase was primarily due to a 128.6% increase in sales volume, which was partially offset by a 15.4% decrease in the average sale price.

Our sales of IMVEXXY were $31.5 million for 2021, an increase of $4.4 million, or 16.2%, compared to 2020. This increase was primarily attributable to a 31.0% increase in the average sale price, which was partially offset by a 11.3% decrease in sales volume. Both the higher average sale price and lower sales volume was primarily a result of a change in the IMVEXXY copay assistance program to increase the price paid by the customer.

Our sales of BIJUVA were $10.6 million for 2021, an increase of $4.2 million, or 66.5%, compared to 2020. Included in our BIJUVA sales for 2021 was $1.4 million of sales made through the Theramex License Agreement. Without the sales made through the Theramex License Agreement, our sales of BIJUVA for 2021 were $9.2 million, an increase of $2.8 million, or 44.4%, compared to 2020. This increase was primarily attributable to a 43.0% increase in the average sale price and a 1.0% increase in sales volume. The higher average sale price reflects a change in the BIJUVA copay assistance program to increase the price paid by the customer.

Sales of our products utilize copay assistance programs that allow eligible enrolled patients to access the products at a reasonable cost regardless of insurance coverage. These programs may change from time to time, as shown above with a change in IMVEXXY and BIJUVA copay assistance program. We expect that our net product revenue will improve from changes in our copay card price in the long-term and increases in commercial and Medicare payer coverage when we fully complete the process needed to adjudicate ANNOVERA, IMVEXXY, and BIJUVA prescriptions at pharmacies.

Our prescription vitamin sales were $5.7 million for 2021, a decrease of $4.0 million, or 41.4%, compared to 2020. This decrease was primarily due to a 36.0% decrease in sales volume and an 8.5% decrease in the average sale price. The decrease in sales volume of our prescription vitamin reflects our sales focus to grow our contraceptive and menopause pharmaceutical products.

On a consolidated basis, our total product sales were $85.8 million for 2021, an increase of $22.9 million, or 36.4%, compared to 2020.

Our license revenue was $1.2 million for 2021, a decrease of $0.8 million, or 41.5%, compared to 2020. This decrease was entirely due to the timing of achieving previously established milestone payment targets.

Gross profit. Our gross profit for 2021 was $68.1 million, an increase of $19.2 million, or 39.3%, compared to 2020.

The following table sets forth our gross profit during these periods (in thousands):

	2021	2020
Product	$ 66,942	$ 46,897
License	1,171	2,000
Total gross profit	$ 68,113	$ 48,897

The increase in our gross profit was primarily a result of an increase of 36.4% in product revenue and a 3.4% increase in our product gross margin from 74.6% for 2020 to 78.1% for 2021, partially offset by a decrease in license revenue of $0.8 million. The increase in product gross margins was mainly due to $3.0 million in lower inventory obsolescence charges in 2021 compared to 2020, partially offset by an overall decrease in profit margins of our products of 1.8%.

Operating expenses. Total operating expenses for 2021 were $207.9 million, an increase of $3.4 million, or 1.7%, compared to 2020. Our operating expenses for 2021 included $12.4 million of severances for former senior executives, including our former chief executive officer and former executive vice president of operations. Of the total severance amount, $8.1 million was related to share-based compensation recorded in connection with accelerated vesting of certain share-based payment awards for the former senior executives. Without such executive severances, our total operating expenses for 2021 would have been $195.5 million, a decrease of $8.9 million,

or 4.4%, compared to 2020. The type of operating expenses reported in prior years have been reclassified to conform to the current year's presentation.

The following table sets forth our operating expense categories (in thousands):

	2021	2020
Selling and marketing	$ 108,195	$ 117,052
General and administrative	92,602	76,954
Research and development	7,086	10,432
Total operating expenses	$ 207,883	$ 204,438

Our selling and marketing costs were $108.2 million for 2021, a decrease of $8.9 million, or 7.6%, compared to 2020. This decrease was primarily due to $12.5 million in lower outsourced sales personnel costs mainly attributable to the onboarding of such sales personnel in the third quarter of 2020, $6.1 million in lower product sample costs mainly due to the write down of product samples in 2020, primarily related to BIJUVA, and $2.9 million in lower marketing costs primarily related to a national selling and marketing event that occurred during 2020 prior to the COVID-19 pandemic. These decreases were partially offset by $3.9 million in higher advertising expenditures in order to support the commercialization of our pharmaceutical products, $7.4 million in higher salaries and employee benefit costs to support the sales growth of our pharmaceutical products, reflecting the continued impact of our formerly outsourced sales personnel who were onboarded in the third quarter of 2020, and $1.6 million in higher costs related to physician education expenses and transportation expenses for traveling sales staff.

Our general and administrative costs were $92.6 million for 2021, an increase of $15.6 million, or 20.3%, compared to 2020. Of the total increase, $12.4 million was related to executive severances recorded in 2021. The remaining increase was $3.3 million, or 4.3%, compared to 2020. This increase was primarily attributable to $1.8 million in higher compensation and employee benefit costs, $0.8 million in higher insurance, and $2.6 million in higher professional fees, such as consulting, recruiting, legal, etc. Overall, these increases are in support of our efforts to expand the commercialization of our pharmaceutical products. These increases were partially offset by $1.5 million in lower expenditures attributable to information technology and dues and subscriptions, and $1.1 million in write-down of our patents and trademarks related to impairment in 2020.

Our R&D costs were $7.1 million for 2021, a decrease of $3.3 million, or 32.1%, compared to 2020. This decrease was primarily attributable to $2.0 million in lower research related costs, $1.0 million in lower compensation and employee benefit costs and $0.4 million in lower legal and professional fees. We have reduced our R&D expenditures since 2019 as we refocus our resources towards the continued commercialization of our pharmaceutical products. Accordingly, we continue to deploy limited resources in the development of new products, to perform stability testing and validation on our pharmaceutical products, to develop and validate secondary manufacturers, to prepare regulatory submissions, and work with regulatory authorities on existing submissions.

Loss from operations. For 2021, we had a loss from operations of $139.8 million, compared to $155.5 million for 2020. This $15.8 million improvement was attributable to $19.2 million in higher gross profit, partially offset by $3.4 million in higher operating expenses. Our loss from operations for 2021 included $12.4 million of severances for former senior executives. Without such executive severances, for 2021, we would have had a loss from operations of $127.4 million. We anticipate that we will continue to have operating losses for the near future until we are able to successfully commercialize IMVEXXY, BIJUVA, and ANNOVERA, although there is no assurance that our efforts will be successful.

Other expense, net. For 2021, our non-operating expenses were $32.6 million, compared to $28.0 million for 2020. This $4.7 million increase was primarily attributable to a $4.7 million increase in interest prepayment fees, including the recording of an $2.2 million accrual for interest prepayment fees for 2021 associated with our future debt service, and $3.2 million in higher amortization expense of deferred financing costs. These increases were partially offset by $3.5 million in lower interest expense due to overall lower average debt balance during 2021 compared to 2020.

Net Loss. For 2021, we had a net loss of $172.4 million, or $0.43 per basic and diluted common share, compared to $183.5 million, or $0.67 per basic and diluted common share, for 2020. Our net loss for 2021 included $12.4 million of executive severances recorded for former senior executives. Without such executive severances, for 2021, we would have had a net loss of $160.0 million, or $0.40 per basic and diluted common share.

2020 compared to 2019

Revenue. Our total revenue 2020 was $64.9 million, an increase of $15.2 million, or 30.7%, compared to 2019. Despite slower than anticipated growth of our product revenue due to the impact of COVID-19 pandemic, product revenue increased primarily due to continued ramping up of sales of ANNOVERA, IMVEXXY and BIJUVA for 2020, as compared to 2019, partially offset by a decrease in prenatal vitamins sales.

The following table sets forth our revenue during these periods (in thousands):

	2020	2019
Product revenue:		
ANNOVERA	$ 19,611	$ 6,167
IMVEXXY	27,139	16,252
BIJUVA	6,354	1,836
Prescription vitamin	9,768	9,886
Product revenue, net	62,872	34,141
License revenue	2,000	15,506
Total revenue, net	$ 64,872	$ 49,647

Our sales of ANNOVERA were $19.6 million for 2020, an increase of $13.4 million, or 218.0%, compared to 2019. This increase was primarily due to a 107.9% increase in sales volume and a 53.0% increase in the average sale price.

Our sales of IMVEXXY were $27.1 million for 2020, an increase of $10.9 million, or 67.0%, compared to 2019. This increase was primarily attributable to an 80.2% increase in the average sale price, which was partially offset by a 7.3% decrease in sales volume.

Our sales of BIJUVA were $6.4 million for 2020, a decrease of $4.5 million, or 246.1%, compared to 2019. This increase was primarily attributable to a 181.3% increase in the average sale price and a 23.0% increase in sales volume.

Sales of our products utilize copay assistance programs that allow eligible enrolled patients to access the products at a reasonable cost regardless of insurance coverage. We expect that our net product revenue will improve from changes in our copay card price in the long-term and increases in commercial and Medicare payer coverage when we fully complete the process needed to adjudicate ANNOVERA, IMVEXXY, and BIJUVA prescriptions at pharmacies.

Our prescription vitamin sales were $9.8 million for 2020, a decrease of $0.1 million, or 1.2%, compared to 2019. This decrease was primarily due to a 14.7% decrease in sales volume, which was partially offset by a 15.9% increase in the average sale price.

On a consolidated basis, our total product sales were $62.9 million for 2020, an increase of $28.7 million, or 84.2%, compared to 2019.

Our license revenue was $2.0 million for 2020, a decrease of $13.5 million, or 87.1%, compared to 2019. This decrease was entirely due to the timing of achieving previously established milestone payment targets.

Gross profit. Our gross profit for 2020 was $48.9 million, an increase of $5.6 million, or 12.9%, compared to 2019.

The following table sets forth our gross profit during these periods (in thousands):

	2020	2019
Product	$ 46,897	$ 27,806
License	2,000	15,506
Total gross profit	$ 48,897	$ 43,312

The increase in our gross profit was primarily a result of an increase of 84.2% in product revenue, partially offset by 6.9% decrease in our product gross margin from 81.4% for 2019 to 74.6% for 2020, and a decrease in license revenue of $13.5 million. The decrease in product gross margin was mainly due to $4.1 million in inventory obsolescence charges for 2020, which was primarily related to the impact of the COVID-19 pandemic on our business, resulting in decreased demand for our products.

Operating expenses. Total operating expenses for 2020 were $204.4 million, an increase of $9.9 million, or 5.1%, compared to 2019. The type of operating expenses reported in prior years have been reclassified to conform to the current year’s presentation.

The following table sets forth our operating expense categories (in thousands):

	2020	2019
Selling and marketing	$ 117,052	$ 114,231
General and administrative	76,954	60,494
Research and development	10,432	19,792
Total operating expenses	$ 204,438	$ 194,517

Our selling and marketing costs were $117.1 million for 2020, a decrease of $2.8 million, or 2.5%, compared to 2019. This increase was primarily due to $14.7 million in lower outsourced sales personnel costs mainly attributable to the onboarding of such sales personnel in the third quarter of 2020, $12.3 million in lower marketing costs, and $3.4 million in lower costs related to physician education expenses and transportation expenses for traveling sales staff. Overall, lower costs for marketing and traveling sales staff reflect our 2020 cost cutting initiatives put in place at the beginning of the COVID-19 pandemic. These decreases were partially offset by (i) $26.8 million in higher advertising expenditures in order 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 continued support of the commercialization of BIJUVA and IMVEXXY, (ii) $5.0 million in higher product sample costs mainly due to the 2019 write down of product samples, primarily related to BIJUVA, and (iii) $1.4 million in higher salaries and employee benefit costs to support the sales growth of our pharmaceutical products, reflecting the continued impact of our formerly outsourced sales personnel who were onboarded in the third quarter of 2019.

Our general and administrative costs were $77.0 million for 2020, an increase of $16.5 million, or 27.2%, compared to 2019. This increase was primarily due to $12.4 million in higher compensation and employee benefit costs, $1.9 million in higher dues and subscriptions, $1.3 million increase in rent primarily due to our new leased offices, $1.4 million in higher insurance expenses, reflecting an overall increase in market insurance rates, and $1.1 million in write-down of our patents and trademarks related to impairment. Overall, higher costs for compensation and employee benefit, dues and subscriptions and rent were mainly in support of our efforts to expand the commercialization of our products. These increases were partially offset by $1.0 million in lower employee traveling costs, and $0.8 million in lower professional fees, such as consulting, recruiting, legal, etc.

Our R&D costs were $10.4 million for 2020, a decrease of $9.4 million, or 47.3%, compared to 2019. This decrease was primarily attributable to $4.2 million in lower research related costs, $3.5 million in lower compensation and employee benefit costs, $1.0 million in lower legal and professional fees, and $0.4 million in lower employee traveling costs. We have reduced our R&D expenditures since 2019 as we refocus our resources towards the continued commercialization of our pharmaceutical products. Accordingly, we continue to deploy limited resources in the development of new products, to perform stability testing and validation on our pharmaceutical products, to develop and validate secondary manufacturers, to prepare regulatory submissions, and work with regulatory authorities on existing submissions.

Loss from operations. For 2020, we had a loss from operations of $155.6 million, compared to $151.2 million for 2019. This $4.3 million of additional loss was attributable to $9.9 million in higher operating expenses, partially offset by $5.6 million in higher gross profit. We anticipate that we will continue to have operating losses for the near future until we are able to successfully commercialize IMVEXXY, BIJUVA, and ANNOVERA, although there is no assurance that our efforts will be successful.

Other expense, net. For 2020, our non-operating expenses were $28.0 million, compared to $24.9 million for 2019. This $3.1 million increase was primarily attributable to $9.5 million in higher interest expense primarily due to overall higher debt balance during 2020 compared to 2019, and $1.7 million in higher amortization expense of deferred financing costs.

Net Loss. For 2020, we had a net loss of $183.5 million, or $0.67 per basic and diluted common share, compared to $176.1 million, or $0.72 per basic and diluted common share, for 2019.

Liquidity and capital resources

Our primary use of cash is to fund the continued commercialization of our hormone therapy and contraceptive products. We have funded our operations primarily through public offerings of our common stock and private placements of equity and debt securities. As of December 31, 2021, we had cash totaling $65.1 million. We maintain cash at financial institutions that at times may exceed the Federal Deposit Insurance Corporation insured limits of $0.25 million per bank. We have never experienced any losses related to these funds.

In November 2020, we entered into an at-the-market offering program (the “2020 ATM Program”) relating to shares of our common stock. The 2020 ATM Program permitted us to offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million from time to time through or to the sales agent under the 2020 ATM Program. Sales of our common stock were permitted to be made from time to time in at-the-market offerings as defined in Rule 415 of the Securities Act of 1933, as amended (the “Securities Act”), including by means of ordinary broker’s transactions on Nasdaq or otherwise at market prices prevailing at the time of sale, at

prices related to prevailing market prices, or as otherwise agreed to with the sales agent. The sales agent was entitled to compensation at a fixed commission rate of 3.0% of the aggregate gross sales price per share sold. As of February 8, 2021, sales of shares of our common stock under the 2020 ATM Program were completed when we sold an aggregate total of 28,600,689 shares of our common stock at an average sale price of $1.75 per share. For the 2020 ATM Program, we received net proceeds of $48.1 million, after deducting the discounts and commissions to the sales agent and estimated offering expenses.

In February 2021, we closed on an underwritten public offering of our common stock, pursuant to which we issued 59,459,460 shares of our common stock at an offering price of $1.85 per share, and we received net proceeds of $96.6 million, after deducting the underwriting discounts and commissions and estimated offering expenses.

In March 2021, we entered into an at-the-market offering program (the "2021 ATM Program") relating to shares of our common stock. The 2021 ATM Program permits us to offer and sell shares of our common stock having an aggregate offering price of up to $100.0 million from time to time through or to the sales agent under the 2021 ATM Program. Sales of our common stock may be made from time to time in at-the-market offerings as defined in Rule 415 of the Securities Act, including by means of ordinary broker's transactions on Nasdaq or otherwise at market prices prevailing at the time of sale, at prices related to prevailing market prices, or as otherwise agreed to with the sales agent. The sales agent will be entitled to compensation at a fixed commission rate of 3.0% of the aggregate gross sales price per share sold. The sales agent is not required to sell any specific number or dollar amounts of securities but will act as sales agent and use commercially reasonable efforts to sell on our behalf all the shares of common stock requested to be sold by us, consistent with its normal trading and sales practices, on mutually agreed terms between us and the sales agent. Through December 31, 2021, we have sold a total of 33,705,315 shares of our common stock under the 2021 ATM Program at an average sale price of $1.21 per share and we received estimated net proceeds of $39.4 million, after deducting discounts and commissions to the sales agent and estimated offering expenses. Subsequently, through the date of this 2021 10-K Report, we have not sold any additional shares of our common stock under the 2021 ATM Program. Future sales, if any, under the 2021 ATM Program will depend on a variety of factors, including among others, market conditions, the trading price of our common stock, determinations by us of the appropriate sources of funding, and potential uses of funding available to us.

On March 6, 2022, we signed a definitive agreement for the vitaCare Divestiture, which is expected to close in the second quarter of 2022, subject to the satisfaction or waiver of certain customary conditions, including the receipt of certain regulatory approvals. Upon the closing of the vitaCare Divestiture, we will receive a cash payment of $150.0 million, subject to adjustment and customary holdbacks. In addition, we may receive up to an additional of $7.0 million in earn-out consideration. We have agreed to utilize the first $120.0 million of net proceeds from the vitaCare Divestiture and all net proceeds of the vitaCare Divestiture in excess of $135.0 million pay to the Lenders as a prepayment of the loans under the Financing Agreement.

Cash flows

The principal use of cash in operating activities was to fund our current expenditures in support of our continued commercialization activities for IMVEXXY, BIJUVA, and ANNOVERA, sales, marketing, scale-up and manufacturing activities, adjusted for non-cash items. Financing activities currently represent the principal source of our cash flow. The following table reflects the major categories of cash flows for each of the periods (in thousands).

	2021	2020	2019
Net cash used in operating activities	$ (142,693)	$ (159,471)	$ (165,718)
Net cash used in investing activities	(2,223)	(1,598)	(23,892)
Net cash provided by financing activities	129,552	80,725	188,827

2021 compared to 2020

Operating Activities. Net cash used in operating activities in 2021 was $142.7 million, compared to net cash used in operating activities of $159.5 million for 2020. This decrease of $16.8 million or 10.5%, was primarily due to a $11.1 million decrease in our net loss, a $2.8 million decrease in cash usage related to changes in operating assets and liabilities, and a $2.8 million increase in non-cash expenditure adjustments.

Investing Activities. Net cash used in investing activities for 2021 was $2.2 million, compared to net cash used in investing activities of $1.6 million for 2020. This increase of $0.6 million, or 39.1%, was primarily due to higher patent related costs.

Financing Activities. Net cash provided by financing activities was for 2021 was $129.6 million, compared to net cash provided by financing activities of $80.7 million for 2020. This increase of $48.8 million, or 60.5%, was primarily related to a $152.4 million increase in proceeds from sale of common stock, partially offset by a $3.9 million increase in the payment of debt financing fees, a $50.0 million in repayment of debt in 2021, and a $50.0 million in borrowing of debt in 2020.

2020 compared to 2019

Operating Activities. Net cash used in operating activities in 2020 was $159.5 million, compared to net cash used in operating activities of $165.7 million for 2019. This decrease of $6.2 million or 3.8%, was primarily due to a $10.7 million decrease in cash usage related to changes in operating assets and liabilities, and a $2.9 million increase in non-cash expenditure adjustments, partially offset by a $7.4 million increase in our net loss.

Investing Activities. Net cash used in investing activities for 2020 was $1.6 million, compared to net cash used in investing activities of $23.9 million for 2019. This decrease of $22.3 million, or 93.3%, was primarily due to a payment for intellectual property license in 2019 and lower purchase of fixed assets.

Financing Activities. Net cash provided by financing activities was for 2020 was $80.7 million, compared to net cash provided by financing activities of $188.8 million for 2019. This decrease of $108.1 million, or 57.2%, was primarily related to a $150.0 million decrease in borrowings of debt and a $45.3 million decrease in proceeds from sale of common stock, partially offset by a $5.4 million increase in the payment of debt financing fees, and a $81.7 million in repayment of debt in 2019.

For additional details, see the consolidated statements of cash flows included in this 2021 10-K Report.

Other liquidity measures

Receivable. Our net days sales outstanding (“DSO”) is calculated by dividing average gross accounts receivable less the reserve for doubtful accounts, chargebacks, and payment discounts by the average daily net product revenue during the last four quarters for each respective quarterly period. As of December 31, 2021, our net DSO was 148 days, compared to 165 days as of December 31, 2020, respectively. Our gross DSO is calculated by dividing average gross accounts receivable by the average daily gross product revenue to distributors during the last four quarters for each respective quarterly period. As of December 31, 2021, our gross DSO was 72 days, compared to 67 days as of December 31, 2020. Our DSO have fluctuated and will continue to fluctuate in the future due to variety of factors, including longer payment terms associated with the continued commercialization 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.

Inventory. We rely on third parties to manufacture our finished products, and we have entered into long-term supply agreements for the manufacture of ANNOVERA, IMVEXXY, and BIJUVA. We do not have a long-term supply agreement for the manufacture of our prescription vitamins. Additionally, we do not have long-term contracts for the supply of the active pharmaceutical ingredient (“API”) used in ANNOVERA and BIJUVA.

Debt. We had $200.0 million and $250.0 million in term loans outstanding under our Financing Agreement as of December 31, 2021 and 2020, respectively. In March 2022, we entered into Amendment No. 9 to the Financing Agreement (“Amendment No. 9”) pursuant to which, among other things: (i) the lenders waived various Company breaches of the Financing Agreement, including breaches of the $60 million minimum cash covenant and the minimum net revenue covenants for the fourth quarter of 2021, and removed the minimum net revenue covenant for the first quarter of 2022; (ii) the Company and the lenders agreed to reduced minimum cash covenants under the Financing Agreement; (iii) the lenders waived the existing $60.0 million prepayment penalty under the Financing Agreement and the Company agreed to a paid in kind amendment fee of $30.0 million, which fee was added to the principal amount of the loans under the Financing Agreement, $16.0 million of which fee is waivable in certain conditions; and (iv) the maturity date of the Financing Agreement was amended to June 1, 2022. The Financing Agreement contains customary restrictions and covenants applicable to us that are customary for financings of this type. Among other requirements, the Financing Agreement also requires us to maintain a minimum unrestricted cash balance. For additional information regarding our debt, see "Note 8. Debt" to the consolidated financial statements included in this 2021 10-K Report.

For additional information, see the discussion of our risks and uncertainties related to COVID-19 in Note 1. Basis of Presentation, new accounting standards and summary of significant accounting policies " to the consolidated financial statements included in "Part IV. Item 15. Exhibits and Financial Statement Schedules" of this 2021 10-K Report.

Going concern

We incurred a net loss of $172.4 million during the year ended December 31, 2021, and as of that date, our current liabilities exceeded our current assets by $133.4 million and our total liabilities exceeded our total assets by $93.6 million. We will need to raise additional capital to repay the entire principal balance of our Financing Agreement, which matures on June 1, 2022, and to provide additional

liquidity to fund our losses until our operations become cash flow positive. To address our capital needs, we are pursuing various equity and debt financing and other alternatives, including the vitaCare Divestiture. The equity financing alternatives may include the private placement of equity, equity-linked, or other similar instruments or obligations with one or more investors, lenders, or other institutional counterparties or an underwritten public equity or equity-linked securities offering. Our ability to sell equity securities may be limited by market conditions, including the price of our common stock and the potential delisting of our common stock from Nasdaq, and our available authorized shares. To the extent that we raise additional capital through the sale of such securities, the ownership interests of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. If we are not successful in obtaining additional financing, we could be forced to discontinue or curtail our business operations, sell assets at unfavorable prices, or merge, consolidate, or combine with a company with greater financial resources in a transaction that might be unfavorable to us.

Along with considering additional financings, we have reviewed numerous potential scenarios in connection with steps that we may take to reduce our operating expenses. Based on our analysis, we believe that our existing cash reserves along with potential proceeds from the sale of certain non-core assets of the Company and proceeds from potential future financings, if available to us, would be sufficient to meet our cash needs arising in the ordinary course of business for the next twelve months from the date of this 2021 10-K Report.

If we are unsuccessful with future financings and if the successful commercialization of IMVEXXY, BIJUVA, or ANNOVERA is delayed, or the continued impact of the COVID-19 pandemic or issues in our supply chains related to our third-party contract manufacturers on our business is worse than we anticipate, our existing cash reserves would be insufficient to maintain compliance with the Financing Agreement covenants or satisfy our liquidity requirements. See Item 1A. Risk Factors – “Our dependence upon third parties for the manufacture and supply of our existing women’s healthcare products may cause delays in, or prevent us from, successfully commercializing, and marketing our products” above for additional information regarding risks associated with our contract manufacturers, particularly for ANNOVERA. The presence of these projected factors in conjunction with the uncertainty of the capital markets raises substantial doubt about the Company's ability to continue as a going concern for the next twelve months from the issuance of these financial statements.

The accompanying consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Contractual obligations, off-balance sheet arrangements, purchase commitments and employment agreements

Our contractual obligations and off-balance sheet arrangements are set forth below. For additional information on any of the following and other obligations and arrangements, see "Note 8. Debt" and "Note 9. Commitments and Contingencies" to the consolidated financial statements included in this 2021 10-K Report.

Contractual obligations

A summary of contractual obligations is as follows:

	Total	Year 1	Years 2-3	Years 4-5	> 5 years
Debt obligations (1)	$ 230,000	$ 230,000	$ —	$ —	$ —
Interest obligations (2)	9,336	9,336	—	—	—
Purchase obligations (3)	36,501	7,258	8,196	9,521	11,526
Operating lease obligations	13,280	1,413	2,920	3,064	5,883
Total contractual obligations	$ 289,117	$ 248,007	$ 11,116	$ 12,585	$ 17,409

(1) Debt obligations are shown based on the contractual obligations of the Financing Agreement in accordance with Amendment No. 9 to the Financing Agreement.

(2) Interest obligations are on the contractual obligations of the Financing Agreement in accordance with Amendment No. 9 to the Financing Agreement and interest rates in place as of December 31, 2021.

(3) Includes manufacturing purchase commitments described below. The amounts presented here represent our estimates of the minimum required payments under our agreements.

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, 2021 and 2020.

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 U.S. GAAP, an estimate is made of the loss and the appropriate accounting entries are reflected in our financial statements.

Purchase commitments

Information regarding purchase commitments is in "Note 9. Commitments and contingencies" to the consolidated financial statements included in this 2021 10-K Report.

Employment agreements

Information regarding employment agreements is in "Note 9. Commitments and contingencies" to the consolidated financial statements included in this 2021 10-K Report.

Critical accounting policies and estimates

Management's discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements included elsewhere in this 2021 10-K Report, which has been prepared in accordance with U.S. GAAP (“U.S. GAAP”). The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to unbilled revenue and associated costs of sales, allowance for credit losses, goodwill and identifiable intangible assets, certain accrued liabilities, and income taxes. We base our estimates on historical experience and on other assumptions that are believed 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 from these estimates under different assumptions or conditions.

We have identified the areas described below as critical to our business operations and the understanding of our results of operations given the uncertainties associated with the assumptions underlying each estimate. For a detailed discussion on the application of these and other significant accounting policies, see “Note 1. Basis of presentation, new accounting standards and summary of significant accounting policies” to the consolidated financial statements included in this 2021 10-K Report.

Segment reporting

We manage and operate 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, which is led by our chief executive officer. 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 within the United States. Accordingly, we view our business as one reportable operating segment.

Revenue recognition

We determine the amount of revenue to be recognized through application of the following steps:

- Identification of the contract with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when or as we satisfy the performance obligations.

Essentially all of our revenue is generated through contracts with our customers, who are primarily wholesale distributors and retail pharmacies. A performance obligation is a promise in a contract to transfer a product 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, and we treat shipping as a fulfillment activity rather than as a separate obligation. We generally recognize revenue at a point in time when all of our performance obligations under the terms of a contract are satisfied. Revenue is recognized upon transfer of control of promised products or services in an amount

that reflects the consideration we expect to receive in exchange for those products or services. The collectability of consideration on the contract is reasonably assured before revenue is recognized. To the extent that customer payment has been received before all recognition criteria are met, these revenues are initially deferred in other accruals on the balance sheet and the revenue is recognized in the period that all recognition criteria have been met.

For additional discussion on prescription products and license revenue, see “K. Revenue recognition” in Note 1. Basis of presentation, new accounting standards and summary of significant accounting policies to the consolidated financial statements included in this 2021 10-K Report.

Share-based payment awards

We account for share-based payment awards on a fair value basis of the equity instrument issued. Under fair value accounting, the grant-date fair value of the share-based payment award is amortized as compensation expense, on a straight-line basis, over the service period (generally, the vesting period) for both graded and cliff vesting awards. We have elected to account for forfeitures as they occur.

Income taxes

Income taxes are accounted for under the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and income tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted income tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in income tax rates is recorded as a component of the income tax provision in the period that includes the enactment date.

Regular assessments are made on the likelihood that our deferred tax assets will be recovered from our future taxable income. Our evaluation is based on estimates, assumptions, and includes an analysis of available positive and negative evidence, giving weight based on the evidence’s relative objectivity. Sources of positive evidence include estimates of future taxable income, future reversal of existing taxable temporary differences, taxable income in carryback years, and available tax planning strategies. Sources of negative evidence include current and cumulative losses in recent years, losses expected in early future years, any history of operating losses or tax credit carryforwards expiring unused, and unsettled circumstances that, if unfavorably resolved, would adversely affect future profit levels.

The remaining carrying value of our deferred tax assets, after recording the valuation allowance on our deferred tax assets, is based on our present belief that it is more likely than not that we will be able to generate sufficient future taxable income to utilize such deferred tax assets. The amount of the remaining deferred tax assets considered recoverable could be adjusted if our estimates of future taxable income during the carryforward period change favorably or unfavorably. To the extent we believe that it is more likely than not that some or all the remaining deferred tax assets will not be realized, we must establish a valuation allowance against those deferred tax assets, resulting in additional income tax expense in the period such determination is made. To the extent a valuation allowance currently exists, we will continue to monitor all positive and negative evidence until we believe it is more likely than not that it is no longer necessary, resulting in an income tax benefit in the period such determination is made.

Our policy is to recognize both interest and penalties related to uncertain tax positions as part of the income tax provision. Significant judgment is required in evaluating our tax positions, and in determining our provisions for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We establish reserves when, despite our belief that the income tax return positions are fully supportable, certain positions are likely to be challenged and we may ultimately not prevail in defending those positions.

Recent accounting pronouncements

Information regarding accounting standards adopted during 2021 is included in "Note 1. Basis of Presentation, New Accounting Standards and Significant Accounting Policies" to the consolidated financial statements.

Item 7A. Quantitative and qualitative disclosures about market risk

As a “smaller reporting company,” as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and pursuant to Instruction 6 to Item 201(e) of Regulation S-K, we are not required to provide this information.

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 2021 10-K 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 2021 10-K Report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2021, 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 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 U.S. 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, 2021. 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, 2021.

This 2021 10-K Report 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 2021 10-K Report.

Item 9B. Other information

2022 executive retention and performance bonus plan

On March 23, 2022, the Company entered into award agreements (the "Award Agreements") with each of Mr. Marlan D. Walker, the General Counsel of the Company, and Mr. Michael C. Donegan, the Vice President – Finance and Chief Accounting Officer of the Company who will become Interim Chief Financial Officer of the Company, under the Company's 2022 Executive Retention and Performance Bonus Plan (the "ERB Plan").

Under the terms of the Award Agreements and the ERB Plan, each of Mr. Walker and Mr. Donegan was granted (i) a retention award of $207,500 and $87,000, respectively (each a "Retention Payment"), and (ii) a performance bonus award of $622,500 and $261,000, respectively (each a "Bonus Target"), based on the achievement of critical strategic, tactical and financial goals of the Company (each a "Performance Bonus Award").

If the employment of a participant under the ERB Plan is terminated by the Company for "cause" or by the participant other than for "good reason" (i) on or before July 1, 2022, the participant will be required to pay back 100% of the after-tax value of the Retention Payment, or (ii) after July 1, 2022, the participant will be required to pay back 50% of the after-tax value of the Retention Payment.

The Performance Bonus Awards will be based on Company performance for four separate six-month performance periods from January 1, 2022 to December 31, 2023 based on performance targets approved by the Compensation Committee of the Board of Directors of the Company and will be payable at up to 150% of the Bonus Target.

The foregoing description of the ERB Plan does not purport to be complete and is qualified in its entirety by reference to the full text of the ERB Plan, which is attached hereto as Exhibit 10.55 and is incorporated herein by reference.

Item 9C. Disclosure regarding foreign jurisdictions that prevent inspections

None.

PART III

Item 10. Directors, executive officers, and corporate governance

The information required by this Item relating to our directors and corporate governance is incorporated herein by reference to the definitive Proxy Statement to be filed pursuant to Regulation 14A of the Exchange Act for our 2022 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 2022 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 2022 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 2022 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 2022 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 Financial Statements on page F-1 of this 2021 10-K 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 No.	Description
2.1	Agreement and Plan of Reorganization, dated July 6, 2009, among Croff Enterprises, Inc., AMHN Acquisition Corp., America's Minority Health Network, Inc., and the Major Shareholders(1)
2.2	Agreement and Plan of Reorganization, dated June 11, 2010, among AMHN, Inc., SHN Acquisition Corp., Spectrum Health Network, Inc., and the Sole Shareholder of Spectrum Health Network, Inc.(2)
2.3	Croff Enterprises, Inc. Plan of Corporate Division and Reorganization, dated October 25, 2007(3)
2.4	Agreement and Plan of Merger, dated July 18, 2011, among vitaMedMD, LLC, AMHN, Inc., and vitaMed Acquisition, LLC(4)
2.5***+	Stock Purchase Agreement, dated March 6, 2022, by and between TherapeuticsMD, Inc. and GoodRx, Inc.(37)
3.1	Articles of Conversion of AMHN, Inc. filed in the State of Nevada, dated July 20, 2010(5)
3.2	Articles of Incorporation of AMHN, Inc. filed in the State of Nevada, dated July 20, 2010(5)
3.3	Composite Amended and Restated Articles of Incorporation of the Company, as amended(6)
3.4	Bylaws of the AMHN, Inc.(7)
3.1	First Amendment to Bylaws of the Company, dated December 17, 2015(8)
4.1	Form of Certificate of Common Stock(9)
4.2	Description of Securities of the Company(10)
10.1	Form of Common Stock Purchase Warrant, dated(11)
10.2*	Form of Non-Qualified Stock Option Agreement(11)
10.3*	TherapeuticsMD, Inc. 2019 Stock Incentive Plan(12)
10.4*	First Amendment to the TherapeuticsMD, Inc. 2019 Stock Incentive Plan(31)
10.5*	Amended and Restated 2012 Stock Incentive Plan(13)
10.6*	2009 Long Term Incentive Compensation Plan, as amended(14)
10.7*	TherapeuticsMD, Inc. 2020 Employee Stock Purchase Plan(15)
10.8	Common Stock Purchase Warrant to Lang Naturals, Inc., dated October 23, 2011(16)
10.9	Form of Common Stock Purchase Warrant, dated February 24, 2012(17)
10.10	Common Stock Purchase Warrant, issued to Plato & Associates, LLC, dated January 31, 2013(18)
10.11	Form of Warrant to Purchase Common Stock, dated August 5, 2020(6)
10.12	Amendment to Company Warrant issued by the Company to the Subscribers party to that certain Subscription Agreement, dated as of August 5, 2020, dated November 8, 2020(19)
10.13	Second Amendment to Company Warrant issued by the Company to the Subscribers party to that certain Subscription Agreement, dated as of August 5, 2020(20)
10.14	Warrant issued by the Company to Robert Finizio(20)

Exhibit No.	Description
10.15	Amendment to Warrant issued by the Company to Robert Finizio(20)
10.16*	Warrant issued by the Company to John C.K. Milligan, IV(20)
10.17*	Amendment to Warrant issued by the Company to John C.K. Milligan, IV(20)
10.18***	Financing Agreement, dated April 24, 2019, by and among TherapeuticsMD, Inc. as the Borrower, vitaMedMD, LLC, BocaGreenMD, Inc. and vitaCare Prescription Services, Inc. as the Guarantors, TPG Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC as the Lenders(21)
10.19	Amendment No. 1 to the Financing Agreement, dated December 27, 2019, by and among TherapeuticsMD, Inc. as the Borrower, vitaMedMD, LLC, BocaGreenMD, Inc. and vitaCare Prescription Services, Inc. as the Guarantors, TPG Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC as the Lenders(11)
10.20	Amendment No. 2 to the Financing Agreement, dated April 17, 2020, by and among TherapeuticsMD, Inc. as the Borrower, vitaMedMD, LLC, BocaGreenMD, Inc. and vitaCare Prescription Services, Inc. as the Guarantors, TPG Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC as the Lenders(6)
10.21	Amendment No. 3 to the Financing Agreement, dated May 1, 2020, by and among TherapeuticsMD, Inc. as the Borrower, vitaMedMD, LLC, BocaGreenMD, Inc. and vitaCare Prescription Services, Inc. as the Guarantors, TPG Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC as the Lenders(6)
10.22	Amendment No. 4 to the Financing Agreement, dated May 13, 2020, by and among TherapeuticsMD, Inc. as the Borrower, vitaMedMD, LLC, BocaGreenMD, Inc. and vitaCare Prescription Services, Inc. as the Guarantors, TPG Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC as the Lenders(6)
10.23	Amendment No. 5 to the Financing Agreement, dated August 5, 2020, by and among TherapeuticsMD, Inc. as the Borrower, vitaMedMD, LLC, BocaGreenMD, Inc. and vitaCare Prescription Services, Inc. as the Guarantors, TPG Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC as the Lenders(6)
10.24	Amendment No. 6 to the Financing Agreement, dated November 8, 2020, by and among TherapeuticsMD, Inc. as the Borrower, vitaMedMD, LLC, BocaGreenMD, Inc. and vitaCare Prescription Services, Inc. as the Guarantors, TPG Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC as the Lenders(19)
10.25	Amendment No. 7 to the Financing Agreement, dated January 13, 2021, by and among TherapeuticsMD, Inc. as the Borrower, vitaMedMD, LLC, BocaGreenMD, Inc. and vitaCare Prescription Services, Inc. as the Guarantors, TPG Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC as the Lenders(20)
10.26***	Amendment No. 8 to the Financing Agreement, dated March 1, 2021, by and among TherapeuticsMD, Inc. as the Borrower, vitaMedMD, LLC, BocaGreenMD, Inc. and vitaCare Prescription Services, Inc. as the Guarantors, TPG Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC as the Lenders(20)
10.27***	Amendment No. 9 to the Financing Agreement, dated March 8, 2022, by and among TherapeuticsMD, Inc. as the Borrower, vitaMedMD, LLC, BocaGreenMD, Inc. and vitaCare Prescription Services, Inc. as the Guarantors, TPG Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC as the Lenders(37)
10.28	Pledge and Security Agreement, dated April 24, 2019, by and among TherapeuticsMD, Inc. as the Borrower, vitaMedMD, LLC, BocaGreenMD, Inc. and vitaCare Prescription Services, Inc. as the Guarantors, TPG Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC as the Lenders(21)
10.29	Subscription Agreement, dated August 5, 2020, by and among TherapeuticsMD, Inc. and the Subscribers identified on the Schedule of Subscribers attached thereto(6)
10.30***	Commercial Supply Agreement, dated September 28, 2018, by and between TherapeuticsMD, Inc. and QPharma AB(22)
10.31**	Softgel Commercial Supply Agreement, dated April 20, 2016, by and between TherapeuticsMD, Inc. and Catalent Pharma Solutions, LLC(23)
10.32***	Amendment No. 2 to the Commercial Supply Agreement, dated September 29, 2020, between TherapeuticsMD, Inc. and Catalent Pharma Solutions, LLC(19)

Exhibit No.	Description
10.33**	Softgel Commercial Supply Agreement, dated June 24, 2016, by and between TherapeuticsMD, Inc. and Catalent Pharma Solutions, LLC(24)
10.34***	Amendment No.1 to Softgel Commercial Supply Agreement, dated December 1, 2017, by and between TherapeuticsMD, Inc. and Catalent Pharma Solutions, LLC(19)
10.35***	Amendment No.2 to Softgel Commercial Supply Agreement, dated September 29, 2020, by and between TherapeuticsMD, Inc. and Catalent Pharma Solutions, LLC(19)
10.36***	License Agreement, dated July 30, 2018, by and between TherapeuticsMD, Inc. and The Population Council, Inc.(25)
10.37*	Agreement to Forfeit Non-Qualified Stock Options, dated May 8, 2013, between the Company and Robert G. Finizio(26)
10.38***	Lease, dated October 5, 2018, by and between 951 Yamato Acquisition Company, LLC and TherapeuticsMD, Inc.(27)
10.39*	Executive Employment Agreement, dated as of August 3, 2021, by and between TherapeuticsMD, Inc. and Hugh O'Dowd(32)
10.40*	TherapeuticsMD, Inc. Inducement Grant Restricted Stock Unit Agreement, dated as of August 31, 2021, by and between TherapeuticsMD, Inc. and Hugh O'Dowd(33)
10.41*	Employment Agreement, dated June 1, 2020, between the Company and James C. D'Arecca(6)
10.42*	Amendment to Employment Agreement, dated October 15, 2021, between TherapeuticsMD, Inc. and James C. D'Arecca(34)
10.43*	Executive Employment Agreement, dated October 15, 2021, by and between TherapeuticsMD, Inc. and Mark Glickman(35)
10.44*	TherapeuticsMD, Inc. Inducement Grant Restricted Stock Unit Agreement, dated October 15, 2021, by and between TherapeuticsMD, Inc. and Mark Glickman(36)
10.45*	Amended and Restated Employment Agreement, dated November 24, 2020, between the Company and Michael Donegan(28)
10.46*	Amended and Restated Employment Agreement, dated November 24, 2020, between the Company and Robert G. Finizio(28)
10.47*	Amended and Restated Employment Agreement, dated November 24, 2020, between the Company and John C.K. Milligan, IV(28)
10.48*	Amendment, dated April 8, 2021, to the Amended and Restated Employment Agreement, dated as of November 24, 2020, by and between TherapeuticsMD, Inc. and John C.K. Milligan, IV(30)
10.49*	Employment Agreement, October 30, 2019, between the Company and Edward J. Borkowski(20)
10.50*	Amendment to Employment Agreement between the Company and Edward J. Borkowski(20)
10.51***	License and Supply Agreement, dated June 6, 2019, by and between TherapeuticsMD, Inc. and Theramex HQ UK Limited(21)
10.52*	Form of Indemnification Agreement between TherapeuticsMD, Inc. and each of its executive officers and directors(19)
10.53	Controlled Equity Offering℠ Sales Agreement, dated November 27, 2020, by and between TherapeuticsMD, Inc. and Cantor Fitzgerald & Co.(28)
10.54	Controlled Equity Offering℠ Sales Agreement, dated March 3, 2021, by and between TherapeuticsMD, Inc. and Cantor Fitzgerald & Co.(29)
10.55*†	2022 Executive Retention and Performance Bonus Plan. (ERB-Plan)
21.1	Subsidiaries of the Company(10)
23.1†	Consent of Grant Thornton LLP
31.1†	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
31.2†	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
32.1††	Section 1350 Certification of Chief Executive Officer
32.2††	Section 1350 Certification of Chief Financial Officer

Exhibit No.	Description
101†	Inline XBRL Document Set for the consolidated financial statements and accompanying notes in Part IV, Item 15(a), “Financial Statements and Financial Statements Schedules” of this Annual Report on Form 10-K
104†	Inline XBRL for the cover page of this Annual Report on Form 10-K, included in the Exhibit 101 Inline XBRL Document Set

* 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)(2). The omitted information is not material and would likely cause competitive harm to the Company if publicly disclosed.

\+ Certain of the exhibits and schedules to this exhibit have been omitted in accordance with Item 601(a)(5) of Regulation S-K. The Company agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

† 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-K for the year ended December 31, 2020 filed with the Commission on March 4, 2021 and incorporated herein by reference (SEC File No. 001-00100).

(21) 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).

(22) 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).

(23) 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).

(24) 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).

(25) 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).

(26) 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).

(27) 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).

(28) 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).

(29) Filed as an exhibit to Registration Statement on Form S-3 filed with the Commission on March 4, 2021 and incorporated herein by reference (SEC File No. 333-253851).

(30) Filed as an exhibit to Form 8-K filed with the Commission on April 12, 2021 and incorporated herein by reference (File No. 001-00100).

(31) Filed as an appendix to the Definitive Proxy Statement filed with the Commission on April 14, 2021 and incorporated herein by reference (File No. 001-00100).

(32) Filed as an exhibit to Form 8-K filed with the Commission on August 9, 2021 and incorporated herein by reference (File No. 001-00100).

(33) Filed as exhibit to Form S-8 filed with the Commission on August 31, 2021 and incorporated herein by reference (File No. 333-259221)

(34) Filed as an exhibit to Form 10-Q for the quarterly period ended September 30, 2021 filed with the Commission on November 11, 2021 and incorporated herein by reference (SEC File No. 001-00100).

(35) Filed as an exhibit to Form S-8 filed with the Commission on October 15, 2021 and incorporated herein by reference (File No. 333-260295).

(36) Filed as an exhibit to Form S-8 filed with the Commission on October 15, 2021 and incorporated herein by reference (File No. 333-260295).

(37) Filed as an exhibit to Form 8-K filed with the Commission on March 10, 2022 and incorporated herein by reference (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 2021 10-K Report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 23, 2022

THERAPEUTICSMD, INC.

/s/ Hugh O'Dowd
Hugh O'Dowd
Chief Executive Officer

/s/ James C. D'Arecca
James C. D'Arecca
Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this 2021 10-K Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated on March 23, 2022.

Signature	**Title**
/s/ Hugh O'Dowd Hugh O'Dowd	Chief Executive Officer and Director (Principal Executive Officer)
/s/ James C. D'Arecca James C. D'Arecca	Chief Financial Officer (Principal Financial Officer)
/s/ Michael C. Donegan Michael C. Donegan	Chief Accounting Officer (Principal Accounting Officer)
/s/ Tommy G. Thompson Tommy G. Thompson	Chairman
/s/ Paul M. Bisaro Paul M. Bisaro	Director
/s/ Cooper C. Collins Cooper C. Collins	Director
/s/ Karen L. Ling Karen L. Ling	Director
/s/ Jules A. Musing Jules A. Musing	Director
/s/ Gail K. Naughton, Ph.D. Gail K. Naughton, Ph.D.	Director
/s/ Angus C. Russell Angus C. Russell	Director

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, 2021 and 2020, the related consolidated statements of operations, stockholders' deficit, and cash flows for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Going concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company incurred a net loss of $172.4 million during the year ended December 31, 2021, and as of that date, the Company's current liabilities exceeded its current assets by $133.4 million and its total liabilities exceeded its total assets by $93.6 million. These conditions, along with other matters as set forth in Note 1, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

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.

Calculation of variable consideration related to rebates

As described further in Note 1 to the financial statements, the transaction price of the Company's prescription products is variable as it is calculated net of estimated product returns, chargebacks, rebates, coupons, discounts and wholesaler fees. We identified the calculation of variable consideration related to rebates as a critical audit matter.

The principal consideration for our determination that the calculation of variable consideration related to rebates was a critical audit matter is that auditing the estimation of variable consideration for rebates requires significant judgement and the amounts are material to the financial statements taken as a whole. These estimates require the consideration of the estimated level of inventory in the distribution channel, average rebate percentage, and expected insurance adjudication rate, all of which are key assumptions and have estimation uncertainty.

Our audit procedures related to testing the calculation of variable consideration related to rebates 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 rebates by verifying management's controls over the completeness of the input data, mathematical accuracy of the calculations and evaluating the reasonableness of the estimated level of inventory in the distribution channel, average rebate percentage, and expected insurance adjudication rate.

- We tested management's rebate estimates by reviewing subsequent events or transactions. Our procedures included reviewing subsequent information related to rebate settlements. We also evaluated the average rebates by vouching a sample of transactions settled during the year to source documentation, agreeing rebate percentages to underlying contracts, and we performed a sensitivity analysis that considered the estimated level of inventory in the distribution channel, average rebate percentage and expected adjudication rate.

/s/ GRANT THORNTON LLP

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

Miami, Florida
March 23, 2022

TherapeuticsMD, Inc. and Subsidiaries
Consolidated Balance Sheets
(In thousands, except per share amounts)

	As of December 31,	
	2021	2020
Assets:		
Current assets:		
Cash	$ 65,122	$ 80,486
Accounts receivable, net of allowance for credit losses of $1,334 and $1,118 as of December 31, 2021 and 2020, respectively	36,176	32,382
Inventory	7,622	7,993
Prepaid and other current assets	10,548	7,543
Total current assets	119,468	128,404
Fixed assets, net	1,199	1,942
License rights and other intangible assets, net	40,318	41,445
Right of use assets	8,234	9,566
Other non-current assets	253	253
Total assets	$ 169,472	$ 181,610
Liabilities and stockholders' deficit:		
Current liabilities:		
Current maturities of long-term debt	$ 188,269	$ —
Accounts payable	20,318	21,068
Accrued expenses and other current liabilities	44,304	38,170
Total current liabilities	252,891	59,238
Long-term debt, net	—	237,698
Operating lease liabilities, non-current	8,063	8,675
Other non-current liabilities	2,139	—
Total liabilities	263,093	305,611
Commitments and contingencies (Note 9)		
Stockholders' deficit:		
Preferred stock, par value $0.001; 10,000 shares authorized, none issued	—	—
Common stock, par value $0.001; 600,000 shares authorized, 429,886 and 299,765 issued and outstanding as of December 31, 2021 and 2020, respectively	430	300
Additional paid-in capital	957,309	754,644
Accumulated deficit	(1,051,360)	(878,945)
Total stockholders' deficit	(93,621)	(124,001)
Total liabilities and stockholders' deficit	$ 169,472	$ 181,610

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

TherapeuticsMD, Inc. and Subsidiaries
Consolidated Statements of Operations
(In thousands, except per share amounts)

	Year ended December 31,		
	2021	2020	2019
Revenue:			
Product revenue, net	$ 85,780	$ 62,872	$ 34,141
License revenue	1,171	2,000	15,506
Total revenue, net	86,951	64,872	49,647
Cost of goods sold	18,838	15,975	6,335
Gross profit	68,113	48,897	43,312
Operating expenses:			
Selling and marketing	108,195	117,052	114,231
General and administrative	92,602	76,954	60,494
Research and development	7,086	10,432	19,792
Total operating expenses	207,883	204,438	194,517
Loss from operations	(139,770)	(155,541)	(151,205)
Other (expense) income:			
Loss on extinguishment of debt	—	—	(10,058)
Interest expense and other financing costs	(32,917)	(28,581)	(17,382)
Other income, net	272	598	2,500
Total other expense, net	(32,645)	(27,983)	(24,940)
Loss before income taxes	(172,415)	(183,524)	(176,145)
Provision for income taxes	—	—	—
Net loss	$ (172,415)	$ (183,524)	$ (176,145)
Loss per common share, basic and diluted	$ (0.43)	$ (0.67)	$ (0.72)
Weighted average common shares, basic and diluted	397,992	275,649	246,353
Comprehensive loss:			
Net loss	$ (172,415)	$ (183,524)	$ (176,145)
Other comprehensive income	—	—	—
Comprehensive loss	$ (172,415)	$ (183,524)	$ (176,145)

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

TherapeuticsMD, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Deficit
(In thousands)

	Common Stock		Additional Paid in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance, January 1, 2019	240,462	$ 240	$ 616,560	$ (519,276)	$ 97,524
Shares issued for sale of common stock, net of cost	29,900	30	77,001	—	77,031
Shares issued for exercise of warrants, net of cashless exercises	471	1	(1)	—	—
Shares issued for exercise of options	344	—	109	—	109
Share-based payment award compensation costs	—	—	10,682	—	10,682
Net loss	—	—	—	(176,145)	(176,145)
Balance, December 31, 2019	271,177	271	704,351	(695,421)	9,201
Shares issued for sale of common stock, net of cost	26,953	27	31,676	—	31,703
Shares issued for exercise of options	1,182	1	271	—	272
Shares issued for vested restricted and performance stock units	453	1	(1)	—	—
Warrants issued in relation to debt financing agreement	—	—	7,668	—	7,668
Share-based payment award compensation costs	—	—	10,679	—	10,679
Net loss	—	—	—	(183,524)	(183,524)
Balance, December 31, 2020	299,765	300	754,644	(878,945)	(124,001)
Shares issued for sale of common stock, net of cost	121,765	122	183,993	—	184,115
Shares issued for exercise of warrants, net of cashless exercises	1,103	1	277	—	278
Shares issued for exercise of options	111	—	44	—	44
Shares issued for vested restricted and performance stock units	6,806	7	(7)	—	—
Shares issued for sale of common stock related to employee stock purchase plan	336	—	233	—	233
Share-based payment award compensation costs	—	—	18,125	—	18,125
Net loss	—	—	—	(172,415)	(172,415)
Balance, December 31, 2021	429,886	$ 430	$ 957,309	$ (1,051,360)	$ (93,621)

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

TherapeuticsMD, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
(In thousands)

	Year ended December 31,		
	2021	2020	2019
Cash flows from operating activities:			
Net loss	$ (172,415)	$ (183,524)	$ (176,145)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,093	4,067	1,392
Charges to provision for doubtful accounts	533	238	318
Inventory charge	1,082	7,205	—
Debt financing fees	5,689	2,532	856
Share-based payment compensation costs	18,125	10,679	10,682
Write-off of patent and trademark	—	1,132	79
Loss of extinguishment of debt	—	—	10,058
Other	720	1,541	1,074
Changes in operating assets and liabilities:			
Accounts receivable	(4,327)	(8,224)	(13,651)
Inventory	(711)	(3,337)	(8,593)
Prepaid and other current assets	(3,005)	3,209	(1,734)
Accounts payable	(750)	1,887	(3,563)
Accrued expenses and other current liabilities	6,134	2,904	13,675
Other non-current liabilities	2,139	220	(166)
Total adjustments	29,722	24,053	10,427
Net cash used in operating activities	(142,693)	(159,471)	(165,718)
Cash flows from investing activities:			
Payment for patent related costs	(2,189)	(1,391)	(1,442)
Payment for intellectual property license	—	—	(20,000)
Purchase of fixed assets	(34)	(207)	(2,450)
Net cash used in investing activities	(2,223)	(1,598)	(23,892)
Cash flows from financing activities:			
Proceeds from sale of common stock, net of costs	184,115	31,703	77,031
Proceeds from exercise of options and warrants	322	272	109
Proceeds from sale of common stock related to employee stock purchase plan	233	—	—
Repayments of debt	(50,000)	—	(81,661)
Borrowings of debt	—	50,000	200,000
Payment of debt financing fees	(5,118)	(1,250)	(6,652)
Net cash provided by financing activities	129,552	80,725	188,827
Net decrease in cash	(15,364)	(80,344)	(783)
Cash, beginning of period	80,486	160,830	161,613
Cash, end of period	$ 65,122	$ 80,486	$ 160,830
Supplemental disclosure of cash flow information:			
Interest paid	$ 25,068	$ 25,849	$ 17,788
Supplemental disclosure of noncash financing activities:			
Warrants issued in relation to debt financing agreement	$ —	$ 7,668	$ —

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

1. Business, basis of presentation, new accounting standards and summary of significant accounting policies

General

TherapeuticsMD, Inc. (the "Company"), a Nevada corporation, and its consolidated subsidiaries are referred to collectively in this Annual Report on Form 10-K ("2021 10-K Report") as "TherapeuticsMD," "we," "our" and "us." This 2021 10-K Report includes our trademarks, trade names and service marks, such as TherapeuticsMD®, vitaMedMD®, BocaGreenMD®, vitaCare™, IMVEXXY®, BIJUVA® and ANNOVERA®, which are protected under applicable intellectual property laws and are the property of, or licensed to, the Company. Solely for convenience, trademarks, trade names and service marks referred to in this 2021 10-K Report may appear without the ®, ™ or ℠ 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.

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 have a portfolio of 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.

Beginning in 2018, the U.S. Food and Drug Administration ("FDA") approval of our pharmaceutical products 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 with the Population Council, Inc. (the "Population Council"), or the Population Council License Agreement. 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 (the "Knight License Agreement") with Knight Therapeutics Inc. ("Knight") pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY and BIJUVA in Canada and Israel.
- In June 2019, we entered into an exclusive license and supply agreement (the "Theramex License Agreement") with Theramex HQ UK Limited ("Theramex") to commercialize IMVEXXY and BIJUVA outside of the U.S., excluding Canada and Israel. In 2021, Theramex secured regulatory approval for BIJUVA in certain European countries and began commercialization efforts in those countries.

COVID-19

With multiple variant strains of the SARS-Cov-2 virus and the COVID-19 disease that it causes (collectively, "COVID-19") still circulating, we continue to be subject to risks and uncertainties in connection with 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. The ultimate global recovery from the pandemic will be dependent on, among other things, actions taken by governments and businesses to contain and combat the virus, including any variant strains, the speed and effectiveness of vaccine production and global distribution, as well as how quickly, and to what extent, normal economic and operating conditions can resume on a sustainable basis globally.

Since the early phase of the COVID-19 pandemic, we have been using substantial virtual options to ensure business continuity. We have also partnered with independent community pharmacies and multiple third-party online pharmacies and telemedicine providers that focus on contraception or menopause which provide patients 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 and we also implemented cost saving measures in 2020 and 2021, 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. In addition, we implemented a significant cost savings initiative that is designed to reduce our annual costs in 2022 by at least $40.0 million. This figure does not include estimated annualized cost savings of approximately $20.0 million from, or the costs associated with the sale of vitaCare for which we signed a definitive agreement on March 6, 2022. See Note 17 – Subsequent events for a description of the vitaCare divestiture.

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 2021. 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 of 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 many of the negative effects 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 remain 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.

Going Concern

We incurred a net loss of $172.4 million during the year ended December 31, 2021, and as of that date, our current liabilities exceeded our current assets by $133.4 million and our total liabilities exceeded our total assets by $93.6 million. We will need to raise additional capital to repay the entire principal balance of our Financing Agreement, which matures on June 1, 2022, and to provide additional liquidity to fund our losses until our operations become cash flow positive. To address our capital needs, we are pursuing various equity and debt financing and other alternatives, including the sale of vitaCare for which we signed a definitive agreement on March 6, 2022. The equity financing alternatives may include the private placement of equity, equity-linked, or other similar instruments or obligations with one or more investors, lenders, or other institutional counterparties or an underwritten public equity or equity-linked securities offering. Our ability to sell equity securities may be limited by market conditions, including the market price of our common stock and the potential delisting of our common stock from the Nasdaq Global Select Market, and our available authorized shares. To the extent that we raise additional capital through the sale of such securities, the ownership interests of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. If we are not successful in obtaining additional financing, we could be forced to discontinue or curtail our business operations, sell assets at unfavorable prices, or merge, consolidate, or combine with a company with greater financial resources in a transaction that might be unfavorable to us.

Along with considering additional financings, we have reviewed numerous potential scenarios in connection with steps that we may take to reduce our operating expenses. Based on our analysis, we believe that our existing cash reserves along with potential proceeds from the sale of certain non-core assets of the Company and proceeds from potential future financings, if available to us, would be sufficient to meet our cash needs arising in the ordinary course of business for the next twelve months from the date of this 2021 10-K Report.

If we are unsuccessful with future financings and if the successful commercialization of IMVEXXY, BIJUVA, or ANNOVERA is delayed, or the continued impact of the COVID-19 pandemic or issues in our supply chains related to our third-party contract manufacturers on our business is worse than we anticipate, our existing cash reserves would be insufficient to maintain compliance with the Financing Agreement covenants or satisfy our liquidity. See "Inventory" in Note 3 for additional information regarding risks associated with our contract manufacturers, particularly for ANNOVERA. The presence of these projected factors in conjunction with

the uncertainty of the capital markets raises substantial doubt about the Company's ability to continue as a going concern for the next twelve months from the issuance of these financial statements.

The accompanying consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

A. Basis of presentation

The consolidated financial statements and related notes include our parent company and all wholly-owned subsidiaries. The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). Our fiscal year-end is as of and for the year ended December 31st for each year presented. All intercompany transactions among our businesses have been eliminated.

Certain amounts in the notes to the consolidated financial statements may not add due to rounding, and all percentages have been calculated using unrounded amounts.

B. New accounting standards

Adoption of new accounting standards

New accounting standards or accounting standards updates were assessed and determined to be either not applicable or did not have a material impact on the Company’s consolidated financial statements or processes.

Accounting standards issued but not yet adopted

Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting and Scope. In March 2020 and January 2021, Accounting Standards Update (“ASU”) 2020-04 and ASU 2021-01 were issued, respectively. These ASUs provide 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). These ASUs include 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. These ASUs were effective upon issuance and may be applied prospectively to contract modifications made or evaluated on or before 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.

Other recently issued accounting standards not yet adopted by us are not expected, upon adoption, to have a material impact on the Company’s consolidated financial statements or processes.

C. Estimates and assumptions

The preparation of consolidated financial statements in conformity to U.S. GAAP requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. We evaluate our estimated assumptions based on historical experience and on various other assumptions that are believed to be reasonable, 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.

D. Cash

We maintain cash at financial institutions that at times may exceed the Federal Deposit Insurance Corporation (“FDIC”) insured limits of $0.25 million per bank. We have never experienced any losses related to these funds.

E. Accounts receivable and allowance for doubtful accounts

Accounts receivable are customer obligations due under normal trade terms and are measured at amortized cost. We extend credit on an unsecured basis to most of our customers based on an evaluation of a customer’s financial condition, and collateral is not required. Our accounts receivable concentration of credit risk is primarily limited customers who are drug wholesalers and retail pharmacy distributors.

We review accounts receivable for uncollectible and delinquent accounts and credit card chargebacks, and we 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 write off uncollectible and 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.

F. 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 inventories for excess and obsolescence, and we 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.

G. Fair Value Measurements

Fair value is the price to sell an asset or transfer a liability and therefore represents an exit price in the principal market (or in the absence of a principal market, the most advantageous market). It represents a market-based measurement that contemplates a hypothetical transaction between market participants at the measurement date.

The unique characteristics of an asset or liability and the availability of observable prices affect the number of valuation approaches and/or techniques used in a fair value analysis. We measure fair value using observable and unobservable inputs. We give the highest priority to quoted prices (unadjusted) in active markets for identical assets or liabilities (Level 1 inputs) and the lowest priority to unobservable inputs (Level 3 inputs).

We apply the following fair value hierarchy:

- Level 1 - Quoted prices (unadjusted) in active markets for identical assets and liabilities.
- Level 2 - Quoted prices in non-active markets or in active markets for similar assets or liabilities, observable inputs other than quoted prices; and inputs that are not directly observable but are corroborated by observable market data.
- Level 3 - Inputs that are unobservable.

The carrying amount of our cash, accounts receivable, accounts payable and accrued expenses approximate their fair value because of the short-term maturity of such instruments, which are considered Level 1 under the fair value hierarchy. The carrying amount of our debt approximates fair value since it bears interest either at variable rates or fixed rates which are not significantly different from market rates, which are considered Level 2 under the fair value hierarchy.

H. Fixed assets

Fixed assets are carried at cost less accumulated depreciation and amortization. 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. Long-lived assets held and used by us, including fixed assets, are assessed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

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.

I. License rights and other intangibles assets

We record license rights and other intangible assets at cost, which includes external costs, consisting primary of legal costs, incurred in securing our patents and trademarks.

We started amortizing license rights cost once ANNOVERA became commercially available for use. License rights cost is amortized over the 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 ANNOVERA, expiring in June 2039. The cost is amortized using the straight-line method as the pattern of economic benefit cannot be reliably determined.

Intangible assets subject to amortization, such as patents, are amortized over the useful 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. Intangible assets not subject to amortization, such as trademarks, are perpetual and have indefinite lives.

We review license rights and other intangible assets subject to amortization on a periodic basis to determine whether events and circumstances would indicate impairment or warrant a revision to their remaining useful lives. We assess other intangible assets not subject to amortization for potential impairment at least annually during the fourth quarter of each year, or more frequently if events occur or circumstances change that would more likely than not reduce the fair value of the intangible assets below their carrying value.

J. Segment reporting

We manage and operate 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, which is led by our chief executive officer. 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 within the United States. Accordingly, we view our business as one reportable operating segment. With one geographic location.

K. Revenue recognition

We determine the amount of revenue to be recognized through application of the following steps:

- Identification of the contract with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when or as we satisfy the performance obligations.

Essentially all of our revenue is generated through contracts with our customers, who are primarily wholesale distributors and retail pharmacies. A performance obligation is a promise in a contract to transfer a product 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, and we treat shipping as a fulfillment activity rather than as a separate obligation. We generally recognize revenue at a point in time when all of our performance obligations under the terms of a contract are satisfied. Revenue is recognized upon transfer of control of promised products or services in an amount that reflects the consideration we expect to receive in exchange for those products or services. The collectability of consideration on the contract is reasonably assured before revenue is recognized. To the extent that customer payment has been received before all recognition criteria are met, these revenues are initially deferred in other accruals on the balance sheet and the revenue is recognized in the period that all recognition criteria have been met.

Prescription products

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). 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).

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. We record distributor fees based on amounts stated in contracts. We estimate chargebacks based on number of units sold during the period taking into account prices stated in contracts and our historical experience. We provide discounts to our customers for prompt payment. Consumer rebates and coupons costs, distribution fees, chargebacks and discounts are deducted from gross product revenue at the time the product revenue is recognized.

For our prescription products, we offer 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.

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.

L. 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 royalty payments based on our net sales of ANNOVERA, which are recorded as a component of cost of sales. Additionally, the amortization costs of license rights are recorded as a component of cost of sales.

M. Research and development

Research and development expenses include internal R&D activities, costs of services of third-party contract research organizations ("CROs") and usage 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 share-based payment award compensation costs. 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.

N. Share-based payment awards

We account for share-based payment awards on a fair value basis of the equity instrument issued. Under fair value accounting, the grant-date fair value of the share-based payment award is amortized as compensation expense, on a straight-line basis, over the service period (generally, the vesting period) for both graded and cliff vesting awards. We have elected to account for forfeitures as they occur.

O. Income taxes

Income taxes are accounted for under the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and income tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted income tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in income tax rates is recorded as a component of the income tax provision in the period that includes the enactment date.

Regular assessments are made on the likelihood that our deferred tax assets will be recovered from our future taxable income. Our evaluation is based on estimates, assumptions, and includes an analysis of available positive and negative evidence, giving weight based on the evidence's relative objectivity. Sources of positive evidence include estimates of future taxable income, future reversal of existing taxable temporary differences, taxable income in carryback years, and available tax planning strategies. Sources of negative evidence include current and cumulative losses in recent years, losses expected in early future years, any history of operating losses or tax credit carryforwards expiring unused, and unsettled circumstances that, if unfavorably resolved, would adversely affect future profit levels.

The remaining carrying value of our deferred tax assets, after recording the valuation allowance on our deferred tax assets, is based on our present belief that it is more likely than not that we will be able to generate sufficient future taxable income to utilize such deferred tax assets. The amount of the remaining deferred tax assets considered recoverable could be adjusted if our estimates of future taxable income during the carryforward period change favorably or unfavorably. To the extent we believe that it is more likely than not that some or all the remaining deferred tax assets will not be realized, we must establish a valuation allowance against those deferred tax assets, resulting in additional income tax expense in the period such determination is made. To the extent a valuation allowance currently exists, we will continue to monitor all positive and negative evidence until we believe it is more likely than not that it is no longer necessary, resulting in an income tax benefit in the period such determination is made.

Our policy is to recognize both interest and penalties related to uncertain tax positions as part of the income tax provision. Significant judgment is required in evaluating our tax positions, and in determining our provisions for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We establish reserves when, despite our belief that the income tax return positions are fully supportable, certain positions are likely to be challenged and we may ultimately not prevail in defending those positions.

P. Earnings per common share

Basic earnings or loss per common share is computed by dividing net income or loss available to common stockholders by the sum of the weighted average number of shares of common stock. Diluted earnings per common share is computed by dividing net income available to common stockholders by the sum of the weighted average number of shares of common stock and the number of additional shares of common stock that would have been outstanding if our outstanding potentially dilutive securities had been issued. Potentially dilutive securities include awards of non-vested or vested and not settled restricted stock units, performance stock units where the performance requirements have been met and not settled, warrants and options. The dilutive effect of potentially dilutive securities is reflected in diluted earnings per common share by application of the treasury stock method, except if its impact is anti-dilutive. Under the treasury stock method, an increase in the fair market value of our common stock can result in a greater dilutive effect from potentially dilutive securities.

Q. Leases

We adopted ASU 2016-02, Leases (Topic 842), including the related codification amendments, in 2019 utilizing the modified retrospective transition method and applying the transition provisions at the effective date.

We determine if an arrangement is a lease at inception. Determining whether a contract contains a lease includes judgment regarding whether the contract conveys the right to control the use of identified property or equipment for a period of time in exchange for consideration.

We account for our lease-related assets and liabilities based on their classification as operating leases or finance leases, following the relevant accounting guidance. For all the lessee arrangements, we have elected an accounting policy to combine non-lease components with the related-lease components and treat the combined items as a lease for accounting purposes. We measure lease related assets and liabilities based on the present value of lease payments, including in-substance fixed payments, variable payments that depend on an index or rate measured at the commencement date, and the amount we believe is probable we will pay the lessor under residual value guarantees when applicable. We discount lease payments based on our estimated incremental borrowing rate at lease commencement (or modification), which is primarily based on our estimated credit rating, the lease term at commencement, and the contract currency of the lease arrangement. We have elected to exclude short-term leases (leases with an original lease term less than one year) from the measurement of lease-related assets and liabilities.

We test right-of-use asset in an operating or finance lease at the asset group level (because these assets are long-lived nonfinancial assets and should be accounted for the same way as other long-lived nonfinancial assets) whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

R. Loss Contingencies

In determining whether an accrual for a loss contingency is required, we first assess the likelihood of occurrence of the future event or events that will confirm the loss. When a loss is probable (the future event or events are likely to occur) and the amount of the loss can be reasonably estimated, the estimated loss is accrued. If the reasonable estimate of the loss is a range and an amount within the range appears to be a better estimate than any other amount within the range, that amount should be accrued. However, if no amount within the range is a better estimate, the minimum amount in the range should be accrued.

When a loss is reasonably possible (the chance of the future event or events occurring is more than remote but less than likely), no accrual is recognized.

2. Accounts receivable

The following sets forth activities in our allowance for credit losses (in thousands):

	2021	2020	2019
Balance as of beginning of period	$ 1,118	$ 904	$ 597
Charges to provision for credit losses	533	238	318
Write-off of uncollectible receivables	(317)	(24)	(11)
Balance as of end of period	$ 1,334	$ 1,118	$ 904

3. Inventory

We rely on third parties to manufacture our finished products, and we have entered into long-term supply agreements for the manufacture of ANNOVERA, IMVEXXY, and BIJUVA. We do not have a long-term supply agreement for the manufacture of our prescription vitamins. Additionally, we do not have long-term contracts for the supply of all the active pharmaceutical ingredient ("API") used in ANNOVERA and BIJUVA.

One of our third-party contract manufacturers that manufactures ANNOVERA has recently experienced an increase in difficulties with manufacturing of ANNOVERA, which has resulted in intermittent supply of ANNOVERA for commercial distribution. The challenges are multifactorial and include variability in raw material supply and normal manufacturing variation due to a semi-manual process. This has recently resulted in challenges to supply ANNOVERA consistently within the approved specification at a rate that meets the projected demand for ANNOVERA. To mitigate the manufacturing challenges, in August 2021, we filed a supplemental New Drug Application ("NDA") with the FDA to modify the testing specifications for ANNOVERA to allow increased consistency of supply of ANNOVERA. In December 2021, FDA determined that it could not approve supplemental NDA without additional information. In its complete response letter ("CRL"), the FDA provided recommendations and requested additional information that could support approval of revisions to certain testing specifications. In January 2022, we responded to the CRL, and provided the requested additional information to the FDA and modified the request for the manufacturing testing limits based on the FDA recommendations. We expect a response from the FDA by the end of second quarter of 2022. We will continue to manufacture and supply ANNOVERA under the existing specifications. In the meantime, our third-party contract manufacturer may not be able to supply us with sufficient ANNOVERA to adequately supply the market, which would have an adverse effect on our business, results of operations and financial condition. Additionally, we may incur increased write-offs of ANNOVERA products manufactured in 2022 that do not meet existing specifications.

We have also experienced a greater than expected amount of raw materials for ANNOVERA being out of specification. If any of our third-party contract manufacturers or any suppliers of raw materials or API experience further difficulties, do not comply with the terms of an agreement between us, or do not devote sufficient time, energy, and care to providing our manufacturing needs, or if the manufacturing specification modifications that we have requested are not approved by the FDA, we could experience additional interruptions in the supply of our products, which may have a material adverse impact on our revenue, results of operations and financial position.

Our inventory consisted of the following (in thousands):

	As of December 31,	
	2021	2020
Raw materials	$ 3,042	$ 3,748
Work in process	1,642	895
Finished products	2,938	3,350
Inventory	$ 7,622	$ 7,993

During 2021 and 2020, we recorded inventory charges of $1.1 million and $7.2 million, respectively. The charge recorded for 2020 was primarily a result of the impact of the COVID-19 pandemic on our business, which decreased demand for our products. No inventory charge was recorded for 2019.

4. Prepaid and other current assets

Our prepaid and other current assets consisted of the following (in thousands):

	As of December 31,	
	2021	2020
Insurance	$ 2,731	$ 2,568
Paragraph IV legal proceeding costs	2,304	—
Other	5,513	4,975
Prepaid and other current assets	$ 10,548	$ 7,543

5. Fixed assets

Our fixed assets, net consisted of the following (in thousands):

	As of December 31,	
	2021	2020
Furniture and fixtures	$ 1,407	$ 1,407
Computer and office equipment	1,855	1,784
Computer software	375	412
Leasehold improvements	80	80
Fixed assets	3,717	3,683
Less: accumulated depreciation and amortization	2,518	1,741
Fixed assets, net	$ 1,199	$ 1,942

We recorded depreciation expense of $0.8 million for 2021 and 2020, and $0.4 million for 2019.

6. Licensed rights and other intangible assets

The following provides information about our license rights and other intangible assets, net (in thousands):

	As of December 31, 2021			As of December 31, 2020		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
License rights and other intangible assets subject to amortization:						
License rights	$ 40,000	$ 6,826	$ 33,174	$ 40,000	$ 3,803	$ 36,197
Hormone therapy drug patents	5,834	1,042	4,792	4,045	749	3,296
Hormone therapy drug patents applied and pending approval	2,020	—	2,020	1,629	—	1,629
License rights and other intangible assets subject to amortization	47,854	7,868	39,986	45,674	4,552	41,122
Intangible assets not subject to amortization:						
Trademarks/trade name rights	332	—	332	323	—	323
License rights and other intangible assets, net	$ 48,186	$ 7,868	$ 40,318	$ 45,997	$ 4,552	$ 41,445

We recorded amortization expense related to the exclusive license rights agreement with Population Council of $3.0 million for 2021 and 2020, and $0.8 million for 2019. We recorded amortization expense related to patents of $0.3 million for 2021 and 2020, and $0.2 million for 2019.

Our license rights and other intangible assets subject to amortization is expected to be amortized as follows (in thousands):

Year ending December 31,	
2022	$ 3,451
2023	3,445
2024	3,447
2025	3,445
2026	3,445
Thereafter	20,733
Total	$ 37,966

We use a combination of qualitative and quantitative factors to assess licensed rights and intangible assets for impairment. As a result of performing these assessments, we determined that no impairment existed as of December 31, 2021, therefore, no write downs were recorded to our licensed rights and other intangible assets for 2021. For 2020 and 2019, we wrote off $1.1 million and $0.1 million, respectively, in costs related to patents and trademarks, which were included in general and administrative expenses in the accompanying consolidated statements of operations.

7. Accrued expenses and other current liabilities

Other accrued expenses and other current liabilities consisted of the following (in thousands):

	As of December 31,	
	2021	2020
Payroll and related costs	$ 13,764	$ 11,179
Rebates	11,010	11,011
Sales returns and coupons	2,422	7,057
Selling and marketing expenses	2,850	228
Research and development expenses	1,995	925
Wholesale distributor fees	3,614	2,632
Professional fees	2,571	925
Operating lease liabilities	1,361	2,254
Other	4,717	1,959
Accrued expenses and other current liabilities	$ 44,304	$ 38,170

We expense advertising costs when incurred, which amounted to $39.7 million, $35.8 million and $9.0 million for 2021, 2020 and 2019, respectively.

8. Debt

Our debt consisted of the following (in thousands):

	As of December 31,	
	2021	2020
Financing Agreement	$ 200,000	$ 250,000
Less: deferred financing fees	11,731	12,302
Debt, net	188,269	237,698
Current maturities of long-term debt	188,269	—
Long-term debt	$ -	$ 237,698

Financing agreement

We are party to a Financing Agreement with Sixth Street Specialty Lending, Inc., as administrative agent (the "Administrative Agent"), various lenders from time-to-time party thereto, and certain of our subsidiaries party thereto from time to time as guarantors. In connection with the initial borrowing under the Financing Agreement, 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 Financing Agreement. Borrowings 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 5.2% as selected by us. As of December 31, 2021, our interest rate was 10.45%. Interest on amounts borrowed under the Financing Agreement is due and payable quarterly in arrears. In addition, we are required to pay an annual administrative fee, and other fees and expense. We have the right to prepay borrowings under the Financing Agreement in whole or in part at any time, subject to a prepayment fee on the principal amount being prepaid.

The Financing Agreement was entered into in April 2019, and it provided us with up to a $300.0 million first lien secured term loan credit facility. The credit facility provided for availability to us in three tranches: (i) $200.0 million was drawn upon entering into the Financing Agreement; (ii) $50.0 million was drawn in February 2020 and (iii) $50.0 million 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 quarterly period ended June 30, 2020 or at such earlier date as the Administrative Agent may have consented to. In the third quarter of 2020, the Administrative terminated the undrawn $50.0 million tranche under the Financing Agreement, therefore, such amount was no longer available to us to borrow.

In August 2020, we entered into Amendment No. 5 to the Financing Agreement ("Amendment No. 5") pursuant to which, among other amendments, 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 were adjusted in order to reflect the impact of COVID-19 on our business. 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 our common stock with an exercise price of $1.58 per share and a ten-year term (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 estimated fair value of the Lender Warrants was $7.4 million, and was recorded as deferred financing cost since Amendment No. 5 was accounted for as a debt modification.

In November 2020, in connection with Amendment No. 6 to the Financing Agreement ("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. Also, in November 2020, we concluded an underwritten public offering of our common stock and received consideration of $1.19 per share, after deducting for underwriting discounts and commissions. This offering of our common stock automatically triggered the down round provision to the exercise price of the Lender Warrants, which lowered the exercise price from $1.58 to $1.19 per share. The estimated fair value of the adjustment to the exercise price of Lender Warrants was $0.2 million and was recorded as deferred financing cost since Amendment No. 6 was accounted for as a debt modification. No other amendment financing fees were paid.

In January 2021, we entered into Amendment No. 7 to the Financing Agreement ("Amendment No. 7") pursuant to which, among other amendments, the minimum quarterly product 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, and we paid amendment financing fees of $5.0 million, which was recorded as deferred financing fees since Amendment No 7 was accounted for as debt modification. Additionally, in connection with entering into Amendment No. 7, the warrants issued to the Administrative Agent and the lenders under the Financing Agreement in August 2020 were further amended to provide for an additional adjustment to the exercise price if we conducted certain dilutive issuances prior to March 31, 2021. No adjustments were made to the exercise price of these warrants prior to the expiration of such period.

In March 2021, we entered into Amendment No. 8 to the Financing Agreement ("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 business. In connection with Amendment No. 8, we (i) repaid $50.0 million in principal under the Financing Agreement during the three months ended March 31, 2021, plus a 5.0% prepayment fee and (ii) agreed to make additional quarterly principal repayments plus the prepayment fees as follows: (a) $5.0 million due in March 2022, June 2022 and September 2022; (b) $10.0 million due in December 2022 and March 2023; and (c) $41.25 million due in June 2023, September 2023, December 2023 and March 2024. Additionally, 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 2022 through March 2023; (iii) 3.0% of the principal amount being repaid from April 2023 through March 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. Based on the contractual quarterly principal repayments in Amendment No. 8, as of December 31, 2021, we recorded an accrual of $2.2 million related to future prepayment fee obligations, of which $1.3 million is included in accrued expenses and other current liabilities and $0.9 million is included in other non-current liabilities in the accompanying consolidated balance sheets.

In March 2022, we entered into Amendment No. 9 to the Financing Agreement ("Amendment No. 9"). See Note 17 – Subsequent events. In accordance with Amendment No. 9, the maturity date of the Financing Agreement was amended to June 1, 2022. Accordingly, the entire debt balance of $200.0 million as of December 31, 2021 will be due and payable in June 2022.

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.

Since the inception of the Financing Agreement, we have incurred a total of $18.8 million in deferred financing fees related to the Financing Agreement. As of December 31, 2021, our unamortized deferred financing fees was $11.7 million, which will be entirely amortized upon the maturity of the Financing Agreement in 2022. Additionally, in connection with Amendment No. 9, we will pay financing fees of $30.0 million, which will be paid in kind ("PIK") by being added to the principal balance of the Financing Agreement, and future prepayment fees were waived. Of the total PIK financing fees, $16.0 million will be waived if one of the two milestones specified in Amendment No. 9 is achieved.

Debt covenants

The Financing Agreement contains customary restrictions and covenants applicable to us that are customary for financings of this type. Among other requirements, prior to execution of Amendment No. 9 in March 2022, we were required to achieve certain minimum quarterly consolidated net revenue amounts attributable to commercial sales of our IMVEXXY, BIJUVA and ANNOVERA products. We were not in compliance with our covenant to achieve certain minimum quarterly product net revenue requirements for the quarterly period ended December 31, 2021 of $26.5 million. In connection with Amendment No 9, this event of default was waived by the Administrative Agent and lenders, and the minimum product net revenue requirement for the quarterly period ending March 31, 2022, which is the final quarterly reporting period, was removed. The Financing Agreement also required us to maintain a minimum unrestricted cash balance. As of December 31, 2021, our cash balance was in excess of the required minimum balance. However, beginning on February 7, 2022, we did not maintain the required minimum unrestricted cash balance of $ 60.0 million. In connection with Amendment No. 9, this event of default was waived by the Administrative Agent and lenders, and the required minimum unrestricted cash balance was reduced.

Credit agreement

In April 2019, we terminated and repaid all amounts outstanding under a Credit and Security Agreement (the "Credit Agreement"), as amended, with MidCap Financial Trust, as agent and as lender and the additional lenders party thereto using a portion of the initial tranche of borrowing under the Financing Agreement. The aggregate amount paid of $81.7 million 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 a $10.1 million loss on extinguishment of debt in 2019.

Interest and financing costs

Interest expense and other financing costs consisted of the following (in thousands):

	2021	2020	2019
Interest expense	$ 22,568	$ 26,049	$ 16,526
Prepayment fees	4,660	—	—
Financing fees amortization	5,689	2,532	856
Interest expense and other financing costs	$ 32,917	$ 28,581	$ 17,382

9. Commitments and contingencies

Leases

Substantially all of our leases are for rental of office space used to conduct our business. In October 2018, we entered into a lease for executive, administrative, operations and sales 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.

For 2021, operating lease expense related to our real estate leases was $2.1 million and variable lease expense was $0.7 million. For 2020, operating lease expense related to our real estate leases was $2.3 million and variable lease expense was $0.4 million. For 2019, operating lease expense related to our real estate leases was $1.6 million and variable lease expense was insignificant.

As of December 31, 2021, our remaining lease payments were as follows (in thousands):

Year ending December 31,		
2022	$	1,413
2023		1,443
2024		1,477
2025		1,513
2026		1,551
Thereafter		5,883
Total undiscounted lease payments		13,280
Less: imputed interest		3,856
Present value of lease payments	$	9,424

The following table sets forth supplemental balance sheet information related to leases (in thousands):

	As of December 31,	
	2021	2020
Assets:		
Operating lease right-of-use assets	$ 8,234	$ 9,566
Liabilities:		
Operating lease liabilities current (included in accrued expenses and other current liabilities)	$ 1,361	$ 2,254
Operating lease liabilities, non-current	8,063	8,675
Total operating lease liabilities	$ 9,424	$ 10,929

The following table presents other information related to leases:

	2021	2020
Weighted average remaining term (years) - operating leases	8.7	9.0
Weighted average discount rate - operating leases	8.3%	8.3%
Cash paid for amounts included in the measurement of lease liabilities from operating lease (in thousands)	$ 2,335	$ 1,618
Right-of-use assets obtained in exchange for new operating lease obligations (non-cash in thousands)	$ —	$ 999

Population Council license agreement

Under the terms of the Population Council License Agreement, we paid the Population Council a milestone payment of $20.0 million in 2018, which was within 30 days following the approval by the FDA of the NDA for ANNOVERA, and $20.0 million in 2019 following the first commercial batch release of ANNOVERA. The aggregate $40.0 million of milestone payments were recorded as license rights, see “Note 6. License rights and other intangible assets” for additional information. The Population Council is also eligible to receive future payments upon the achievement of certain commercial sales milestones of ANNOVERA. We are required to pay the Population Council additional milestone payments of $40.0 million upon cumulative net sales of ANNOVERA in the U.S. by us and our affiliated and permitted sublicensees of each of $200.0 million, $400.0 million and $1.0 billion. We will record any future milestone payment as incremental license rights cost when incurred, and amortize such costs over the remaining useful life over which the license rights will contribute directly or indirectly to our cash flows based on when ANNOVERA became commercially available for use. Accordingly, if and when we incur the incremental license rights cost, we will immediately record an additional amortization amount that assumed the incremental cost was incurred when the first commercial batch of ANNOVERA was released in 2019.

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 $20.0 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. To the extent that the Population Council does not fulfil these studies to FDA’s satisfaction, FDA may impose additional requirements and penalties against us, as we hold the NDA for ANNOVERA. In July 2021, we received a letter from FDA indicating that the post-marketing commitment study being conducted by the Population Council for ANNOVERA to characterize the in vivo release rate of ANNOVERA was not fulfilled to FDA’s satisfaction. In addition, the final reports

for the two post-marketing requirement studies being performed by the Population Council for ANNOVERA were not submitted by the initial listed submission deadline, which deadlines have since been extended by FDA. We are working with Population Council to complete the post-marketing commitment study to FDA's satisfaction and reduce the delay in submitting the post-marketing requirement final reports. To the extent that the Population Council does not fulfil these studies to FDA's satisfaction, FDA may impose additional requirements and penalties against us, as we hold the NDA for ANNOVERA.

We and the Population Council have agreed to form a joint product committee responsible for overseeing activities under the Population Council License Agreement. We are responsible for all aspects of marketing, 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.

We are also required to pay the Population Council, on a quarterly basis, step-based royalty payments based on our annual net sales of ANNOVERA as follows: (i) if annual net sales are less than or equal to $50.0 million, a royalty of 5% of net sales; (ii) for annual net sales greater than $50.0 million and less than or equal to $150.0 million, a royalty of 10% of such net sales; and (iii) for net sales greater than $150.0, 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.

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.

Purchase commitments

We have manufacturing and supply agreements whereby we are required to purchase from Catalent, Inc. ("Catalent") a minimum number of units of BIJUVA and IMVEXXY softgels during each respective annual contract year. The annual contract period for BIJUVA and IMVEXXY ends each April and July, respectively. If the minimum order quantities of BIJUVA or IMVEXXY are not met, we are required to pay a minimum commitment fee equal to 50% or 60%, respectively, of the difference between the total amount we would have paid if the minimum requirement had been fulfilled and the total amount of purchases of BIJUVA or IMVEXXY during each product's respective contract year. Our estimated minimum commitments for Catalent are as follows: $5.2 million for 2022, $3.9 million for 2023, $4.3 million for 2024, $4.7 million for 2025, $4.8 million for 2026, and $11.5 million thereafter.

Additionally, with another third-party manufacturer, we have a manufacturing and supply agreement, renewable annually, whereby we are required to purchase a minimum number of units of ANNOVERA during a contract year. The annual contract period for ANNOVERA ends each August. If the minimum order quantities of ANNOVERA are not met, we are required to pay a minimum commitment fee equal to the difference between the total amount we would have paid if the minimum requirement had been fulfilled and the total amount of purchases of ANNOVERA during the contract year. Our estimated minimum commitment for ANNOVERA is $2.1 million for 2022.

For each of the three annual contract years ending in 2021, we have met our minimum purchase number of units in all material respects. For annual contract years ending in 2022 and thereafter, we will continue to evaluate whether we will be able to meet each annual contract year's respective minimum purchase commitment and will record a liability for estimated minimum commitment fees if we believe that we will not be able to reasonably meet the minimum purchase commitment. We believe that minimum commitment fees that we may pay, if any, will not have a material impact to our financial position and operating results.

Legal proceedings

In February 2020, we received a Paragraph IV certification notice letter (the "IMVEXXY Notice Letter") regarding an Abbreviated New Drug Application ("ANDA") submitted to FDA by Teva Pharmaceuticals USA, Inc. ("Teva"). The ANDA seeks approval from 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 FDA's Orange Book that claim compositions and methods of IMVEXXY (the "IMVEXXY Patents"), are invalid, unenforceable, and/or will not be infringed by Teva's commercial manufacture, use, or sale of its proposed generic drug product. The IMVEXXY Patents identified in the IMVEXXY Notice Letter expire in 2032 or 2033. In April 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. In July 2021, following a proposal by Teva, the District Court entered an order temporarily staying all proceedings in the IMVEXXY litigation, which order was filed under seal. In September 2021, the District Court made available a public version of the

order following the parties' agreement to a consent motion to redact information Teva contended was confidential. The order provides that the statutory stay that prevents FDA from granting final approval of the ANDA for 30 months from the date of the Notice Letter will be extended for the number of days that the stay of the IMVEXXY litigation is in place. The length of the stay of the IMVEXXY litigation is dependent on further action by Teva.

In March 2020, we received a Paragraph IV certification notice letter (the "BIJUVA Notice Letter") regarding an ANDA submitted to FDA by Amneal Pharmaceuticals ("Amneal"). In April 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 FDA. In December 2021, we entered into a settlement agreement (the "Settlement Agreement") with Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York LLC (collectively "Amneal") to resolve the litigation over our patents listed in FDA's Orange Book that claim compositions and methods of BIJUVA (the "BIJUVA Patents"). Under the terms of the Settlement Agreement, the parties filed a consent judgment with the U.S. District Court for the District of New Jersey that enjoins Amneal from marketing a generic version of BIJUVA (1 mg estradiol and 100 mg progesterone) before the expiration of the patents-in-suit, except as provided in the Settlement Agreement, and the Company granted Amneal a non-exclusive, non-transferable, royalty-free license to commercialize Amneal's generic formulation of BIJUVA in the U.S. commencing in May 2032 (180 days before the current expiration date in November 2032 for the last to expire of our BIJUVA Patents), or earlier under certain circumstances customary for settlement agreements of this nature.

As of December 31, 2021, for the IMVEXXY paragraph IV legal proceeding, we have incurred and recorded legal costs amounting to $2.3 million in prepaid expenses and other current assets since we believe that we will successfully prevail in this legal proceeding. Upon the successful conclusion of the legal proceeding, the related capitalized legal costs will be reclassified to patents, in license rights and other intangible assets, net, in the accompanying consolidated balance sheets, and such costs will be amortized over the remaining useful of the patent. If we are unsuccessful in this legal proceeding, then the related capitalized legal costs for this legal preceding and any unamortized IMVEXXY patent costs that were previously capitalized will be immediately expensed in the period in which we become aware of unsuccessful legal proceeding.

From time to time, we are involved in other litigations and proceedings in the ordinary course of business. We are currently not involved in any other litigations and proceedings 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, 2021, 2020 and 2019, 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.

In September 2021, our former Executive Vice President of Operations ("EVP of Operations") and us mutually agreed that the EVP of Operations would separate from the company. The separation was for "Good Reason" under the employment agreement of the EVP of Operations; accordingly, he received the separation benefits provided therein. Then, in December 2021, our Board of Directors (the "Board") appointed our current Chief Executive Officer ("CEO"). Our former CEO's separation as CEO was a termination without "Cause," as defined in his employment agreement. Accordingly, our former CEO received the separation benefits provided therein. Additionally, in 2021, three other senior executives separated from the Company, and they received separation benefits provided by their respective employment agreements. In the aggregate, for 2021, we recorded executive officer severance expenses of $12.4 million, of which $8.0 million was related to share-based compensation recorded in connection with accelerated vesting of certain share-based payment awards for the former senior executives.

Employee benefit plan

We maintain 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 two thousand 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 $0.6 million for 2021, and $0.5 million for each of 2020 and 2019.

10. Stockholders' deficit

Common stock

In March 2021, we entered into an at-the-market equity offering program (the "2021 ATM Program") relating to shares of our common stock. The 2021 ATM Program permits us to offer and sell shares of our common stock having an aggregate offering price of up to $100.0 million from time to time through or to the sales agent under the 2021 ATM Program. Sales of our common stock may be made from time to time in at-the-market offerings as defined in Rule 415 of the Securities Act, including by means of ordinary broker's transactions on The Nasdaq Stock Market LLC ("Nasdaq") or otherwise at market prices prevailing at the time of sale, at prices related to prevailing market prices, or as otherwise agreed to with the sales agent. The sales agent will be entitled to compensation at a fixed commission rate of 3.0% of the aggregate gross sales price per share sold. The sales agent is not required to sell any specific number or dollar amounts of securities but will act as sales agent and use commercially reasonable efforts to sell on our behalf all the shares of common stock requested to be sold by us, consistent with its normal trading and sales practices, on mutually agreed terms between us and the sales agent. Through December 31, 2021, we have sold a total of 33,705,315 shares of our common stock under the 2021 ATM Program at an average sale price of $1.21 per share and we received estimated net proceeds of $39.4 million, after deducting discounts and commissions to the sales agent and estimated offering expenses. Subsequently, through the date of this 2021 10-K Report, we have not sold any additional shares of our common stock under the 2021 ATM Program. Future sales, if any, under the 2021 ATM Program will depend on a variety of factors, including among others, market conditions, the trading price of our common stock, determinations by us of the appropriate sources of funding, and potential uses of funding available to us.

In February 2021, we closed on an underwritten public offering of our common stock, pursuant to which we issued 59,459,460 shares of our common stock at an offering price of $1.85 per share, and we received net proceeds of $96.6 million, after deducting the underwriting discounts and commissions and estimated offering expenses.

In November 2020, we entered into an at-the-market offering program (the "2020 ATM Program") relating to shares of our common stock. The 2020 ATM Program permitted us to offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million from time to time through or to the sales agent under the 2020 ATM Program. Sales of our common stock were permitted to be made from time to time in at-the-market offerings as defined in Rule 415 of the Securities Act of 1933, as amended (the "Securities Act"), including by means of ordinary broker's transactions on Nasdaq or otherwise at market prices prevailing at the time of sale, at prices related to prevailing market prices, or as otherwise agreed to with the sales agent. The sales agent was entitled to compensation at a fixed commission rate of 3.0% of the aggregate gross sales price per share sold. As of February 8, 2021, sales of shares of our common stock under the 2020 ATM Program were completed when we sold an aggregate total of 28,600,689 shares of our common stock at an average sale price of $1.75 per share. For the 2020 ATM Program, we received net proceeds of $48.1 million, after deducting the discounts and commissions to the sales agent and estimated offering expenses.

Also, in November 2020, we closed on an underwritten public offering of our common stock, pursuant to which we issued 26,953,125 shares of our common stock, which includes 3,515,625 shares issued for the exercise of an underwriter option, at an offering price of $1.28 per share, and we received net proceeds of $31.7 million, after deducting the underwriting discounts and commissions and estimated offering expenses.

Also, in October 2019, we closed on an underwritten public offering of our common stock, pursuant to which we issued 29,900,000 shares of our common stock, which includes 3,900,000 shares issued for the exercise of an underwriter option, at an offering price of $2.75 per share, and we received net proceeds of $77.0 million, after deducting the underwriting discounts and commissions and estimated offering expenses.

Warrants

As disclosed in "Note 8. Debt", in 2020, we issued to the Administrative Agent and the lenders under the Financing Agreement warrants to purchase an aggregate of 4,752,116 shares of our common stock. In 2019, we granted warrants to purchase an aggregate of 75,000 shares of our common stock to outside consultants.

The following table summarizes the status of our outstanding and exercisable warrants and related for each of the following years (in thousands, except weighed average exercise price and weighted average remaining contractual life data):

	Warrants outstanding and exercisable			
	Warrants	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (in Years)
Balance, January 1, 2019	3,008	$ 2.78	$ 4,826	1.6
Issued/granted	75	5.63		
Exercised	(1,250)	3.20	2,263	
Balance, December 31, 2019	1,833	2.62	2,448	2.0
Issued/granted	4,752	1.19		
Cancelled/Forfeited	(50)	6.35		
Balance, December 31, 2020	6,535	1.55	1,041	7.3
Exercised	(1,163)	0.31	1,146	
Expired	(245)	7.90		
Balance, December 31, 2021	5,127	$ 1.52	$ —	8.3

We used the Black Scholes option pricing model to estimate the fair value of warrants issued. The weighted average fair value of the warrants issued in 2020 was $1.56 per warrant and the assumptions used to determine such fair value were as follows: expected term of 10 years, volatility of 68.8%, dividend yields of 0% and risk-free interest rates of 0.3%. The weighted average fair value of the warrants granted in 2019 was $3.00 per warrant and the assumptions used to determine such fair value were as follows: expected term of 5 years, volatility of 60.8%, dividend yields of 0% and risk-free interest rates of 2.5%.

Share-based payment award plans

Plan summary and description

In June 2019, our stockholders approved the TherapeuticsMD, Inc. 2019 Stock Incentive Plan, as amended (the “2019 Plan”), which replaced our previously adopted 2012 Stock Incentive Plan, as amended, and the 2009 Long-Term Incentive Compensation Plan (referred to collectively as the “Prior Plans”). Outstanding awards granted under the Prior Plans will remain subject to the terms and conditions in the Prior Plans.

The 2019 Plan is administered by the Compensation Committee of the Board. The purpose of the 2019 Plan is to provide a means for us and our subsidiaries and other designated affiliates (the “Related Entities”) to attract key personnel to provide services to us and the Related Entities, as well as to provide a means by which those key persons can acquire and maintain stock ownership, resulting in a strengthening of their commitment to our welfare and the welfare of the Related Entities and promoting the mutuality of interests between participants and our stockholders. A further purpose of the 2019 Stock Incentive Plan is to provide participants with additional incentive and reward opportunities designed to enhance our profitable growth and the profitable growth of the Related Entities, and provide participants with annual and long-term performance incentives to expend their maximum efforts in the creation of stockholder value. The persons eligible to receive awards under the 2019 Plan are our employees, officers, members of the Board, and consultants who provide services to us or any subsidiary.

The provisions of the 2019 Plan authorize the grant of (i) stock options, which can be “qualified” or “nonqualified” under the Internal Revenue Code of 1986, as amended, (ii) stock appreciation rights, (iii) restricted stock, (iv) restricted stock units (“RSUs”), (v) performance shares and performance units, such as performance stock units (“PSUs”), and (vi) other share-based awards. The 2019 Plan will terminate at the earliest of (i) such time as no shares remain available for issuance under the 2019 Stock Plan, (ii) termination of the 2019 by the Board, or (iii) the tenth anniversary of the effective date of the 2019 Stock Incentive Plan. Awards outstanding upon termination of the 2019 Plan will remain in effect until they have been exercised or terminated, or have expired. The term and vesting period of awards granted under the 2019 Plan are established on a per grant basis, and option expiration date is generally ten years from the date of grant.

Under the 2019 Plan, 37,475,000 shares of common stock are authorized for issuance, which includes 22,475,000 shares from the First Amendment to the 2019 Plan, which was approved by our stockholders in May 2021 plus any unallocated shares previously available for issuance under the Prior Plans that were not then subject to outstanding awards. Any shares subject to outstanding share-based payment awards under the 2019 Plan and Prior Plans 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.

In August 2021, the Company hired a new President, who became our CEO in December 2021, and granted an "inducement grant" under Listing Rule 5635(c)(4) of Nasdaq of 2,750,000 RSUs (designated as "Time-Based Units") and 2,750,000 PSUs (designated as "Performance Units"). In October 2021, the Company appointed a new Chief Business Officer and granted an "inducement grant" under Listing Rule 5635(c)(4) of Nasdaq of 660,000 RSUs (designated as "Time-Based Units") and 260,000 PSUs (designated as "Performance Units"). The Time-Based Units and Performance Units were granted pursuant to certain Inducement Grant Restricted Stock Unit Agreement; accordingly, these equity awards were not counted against the shares of common stock available for issuance under the 2019 Plan.

As of December 31, 2021, 39,440,678 shares of common stock were subject to outstanding awards under our share-based payment award plans and inducement grants (calculated using the base number of PSUs that may vest). If we assume the maximum achievement of performance goals for PSUs, then 42,925,277 shares of common stock will be subject to outstanding awards under our share-based payment award plans and inducement grants.

The following table summarizes the outstanding awards issued pursuant to our share-based payment award plans and inducement grants as of December 31, 2021 and the remaining shares of common stock available for future issuance (in thousands):

Plan Name	Options	RSUs	PSUs (1)	Remaining shares of common stock available for future issuance (2)
2019 Plan (3)	3,332	10,174	5,193	13,054
2012 Plan (4)	4,601	—	—	—
2009 Plan (5)	9,722	—	—	—
2021 Inducement Grants (6)	—	3,410	3,010	—

(1) The number of PSUs represents the base number of PSUs that may vest. The actual number of PSUs that will vest will be between zero and 11,687,530 depending on the Company's achievement of certain performance goals.

(2) The number of remaining shares of common stock available for future issuance is based on an assumption that the maximum performance goals for PSUs were achieved, where applicable.

(3) As of December 31, 2021, outstanding options have exercise prices ranging from $1.07 to $2.73 and will expire between January 2022 and June 2030. Unvested RSUs will vest between January 2022 and December 2024. If and when certain performance goals are achieved, then unvested PSUs will vest between June 2022 and March 2024.

(4) As of December 31, 2021, outstanding options have exercise prices ranging from $2.55 to $8.92 and will expire between March 2022 and February 2029.

(5) As of December 31, 2021, outstanding options have exercise prices ranging from $1.80 to $8.92 and will expire between January 2022 and February 2029.

(6) As of December 31, 2021, unvested RSUs will vest between August 2022 and October 2024 and unvested PSUs upon achievement of certain performance goals will vest between October 15, 2022 and August 2024.

2021 Exchange of eligible options for RSUs

In May 2021, our stockholders approved an Offer to Exchange Eligible Options for Restricted Stock Units (the "Exchange Offer"). The Exchange Offer allowed certain employee option holders, excluding the Company's named executive officers, advisers, consultants, contractors, or present or past non-employee directors, to exchange some or all of their outstanding options to purchase shares of common stock that were granted before August 26, 2019, and had a per share exercise price equal to or greater than $5.01 ("Eligible Options"), for an award of RSUs of the Company ("New RSUs"), subject to specified conditions. In September 2021, following the expiration of the Exchange Offer, 69 eligible employees elected to exchange Eligible Options, and the Company accepted for cancellation Eligible Options to purchase an aggregate of 4,493,000 shares of common stock, representing approximately 91.5% of the total shares of common stock underlying the Eligible Options. Also, in September 2021, promptly following the expiration of the Exchange Offer, the Company granted 700,264 New RSUs in exchange for the cancellation of the tendered Eligible Options. The New RSUs vest in three equal annual installments beginning in September 2022, subject to the terms and conditions of the 2019 Plan.

Options

The following table summarizes the status of our outstanding and exercisable options and related transactions, including the Exchange Offer, for each for the following years (in thousands, except weighed average exercise price and weighted average remaining contractual life data):

	Options awards outstanding				Options awards exercisable			
	Options Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (in Years)	Options Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (in Years)
Balance, January 1, 2019	20,873	$ 4.93	$ 12,240	5.9	16,069	$ 4.61	$ 12,240	5.1
Granted	4,620	3.10						
Exercised	(344)	0.32	1,427					
Cancelled/Forfeited	(93)	5.16						
Expired	(26)	5.57						
Balance, December 31, 2019	25,030	4.65	3,668	5.8	18,026	4.88	3,320	4.6
Granted	737	1.58						
Exercised	(1,182)	0.23	1,739					
Cancelled/Forfeited	(416)	3.80						
Expired	(387)	3.76						
Balance, December 31, 2020	23,782	4.80	152	5.2	19,863	5.06	117	4.6
Granted	60	1.21						
Exercised	(111)	0.03	61					
Cancelled/Forfeited	(5,048)	6.01						
Expired	(1,028)	4.02						
Balance, December 31, 2021	17,655	$ 4.52	$ —	3.8	16,776	$ 4.62	$ —	3.6

We used the Black Scholes option pricing model to estimate the fair value of options granted. The weighted average fair value of the options granted in 2021 was $0.77 per option, and the assumptions used to determine such fair value were as follows: expected term of 6.9 years, volatility of 67.6%, dividend yields of 0% and risk-free interest rates of 1.1%. The weighted average fair value of the options granted in 2020 was $1.58 per option and the assumptions used to determine such fair value were as follows: expected term of 6.0 to 6.8 years, volatility of 63.5% to 67.9%, dividend yields of 0% and risk-free interest rates of 0.3% to 1.7%. The weighted average fair value of the options granted in 2019 was $3.10 per option and the assumptions used to determine such fair value were as follows: expected term of 5.5 to 6.5 years, volatility of 61.3% to 64.58%, dividend yields of 0% and risk-free interest rates of 1.6% to 2.5%.

Restricted stock units

The following table summarizes the status of our RSUs and related transactions, including the Exchange Offer, for each for the following years (in thousands, except weighed average grant date fair value):

	RSUs awards outstanding			RSUs awards vested and not settled		
	RSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value	RSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Balance, January 1, 2019	1,040	$ 4.06	$ 3,962	—	$ —	$ —
Granted	200	2.18				
Balance, December 31, 2019	1,240	3.56	3,001	150	4.06	363
Granted	6,153	1.39				
Vested and settled	(301)	1.78	479			
Cancelled/Forfeited	(31)	1.07				
Balance, December 31, 2020	7,061	1.76	8,544	—	—	—
Granted	12,977	1.05				
Vested and settled	(5,126)	1.57	4,021			
Cancelled/Forfeited	(1,328)	1.47				
Balance, December 31, 2021	13,584	$ 1.16	$ 4,890	1,573	$ 2.11	$ 566

Performance stock units

The following table summarizes the status of our PSUs and related transactions for each for the following years (in thousands, except weighed average grant date fair value):

	PSUs awards outstanding			PSUs awards vested and not settled		
	PSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value	PSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Balance, January 1, 2019	—	$ —	$ —	—	$ —	$ —
Granted	2,586	1.08				
Vested and settled	(152)	1.14	226			
Cancelled/Forfeited	(30)	1.07				
Balance, December 31, 2020	2,404	1.08	2,909	—	—	—
Granted	7,597	1.04				
Vested and settled	(1,680)	1.16	1,057			
Cancelled/Forfeited	(118)	1.07				
Balance, December 31, 2021	8,203 (1)	$ 1.03	$ 2,953	1,968	$ 1.18	$ 709

(1) The number of PSUs represents the base number of PSUs that may vest. The actual number of PSUs that will vest will be between zero and 11,687,530 depending on the Company's achievement of certain performance goals.

Employee stock purchase plan

In June 2020, our stockholders approved the TherapeuticsMD, Inc. 2020 Employee Stock Purchase Plan ("ESPP"), which reserved 5,400,000 shares of our common stock for purchase by eligible employees. The ESPP permits eligible employees to purchase our common stock at a price per share which is equal to 85% of the lesser of (i) the fair market value of the shares on the offering date of the offering period or (ii) the fair market value of the shares on the purchase date. In 2021, 336,056 shares were sold under the ESPP at an average sale price of $0.69 per share and we received proceeds of $0.2 million.

Share-based payment compensation cost

Share-based payment compensation expense for PSUs is based on our current assessment of the most likely probability of the Company's achievement of certain performance goals. We recorded share-based payment award compensation costs related to previously issued options, RSU and PSUs, as well as shares of common stock issued under the ESPP totaling $18.1 million for 2021, and $10.7 million for 2020 and 2019.

As of December 31, 2021, we had $16.2 million of unrecognized share-based payment award compensation cost related to unvested options, RSUs and PSUs as well as shares issuable under the ESPP, which may be adjusted if certain performance targets are achieved and for future changes in forfeitures and is included as additional paid-in capital in the accompanying consolidated balance sheets. No tax benefit was realized due to a continued pattern of net losses.

The unrecognized compensation cost as of December 31, 2021is expected to be recognized as share-based payment award compensation over a weighted average period of 2.1 years as follows (in thousands):

Year ending December 31,	
2022	$ 8,646
2023	5,199
2024	2,355
	$ 16,200

11. Revenue

Disaggregated revenue

The following table provides information about disaggregated revenue by product mix and service (in thousands):

	2021	2020	2019
Product revenue:			
ANNOVERA	$ 37,943	$ 19,611	$ 6,167
IMVEXXY	31,533	27,139	16,252
BIJUVA	10,579	6,354	1,836
Prescription vitamin	5,725	9,768	9,886
Product revenue, net	85,780	62,872	34,141
License revenue	1,171	2,000	15,506
Total revenue, net	$ 86,951	$ 64,872	$ 49,647

License agreements with customers

Knight license agreement

Pursuant to the terms of the Knight License Agreement, in 2020, Knight paid us $2.0 million in milestone fees upon the first regulatory approval in Canada for IMVEXXY and BIJUVA, 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.

As of December 31, 2021, no IMVEXXY or BIJUVA sales have been made through the Knight License Agreement.

Theramex license agreement

Under the terms of the Theramex License Agreement, Theramex paid us EUR 14 million, or $15.5 million, 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. In 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 recognized the revenue related to the upfront fee, which was a non-refundable payment.

In 2021, we received additional milestone payments comprised of an aggregate of EUR 1.0 million, or $1.2 million, in regulatory milestone payments based on regulatory approvals for BIJUVA in certain specified markets. Additionally, in December 2021, we received EUR 0.5 million, or $0.6 million, in additional upfront payments for the license grants of IMVEXXY in Brazil and Mexico. The additional upfront payment for the license grants of IMVEXXY in Brazil and Mexico may be returned to Theramex under certain conditions if IMVEXXY fails to obtain marketing authorization in one of Brazil or Mexico within a prespecified period. Accordingly, the additional upfront payment for the license grants of IMVEXXY in Brazil and Mexico was recorded as other non-current liabilities as of December 31, 2021 in the accompanying balance sheets.

We are eligible to receive additional sales milestone payments 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 outside of the U.S., excluding Canada and Israel (collectively 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.

In 2021, we recorded BIJUVA sales of $1.4 million made through the Theramex License Agreement. As of December 31, 2021, no IMVEXXY sales have been made through the either of the licensing agreements.

12. Income taxes

Our loss before income taxes is as follows (in thousands):

	2021	2020	2019
United States	$ (172,415)	$ (183,524)	$ (176,145)

For 2021, 2020 and 2019, there was no current or deferred provision for income taxes, current or deferred.

As of December 31, 2021, we had a federal net operating loss (“NOL”) carryforwards of $885.1 million, which is available to offset future taxable income. Of the total NOL, $338.8 million can be carried forward for 20 years and will begin to expire in 2031. The remaining $546.3 million can be carried forward indefinitely. In the event of future income, the NOL deduction arising from NOL generated in taxable years beginning in 2021 will be limited to 80% of the excess taxable income.

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

	2021	2020	2019
Federal statutory tax rate	21.0%	21.0%	21.0%
State tax rate, net of federal tax benefit	4.7%	5.1%	4.0%
Adjustment in valuation allowances	(22.1%)	(27.0%)	(22.5%)
Excess stock benefits	(1.5%)	0.1%	0.2%
Permanent and other differences	(2.1%)	0.8%	(2.7%)
Provision (benefit) for income taxes	0.0%	0.0%	0.0%

The components of the net deferred income tax asset as of December 31, 2021 and 2020 are as follows (in thousands):

	As of December 31,	
	2021	2020
Deferred income tax assets:		
Net operating loss	$ 224,660	$ 195,008
Share-based payment compensation	17,698	17,252
Interest expense limitation	20,391	12,992
Accrual for sales returns and coupons	3,779	5,060
R&D credit	186	186
Other, net	1,674	(241)
Deferred income tax asset	268,388	230,257
Valuation allowance	(268,388)	(230,257)
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. Accordingly, a valuation allowance has been established against the deferred tax assets as of December 31, 2021 and 2020.

Since our first year of operations in 2011, we generated net operating losses, and our U.S. federal and state tax returns remain open to examination.

As of December 31, 2021 and 2020, we had no tax positions relating to open tax returns that were considered to be uncertain, and we had no unrecognized tax benefits.

13. Loss per common share

The following table sets forth the computation of basic and diluted loss per common share for the periods presented (in thousands, except per share amounts):

	2021	2020	2019
Numerator:			
Net loss	$ (172,415)	$ (183,524)	$ (176,145)
Denominator:			
Weighted average common shares for basic loss per common share	397,992	275,649	246,353
Effect of dilutive securities	—	—	—
Weighted average common shares for diluted loss per common share	397,992	275,649	246,353
Loss per common share, basic and diluted	$ (0.43)	$ (0.67)	$ (0.72)

Since we reported a net loss for 2021, 2020 and 2019, our potentially dilutive securities are deemed to be anti-dilutive, accordingly, there was no effect of dilutive securities. Therefore, our basic and diluted loss per common share and our basic and diluted weighted average common share are the same for 2021, 2020 and 2019.

The following table sets forth the outstanding securities as of the periods presented which were not included in the calculation of diluted earnings per common share during 2021, 2020 and 2019 (in thousands):

	As of December 31,		
	2021	2020	2019
Stock options	17,655	23,782	25,030
RSUs	13,584	7,061	1,240
PSUs	8,203	2,404	—
Warrants	5,127	6,535	1,833
	44,569	39,782	28,103

14. Related parties

A former member of our Board, J. Martin Carrol, who resigned in December 2021, is also a director of Catalent. From time to time, we have entered into agreements with Catalent and its affiliates in the normal course of business. From July 2015 to December 2021, agreements with Catalent have been reviewed by independent directors of our Company, or a committee consisting of independent directors of our Company. For manufacturing activities, Catalent billed us $4.1 million, $3.0 million and $6.1 million for 2021, 2020 and 2019, respectively. As of December 31, 2021 and 2020, estimated amounts payable to Catalent was $0.9 million and $0.3 million, respectively. In addition, we have minimum purchase requirements in place with Catalent as disclosed in Note 9, Commitments and contingencies.

In April 2020, Karen L. Ling was appointed to our Board, who was an executive vice president and chief human resources officer of American International Group, Inc. (“AIG”) until May 2021. From time to time, we have entered into agreements with AIG in the normal course of business. From April 2020 to May 2021, agreements with AIG have been reviewed by independent directors of our Company, or a committee consisting of independent directors of our Company. For various insurance premiums, AIG billed us less than $0.1 million and $0.2 million for 2021 and 2020, respectively. As of December 31, 2021 and 2020, we have no amounts payable to AIG.

15. Business concentrations

We sell our products to wholesale distributors, specialty pharmacies, specialty distributors, and chain drug stores that generally sell products to retail pharmacies, hospitals, and other institutional customers.

Customers with product revenue equal to or greater than 10% of our total revenue for the periods indicated were as follows:

	2021	2020	2019
Customer A	11%	21%	37%
Customer B	15%	16%	11%
Customer C	17%	28%	13%
Customer E	12%	*	*
Customer F	*	*	12%

* Less than 10% of total product revenue

Customers that accounted for 10% or greater of our accounts receivable as of the periods indicated were as follows:

	As of December 31,	
	2021	2020
Customer A	*	17%
Customer B	21%	19%
Customer C	35%	25%
Customer D	11%	11%

* Balance was less than 10% of accounts receivable, gross

We rely on third parties for the manufacture and supply of our products, as well as third-party logistics providers. In instances where these parties fail to perform their obligations, we may be unable to find alternatives suppliers or satisfactorily deliver our products to our customers on time, if at all.

Vendors with product purchases equal to or greater than 10% of our total purchases for the periods indicated were as follows:

	2021	2020	2019
Catalent	33%	30%	24%
Vendor A	36%	25%	*
Vendor B	27%	36%	27%
Vendor I	*	*	35%

* Less than 10% of total product purchases

Vendors that accounted for 10% or greater of our accounts payable as of the periods indicated were as follows:

	As of December 31,	
	2021	2020
Vendor E	19%	17%
Vendor F	20%	16%
Vendor G	*	10%

* Balance was less than 10% of total accounts payable

16. Summary quarterly information (unaudited)

The following table sets forth a summary of the unaudited quarterly results for 2021 and 2020 (in thousands, except per share amounts):

	March 31, 2021	June 30, 2021	September 30, 2021 (2)	December 31, 2021 (3)
Revenue, net	$ 19,866	$ 23,001	$ 25,406	$ 18,678
Gross profit	$ 15,179	$ 18,869	$ 20,124	$ 13,941
Loss from operations	$ (29,278)	$ (35,179)	$ (39,921)	$ (35,392)
Net loss	$ (39,383)	$ (42,652)	$ (47,420)	$ (42,960)
Loss per common share, basic and diluted (1)	$ (0.11)	$ (0.11)	$ (0.11)	$ (0.10)

	March 31, 2020	June 30, 2020	September 30, 2020 (4)	December 31, 2020 (5)
Revenue, net	$ 12,251	$ 10,701	$ 19,342	$ 22,578
Gross profit	$ 9,536	$ 6,301	$ 16,063	$ 16,997
Loss from operations	$ (50,922)	$ (45,038)	$ (24,974)	$ (34,607)
Net loss	$ (56,849)	$ (51,976)	$ (32,612)	$ (42,087)
Loss per common share, basic and diluted (1)	$ (0.21)	$ (0.19)	$ (0.12)	$ (0.15)

(1) Basic and diluted loss per common share are computed independently for each quarter and the full year based upon respective weighted average shares outstanding. Therefore, the sum of the quarterly basic and diluted earnings per share amounts may not equal the annual basic and diluted earnings per share amounts reported.

(2) Included $7.3 million in senior executive severances, which included our former EVP of Operations.

(3) Included $5.1 million in senior executive severances, which included our former CEO.

(4) Included (i) $2.0 million in license revenue related to the Knight License Agreement, (ii) $5.7 million in inventory charge, primarily related to BIJUVA, and (iii) $0.6 million in write off of certain costs related to trademarks and patents.

(5) Included $0.5 million in write off of certain costs related to trademarks and patents.

17. Subsequent events

vitaCare divestiture

On March 6, 2022, we entered into a stock purchase agreement (the “Purchase Agreement”) with GoodRx, Inc. (“GoodRx”). which provides for the sale of all of the issued and outstanding capital stock of vitaCare to GoodRx (the “vitaCare Divestiture”). Under the terms of the Purchase Agreement, upon the closing of the vitaCare divesture (the “Closing”), we will receive a cash payment of $150.0 million, subject to adjustment as provided in the Purchase Agreement and customary holdbacks. In addition, we may receive up to an additional of $7.0 million in earn-out consideration (the “Earnout”), contingent upon vitaCare’s financial performance through 2023 as determined in accordance with the terms of the Purchase Agreement. The Earnout will be earned in two equal tranches of $3.5 million each, based on vitaCare’s revenue for 2022 and 2023.

The Purchase Agreement contains customary representations and warranties, covenants and indemnities of the parties thereto. In addition, the Purchase Agreement provides that at the Closing: (i) we will enter into a long-term services agreement with vitaCare to continue utilization of the vitaCare platform with respect to our products; (ii) we and vitaCare will enter into a transition services agreement for us to provide certain transition services to vitaCare for up to 12 months following the Closing; and (iii) certain employees of ours and/or vitaCare will enter into employment agreements with GoodRx.

The vitaCare Divestiture is expected to close in the second quarter of 2022, subject to the satisfaction or waiver of certain customary conditions, including the receipt of certain regulatory approvals.

Amendment No. 9 to the Financing Agreement

In March 2022, we entered into Amendment No. 9 pursuant to which, among other things, (i) the lenders waived various Company breaches of the Financing Agreement, including breaches of the $60.0 million minimum cash covenant and the minimum net revenue covenants for the fourth quarter of 2021; (ii) the Company and the lenders agreed to reduced minimum cash covenant and to the removal of the minimum net revenue covenant for the first quarter of 2022; (iii) the lenders waived the existing $60.0 million prepayment penalty under the Financing Agreement and the Company agreed to a paid in kind amendment fee of $30.0 million, which fee was added to the principal amount of the loans under the Financing Agreement, $16.0 million of which fee is waivable in certain conditions; and (iv) the maturity date of the Financing Agreement was amended to June 1, 2022.

TherapeuticsMD, Inc.
2022 Executive Retention and Performance Bonus Plan. (ERB-Plan)

I. Purpose

The purpose of this one-time special 2022 Executive Retention and Performance Bonus Plan (the "ERB-***Plan***") is to promote the success of the Company by providing to participating executives a) a Retention Payment and b) cash incentives in the form of Performance Bonus Awards based on achievement of critical strategic, tactical and financial goals. The intent of this plan is to retain participating executives with the Company in light of business uncertainty, to foster business continuity and engagement, and to reward participating executives for achieving performance measures. This plan is a one-year only plan that will pay out over the course of two years.

II. Definitions

After-Tax Value. The amount of the Performance Bonus Award and Retention Payment paid, if any, calculated as the gross amount of the Performance Bonus Award, minus applicable taxes and withholdings as determined on the applicable payment date.

Award Setting Deadline. The deadline by which to approve Performance Measures for a Participant for an applicable portion of the Performance Period.

Base Salary. The aggregate gross base annualized salary of a Participant as of January 1, 2022, but prior to reductions or deductions for salary deferred pursuant to any deferred compensation plan or for contributions to a plan qualifying under Code Section 401(k), deductions for parking benefits, health insurance, or non-cash benefits or perquisites. Notwithstanding the foregoing, Base Salary does not include any actual or imputed income from Company-provided benefits or perquisites.

Bonus Target. The Performance Bonus Award that may be paid if Performance Measures for the Company are achieved at the one-hundred percent (100%) payout level during a given six-month performance period.

Cause. Cause shall have the meaning ascribed to such term in a Participant's employment agreement with the Company, if any, or otherwise in the TherapeuticsMD, Inc. 2019 Stock Incentive Plan, as amended.

Code. U.S. Internal Revenue Code of 1986, as amended from time to time.

Company. TherapeuticsMD, Inc., a Nevada corporation, and its subsidiaries.

Committee. The Compensation Committee of the Company's Board of Directors.

ERB-Plan Value. The total cash payment available to each Participant under this ERB-Plan.

GAAP. U.S. General Accepted Accounting Principles.

Good Reason. Good Reason shall have the meaning ascribed to such term in a Participant's employment agreement with the Company, if any, or otherwise in the TherapeuticsMD, Inc. 2019 Stock Incentive Plan, as amended.

Participant. Any Company executive selected and approved by the Committee or its delegate to participate in the ERB-Plan for the Performance Period.

Performance Bonus Award. The total cash payment available for each Participant in the ERB-Plan during the Performance Period amounts to 75% of the total ERB-Value established for each Participant in the ERB-Plan. As the Performance Period includes four (4) separate six-month performance periods, the value of the Performance Bonus Award available for each Participant in a given six-month performance period is one quarter (1/4) of the total Performance Bonus Award cash payment available for each Participant in the ERB-Plan during the corresponding six-month performance period of the Performance Period.

Depending on the Performance Measures defined and established for the Company for a given six-month performance period, pay-out of the Performance Bonus Award for that given six-month performance period to Participants may be anywhere from 50% ("Threshold") to 100% ("Bonus Target") or 150% ("Maximum") of the Bonus Target for that given six-month performance period, depending on achievement relative to performance compared to the Bonus Target during such given six-month performance period. Interpolation between levels above the identified "Threshold" level will be at the joint discretion of the CEO of the Company and the Committee. Any Performance Bonus Award may not exceed 150% of the Bonus Target.

Performance Measure(s). Any one or a combination of pre-determined business goals and/or objectives selected and approved by the Committee or its delegate, measured either on an objective or subjective basis, applicable to the Company or an affiliate of the Company, business unit or market segment.

Performance Measures selected by the CEO applicable to the Company or an affiliate of the Company, business unit or market segment, may include, but are not limited to, the following measures (whether or not in comparison to other peer companies): profit before tax; revenue; net revenue; earnings (which may include earnings before interest and taxes, earnings before taxes, and net earnings, among other metrics); operating income; operating margin; operating profit; controllable operating profit, or net operating profit; net profit; gross margin; operating expenses or operating expenses as a percentage of revenue; net income; earnings per share; total stockholder return; market share; return on assets or net assets; the Company's stock price; growth in stockholder value relative to a pre-determined index; return on equity; return on invested capital; cash flow (including free cash flow or operating cash flows); cash conversion cycle; economic value added; individual confidential business objectives; contract awards or backlog; overhead or other expense reduction; credit rating; strategic plan development and implementation; succession plan development and implementation; improvement in workforce diversity; customer indicators; new product invention or innovation; attainment of research and development or product delivery milestones; improvements in productivity; bookings; attainment of objective operating goals and employee metrics; continued employment; any other metric that is capable of measurement as determined by the Committee.

Performance Period. January 1, 2022 to December 31, 2023, which shall include four separate six-month performance periods.

Performance Target(s). The value or weight, expressed in a percentage defined and approved by the Committee, attached to a Performance Measure.

Retention Payment. The cash payment, representing 25% of the total ERB-Plan Value for a Participant, made pursuant to this ERB-Plan as a retention payment, and subject to recoupment as described in Section VIII.

III. Eligibility

The CEO of the Company, with approval by the Committee, shall select Participants for participation in the ERB-Plan.

IV. Administration

A. Administrator

This ERB-Plan shall be administered by the Committee in accordance with ERB-Plan provisions.

B. Authority

The Committee shall have all powers and discretion, as described in this document, necessary or appropriate to interpret and administer the ERB-Plan and to control its operation. Such authority includes selecting and approving Participants in the Plan, determining and approving Bonus Targets for each Participant, determining and approving Performance Measures, approving the Performance Bonus Award granted to Participants for a given six-month performance period, and determining the form and manner in which Retention Payments and Performance Bonus Awards will be made. The Committee may delegate all or some of the powers and discretion herein to the CEO of the Company, except that all final approvals will rest solely with the Committee.

C. Decisions Binding

All determinations and decisions made by the Committee pursuant to the provisions of the ERB-Plan shall be final, conclusive, and binding on all persons, and shall be given the maximum deference permitted by law.

D. Delegation by Committee

The Committee, in its sole discretion and on such terms and conditions as it may provide, may delegate all or part of its authority and powers under the ERB-Plan to one or more directors or officers of the Company; provided, however, that the Committee shall review and approve all recommendations for any payments pursuant to the ERB-Plan prior to such payments being made.

E. Term of ERB-Plan

Once approved by the Committee, this ERB-Plan shall be effective as of the start of the Performance Period. Once approved, this ERB-Plan shall continue until termination of the Plan on December 31, 2024, or earlier as described in Section IX below.

V. Applicable Bonus Provisions and Award Agreement

The Committee shall designate or approve the following and set forth such terms in the applicable award agreement (the "***Award Agreement***"):

1. Executives who will be Participants;

2. Retention Payment for each Participant;

3. Bonus Target for each Participant;

4. Performance Targets for a given six-month performance period; and

5. Performance Measures established for a given six-month performance period.

Prior to the Award Setting Deadline for a given six-month performance period, the Committee shall approve the Performance Measures and the Performance Targets proposed by the CEO of the Company for such given six-month performance period, and the Participants shall be provided notice thereof by Company management.

VI. Performance Bonus Award Determination

After the end of a given six-month performance period, the Committee shall approve the extent to which the Performance Targets relative to the Performance Measures used during such given six-month performance period were achieved by the Participants to the ERB-Plan. The Performance Bonus Award for such given six-month performance period for each Participant shall be determined according to the level of actual performance. The Committee, at its sole discretion, may eliminate, reduce, or increase the Performance Bonus Award payable to any Participant below or above that which otherwise would be payable.

The Committee may appropriately adjust any evaluation of performance under a Performance Measure to exclude any of the following events that may occur during the applicable portion of the Performance Period:

1. Any or all items excluded, or that could be excluded, from the calculation of non-GAAP earnings as reflected in any Company press release or 8-K filing relating to an earnings announcement;

2. Asset write-downs;

3. Litigation or claim judgments or settlements;

4. Effects of changes in tax law, accounting principles or other such laws or provisions affecting reported results;

5. Accruals for reorganization and restructuring programs;

6. Any other extraordinary or non-operational items;

7. Acquisition or disposition costs; and

8. Gain or losses as a result of a Board approved acquisition or disposition, including current year impact on bonus year targets planned without consideration of the transaction.

VII. Payments

A. Performance Bonus Award Timing

The Company shall pay a Performance Bonus Award to a Participant, less applicable withholdings and deductions, as soon as is administratively practicable following the determination and written certification by the Committee to the degree that the Performance Targets, relative to the Performance Measures, were achieved during a given six-month performance period, but in no event later than sixty (60) days following the end of the applicable portion of the Performance Period.

B. Retention Payment Timing

The Retention Payment shall be paid to each Participant in March 2022, subject to the recoupment provisions below. The following recoupment provisions shall apply to the Retention Payment:

1. If a Participant is terminated for Cause or voluntarily terminates employment for any reason other than Good Reason on or before July 1, 2022, the Participant shall pay back 100% of the After-Tax Value of the Retention Payment.

2. If a Participant is terminated for Cause or voluntarily terminates employment for any reason other than Good Reason after July 1, 2022, but on or before January 1, 2023, the Participant shall pay back 50% of the After-Tax Value of the Retention Payment.

3. If recoupment is required, the Participant shall pay back the required amount to the Company within 60 days following the Participant’s employment termination date.

C. Manner of Payment

Performance Bonus Awards and the Retention Payment will be payable in cash as a single lump sums, subject to all applicable taxes and contributions required to be withheld by law

or in accordance with established Company payroll procedures.

D. Recoupment of Performance Bonus Award in the Event of Restatement

Except as otherwise provided by the Committee, Performance Bonus Awards and Retention Payments granted under the ERB-Plan (and in addition to as otherwise provided herein with respect to the Retention Payment) shall be subject to any and all policies, guidelines, codes of conduct, or other agreement or arrangement adopted by the Board or Committee with respect to the recoupment, recovery, or clawback of compensation (collectively, the "***Recoupment Policy***").

E. Code Section 409A

It is intended that this ERB-Plan comply with the requirements of Code Section 409A so that none of the Performance Bonus Award payments and Retention Payments to be provided under this ERB-Plan will be subject to the additional tax imposed under Code Section 409A. Any ambiguities will be interpreted to so comply. Notwithstanding the foregoing, the Company makes no representations that the payments provided under the ERB-Plan comply with Code Section 409A and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by the Participant on account of non-compliance with Code Section 409A.

VIII. Right to Receive Payment

A. ERB-Plan Unfunded and Unsecured

The Performance Bonus Award and Retention Payment under this ERB-Plan shall be paid solely from the general assets of the Company. This ERB-Plan is unfunded and unsecured; nothing in this ERB-Plan shall be construed to create a trust or to establish or evidence any Participant's claim of any right to, or form of, payment of a Performance Bonus Award payment or Retention Payment other than as an unsecured general creditor with respect to any payment to which such Participant may be entitled.

B. Termination of Employment

Except as may otherwise be provided for in the "Payments" section above with respect to the Retention Payment, if a Participant terminates employment with the Company prior to the payment of the Retention Payment, such Participate will not be entitled to receive the Retention Payment. If a Participant terminates employment with the Company prior to the end of the applicable portion of the Performance Period, such Participant shall not be entitled to payment of the portion of any Performance Bonus Award for the applicable portion of the Performance Period under this ERB-Plan.

IX. Amendment and Termination Provisions

The Board of Directors or the Committee may amend, modify, suspend, terminate, or reinstate this ERB-Plan, in whole or in part, at any time, including adopting amendments deemed

necessary or desirable to correct any defect or to supply omitted data, to reconcile any inconsistency in this ERB-Plan or in any Performance Bonus Award granted hereunder or to adapt the ERB-Plan, including, but not limited to, Performance Measures under this ERB-Plan, to material changed circumstances (as determined by the Committee in its sole discretion).

X. General Provisions

A. Non-transferability of Awards

No Performance Bonus Award or Retention Payment granted under the ERB-Plan may be sold, transferred, pledged, assigned, or otherwise alienated or hypothecated, other than by will, by the laws of descent and distribution, or to the limited extent provided in the prior subsection. All rights with respect to a Performance Bonus Award granted to a Participant shall be available during his or her lifetime only to the Participant.

B. No Additional Participant Rights

Employees selected to participate in this ERB-Plan shall not have any right to be retained in the Company's employ, and the right of the Company to dismiss such Participant or to terminate any arrangement pursuant to which any such Participant provides services to the Company, with or without cause, is specifically reserved. No person shall have claim to a Performance Bonus Award or Retention Payment under this ERB-Plan, except as otherwise provided for herein, or to continued participation under this ERB-Plan. There is no obligation for uniformity of treatment of Participants under this ERB-Plan. The benefits provided for Participants under this ERB-Plan shall be in addition to and shall in no way preclude other forms of compensation to or in respect of such Participants.

C. Successors

All obligations of the Company under this ERB-Plan with respect to Performance Bonus Awards and Retention Payments shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business or assets of the Company.

D. Indemnification

Each member of the Company's Board of Directors and each Committee member shall be indemnified and held harmless by the Company against and from (i) any loss, cost, liability, or expense that may be imposed upon or reasonably incurred by such member in connection with or resulting from any claim, action, suit, or proceeding to which such member may be a party or in which such member may be involved by reason of any action taken or failure to act under the ERB-Plan or any award, and (ii) from any and all amounts paid by such member in settlement thereof, with the Company's approval, or paid by such member in satisfaction of any judgment in any such claim, action, suit or proceeding against such member, provided such member shall give the Company an opportunity, at its own expense, to handle and defend the same before such member undertakes to handle and defend it on his/her own behalf. The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which such

persons may be entitled under the Company's Certificate of Incorporation or Bylaws, by contract, as a matter of law, or otherwise, or under any power that the Company may have to indemnify them or hold them harmless.

E. Severability

The provisions of this ERB-Plan are severable. If a court of competent jurisdiction rules that any provision of this ERB-Plan or the Award Agreement is invalid or unenforceable, the court's ruling will not affect the validity and enforceability of the other provisions of this ERB-Plan.

F. Requirements of Law

Performance Bonus Awards and Retention Payment granted under this ERB-Plan shall be subject to all applicable laws, rules and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

G. Governing Law

The validity, interpretation, construction and performance of the ERB-Plan and awards under it shall be governed and interpreted in accordance with the laws of the State of Florida.

FORM OF
THERAPEUTICSMD, INC. EXECUTIVE RETENTION AND BONUS PLAN
AWARD AGREEMENT

THIS THERAPEUTICSMD, INC. EXECUTIVE BONUS PLAN AWARD AGREEMENT (the "***Award Agreement***"), entered into as of [●], 2022 is made by and between TherapeuticsMD, Inc. ("***Compan***y"), a Nevada corporation, and [●] ("***Executive***"), an executive of Company, under the terms and conditions of the TherapeuticsMD, Inc. Executive Bonus Plan (the "***Plan***"), which provides for a cash Retention Payment and Performance Bonus Award to certain key executives of the Company. Any defined term not otherwise defined herein shall have the meaning set forth in the Plan.

1. Terms of the Retention Payment. Company hereby grants to Executive the opportunity to earn a special, one-time cash Retention Payment pursuant to the terms of the Plan and this Award Agreement. In addition to the terms and conditions set forth in the Plan, the following terms shall apply:

a. The Retention Payment shall equal: [_____].

b. The Retention Payment shall be repaid to the Company as set forth in the Plan if Executive is terminated for Cause or voluntarily terminates employment for any reason other than Good Reason on or before January 1, 2023.

2. Terms of Performance Bonus Award. Company hereby grants to Executive the opportunity to earn a special, one-time Performance Bonus Award pursuant to the terms of the Plan and this Award Agreement. In addition to the terms and conditions set forth in the Plan, the following terms shall apply for purposes of determining the Performance Bonus Award of Executive for the Performance Period:

a. The Performance Bonus Award shall equal: [_____], which shall be paid in four equal installments for each separate six-month period in the Performance Period, subject to the terms of the Plan and satisfaction of the applicable Performance Targets.

b. The Performance Targets for the Performance Period shall be approved by the Compensation Committee for each separate six-month period.

2. **Miscellaneous**. This Award Agreement and the Plan contain the entire agreement and understanding of the parties with respect to the subject matter contained in this Award Agreement, and supersede all prior communications, representations, and negotiations in respect thereto. The terms and conditions of Executive's Retention Payment and Performance Bonus Award for the Performance Period set forth herein shall be governed by this Award Agreement and the Plan. Should the terms and conditions of this Award Agreement conflict with the Plan, the terms and conditions of the Plan will control. This Award Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. This Award Agreement may be modified only in writing signed by the original parties hereto, their successors, or by their authorized representatives.

IN WITNESS WHEREOF, this Agreement has been executed by the parties effective as of the date set forth above.

EXECUTIVE	THERAPEUTICSMD, INC.
_____	By: _____
[INSERT NAME]	Name: _____
	Title: _____

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Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We have issued our report dated March 23, 2022, 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, 2021. We consent to the incorporation by reference of said report in the Registration Statements of TherapeuticsMD, Inc. on Forms S-3 (File No. 333-226452 and File No. 333-253851) and on Forms S-8 (File No. 333-191730, File No. 333-232268, File No. 333-242363, File No. 333-256879, File No. 333-259221, and File No. 333-260295).

/s/ GRANT THORNTON LLP

Miami, Florida
March 23, 2022

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Hugh O'Dowd, certify that:

(1) I have reviewed this Annual Report on Form 10-K of TherapeuticsMD, Inc. (the "10-K Report");

(2) Based on my knowledge, this 10-K 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 10-K 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 our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this 10-K Report based on such evaluation; and

(d) disclosed in this 10-K 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 23, 2022

/s/ Hugh O'Dowd
Hugh O'Dowd
Chief 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. (the "10-K Report");

(2) Based on my knowledge, this 10-K 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 10-K 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 our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this 10-K Report based on such evaluation; and

(d) disclosed in this 10-K 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 23, 2022

/s/ James C. D'Arecca
James C. D'Arecca
Chief Financial Officer

Exhibit 32.1

SECTION 1350 CERTIFICATION OF CHIEF EXECUTIVE OFFICER

In connection with the Annual Report on Form 10-K of TherapeuticsMD, Inc. (the "Company") for the year ended December 31, 2021 (the "10-K Report"), as filed with the Securities and Exchange Commission on the date hereof, I, Hugh O'Dowd, 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 10-K 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 10-K Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 23, 2022

/s/ Hugh O'Dowd
Hugh O'Dowd
Chief 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 on Form 10-K of TherapeuticsMD, Inc. (the "Company") for the year ended December 31, 2021 (the "10-K Report"), as filed with the Securities and Exchange Commission on the date hereof, 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:

(1) The 10-K 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 10-K Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 23, 2022

/s/ James C. D'Arecca
James C. D'Arecca
Chief 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.